

Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries

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The typical federal agency issues a vast amount of guidance, advising the public on how it plans to exercise discretion and interpret law. Under the Administrative Procedure Act (APA), the agency must follow onerous procedures to issue full-blown regulations (including notice and comment) but can issue guidance far more easily. What justifies this difference, in the familiar telling, is that guidance is not binding in the way regulations are. Agencies are supposed to use guidance flexibly. But critics claim that agencies are not flexible—instead they follow guidance rigidly and thus pressure regulated parties to do the same. If true, this claim means agencies can issue de facto regulations simply by calling them guidance, threatening to make a dead letter of the APA’s constraints.

I evaluate this claim from a qualitative empirical perspective, drawing upon interviews I conducted with 135 individuals across government, industry,

[†] Professor of Law, Yale Law School. This Article draws upon a study that I conducted as a consultant to the Administrative Conference of the United States (ACUS) in 2016-17. NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE, FINAL REPORT TO THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES (Oct. 12, 2017), <https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf> [<https://perma.cc/L4BU-85YW>] [hereinafter PARRILLO REPORT]. The study provided the empirical basis for ACUS Recommendation 2017-5: Agency Guidance Through Policy Statements, 82 Fed. Reg. 61728, 61734 (Dec. 29, 2017). I am grateful to the Conference for its financial and logistical support and advice, particularly to Gisselle Bourns, staff counsel; Alissa Ardito, former staff counsel; Lee Liberman Otis, committee chair; Reeve Bull, research chief; Matthew Wiener, vice chair; and Paul Verkuil, former chair. ACUS agency contacts performed the service of identifying, and often setting up interviews with, agency officials. Public members of ACUS did the same in identifying other knowledgeable interviewees. Notwithstanding ACUS’s support, I formulated my analysis and drew my conclusions independently, on my own responsibility. As noted on the cover page of my report: “This report was prepared for the consideration of the Administrative Conference of the United States. The opinions, views and recommendation expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees, except where formal recommendations of the Conference are cited.” For advice about the project, I am also grateful to Cary Coglianese, Cynthia Farina, Ron Levin, Jerry Mashaw, Ricky Revesz, Sarah Ryan, Jason Schwartz, Kevin Stack, Wendy Wagner, and Chris Walker. I would also like to thank participants in ACUS’s committee meetings and plenary session; in talks at Fordham, St. John’s, the University of Texas, Vanderbilt, and the District of Columbia Bar; and in conferences hosted by the ABA Administrative Law Section, Loyola University Chicago, and the University of Wisconsin. For help in the quantitative research for the project (reflected mainly in parts of the study on which this Article does not draw), as well as some of the legal research and citation checking, I thank Yale Law School student research assistants Juliana Brint, Katie Choi, José Argueta Funes, Samir Doshi, Julia Hu, Arjun Ramamurti, Christine Smith, Isra Syed, and Garrett West. For additional financial support I thank the Oscar M. Ruebhausen Fund and Yale Law School. For thoughtful and careful editing, I thank Isabelle Hanna and the staff of the *Yale Journal on Regulation*. All errors are my own.

and NGOs in eight different regulatory fields. I make three findings. First, the critics have a genuine basis for their claim. Regulated parties often face overwhelming pressure to follow guidance, and agencies are sometimes inflexible. Second, pressure and inflexibility, though real, are not universal. One can identify regulated parties who feel little pressure and agencies who are open-minded. The degree of pressure and inflexibility can be predicted on the basis of certain organizational and legal factors that are present in some regulatory schemes but not others. Third, even when regulated parties are strongly pressured, or when officials are inflexible, this is normally not because agency officials are engaged in a bad-faith effort to coerce the public without lawful procedures. The sources of pressure on regulated parties are mostly hard-wired into the structure of the regulatory schemes Congress has imposed and are beyond the control of agency officials who issue or administer guidance. And when agencies are inflexible in the face of a regulated party’s plea to depart from guidance, that is usually because (a) officials face competing pressures from other stakeholders to behave consistently and predictably—pressures that spring from rule-of-law values that agencies would be remiss to ignore; and (b) officials are trapped by organizational tendencies that cause rigidity, which the officials do not intend but cannot redress without costly reforms.

The problem with guidance, though real, is largely an institutional problem that calls for an institutional-reform response, not a problem of bureaucratic bad faith that calls for accusation and blame.

- Introduction167
- I. Regulated Parties’ Incentives to Follow Guidance.....184
 - A. Pre-Approval Requirements.....184
 - B. Maintaining Relationships191
 - C. Intrafirm Constituencies for Following Guidance.....200
 - D. The Prospect of a One-Off Enforcement Proceeding.....208
 - 1. Probability of Detection209
 - 2. Cost of the Enforcement Proceeding Irrespective of Outcome.....209
 - 3. Probability of a Violation Being Found213
 - 4. Cost of Sanction for a Violation214
 - E. When Incentives to Follow Guidance Are Weak.....219
 - 1. OSHA Regulation Beyond Large Firms219
 - 2. FTC Consumer Protection225
 - 3. CFPB Regulation of Nonbank Institutions227
 - 4. Ex Post Enforcement Against Permittless Discharges Under the Clean Water Act.....229
- II. Agency Flexibility and Inflexibility.....231
 - A. Legitimate Pressures for Consistency.....232
 - 1. Industry Preferences for Consistency232
 - 2. Demands for Consistency by NGOs, the Media, and

Federal Agency Guidance and the Power to Bind

Congress	237
3. Fear That Inconsistency Will Open the Floodgates	239
B. <i>Principled Flexibility: A Good Solution, in Principle</i>	241
C. <i>Organizational and Resource-Based Obstacles to Principled Flexibility</i>	244
1. Cost of Evaluating Departures in the First Instance.....	245
2. Cost of Obtaining High-Level Approval for Departures ..	248
3. Cost of Recording and Disseminating Departure Decisions	251
D. <i>Organizational and Resource-Based Obstacles to Any Kind of Flexibility</i>	252
1. Fear that Challenges May Damage Relationships with Officials	253
2. Superiors' Institutional Motivations to Affirm Subordinates	256
3. Understanding of Rule/Guidance Distinction Is Not Intuitive.....	258
4. Nature of Relationships to Stakeholders May Affect Flexibility.....	259
5. Training to Be Flexible	261
E. <i>Inflexibility by Reason of Agency Commitment to Guidance's Substance</i>	262
III. Deregulatory Guidance and Regulatory Beneficiaries.....	266
IV. Conclusion.....	271

Introduction

For individuals and firms regulated by federal agencies, actual regulations are just the beginning of the story. Despite being voluminous and complex, regulations leave numerous important decisions to the agency's discretion or interpretation. Individuals and firms want to know how the agency will use its discretion and how it will read the regulations' ambiguous provisions. And agency officials want individuals and firms to have that knowledge in order to facilitate compliance. So officials provide the public with lots of "guidance," that is, general statements advising the public on how the agency proposes to exercise discretion or interpret law.¹ Guidance comes in an endless variety of labels and formats, depending on the agency: advisories, circulars, bulletins, memos, interpretive letters, enforcement manuals, fact sheets, FAQs, highlights, you name it. Nobody knows exactly how much guidance there is, because it is not comprehensively collected anywhere, but its page count for any given agency is estimated to dwarf that of actual regulations by a factor of twenty, forty, or even

1. On the exact definition of guidance and the scope of this Article, see *infra* note 6.

two hundred.² Guidance is “the bread and butter of agency practice,” declares a veteran EPA lawyer.³ “I cannot imagine a world without guidance,” says a former senior FDA official.⁴

Though guidance is a ubiquitous and essential feature of the administrative state, it is also controversial. Full-blown regulations that officially bind the agency and the public—known as “legislative rules”—can be enacted by an agency only through a costly, time-consuming set of procedures imposed by the Administrative Procedure Act (APA), including notice and comment, in which the parties who will be bound by a policy can participate in its formulation before it is set in stone. By contrast, agencies can issue guidance without any such process, because of the APA’s exemptions for “general statements of policy” and “interpretative rules,” which together cover guidance in all its varieties.⁵ Thus guidance can be produced and altered much faster, in higher volume, and with less accountability than legislative rules can. What justifies this disparity, in the familiar telling, is that guidance, unlike a legislative rule, is not binding on the agency or the public.⁶ It is only a suggestion—a mere tentative announcement of

2. Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468-69 (1992) [hereinafter Strauss, *Rulemaking Continuum*]; Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 805 (2001) [hereinafter Strauss, *Publication Rules*].

3. Interview with Carrie Wehling, Office of Gen. Counsel, U.S. Env’tl. Prot. Agency. On the methodology and timing of all interviews cited in this Article, see *infra* text and accompanying notes 25-28.

4. Interview with Source 80, former senior official, U.S. Food & Drug Admin.

5. 5 U.S.C. § 553(b)(A) (2018).

6. A word about exactly which guidance documents have nonbinding status—and, relatedly, about the scope of this Article—is in order. In general parlance, an agency statement qualifies as guidance if it is either a “general statement of policy” (“policy statement”) or an “interpretative rule” under § 553(b)(A) of the APA. Neither term is defined in the APA itself. According to the widely cited ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947), policy statements are “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power,” while interpretive rules are “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.” *Id.* at 30 n.3. It is universally agreed that policy statements are supposed to be nonbinding. For a thorough discussion of the case law on policy statements, see Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 287-317 (2018). Whether interpretive rules are supposed to be nonbinding is a question subject to much confusion that is not fully settled. Some cases indicate that all guidance documents, interpretive rules and policy statements alike, must preserve case-by-case discretion. *E.g.*, *Ass’n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 716-18 (D.C. Cir. 2015); *Am. Tort Reform Ass’n v. OSHA*, 738 F.3d 387, 395, 397 (D.C. Cir. 2013); *Vietnam Veterans of Am. v. Secretary of the Navy*, 843 F.2d 528, 537-38 (D.C. Cir. 1988). But more cases indicate that agencies can adhere as rigidly to an interpretive rule as they can to a legislative rule; by this thinking, what defines an interpretive rule (and renders it exempt from notice and comment) is not any sort of nonbinding status, but rather the fact that its content is drawn from the underlying legislative rule or statute by a reasoning process that is interpretive in nature. For a thorough review of the confused case law on interpretive rules—including a forceful argument that courts should require interpretive rules to be nonbinding just as policy statements are—see Levin, *supra*, at 317-53. In setting the bounds of my study (e.g., in telling interviewees what kinds of guidance documents I was interested in), I focused on any and all agency guidance that was legally supposed to be nonbinding. This includes (a) all policy statements and (b) interpretive rules insofar as the interviewee thought interpretive rules were nonbinding. Usually the legal categories of “policy statement” and “interpretive rule” played little to no role in the interviews. Instead the interviewee would instantly recognize a category of “guidance” that was supposed to be nonbinding and discuss it, not

the agency’s current thinking about what to do in individual adjudicatory or enforcement proceedings, not something the agency will follow in an automatic, ironclad manner as it would a legislative rule. Guidance is supposed to leave space for the agency’s case-by-case discretion. If a particular individual or firm wants to do something (or wants the agency to do something) that is different than what the guidance suggests, the agency is supposed to give fair consideration to that alternative approach.⁷ If officials treat guidance with this kind of flexibility, it doesn’t seem so bad for the agency to be unconstrained in issuing guidance to begin with.⁸

The great fear is that agency officials, in real life, are not tentative or flexible when it comes to guidance but instead follow guidance as if it were a binding legislative rule, and regulated parties are under coercive pressure to do the same. If true, this complaint reveals a giant loophole in the APA: agencies can issue de facto regulations at will, simply by calling them “guidance,” with no say from individuals and firms who will be effectively bound. The fear and the controversy have burned for decades, and most hotly in the last few years, giving rise to exposés,⁹ congressional hearings,¹⁰ bills,¹¹ a 4-4 Supreme Court

pausing to think about whether this category consisted solely of policy statements or also encompassed interpretive rules. Indeed, the question of whether to label a guidance document “policy statement” or “interpretive rule” may never occur to many agency officials or stakeholders unless and until there is a lawsuit about the document under the APA. For a fuller elaboration of the study’s scope, see PARRILLO REPORT, *supra* note †, at 22-26. Because it is uncertain whether interpretive rules can or should be nonbinding, ACUS, in formulating its best practices on the basis of my study, confined those best practices to policy statements, while noting that they might be “helpful” in administering interpretive rules as well. ACUS Recommendation 2017-5, *supra* note †. (I should also note that the study encompasses not only guidance documents that are directly addressed to the public, but also guidance documents that are officially addressed internally to agency personnel insofar as those documents are public and shape official action that affects the public, e.g., permit-writing manuals or enforcement manuals. See PARRILLO REPORT, *supra* note †, at 26-27.)

7. Although a guidance document might lawfully bind some officials within the agency (e.g., frontline officials at a low level in the agency hierarchy), the mandate that the document remain nonbinding on the agency itself (and on the public) would require that there be some officials (e.g., higher-level ones) who are empowered to consider and approve approaches different than in the guidance—and that those officials be reasonably accessible to regulated parties. See PARRILLO REPORT, *supra* note †, at 26-27.

8. See Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 391.

9. CLYDE WAYNE CREWS JR., *MAPPING WASHINGTON’S LAWLESSNESS: AN INVENTORY OF REGULATORY DARK MATTER* (2017); NATIONAL FEDERATION OF INDEPENDENT BUSINESSES, *THE FOURTH BRANCH & UNDERGROUND REGULATIONS* (2015) [hereinafter NFIB REPORT].

10. *Examining the Use of Agency Regulatory Guidance, Part II: Hearing Before the Subcomm. on Regulatory Affairs & Fed. Mgmt. of the S. Comm. on Homeland Sec. & Governmental Affairs*, 114th Cong. (2016); *Examining the Use of Agency Regulatory Guidance: Hearing Before the Subcomm. on Regulatory Affairs & Fed. Mgmt. of the S. Comm. on Homeland Sec. & Governmental Affairs*, 114th Cong. (2015).

11. Regulatory Accountability Act, H.R. 5, S. 951, 115th Cong. (2017); Truth in Regulations Act, S. 580, 115th Cong. (2017); Regulatory Predictability for Business Growth Act, H.R. 288, 115th Cong. (2017).

deadlock,¹² and a directive from then-Attorney General Sessions condemning “improper guidance documents.”¹³

The stakes of the controversy are high, and resolving it has proven remarkably tough. The main obstacle is that it is hard to say, much less agree upon, what it means for an agency statement to be “binding” and how to prevent it from becoming so.¹⁴ Obviously this question can arise in litigation, when a private party challenges a purported guidance document for being a binding rule in nonbinding disguise—and thus unlawful and subject to invalidation by the court because it did not go through notice and comment. But litigation is only the tip of the iceberg.¹⁵ The iceberg itself is administrative practice: the workaday world of agency officials and their attorneys who must constantly decide how to formulate and use guidance documents that are officially supposed to be nonbinding. Given the importance of guidance, lamented then-Judge Kavanaugh, one would hope that “all relevant parties should instantly be able to tell” whether an agency statement falls into that category or is instead a legislative rule, yet the “inquiry turns out to be quite difficult and confused.”¹⁶ Then-Judge Kavanaugh called upon the whole administrative state and its surrounding community (not just the courts) to tackle the problem: “An important continuing project for the Executive Branch, the courts, the administrative law bar, and the legal academy—and perhaps for Congress—will be to get the law” regarding guidance “into . . . a place of clarity and predictability.”¹⁷

Thus far, we have lacked a sufficient empirical foundation to meet this challenge of identifying guidance that is binding and preventing it from becoming so. There is a substantial academic literature on how to distinguish guidance from legislative rules and on how this distinction should relate (if at all) to guidance’s potential coercive power, but it does not investigate firsthand how officials and stakeholders use and react to guidance documents. Instead it is

12. *United States v. Texas*, 136 S. Ct. 2271 (2016).

13. ATTORNEY GEN., MEMORANDUM FOR ALL COMPONENTS: PROHIBITION OF IMPROPER GUIDANCE DOCUMENTS (Nov. 16, 2017), <https://www.justice.gov/opa/press-release/file/1012271/download> [<https://perma.cc/29JF-PXER>]; *see also* ASSOC. ATTORNEY GEN., MEMORANDUM: LIMITING USE OF AGENCY GUIDANCE DOCUMENTS IN AFFIRMATIVE CIVIL ENFORCEMENT CASES (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download> [<https://perma.cc/538S-WTRZ>] (taking a similar approach to the Justice Department’s management of affirmative civil enforcement).

14. Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 346-49, 351-52 (2011).

15. *See* Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1372 (1992) (“To induce agency observance of proper rulemaking procedures, it is not efficient to rely upon judicial review, which is uncertain and spasmodic and at best a belated curative. It would seem much more productive to set forth for the agencies a clear and comprehensive statement of the precepts they should obey.”).

16. *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014).

17. *Id.*

a doctrinal and theoretical literature based overwhelmingly on case law.¹⁸ This approach, for all its value, has two limitations. First, only a tiny and unrepresentative fraction of guidance is likely to end up in litigation.¹⁹ Second, the cases turn mainly on whether the text of the contested guidance document contains mandatory wording (e.g., “shall” rather than “may”) while delving far less into whether officials act rigidly in applying the document,²⁰

18. E.g., Asimow, *supra* note 8; David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276 (2010); William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321 (2001) [hereinafter Funk, *Primer*]; William Funk, *When Is a “Rule” a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN. L. REV. 659 (2002); Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705 (2007); Stephen M. Johnson, *Good Guidance, Good Grief!*, 72 MO. L. REV. 695 (2007); Stephen M. Johnson, *In Defense of the Short Cut*, 60 KAN. L. REV. 495 (2012); Sam Kalen, *The Transformation of Modern Administrative Law: Changing Administrations and Environmental Guidance Documents*, 35 ECOLOGY L.Q. 657 (2008); Levin, *supra* note 6; Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497 (1992) [hereinafter Levin, *Open Mind*]; John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893 (2004); Richard J. Pierce Jr., *Distinguishing Legislative Rules from Interpretive Rules*, 52 ADMIN. L. REV. 547 (2000); Seidenfeld, *supra* note 14. A few pieces in this literature draw, at least implicitly, on the author’s personal experience in government service. E.g., E. Donald Elliott, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490 (1992); Strauss, *Rulemaking Continuum*, *supra* note 2; Strauss, *Publication Rules*, *supra* note 2; Cass R. Sunstein, “Practically Binding”: *General Policy Statements and Notice-and-Comment Rulemaking*, 68 ADMIN. L. REV. 491 (2016). For a proposed bill to clarify and reform the case law, see William Funk, *Legislating for Nonlegislative Rules*, 56 ADMIN. L. REV. 1023 (2004).

19. On the rarity of litigation challenging guidance in proportion to guidance’s volume, see Strauss, *Publication Rules*, *supra* note 2, at 806. Whatever guidance does reach the courts is likely unrepresentative in that guidance under certain kinds of regulatory schemes entails strong disincentives to litigate. For example, legislation creating a high-stakes licensing scheme strongly discourages regulated parties from seeking judicial review of any policy made by the agency on how to do the licensing. Ashutosh Bhagwat, *Modes of Regulatory Enforcement and the Problem of Administrative Discretion*, 50 HASTINGS L.J. 1275, 1304-10 (1999). The additional disincentives for regulated parties to defy guidance described in Sections I.B, I.C, and I.D, *infra*, could well extend to discouraging litigation against the agency regarding guidance.

20. While there are some cases that invoke rigid official application of a guidance document *in addition to* mandatory-sounding text to find the document binding, e.g., *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1324 (D.C. Cir. 1988), I can only find one case in which an appellate court clearly relies exclusively on rigid official application alone (and that over a vehement dissent), *Texas v. United States*, 809 F.3d 134, 171-76 (5th Cir. 2015), *aff’d by an equally divided court*, 136 S. Ct. 2271 (2016), and only one other in which an appellate court arguably relies exclusively on rigid official application, *U.S. Tel. Ass’n v. FCC*, 28 F.3d 1232, 1234-35 (D.C. Cir. 1994). As noted by Bradley Merrill Thompson, counsel to medical-device-maker associations, the FDA has become quite careful to avoid mandatory language in the text of its guidance documents. The question in litigation challenging FDA guidance, therefore, would be whether the agency is *applying* the document in an inflexible manner, which presents “issues of fact” that are “hard to overcome.” Interview with Bradley Merrill Thompson, Member, Epstein, Becker & Green, P.C. Similarly, an executive at a drug manufacturer said that, in litigation, it would be a “really uphill” battle to “pierce” the facially nonbinding language of an FDA guidance document. Interview with Source 108, executive at a drug manufacturer. Nor is the FDA the only agency that is careful in its drafting. The EPA’s Office of General Counsel has become more vigilant in the last several years when vetting guidance documents to ensure they are not couched in mandatory terms. Interview with Carrie Wehling, Assistant Gen. Counsel, Evtl. Prot. Agency; Interview with Source 99, official, Evtl. Prot. Agency. Officials at the Federal Aviation Administration (FAA) and the Department of Energy were likewise mindful that mandatory language had to be avoided. Interview with Sources 3, 4, and 5, officials, Office of Gen. Counsel, Dep’t of Energy; Interview with Sources 8, 9, and 10, officials, Fed. Aviation Admin. Eric Schaeffer, former director of EPA civil enforcement and head of an environmental NGO, said that the EPA’s “OGC knows to put in boilerplate” disclaiming mandatory status, which would “usually satisfy a court.” Interview with Eric Schaeffer, Exec. Dir., Evtl. Integrity

meaning the case law largely misses structural, organizational, and behavioral factors—invisible in guidance’s text and perhaps in any documentary sources—that can determine whether guidance practically operates like a legislative rule in the real world. That said, there have been several articles that move beyond case law to consider guidance’s power through lenses other than litigation.²¹ But these works each focus on one particular regulatory area and have nearly all been written in isolation from each other (though they often engage the general doctrinal literature); there have been only a few limited efforts to use comparisons or contrasts between different agencies or industries to draw more general, transsubstantive conclusions about the behavior and expectations of officials and regulated parties with respect to guidance.²² Further, all but three of these agency-specific works are confined to published documentary sources, meaning they mostly do not delve into unwritten expectations and understandings that can be critical.²³

Project, and former Dir. of Civil Enf’t, Evtl. Prot. Agency. The courts’ reluctance to delve into and rely upon agencies’ official practice presumably results from the thorny fact-finding issues raised by such an inquiry. Cf. Levin, *supra* note 6, at 354 (“[C]ourts may not always have enough information or perspective to assess the elusive variables that bear on ‘practical binding effect’”).

21. On the EPA, see James W. Conrad Jr., *Draft Guidance on the Appropriate Use of Rules Versus Guidance*, 32 ENVTL. L. REP. 10721 (2002). On immigration, see Adam B. Cox & Cristina M. Rodriguez, *The President and Immigration Law Redux*, 105 YALE L.J. 104 (2015); Jill E. Family, *Easing the Guidance Document Dilemma Agency by Agency: Immigration Law and Not Really Binding Rules*, 47 U. MICH. J.L. REFORM 1 (2013); and Marjorie S. Zatz & Nancy Rodriguez, *The Limits of Discretion: Challenges and Dilemmas of Prosecutorial Discretion in Immigration Enforcement*, 39 LAW & SOCIAL INQUIRY 666 (2014). On tax, see Kristin E. Hickman, *Coloring Outside the Lines: Examining Treasury’s (Lack of) Compliance with Administrative Procedure Act Rulemaking Requirements*, 82 NOTRE DAME L. REV. 1727 (2007) [hereinafter Hickman, *Coloring*]; Kristin E. Hickman, *IRB Guidance: The No Man’s Land of Tax Code Interpretation*, 2009 MICH. ST. L. REV. 239; and Kristin E. Hickman, *Unpacking the Force of Law*, 66 VAND. L. REV. 465 (2013). On the FDA, see Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89 (2014); and Erica Seiguer & John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD & DRUG L.J. 17 (2005). On the Department of Labor, see Stuart Shapiro, *Agency Oversight as “Whac-a-Mole”*: *The Challenge of Restricting Agency Use of Nonlegislative Rules*, 37 HARV. J.L. & PUB. POL’Y 523 (2014). On the Office of Civil Rights and the EEOC, see Ming Hsu Chen, *Governing by Guidance: Civil Rights Agencies and the Emergence of Language Rights*, 49 HARV. C.R.-C.L. L. REV. 291 (2014). There are also studies that reach beyond case law and discuss guidance but in a manner that does not focus on the question of binding power. E.g., Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782 (2010).

22. Chen undertakes a sustained comparison between the efficacy of guidance at the Office of Civil Rights and at the EEOC. Chen, *supra* note 21. Family, writing on the Department of Homeland Security (DHS), makes a comparison with the FDA, Family, *supra* note 21, at 31-38, ultimately concluding that each agency should follow its own path within the loose general structure of specifying agency-wide good guidance practices, *id.* at 38-48. Noah, writing on the FDA, briefly cites works on guidance on immigration and tax. Noah, *supra* note 21, at 93; see also Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873 (giving a transsubstantive discussion of agency use of various kinds of pressure to impose extra-legal demands on regulated parties, touching upon guidance documents but ranging far more broadly).

23. The three exceptions are: Chen, *supra* note 21, at 308 n.76 (interviewing seven named attorneys and activists, plus two oral histories, as well as “attorneys” at three components of the EEOC and “staffs” to four officials at the EEOC); Seiguer & Smith, *supra* note 21 (interviewing eight current FDA officials and twelve FDA-regulated industry representatives); Zatz & Rodriguez, *supra* note 21, at 668 (interviewing “twenty-five immigration attorneys, advocates, policy analysts, and former

In this Article, I seek to strengthen our empirical foundation for thinking about guidance, how it may bind, and what to do about it. To this end, I have conducted interviews about guidance with 135 individuals, ranging from agency officials to industry attorneys and executives to NGO representatives. The interviews range across eight distinct areas of regulation, whose similarities and differences allow for a transsubstantive analysis.²⁴

To give an idea of how the interviews worked: they all took place from September 2016 through July 2017. The vast majority lasted between 60 and 90 minutes each. Of the 135 interviewees, 26% were in the agencies (all career officials), 48% in industry, 19% in NGOs and unions, and 7% “other.” Of the people outside the agencies (that is, in industry, NGOs, unions, or “other”), who totaled exactly 100, there were 58 former agency officials (of whom 35 had been career, 10 had been Democratic political appointees, and 13 had been Republican political appointees). I located the interviewees through a chain-referral process, beginning with a nucleus of well-networked individuals with diverse sectoral affiliations: agency contacts and non-government members at the Administrative Conference of the United States (ACUS), which supported this research.²⁵ I asked the agency contacts and nongovernment members for names of people who knew about guidance from experience, interviewed those people, asked those interviewees for yet more names, and so forth iteratively. This method leverages the knowledge of people within the system to find out who the knowledgeable people are; it is a method suited to a subject like the everyday workings of guidance, which is relatively unexplored and fraught with “unknown unknowns.” (For that same reason, the interviews were unstructured and free-ranging.) In selecting interviewees, I sought to strike a balance between breadth and depth, following the chain-referral process for one “link” of the chain wherever it led, then following it for the second “link” only for certain regulatory areas, and then for the third “link” only for two agencies on which I wanted to go into particular depth (those being the EPA, because of the unmatched scale of its regulatory operations and its unmatched prevalence in legal controversy over guidance, and the FDA, given its heavy reliance on guidance documents and its use of an unusually formalized process for issuing guidance).²⁶ In the end, 24% of the interviewees were experts on the EPA, 23% on the FDA, and between 4%

government officials; and informal conversations with five current government officials”). Note also that interviews are referenced in Hickman, *Coloring*, *supra* note 21, at 1796, but only as a background means to check documentary research. Interviews pertaining to various agencies with eleven individuals (several of the interviews at a group meeting) are cited on a scattered basis throughout the predominantly case- and document-based argument in Anthony, *supra* note 15, at 1336, 1338, 1351, 1361, 1365, 1368, 1375; my critique of Anthony is set forth below, *see infra* notes 38-58 and accompanying text.

24. The three prior interview-based studies, cited in *supra* note 23, each focus on one regulatory area.

25. The interviews were conducted for a study that I conducted under contract for ACUS, see *supra* note †, on which this Article draws.

26. I also sought additional referrals on a supplemental basis to fill certain gaps in my understanding, yielding a small number of interviewees, as fully described in PARRILLO REPORT, *supra* note †, app. at 198-202.

and 11% each on the Occupational Safety and Health Administration (OSHA), the Department of Energy, the U.S. Department of Agriculture (USDA), the Federal Aviation Administration (FAA), the Department of Health & Human Services (HHS) (besides the FDA), and the banking regulatory agencies.²⁷

From these interviews, I make three conclusions. First, the critics of guidance have a genuine basis for their complaints. Regulated parties often face overwhelming practical pressure to follow what a guidance document “suggests,” at least absent an individual dispensation from the agency saying that it is okay, in the present instance, for a regulated party to act differently from the guidance. Yet agencies are sometimes inflexible about guidance, that is, they are not practically open to entertaining regulated parties’ arguments for such individual dispensations. Second, pressure and inflexibility, though real, are not universal. One can identify regulated parties who feel little pressure to follow guidance, as well as agencies who are open-minded. Moreover, the existence of pressure on regulated parties, and of inflexibility among agency officials, can be predicted on the basis of certain organizational and legal factors that are present in some regulatory schemes but not others. These factors are enumerated and documented throughout this study. Third, even when regulated parties are strongly pressured, or when officials are inflexible, this is normally not because agency officials are engaged in some sort of bad-faith effort to coerce the public without the legally required APA procedures. Rather, the sources of pressure on regulated parties to follow guidance are mostly hard-wired into the structure of the regulatory scheme that Congress has imposed on them. These factors are far beyond the control of agency officials who issue or administer guidance; mitigating their coercive effect would demand fundamental reforms of the regulatory state ranging well beyond the topic of guidance. Further, even when agency officials themselves resist regulated parties’ entreaties for flexibility on guidance, this is usually because of two factors that do not imply any bad faith. First, officials face competing pressures from other stakeholders to behave consistently and predictably—pressures that spring from rule-of-law values that agencies would be remiss to ignore. Second, officials are trapped by unconscious organizational tendencies in favor of rigidity, which the officials do not intend but also cannot redress without undertaking reforms that are costly in terms of resources and managerial energy. All in all, the problem with guidance is quite real, but it is largely an institutional problem that calls for an institutional-reform response (conditioned on available resources and hard choices about tradeoffs

27. For a complete description of the study’s methods, see PARRILLO REPORT, *supra* note †, app. at 196-205. While the most common topics in the interviews were incentives to follow guidance and agencies’ (in)flexibility in using guidance, I also spoke with many interviewees about agency processes for issuing guidance and public participation therein; my findings on this latter topic are set forth in PARRILLO REPORT, *supra* note †, at 137-86, and do not appear in this Article. Note that, for interviewees who wished their identities to remain confidential, I have arbitrarily assigned male and female pronouns in different Parts of the Article—male for the Introduction and Part II and female for Parts I and III—to avoid giving information on the identities of these sources.

with other legal values). It is not a problem of bureaucratic bad faith that calls for accusation and blame.

In arguing for these conclusions, I seek to shift the discourse on guidance—a discourse in which accusation and blame are all too prevalent, to the point of distracting from the unintended pressures and rigidities that are the main causes of the problem and the most promising objects of reform. Probably the biggest source of the tone of accusation and blame is a 1992 article on guidance by Robert Anthony,²⁸ which is the most cited and influential scholarly work on the subject to this day.²⁹ Anthony contended that agencies were often engaged in a deliberate and conscious effort to coerce regulated parties through guidance while pretending the guidance was not binding.³⁰ Ever since Anthony’s publication, this notion—that coercion by guidance is something agency officials *intend*—has been a running theme in how people talk about guidance. ACUS’s longstanding best practices for the use of guidance, which were adopted on the basis of Anthony’s work, speak in terms of agency *intent* to bind.³¹ More recently, the Attorney General’s memo on “improper guidance documents” partakes of intent-based thinking when it says such documents “should not be used *for the purpose* of coercing persons or entities outside the federal

28. Anthony, *supra* note 15.

29. According to the Westlaw database, Anthony’s 1992 article has been cited in 193 law review articles from 2003 through 2017, for an annual rate of 12.9 citations over the period (it was cited in 11 times in 2017 and 26 times in 2016). This is a higher annual rate (counting from 2003 or from the year of publication, whichever is later) than any other of the articles on guidance cited in note 18, *supra*. The ones that come nearest are Franklin (10.1) and Manning (8.4). On Anthony’s influence, see *infra* text and accompanying notes 33-34.

30. According to Anthony, “agencies often inappropriately issue [guidance documents] with the intent or effect of imposing a practical binding norm upon the regulated or benefited public.” Anthony, *supra* note 15, at 1315 (emphasis omitted). These were Anthony’s twin concerns: “intent” and “effect.” He used that paired formulation repeatedly (sometimes substituting “purpose” for “intent”). *Id.* at 1328, 1355-59, 1373. But of the two, his concept of a binding “effect” was not seriously formulated or analyzed; the longest discussion of it is at *id.* at 1358-59 (referring to situations in which an agency’s frontline decisionmakers treat a guidance document as dispositive of the questions that come before them). It was “intent” that drew most of Anthony’s intellectual energy, for he believed that agencies’ abuses were quite often deliberate. *Id.* at 1360 (“[T]he agency may well have settled firmly upon its policies, with every intent of exacting conformity from those affected. The fact that the policy is announced in a nonlegislative document—and speaks of reserved discretion to act at variance with it—does not change that intent. But under the D.C. Circuit’s test [which upholds a guidance document if it is tentative], this tactic furnishes the agency with a convenient chance to have things both ways: to impose a practical binding effect upon private parties, but also plausibly to argue to the courts that the informal issuance and reserved discretion prove there was no obligation to proceed legislatively. This strategy may through bureaucratic habit be pursued in the best of faith. But in reviewing the cases one cannot avoid suspecting that the agencies consider it easy to fool the courts on these points, or at least think it is worth arguing, in the face of manifest reality, that their reservation of discretion means that they have not bound the complaining members of the public.”); see also Elliott, note 18, at 1490 (stating that Anthony wanted courts to “go behind the objective terms of a statement of agency policy to speculate about whether the statement was ‘really intended’ to bind the public”).

31. ACUS Recommendation 92-2: Agency Policy Statements, 57 Fed. Reg. 30103, 30104 (July 8, 1992) (“Agencies should not issue statements of general applicability that are *intended* to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures.”) (emphasis added). The “effect” prong from Anthony’s study, noted in *supra* note 30, was deleted during ACUS’s deliberations. Strauss, *Rulemaking Continuum*, *supra* note 2, at 1488 n.74.

government.”³² In the case law on whether guidance is binding, in which Anthony has been a leading authority,³³ courts have repeatedly looked to whether agency officials “intend” guidance to bind.³⁴ In the political discourse on guidance, implications of bad faith—of the idea that officials using guidance are secretly trying to exercise coercive power without legal safeguards—are prominent. Advocacy pieces say, in their titles, that guidance documents are “Underground Regulations,”³⁵ or “Backdoor and Backroom Regulation,”³⁶ or that they amount to “Washington’s Lawlessness.”³⁷

The time has come for a less moralistic and more realistic assessment. Anthony was correct to say that regulated parties often have no practical choice but to follow a guidance document (I stress that I say *often*, not *always*). But he was mistaken to view this phenomenon primarily in terms of the agency’s “intent” to produce this unhappy outcome. To understand why, we must break the subject into two parts. First, we must consider what pressure a regulated party feels to follow guidance when the guidance is operative, that is, when the agency has not granted a party’s individual request for a dispensation from the guidance. Second, we must consider agencies’ willingness or unwillingness to grant such dispensations—in other words, agency flexibility.

Part I of this Article addresses the pressure that regulated parties feel to follow guidance when it is operative. The origins of this pressure usually lie not in some plot hatched by the agency but instead in a series of structural features of modern regulation and of the legislation that establishes it, nearly all of which

32. ATTORNEY GEN., *supra* note 13, at 2 (emphasis added).

33. Gen. Elec. Co. v. EPA, 290 F.3d 377, 382-83 (D.C. Cir. 2002) (quoting Anthony repeatedly and at length on how to distinguish guidance from a legislative rule, including his statement that “[i]f a document expresses a change in substantive law or policy . . . which the agency intends to make binding or administers with binding effect,” the document cannot be legitimate guidance; it must go through notice and comment or be unlawful); *see also* Catawba Cty. v. EPA, 571 F.3d 20, 33 (D.C. Cir. 2009) (quoting this same language to state the law); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (citing Anthony). Of the various schools of thought on guidance, Anthony led the school contending that guidance should be judicially invalidated if binding, Seidenfeld, *supra* note 14, at 345, which is the one accepted by the judiciary, as evidenced by the fact that only for this “school” does Seidenfeld cite current case law consciously following the views of the school, *id.* at 344-64.

34. Cohen v. United States, 578 F.3d 1, 7 (D.C. Cir. 2009) (quoting Syncor Int’l Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997)) (stating that the “primary distinction” between a legislative rule and a policy statement “turns on whether an agency intends to bind itself to a particular legal position”), *vacated but reaff’d in relevant part on rehearing en banc*, 650 F.3d 717, 723 (D.C. Cir. 2011); *see also* Molycorp, Inc. v. EPA, 197 F.3d 543, 546 (D.C. Cir. 1999) (quoting same language); U.S. Tel. Ass’n v. FCC, 28 F.3d 1232, 1234 (D.C. Cir. 1994) (containing similar language about intent); Vietnam Veterans of Am. v. Secretary of the Navy, 843 F.2d 528, 537 (D.C. Cir. 1988) (containing similar language about intent). Admittedly, one cannot say that agency intent is “the test” for whether guidance binds, the case law being too confused for reduction to any single test. On the confusion in the case law, which Seidenfeld argues is inevitable given the nature of the binding-status inquiry, *see* Seidenfeld, *supra* note 14, at 346-49, 351-52.

35. NFIB REPORT, *supra* note 9.

36. Hester Peirce, *Backdoor and Backroom Regulation*, THE HILL (Nov. 10, 2014, 06:30 AM EST), <https://thehill.com/blogs/pundits-blog/finance/223472-backdoor-and-backroom-regulation> [<https://perma.cc/9E96-W4N8>].

37. CREWS, *supra* note 9.

are vastly beyond the control of the agency officials who issue or use a guidance document.³⁸ Part I examines four such features. First, legislation may require regulated parties to obtain pre-approval, that is, to seek the affirmative assent of the agency in order to get some legal advantage, like a permit or monetary benefit. If the advantage sought is important to the party, and if the agency's decision is uncertain and subject to delay, the incentive to follow whatever the agency's wishes appear to be (including guidance) can be overwhelming. Second, the legislative scheme may subject the regulated party to continuous monitoring and frequent evaluations by the agency. If the law is complex, the regulated party will inevitably end up failing to comply with at least a few prohibitions or approval requirements. To insure against this contingency, the party will invest in its relationship to the agency, that is, seek to build up the agency's trust and confidence in its good faith and cooperativeness, including by following guidance. Third, the regulated firm is a "they," not an "it," and the last generation has seen rapid growth in new cohorts of corporate personnel—most prominently "compliance officers"—whose backgrounds, socialization, and career incentives arguably give them an especially strong incentive to maintain good relations with the agency and therefore to follow guidance. Although one may argue that this growth is driven partly by governmental pressure, that pressure emanates mainly from the U.S. Sentencing Commission's Organizational Guidelines and from DOJ prosecutorial practice rather than from any regulatory agency.³⁹ Fourth, a regulated party subject to *ex post* enforcement will have an incentive to follow guidance that increases with the probability of detection of noncompliant behavior, the cost of an enforcement proceeding irrespective of outcome, the probability of an unfavorable outcome, and the cost of a sanction in that event. This fourth factor is probably the most obvious, but I must emphasize that its incentive power cannot be simply assumed, for it varies greatly depending on the structure of the statute and the agency. In some (though far from all) contexts, dynamics arise similar to those in coercive plea-bargaining, meaning the regulated party cannot expect, without prohibitive risk, meaningful examination and adjudication of the accusation by an official distinct from the enforcement personnel. This situation creates a strong incentive to avoid being accused in the first place.

Finally, in the fifth and last section of Part I, I identify certain areas of regulation—OSHA regulation of most employers, FTC consumer protection, CFPB regulation of most nonbanks, and EPA enforcement against permitless discharges into protected waters—as ones in which guidance is relatively less

38. Insofar as agency officials do play a role in bringing these structural features into being, it would involve a host of official activities—such as advising Congress on major decisions in designing legislation—that go far beyond what officials are thinking about with respect to a guidance document.

39. The rise of compliance personnel has occurred largely in the years since Anthony's 1992 article.

likely to be followed, according to interviews. I note that in all these areas, the four structural features discussed earlier in Part I are mostly weak or absent.

If an agency official works within a statutory and regulatory structure where most or all of these four factors are robust, then whatever that official issues in the form of guidance will quite likely be followed by regulated parties. But that is not because of any “intent” on the part of the official to bind anyone. The structural incentives to follow the guidance will operate on regulated parties regardless of the official’s subjective state of mind. Of course, it is possible that an official may consciously recognize these structural incentives and anticipate that they will operate in a way that shifts regulated parties’ behavior toward what the guidance says. Indeed, it seems fair to assume that most high-ranking agency officials would be aware of these factors. But if such knowledge disqualifies those officials from issuing guidance, on the ground that this entails an impermissible intent to bind, then all agencies operating in areas where most or all of the four factors listed above are robust (pre-approval requirements, long-term firm-agency relationships, compliance cohorts in industry, and ex post enforcement) would be largely disqualified from ever issuing guidance. That is to say, many and perhaps most agencies would be disqualified from ever issuing guidance. This interpretation cannot be right.⁴⁰

If we really want to protect regulated parties from feeling pressured to follow guidance when operative, we would have to substantially reform the structural features of the administrative state that create strong incentives to discern and follow an agency’s wishes. There *are* arguments for reforming those structural features, but these would have major consequences and implicate a host of issues ranging well beyond the controversy over guidance. Pre-approval requirements have been condemned by some as intolerable encroachments on liberty,⁴¹ but abolishing them would entail radical rollbacks of health, safety, and environmental regulation. More incremental reforms are also possible, but these, too, implicate wide-ranging questions.⁴² The tendency of heavily regulated businesses to invest in positive relationships to their regulator may create dangers of coercion or favoritism, and there are obvious (if costly) means of preventing

40. Perhaps the real concern is that an official, wishing to implement a policy by one means or other, will choose guidance as the vehicle rather than legislative rulemaking because he/she knows guidance is less costly to issue yet likely for structural reasons to elicit nearly the same alteration in regulated parties’ behavior. *E.g.*, Funk, *Primer*, *supra* note 18, at 1333 (raising this issue at a theoretical level). But this argument does not turn on whether the policy is binding or not. Instead it turns on whether the policy is a “big enough deal” that regulated parties should have been bound to it only through the formalities of legislative rulemaking, rather than being bound to it by guidance reinforced by structural incentives. In other words, the argument is a revival of the old “substantial impact” doctrine that identified any policy having a “substantial impact” on the public as one that had to go through legislative rulemaking. The courts rejected that doctrine decades ago in favor of the present “binding effect” test. Anthony, *supra* note 15, at 1376 n.370.

41. Richard A. Epstein, *The Permit Power Meets the Constitution*, 81 IOWA L. REV. 407 (1995).

42. Eric Biber & J.B. Ruhl, *The Permit Power Revisited: The Theory and Practice of Regulatory Permits in the Administrative State*, 64 DUKE L.J. 133 (2014) (discussing the use of general permits).

those relationships from forming (as by rotating agency personnel). Yet doing so would dramatically increase information costs to the agency⁴³ and might incline the agency to become more impersonal, exacting, and punitive.⁴⁴ The rise of the compliance profession has been attacked as a stealth reform imposed on corporate America by unelected and ill-informed DOJ prosecutors,⁴⁵ but corporate compliance programs are now the norm across many industries and are considered by many to be a salutary development. In any case, they cannot be eliminated without a major dislocation. And while there are proposals to reform administrative law enforcement to make settlement bargaining less coercive—for example, to redraft statutes to diminish liability and penalties or to establish more neutral, independent institutions to oversee enforcement personnel⁴⁶—these, too, have high costs and wide-ranging implications.

Part II of the Article turns to agency flexibility. If structural features create a strong incentive to follow certain guidance whenever the guidance is operative—a point we must take as given in the near term—there is still one escape hatch: the agency itself is in control of whether the guidance is operative for any particular regulated party. As Anthony memorably phrased it: “If the agency genuinely maintains an open mind, so that an applicant has a realistic chance to persuade [the agency] to adopt a different position [than the one in the guidance] when the applicant’s particular case is passed upon, [then] the original [guidance] had neither the intent nor the effect of imposing mandatory constraints on the applicant.”⁴⁷ ACUS’s best practices elaborated this principle by declaring that an agency is supposed to afford every regulated party a “fair opportunity” to seek departure from guidance “in an agency forum that assures adequate consideration by responsible agency officials.”⁴⁸ The D.C. Circuit has said that a guidance document preserves the required discretion when “the agency’s position” on the subject matter of the guidance “remains flexible.”⁴⁹

Yet, in the view of critics like Anthony, the agency’s mind is frequently closed, and intentionally so, even if the agency tries to hide this fact. “Where the [guidance document] reserves discretion to decide cases individually and to vary

43. Cf. DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 663 (2010) (“Firms’ reputations matter in part because a resource-constrained and uncertain regulator is compelled to rely partially upon trust.”).

44. If a regulator has a continuing series of interactions with a regulated party, the regulator may need to be punitive only as a last resort within a larger framework that begins (and usually ends) with presumptive mutual trust. See generally IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 19-53 (1992).

45. Sean J. Griffith, *Corporate Governance in an Era of Compliance*, 57 WM. & MARY L. REV. 2075, 2117-30 (2016).

46. Rachel E. Barkow, *Overseeing Agency Enforcement*, 84 GEO. WASH. L. REV. 1129, 1143-50 (2016).

47. Anthony, *supra* note 15, at 1362.

48. ACUS Recommendation 92-2: Agency Policy Statements, 57 Fed. Reg. 30103, 30104 (July 8, 1992).

49. *Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 809 (D.C. Cir. 2006); see also Levin, *Open Mind*, *supra* note 18, at 1500 (“The essence of the agency’s duty, I suggest, should be an obligation, first, to allow the challenger to present a case, and second, to respond meaningfully to that case.”).

the standards,” said Anthony, “a challenger will find it difficult to show a resolve [on the agency’s part] to apply the standards rigorously even if that is in fact the [agency’s] intention.”⁵⁰ Anthony admitted that “the agency heads may be genuinely uncertain about what they will want to do when cases arise.”⁵¹ “The trick,” he said, “is to distinguish their announcements in these situations of authentic uncertainty . . . from those announcements where they *do* intend to do exactly what they say they are going to do (as to which legislative rulemaking should be required, since the public will be bound).”⁵²

Again, Anthony was correct that agencies are sometimes practically inflexible in their use of guidance (*sometimes*, not *always*). And he was correct that agency inflexibility can have a burdensome and coercive effect on regulated parties who want to do things differently from the guidance. But again, his focus on “intent” obscures more than it illuminates.

I break down the reasons for agency inflexibility in a manner that is more concrete, specific, and variegated than a monolithic concept of “intent” allows. One might assume that flexibility is the path of least resistance for an organization, such that any inflexibility must reflect some conscious and nefarious plan. But that is wrong. Federal agencies face a host of external pressures and internal dynamics that can make them naturally inflexible. The very real fact of agency inflexibility can be mostly (though not entirely) explained by agencies’ sensitivity to competing rule-of-law values that favor consistency, by their lack of resources, and by their inertia in the face of unintended organizational tendencies that foster rigidity.⁵³

First off, we must recognize that agencies are quite often under active stakeholder pressure *to be inflexible* (i.e., to be consistent) and that these stakeholder pressures spring from legitimate concerns that agencies cannot simply ignore. Most prominently, any regulated firm that receives a favorable departure from guidance will put its competitors at a disadvantage, and those competitors will protest. Further, they may come to lose faith in the predictability of the agency and in the idea that the agency provides them a level playing field—a shift that may cause them to withdraw from cooperation with the agency, thereby diminishing compliance and making the whole regulatory program less effective. Meanwhile, individualized flexibility on guidance, if it favors a particular regulated party, smacks of favoritism and thereby attracts the

50. Robert A. Anthony, “Well, You Want the Permit, Don’t You?” *Agency Efforts to Make Nonlegislative Documents Bind the Public*, 44 ADMIN. L. REV. 31, 37 (1992).

51. *Id.*

52. *Id.*

53. Anthony did briefly acknowledge that agencies might act inflexibly for reasons other than an intentional plan to bind regulated parties. Anthony, *supra* note 15, at 1364-65 (noting that agency staff may rigidly apply guidance because it “is the quick and simple thing to do” and out of fear of “criticism” or “disapproval,” without elaborating on who might be the source of such criticism or disapproval, and then reemphasizing the bad-faith scenario: “it can often be quite clear that [the agency’s] nonlegislative document was intended to control the staff’s basis for decision”). Overall, Anthony placed far more emphasis on the intentional-plan scenario.

negative scrutiny of the media, NGOs, and members of Congress. On top of all this, some competitors of the firm that received the favorable departure from guidance will be stung by the apparent unfairness and understandably ask, “why can’t I get this exception, too?” One departure thus invites other requests for departure, and these requests eat up the agency’s resources and pose the danger that any coherent policy will unravel. To prevent all this from happening, the agency may simply deny departure requests to avoid opening the floodgates.

Significantly, there is a way for an agency to maintain flexibility while addressing these legitimate pressures for consistency: it can take the approach of *principled flexibility*.⁵⁴ That is, for each departure the agency makes, it gives a written explanation that is accessible to other agency officials and to the public, with the understanding that the exception then becomes generally applicable to like cases prospectively. The departure explanations accumulate to form a body of evolving precedent. Principled flexibility helps refute accusations of favoritism, cabins the rationale for each departure so as to avoid opening the floodgates to more requests, promotes fairness among competitors by ensuring that all exceptions become generally available on a prospective basis, and aids predictability because the obligation to provide a reason for each departure will tamp down the number of departures and make it easier to anticipate when departures may happen.⁵⁵

Crucially—and unfortunately—principled flexibility is not easy to implement, though many agencies try. It takes resources and runs into certain managerial obstacles. Most important, the reason-giving mandate means that every request for departure requires time and money to evaluate. Regulated parties requesting departures can bear some of this cost, but saddling them with it chills requests for departures to begin with (thereby increasing practical inflexibility). And besides, the agency itself has to do some independent investigation. Inflexibility resulting from the cost of evaluation and reason-giving manifests itself especially in programs that combine a high volume of individual decisions, scant resources, and time pressure. Further, the need for a higher-level official to sign off on each departure—which many agencies require and many commentators and institutional pronouncements endorse—forces departures through a bottleneck of political appointees and senior civil servants

54. My formulation of principled flexibility is inspired by two sources. One is Robert Kagan’s study of the Nixon wage-price freeze (which is not about guidance but policy application more generally), and particularly Kagan’s distinction between the “judicial mode” of policy application (corresponding to principled flexibility) and “legalism” (corresponding to inflexibility). ROBERT A. KAGAN, *REGULATORY JUSTICE: IMPLEMENTING A WAGE-PRICE FREEZE* 91-96 (1978). The other source is Peter Strauss’s response to Robert Anthony’s ACUS study of guidance, particularly Strauss’s suggestion that guidance be treated like agency adjudicatory precedent, with an APA-style obligation to give reasons for any departure. Strauss, *Rulemaking Continuum*, *supra* note 2, at 1472-73, 1485-86.

55. In some contexts (though certainly not all), principled flexibility may be required by the APA’s arbitrary-or-capricious standard, *see infra* notes 327-331 and accompanying text, though it is not practical to think judicial enforcement will be the main driving force behind agencies’ adoption of it.

who have especially limited time and lack fine-grained information about the matters they are reviewing. This renders departures yet harder to grant.

On top of these organizational and resource-based obstacles to principled flexibility, there are additional obstacles that stand in the way of flexibility of any kind, principled or not. Flexibility requires that regulated parties be able to go over the heads of frontline officials who deny departures and act too rigidly, but such parties may fear that such appeals will damage their relationships with the frontline officials, and this fear, even if baseless, can have consequences unless affirmatively dispelled. When faced with appeals, higher-level officials have various institutional motives to back up their subordinates irrespective of the merits of the case. More subtly, the rule/guidance distinction is not intuitive to most people (except perhaps lawyers), and that lack of understanding can make flexibility harder to achieve. In addition, the day-to-day business of a government office can socialize its personnel to be less receptive to regulated-party requests, though sometimes more receptive. Offices that have day-to-day habits of cooperating with industry (like program offices engaged in rulemaking) tend to be more flexible on guidance-related matters than, say, enforcement offices. Finally, it is possible to get agencies to be more flexible by giving training on the rule/guidance distinction to their personnel, though this tends to be most effective when the trainers are embedded relatively close to the decisionmakers and can monitor and counsel them on an ongoing basis—something that is not cheap.

All that said, there *are* some instances in which agencies hold fast to guidance not because of legitimate external pressures for consistency, nor because of inertia or resource poverty in the face of organizational pathologies, but instead because agency personnel just think the guidance is right. That is, they are committed to the substantive content of the guidance, and they therefore close their minds to reconsideration or departure. Of the many reasons why agencies are inflexible, this one is the most problematic. If an agency wants to shut off the possibility of departing from a policy simply because it thinks the policy is right, that is the archetypal scenario for legislative rulemaking.

What is to be done? We must recognize that agency flexibility is a good aspiration, but it is not the path of least resistance, at least not when undertaken in the principled manner for which agencies ought to strive. Being flexible in a good way requires spending resources and undertaking active managerial reform. Therefore, agencies cannot, as a practical matter, be flexible on everything all the time. Priorities must be set. In deciding which guidance documents warrant the most active exertions in favor of flexibility, we should assign a higher priority to a document (a) the more it is likely to alter regulated-party behavior when operative, given the incentives discussed in Part I, (b) the less it is subject to the legitimate external pressures for consistency discussed at the start of Part II, and (c) the more the agency clings to the document by reason of commitment to the document's substantive content. On this very last point (c), one may think I am being utopian. If an agency thinks the substance of a guidance

document is right, is that not the scenario in which the agency would be *least* willing to keep an open mind? Not necessarily. For one thing, as discussed at the end of Part II, the agency personnel who are committed to the substance of a guidance document are often the political appointees or the career officials—but not both. If a strong norm in favor of flexibility can be articulated, it will sometimes be possible for the political appointees to effectively invoke the norm against the career officials and vice versa.

The Article closes with Part III, which considers a distinct phenomenon from the ones examined above: deregulatory guidance—guidance that promises, at least tentatively, to treat regulated entities favorably, as by suggesting that a certain course of regulated-party conduct enjoys a safe harbor in permit applications or is a low priority for enforcement. One can expect regulated parties to alter their behavior according to such guidance, not because of any of the coercive structural features discussed in Part I, but simply because they have new latitude to do what they want. Yet if this happens, the people Congress intended to protect by regulation—regulatory beneficiaries—may be harmed. Under D.C. Circuit case law, such beneficiaries can get the guidance struck down if it is too rigid, meaning the agency must either go through legislative rulemaking or rework the guidance to be more flexible. Flexibility, in this context, means the agency, in any particular enforcement or adjudicatory proceeding, remains open-minded to the possibility of treating the regulated party *more stringently* than the deregulatory guidance suggests.

But is flexibility in deregulatory guidance really a useful remedy for regulatory beneficiaries? Remember that flexibility operates at the microlevel of individual adjudicatory and enforcement proceedings. In most such proceedings, no regulatory beneficiaries are going to show up. There will thus be nobody to make the requests for departure that are the lifeblood of flexibility. It seems the best approach—except in the select areas where NGOs representing beneficiaries have the practical capacity to participate in individual adjudication and enforcement—is for agencies to promote participation by regulatory beneficiaries by soliciting such beneficiaries' views (and the views of NGOs who represent them) on a wholesale rather than retail basis at the time when guidance is initially issued. This will usually be the form of participation most suited to NGOs' limited resources.

* * *

Finally, a word about the intended audience for the proposals in this Article. Mitigating the binding power of guidance documents entails interventions that are essentially structural and managerial in nature. The people best suited to take and/or encourage such actions are agency officials themselves, inspectors general, and pangovernmental institutions specializing in agency management, including the Office of Management and Budget (OMB), congressional

oversight committees, and the Government Accountability Office (GAO).⁵⁶ One may naturally ask whether the courts, too, should take account of the Article's findings. As it is, the courts, in deciding whether a guidance document is binding (and thus unlawful), look officially to the document's text and to agency practice. But really, they look mainly to the document's text, combing through the language for impermissibly mandatory wording like "shall" rather than "may" (the reading of documents being a task within the judicial comfort zone). Courts almost never invalidate guidance for rigidity on the basis of agency practice alone.⁵⁷ The Article provides a map of administrative realities that courts might use if they were to venture more aggressively into interrogating whether agency practices rendered a guidance document binding—including the likely irrelevance of officials' intent to that inquiry. But at the same time, the very complexity of the factors that create pressure on stakeholders and inflexibility among officials may indicate that the inquiry is largely beyond judicial competence, such that judicial restraint of the kind largely practiced so far (if implicitly) is warranted.⁵⁸

I. Regulated Parties' Incentives to Follow Guidance

This Part analyzes four major factors that incentivize regulated parties to follow guidance even if legally nonbinding: (A) pre-approval requirements, (B) investment in relationships to the agency, (C) intrafirm constituencies for compliance beyond legal requirements, and (D) the risks associated with one-off enforcement. The Part concludes (in Section I.E) with a discussion of certain regulatory areas where these factors are weak or absent, and incentives to comply with guidance are less.

A. Pre-Approval Requirements

Regulated parties have a strong incentive to follow guidance when they face a pre-approval requirement, that is, when the relevant statutes and legislative rules require them to obtain the affirmative assent of the agency in order to get some legal advantage, such as a permit, license, accreditation, monetary benefit, reimbursement, etc.⁵⁹ The strength of the incentive varies with four factors.

56. The study from which the Article draws has already provided one such pangovernmental institution, ACUS, with the basis for adopting a new set of best practices on guidance, adopted in December 2017. ACUS Recommendation 2017-5: Agency Guidance Through Policy Statements, 82 Fed. Reg. 61728, 61734 (Dec. 29, 2017).

57. See *supra* note 20.

58. In the one case I have located in which a court clearly relied exclusively on rigidity in agency practice to invalidate a guidance document for being binding, the panel was split by a complicated disagreement over the very facts of agency practice. *Compare Texas v. United States*, 809 F.3d 134, 171-76 (5th Cir. 2015), with *id.* at 207-14 (King, J., dissenting).

59. The strong incentive that regulated parties have to follow guidance in a pre-approval regime is briefly discussed by Anthony, *supra* note 15, at 1340, and by Raso, *supra* note 21, at 803-04. For an in-depth theoretical treatment of how pre-approval regimes generally give agencies more leverage

First, the incentive increases with the importance of the sought-for legal advantage to the regulated party. In the business context, think of FDA approvals for drug manufacturers or Medicare reimbursements to healthcare providers, which determine their very survival. In the individual context, think of lawful status for a deportable immigrant, which may determine his or her livelihood and be necessary to family connections.

Second, the incentive to follow guidance increases with the uncertainty of obtaining the agency's assent in the absence of guidance. Uncertainty can be reduced or eliminated by highly specific criteria set forth in statutes or legislative rules, or by a preapplication adjudicatory process that tells the party what it must do before it goes down the wrong path, or simply by an agency's reputation for granting pre-approvals as a rubber stamp. But if the statute, legislative rules, and application process leave a grey area—and if the agency has demonstrated the gumption to deny requests that fall into that grey area—then regulated parties feel the need to learn as much as they can about what the agency wants, however those wants are expressed. Guidance becomes like water in the desert.

Third, the incentive to follow guidance increases with the marginal cost to the regulated party of reapplying successfully after its initial application is denied. That cost includes any nonreusable investment made in the initial application. If the reapplication requires a costly redo of the initial submission, or worse, investment in a different product or service, that can mean a big loss of money and time. The prospect of such loss incentivizes the party to simply follow guidance in the first go-around.

Fourth, the incentive to follow guidance increases the more discretion the agency has to delay its pre-approval decision and, with it, the regulated party's receipt of the legal advantage. For a firm, time spent getting to market means the loss of profits and (potentially) competitive advantage. The agency's power to leverage delay can be reduced if the party is permitted to enjoy the sought-for advantage while its application is pending, if agency delay is subject to a time limit or efficacious complaint system, or if the agency must decide requests in a queue. But otherwise, the regulated party is at the agency's mercy and must do whatever it can to make the agency's decision as easy and comfortable as possible. Once again, the party must gain as complete a picture as it can of what the agency wants, with guidance being an obvious source.

over regulated parties than do ex post enforcement regimes, see Bhagwat, *supra* note 19. Bhagwat provides a valuable frame for thinking about pre-approval schemes, particularly on how pre-approval makes outright noncompliance easier to detect, *id.* at 1314-15, forces regulated parties to volunteer information to agencies, *id.* at 1311-12, and shifts the cost of delay and inaction from the agency to regulated parties, *id.* at 1295-1300. That said, Bhagwat says nothing about the rule/guidance distinction or how the leverage associated with pre-approval makes it easier for agencies to influence regulated parties' behavior without legislative rulemaking (except for a passing reference to this issue, *id.* at 1306). Rather his focus, insofar as it goes to APA issues, is on how pre-approval empowers agencies to make policy, by whatever means, that goes beyond the enabling act or the arbitrary-or-capricious standard, as pre-approval's incentives make it practically difficult for regulated entities to seek judicial review. *Id.* at 1304-10.

A classic pre-approval regime is the statutory requirement that drugs and medical devices be approved by the FDA as safe and effective before marketing. Consistent with this, interviewees observed that the FDA's published guidance documents have extremely strong influence on how drug and device makers design studies and, concomitantly, how they design the drug or device itself in contemplation of needing to perform adequately in such studies—decisions involving investments in the tens or hundreds of millions of dollars.⁶⁰ Given the nature of premarket approval, explained one food and drug industry attorney when discussing conformity to guidance, an applicant must anticipate how the FDA thinks; it would be “foolish” to proceed with an application without following the agency's guidance.⁶¹ According to a former senior FDA official, there are two rules for obtaining premarket approval: “first, find out what FDA wants”; and “second, do it and don't argue.” What matters, said the former official, is “what FDA wants,” and guidance is a very important source for finding that out. The guidance, combined with other means of communicating the FDA's expectations before a drug maker invests in the requisite studies, is something for which the former official thought applicants should be grateful—“thank God I found out” that the FDA would not accept this protocol “before I spent \$100 million on it!”⁶² According to another former FDA official, companies' investment in their products is so large that they cannot depart from FDA guidance without a “gold-plated assurance” from the agency that the course they propose will be acceptable.⁶³ The general counsel of GlaxoSmithKline stated that, especially on premarket approvals (as compared with other dealings between drugmakers and the agency), if the FDA says, “jump,” you ask, “how high?”⁶⁴ When the FDA has published a guidance document in draft for public comment and has not yet made it final, said a trade association official, a company's decision whether to comply with the draft's contents depends on the contents' impact and on the company's risk tolerance—but, in the specific context of premarket approval (as distinct from other FDA-industry interactions), companies will always follow the draft's contents with almost no exceptions because premarket approval decisions are discretionary, and the draft represents the FDA's latest thinking on the matter. It would be “folly” not to follow it.⁶⁵

60. For an argument that the FDA has used its leverage in the licensing context to extract concessions from companies that effectively expand the agency's power beyond what is allowed by statute (with some reference to the force of guidance in this context), see Noah, *supra* note 21, at 122-24, 130-37.

61. Interview with Source 92, food and drug industry attorney. The interviewee added that one could go to the FDA before submitting the application and “work something out” beforehand regarding departure from guidance; on that process, see *infra* Part II.

62. Interview with Source 110, former senior official, U.S. Food & Drug Admin.

63. Interview with Source 20, former official, U.S. Food & Drug Admin.

64. Interview with Daniel Troy, Gen. Counsel, GlaxoSmithKline.

65. Interview with Source 24, official, trade association. For additional evidence for guidance's peculiar force in premarket approval, see PARRILLO REPORT, *supra* note †, at 40 n.91.

Importantly, this view of the relatively greater force of guidance in the pre-approval context is shared not only by industry interviewees and former FDA officials but also by officials at Public Citizen’s Health Research Group, a leading FDA watchdog. In discussing FDA guidance on abuse-deterrent opioids, the Public Citizen advocates noted this guidance was an example of the FDA holding high leverage over industry because the context was premarket approval. It is with *post*-approval industry activities, they said, that industry compliance becomes a serious problem.⁶⁶

Although FDA review times have been subjected to statutory deadlines and targets and thereby reduced since the 1990s, the amount of time it takes for the FDA to decide an application is still variable enough that observers think following guidance significantly helps a firm get to market more quickly.⁶⁷ As noted by a partner in a large law firm and former senior federal official, approval is not an on/off switch, in part because the FDA has great discretion on matters like delay; companies will follow guidance to get their applications approved faster.⁶⁸ Another former senior FDA official likewise said that on premarket review the reason to follow guidance is to obtain approval faster.⁶⁹

As a former senior FDA official noted, agency personnel will engage in pre-submission correspondence and meetings with an applicant to clarify what they expect, thus reducing uncertainty and helping the applicant avoid investing in protocols that will not meet with approval. Mainly, however, these communications are a means of implementing and elaborating the FDA’s published guidance documents, which the agency cites and always follows in these communications, albeit with some latitude for interpretation.⁷⁰ And even with this back-and-forth, the FDA may refrain from answering some applicants’ questions, leaving them with nothing except published guidance documents to fall back on. If a new drug applicant asks to proceed differently than the guidance suggests, says a former FDA official, the agency will often reply, “you can, but it will be a review issue”—that is, only after you invest large sums in certain studies and submit the application will we decide whether those studies are acceptable.⁷¹ In either case, the applicant ends up strongly incentivized to follow the guidance.

Pre-approval requirements with strong incentives to follow guidance are also in place in several programs at the EPA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a maker of pesticides cannot sell a new

66. Interview with Michael Carome, Director, and Sammy Almashat, Research Associate, Pub. Citizen Health Research Group.

67. On the effect of review deadlines for new drugs, see Daniel Carpenter et al., *The Complications of Controlling Agency Time Discretion: FDA Review Deadlines and Postmarket Drug Safety*, 56 AM. J. POL. SCI. 98 (2011).

68. Interview with Source 78, Partner, large law firm, and former senior federal official.

69. Interview with Source 80, *supra* note 4.

70. Interview with Source 110, *supra* note 62.

71. Interview with Source 20, *supra* note 63.

product until it obtains registration from the EPA, which requires showing through scientific studies that the product is not unreasonably risky.⁷² As explained by an EPA official, the office that makes FIFRA registration decisions issues guidance to the pesticide makers on what studies to do and how. Following the guidance provides assurance that the EPA will consider the studies scientifically acceptable (although the agency's ultimate decision on registration depends on what the studies actually show). The statute and legislative rules do not require a manufacturer to do the studies according to the guidance, but it is unwise not to do them that way. The office can more easily evaluate a submission that does follow the guidance, so the manufacturer will obtain approval more quickly. Industry thus cares intensely about this preregistration guidance. If the FIFRA office says it wants something pre-registration, the manufacturer will do it. However, under FIFRA, most types of pesticide registrations, once obtained, remain in place permanently (they are subject to review every fifteen years, but even then, if the EPA discovers a problem, it can cancel the registration only by undertaking a lengthy affirmative proceeding). Thus, the manufacturer prior to registration is "on the outside looking in," but once registration is done, if the EPA wants something, the manufacturer is in a strong position to say, "thanks, we're not interested." The incentive is no longer there.⁷³

A former senior EPA official with cross-office responsibilities, reflecting on the role of guidance in different parts of the agency, singled out two offices where, in comparison to other parts of the EPA, there was both extensive use of guidance and general acceptance of guidance by industry: (1) the office handling FIFRA, described above, and (2) the office handling the Toxic Substances Control Act (TSCA), which likewise centers on pre-approval. The reason, she confirmed, was that both offices were registration programs (i.e., pre-approval regimes). In both, businesses understood that the agency had a broad mandate to approve individual compounds and that they, as seekers of approvals, needed predictability about what tests and studies to invest in. There was likely to be more industry "paranoia" about agency use of guidance at offices where industry was not "under the thumb" of the agency as it was in the FIFRA and TSCA offices.⁷⁴

Of course, there are pre-approval regimes in EPA programs other than FIFRA and TSCA. Under the Clean Air Act, automakers cannot ship a new model car until the Office of Transportation and Air Quality certifies that it meets tailpipe emissions standards.⁷⁵ Whatever that office says, observed a partner in a

72. 7 U.S.C. §§ 136(bb), 136a(a), 136a(c)(5)(D) (2018).

73. Interview with Source 41, official, Evtl. Prot. Agency.

74. Interview with Source 96, former senior official with cross-office responsibilities, Evtl. Prot. Agency.

75. See DAVID R. WOOLEY & ELIZABETH M. MORSS, CLEAN AIR ACT HANDBOOK: A PRACTICAL GUIDE TO COMPLIANCE § 5.16 (2018); *About the Office of Air and Radiation*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/aboutepa/about-office-air-and-radiation-oar#otaq> [<https://perma.cc/5FU3-P53K>] (noting the role of OTAQ).

large law firm and former senior EPA official, the automakers have to do it. It is not just the risk of a denial of certification that creates this pressure, she explained, but the office’s discretion over how long to take with the decision. If the agency just keeps asking questions, thereby deferring any decision, the delay itself puts the company’s investment at risk. This is especially true because auto industry investment decisions must be made well in advance (as they go by model years). One can sue for a delay on the order of five years, she noted, but not the one or two years that is enough for a competitor to get ahead. However, this same interviewee pointed out that not all pre-approval regimes created equal pressure to follow guidance. Under a different provision of the Clean Air Act, she noted, a pulp and paper mill must obtain a new permit for its emissions every five years, but as long as the mill submits a good-faith application on time, the law provides for its old permit to stay in place until the new one issues. Not bearing the burden of delay, the mill can push the EPA relatively hard in a way that the automakers are not willing to push the EPA regarding tailpipe emission certifications.⁷⁶

Another instance of pre-approval incentives to follow guidance can be found at the Department of Agriculture’s National Organic Program (NOP), though this one exemplifies how the incentives can be moderated in certain ways. The agency accredits nonfederal organizations as “certifying agents” (certifiers), each with a five-year term, to do inspections of farms and businesses to determine whether they can use the “USDA Organic” label.⁷⁷ A certifier that fails to obtain or maintain accreditation is out of business. As noted by a former chair of the NOP’s National Organic Standards Board (NOSB), the five-year renewal process involves an in-depth audit where the NOP reviews the certifier’s records and conducts site visits to see if the certifier is in conformity with all legislative rules. There is much guidance on just what the NOP expects. The legislative rules and the audit are complicated enough that the NOP will inevitably find some noncompliance that it will tell the certifier to correct. Though the NOP cannot issue warnings of noncompliance simply on the basis of guidance, it can issue warnings on the basis of applications of the legislative rules that track the guidance. Certifiers thus have an incentive to follow the guidance to avoid noncompliance warnings.⁷⁸ But the incentive is somewhat blunted in that (a) the certifier’s five-year accreditation is automatically extended for as long as the renewal application process runs,⁷⁹ and (b) the NOP, upon finding noncompliance within that process, will give the certifier time to correct

76. Interview with Source 52, Partner, large law firm, and former senior official, *Envtl. Prot. Agency*.

77. NAT’L ORGANIC PROGRAM, NOP 2000, INSTRUCTION: ACCREDITATION POLICIES AND PROCEDURES (2015), <https://www.ams.usda.gov/sites/default/files/media/General%20Accreditation%20Policies%20and%20Procedures.pdf> [<https://perma.cc/UJF4-4PW5>].

78. Interview with Jean Richardson, former Chair, Nat’l Organic Standards Bd., U.S. Dep’t Agric.

79. 7 C.F.R. § 205.510(c)(2) (2018).

it.⁸⁰ Thus, this is not quite like the FDA, where an applicant defying guidance risks being denied outright and prohibited from selling its product.⁸¹ The certifier departing from guidance is not immediately at risk of outright shutdown but will have a chance to come into compliance if the NOP should insist upon the course outlined in the guidance.⁸² However, explained the former NOSB chair, initial noncompliance findings can lead to incremental sanctions short of losing accreditation, like fines.⁸³ Plus, noted the president of a large certifier, the noncompliance warning itself can have collateral consequences like bad publicity.⁸⁴ Faced with this mix of incentives—and given the sense among certifiers that the integrity of organic food is their common endeavor with NOP⁸⁵—certifiers have strong reason to follow guidance. The NOP’s top official noted certain guidance documents about which certifiers were complaining even as they complied with them “reluctantly.”⁸⁶ Certifiers will push back when the guidance is being formulated, but if and when it becomes final, they will “suck it up” and try to comply and “make it work,” said the former NOSB chair.⁸⁷

Beyond permission to sell a product or provide a service, pre-approval incentives also kick in when a regulated party seeks money from the government. When it comes to Medicare reimbursement, a former Centers for Medicare & Medicaid Services (CMS) division director said that healthcare providers, in her experience, would “leave no rock unturned” to find the latest guidance. The “typical attitude” among attorneys in the area was to advise against making an investment in a manner not consistent with Medicare guidance, even if the guidance made no sense. Medicare is famous for punishments imposed through ex post enforcement by the Department of Health & Human Services (HHS) Office of Inspector General or by qui tam relators—False Claims Act penalties and treble damages, or even exclusion from the program. But the former division director, when she began discussing why healthcare providers follow Medicare guidance, first cited *not* the enforcement regime but instead the pre-approval structure: providers want to get paid. They do not want to invest in a piece of equipment or a service, bill for it, and then be denied. Nonpayment, she said, is the “scenario feared” by healthcare providers and is independent of the False

80. *Id.* § 205.507(a)(3).

81. Of course, the difference between the FDA and the NOP may be justified on the ground that the public-health consequences of the marketing of unapproved drugs are more severe than of marketing bogus organic products.

82. If the certifier contests rather than complies after receiving the warning, “then you’re playing for all the marbles,” in the words of one certifier president—that is, you are risking denial of accreditation, which can take away “your ability to function.” Interview with Jake Lewin, President, CCOF Certification Servs.

83. Interview with Jean Richardson, *supra* note 78.

84. Interview with Jake Lewin, *supra* note 82.

85. *Id.*; Interview with Jean Richardson, *supra* note 78.

86. Interview with Miles McEvoy, Deputy Adm’r, Nat’l Organic Program, Agric. Mktg. Serv., U.S. Dep’t Agric. Within the overall mix of incentives, accreditation is said to be “pretty significant” and a “big deal.” Interview with Jake Lewin, *supra* note 82.

87. Interview with Jean Richardson, *supra* note 78.

Claims Act (which, she acknowledged, is “also very scary”).⁸⁸ To be sure, there is some guidance that pertains to the initial claim-allowance stage and other guidance that pertains more to a subsequent audit where claims must be supported with documentation, with the remedy being a clawback. Consistent with this, a trade association official noted that healthcare providers’ conformity to CMS guidance varies with the perceived probability of an audit.⁸⁹

B. Maintaining Relationships

Regulated parties will have a strong incentive to follow guidance if they are invested in maintaining a good relationship with the agency. The need to maintain such a relationship arises when a regulated party is monitored by an agency continuously and must interact with it repeatedly under a regulatory scheme that is so complicated that the regulated party will inevitably engage in some conduct that is arguably noncompliant with the relevant statutes or legislative rules. (By *noncompliant*, I mean conduct for which the party would be liable in an enforcement setting, or that would warrant denial of a sought-for advantage in a pre-approval setting.) Under these conditions, it is to the regulated party’s advantage to win the trust of the agency—that is, to build a reputation with the agency for generally seeking in good faith to comply and cooperate. If the regulated party wins the agency’s trust, then the agency will likely reduce its scrutiny of the regulated party, thus diminishing the chance of the agency finding arguably noncompliant conduct, and also reducing the process costs borne by the regulated party of being scrutinized or investigated. Further, the agency will likely give the regulated party the benefit of the doubt if and when the agency does discover arguably noncompliant conduct; that is, the agency will interpret that conduct as relatively less deserving of adverse consequences (e.g., as accidental rather than deliberate).⁹⁰

The relationship between an agency and a regulated party may operate at one or more levels. It may operate at an institutional and official level, if, say, the agency has an announced policy of reducing the frequency of inspections for parties who have a good track record. Or the relationship may be institutional and unofficial, e.g., if the agency has no announced policy but its personnel (perhaps through internal word of mouth) have a common understanding that certain parties are trustworthy and generally deserve to be cut some slack. Or the relationship may be individual: a regulated party may have occasion to interact repeatedly with the exact same inspector, permit-writer, etc., and that particular

88. Interview with Source 93, former division director, Ctrs. for Medicare & Medicaid Servs.

89. Interview with Source 24, *supra* note 65.

90. Treatments of agency-regulatee relationships in the literature, from which this discussion draws, include: CARPENTER, *supra* note 43, at 662-84; Winston Harrington, *Enforcement Leverage When Penalties Are Restricted*, 37 J. PUB. ECON. 29 (1988); David P. McCaffrey et al., “*Then Let’s Have a Dialogue*”: *Interdependence and Negotiation in a Cohesive Regulatory System*, 17 J. PUB. ADMIN. RES. & THEORY 307, 323 (2006).

official's past experience with the party may color his or her perception of anything the party does. Even if the agency and its officials do *not* treat regulated parties differently based on relationships, a regulated party may *believe* that they do, and that mere belief may cause the regulated party to invest in building and maintaining what it thinks is a good relationship.

Following guidance is often an important way for a regulated party to build up goodwill and mutual trust with the agency or its officials (or, at least, to think it is doing so). Such behavior signals to the agency that the regulated party is not seeking to push the edge of the law but is instead sensitive to and respectful of what the agency thinks is the preferred course of conduct. It means the regulated party is not putting the agency to the trouble of figuring out whether guidance-noncompliant behavior is still lawful.

A regulated party who feels the need to maintain a good relationship with the agency will often be one who is subject to a pre-approval requirement, e.g., a large drug maker who must repeatedly seek approvals from the FDA. But relationship-building and pre-approval are nonetheless logically distinct, and they do not perfectly overlap. A company might be subject to *ex post* enforcement actions by an agency (rather than pre-approvals), but its operations might be vast and complex enough—and reporting requirements robust enough—that technical violations are detected with some frequency, so the company invests in good relations with the agency enforcement office. Conversely, a firm might be subject to a pre-approval requirement for something it does one-off, after which it does not expect to see the agency again. Most interestingly, as we shall see, a regulated party that is subject to both pre-approval requirements and *ex post* enforcement at the same agency may find or believe that its track record in *ex post* enforcement affects the agency's solicitude toward its pre-approval requests. If so, the agency's leverage on pre-approvals can be extended to other, non-pre-approval dealings between the agency and the party (and to guidance on those latter dealings).

Banks are a prime example of regulated parties who are invested in good relationships with agencies and thus are sensitive to guidance. When a bank is regulated by an agency, it will regularly be subject to an *examination* by that agency. An agency exam team will visit the bank for some period (say, three weeks) empowered to inspect whatever internal documents they want and to interview whichever bank employees they want, culminating in an exit interview between the examiners and bank officials, then finally a report from the examiners to the agency.⁹¹ The report will provide supervisory feedback and identify areas where the bank needs improvement. Such feedback, particularly if the bank does not respond adequately, may result in a number of supervisory responses, such as the agency downgrading the bank's confidential supervisory rating. This can trigger restrictions on the bank's business, e.g., potentially

91. Interview with Source 72, former Fed. Reserve senior official who has counseled financial institutions.

weighing on the bank’s ability to obtain the agency approval that is required to engage in certain expansionary activities like opening new branches or undertaking a merger.⁹² If problems caught during the examination are sufficiently bad and go uncorrected, the agency can bring a public enforcement action that may result in fines, removal of officers, or ultimately the shutdown of the bank by revocation of its charter.

A bank often has a relationship with not just one examining regulatory agency, but several. The Office of the Comptroller of the Currency (OCC) covers nationally chartered banks; the Federal Reserve (the Fed) covers state-chartered banks that are members of the Federal Reserve System, and also bank holding companies; the Federal Deposit Insurance Corporation (FDIC) covers state-chartered banks that are not members of the Federal Reserve System; and the Consumer Financial Protection Bureau (CFPB) covers large banks (national or state) for consumer protection issues.⁹³ As noted by a former senior Federal Reserve official, a single bank will often be subject to regular examinations by multiple agencies; one common combination would be the OCC (nationally chartered), the Fed (bank holding company), and the CFPB (consumer protection issues). For each bank-agency pairing, the usual time between examinations is one to three years, more or less. Thus, it would be common for a bank to have a multiweek examination by some agency or other about once a year (with some variation depending on bank size, as the smallest institutions are examined less, while the biggest ones have examiners on site year-round). Plus, banks interact frequently with examining agencies outside the actual exams: weekly reports are not unusual, nor are phone calls on a quarterly basis or whenever there is an adverse media report or major consumer complaint. Notably, the various agencies often issue legislative rules and guidance jointly, or at least in coordination with each other.⁹⁴ Further, the agencies frequently reinforce one another in day-to-day administration. For instance, if one banking agency has authority to pre-approve a certain transaction by a bank, it will have “no hesitation” in telling the bank—as a condition of the pre-approval—to fix a problem that *another* agency has identified in an examination.⁹⁵ To give one example cited by an interviewee: the CFPB made certain demands on a bank, the bank disagreed, and the OCC then said it would not allow the bank to grow until it settled with the CFPB, on the ground that a dispute with the CFPB over bad consumer practices would undermine the bank’s safety and soundness.⁹⁶

92. Interview with Source 51, official, Fed. Reserve.

93. Julie Stackhouse, *Why Are There So Many Bank Regulators?*, FED. RES. BANK ST. LOUIS (Apr. 25, 2017), <https://www.stlouisfed.org/on-the-economy/2017/april/why-many-bank-regulators> [<https://perma.cc/TH57-ZJE6>].

94. Interview with Source 72, *supra* note 91.

95. Interview with Source 90, person who held senior posts at the CFPB and other federal agencies.

96. Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

Amid such intense interaction, banks consider it important to stay on the agencies' good side, and sensitivity to guidance is an important part of that. A former senior Federal Reserve official, who has counseled financial institutions, emphasized that guidance's role must be understood against the backdrop of regular exams and the larger ongoing agency-bank relationship. For one thing, the agencies have an official practice of examining a bank more frequently when its past exams have gone worse. But, as the interviewee made clear, both official practice and more intangible factors are in play. If I am a depository institution, said the interviewee, "I have a great need to make sure that [the regulators] like me." The interviewee would tell bank clients, "If you lose the trust of the agency, nothing else matters," "there is no salvaging that." In particular, clients were well-advised not to respond to the regulator "too literally," that is, too legalistically or technically—the distinction between guidance and legislative rules being a legalistic point. Whenever the agency issues guidance, the interviewee would advise the bank to follow it or have a compelling reason for not doing so. If an examiner identifies an issue and asks, "did you see and review our guidance on this?," the bank should not reply, "it was only guidance" as opposed to a regulation.⁹⁷ The rationale for generally following guidance, said the interviewee, is that it is practically impossible for a bank to comply with all legislative rules all the time, so you want the examiner to think that any mistakes you make were made in a good-faith effort to comply. In particular, the bank must show that it has internal procedures in place to check itself, the presence of which can show that any problems the bank has are not systemic; these internal procedures are patterned on agency bulletins (guidance), but it does not matter if these bulletins are "guidance or [legislative] rules or what." Banks do not want to cross their examiners, said the interviewee. You do not want to be the bank that says, "this is just guidance." Although examiners cannot cite a bank for not following guidance per se, you do not want to make the examiners unhappy. You want the examiner to "cut you a break if you screw up in some *other way*."⁹⁸

Former CFPB officials expressed similar views. According to one, the main reasons for a bank to comply with CFPB guidance were that (a) the bank valued its relationship to the agency and wanted to avoid conflict and (b) the bank wanted to avoid any activity that would invite agency scrutiny, so as to avoid the costs of undergoing an additional examination, or worse, the costs of undergoing an investigation.⁹⁹ Another former CFPB official, who now counsels CFPB-

97. The interviewee also said, "I can't tell" if clients take the advice but did think depository institutions were in a risky position if they did not comply with guidance.

98. Interview with Source 72, *supra* note 91. Another interviewee, who held senior posts at the CFPB and other federal agencies, likewise emphasized that the examination function and a bank's expectation of ongoing oversight form the basis for guidance's influence, though she was somewhat more qualified in characterizing its level of influence. When guidance is issued, she said, most banks accept that the issuing agency expects banks to at least consider the guidance. That is, banks accept, even if sometimes grudgingly, that they have to pay attention to the agencies. Banks read the guidance, and they usually do more than read it. Interview with Source 90, *supra* note 95.

99. Interview with Source 18, former official, Consumer Fin. Prot. Bureau.

regulated entities, said that an agency can “make life miserable” for a bank in all sorts of ways, and noncompliance on one dimension can have bad consequences on other dimensions. The culture, said the interviewee, is to figure out what you are supposed to do—to get any guidance you can. She recalled one instance in which, during the examination of a bank she counseled, the examiner criticized the bank for a regulatory violation by citing an article that he (the examiner) had written in the Federal Reserve’s magazine. The interviewee and her colleagues thought this was improper. But the bank opted not to resist, saying, “we don’t want to fight with our examiner.”¹⁰⁰ (On this point, it should be noted that the exam team a bank sees may consist of the very same individuals from one exam to the next. Agency headquarters will sometimes switch examiners around, for fear of them getting too close to the institutions they examine, but it also sees some attraction in having the same people in place over time, as they know what the bank is like and know who at the bank is knowledgeable.¹⁰¹)

That the bank-agency relationship promotes compliance with guidance is recognized not only among former officials and industry counselors but also by an official I interviewed at a nonprofit public policy research organization (who was formerly a consultant and product manager in the consumer finance industry). Overall, she said, a bank’s relationship to its regulators was “fundamental” to its business and was like that of a child to its parents, right down to the point that parents can often get their children to change behavior by informal means (“raising an eyebrow” rather than “spelling out rules”), much as an agency can do through guidance. When it comes to guidance, observed the interviewee, you generally would not expect a bank to stand on its formal legal privilege to depart from anything that is not a legislative rule. For a bank to make such a departure, there would have to be a lot of money at stake and following the guidance would have to constrain the bank on something core to its business model. A bank would make sure not to “piss off” its regulator on something not essential to its core business, because doing so would risk causing the agency to give “greater scrutiny” to that core business. For example, if the business line opposed by the guidance amounted to \$10 million or \$20 million, that would not be worth antagonizing the agency, but if it were \$100 million, it might be worth it. The interviewee noted that many potential bank initiatives that could improve access to financial services for the poor (for which she advocates) were in the former low-dollar category, meaning guidance aimed at reducing a bank’s risk could practically block them (it being riskier to lend to poor people).¹⁰²

While banking is an especially strong example, the link between relationships and guidance comes up at other agencies, notably the EPA. For one thing, a regulated party may face EPA pre-approval requirements on a repeated

100. Interview with Source 81, *supra* note 96.

101. Interview with Source 72, *supra* note 91.

102. Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

basis, meaning the incentives associated with pre-approvals per se are coupled with the incentives associated with maintaining a trusting relationship with the agency. At the FIFRA office, observed a DC large law firm partner who represents pesticide makers there, a regulated company needs a “good relationship” with the agency because, given the pre-approval scheme, “your livelihood depends on it.” He observed close coordination on guidance between pesticide makers and that office. The TSCA office, where he also represents applicants seeking pre-approval, is somewhat in the same position, because the regulated party must go to that office “with hat in hand.” He compared these two offices with OSHA, before which he also represents clients. With OSHA, people often note that the agency has so few inspectors in proportion to its jurisdiction that each employer regulated by OSHA can be inspected on average only once every seventy years. Nevertheless, he stated that the enforcement capacity for FIFRA is even *less* proportionally than what OSHA has, yet there is a thick relationship between the FIFRA office and regulated parties because of the pre-approval requirement (to which OSHA has nothing analogous).¹⁰³ The same dynamic operates elsewhere at the EPA. A partner in a large law firm and former senior EPA official said that regulated parties wanted to maintain a good relationship with the EPA whenever they had continuing need for pre-approvals. She cited, *inter alia*, automakers seeking tailpipe emission certifications and electrical utilities seeking approvals for modifications to facilities and selection of fuels.¹⁰⁴

But it is not just within pre-approval regimes that regulated parties feel a need to maintain relationships with the EPA. The phenomenon arises, to some degree, in the realm of pure *ex post* enforcement. Adam Kushner, who served as an environmental enforcement attorney at DOJ and ultimately in career positions as director of the EPA’s air enforcement division (2003-2008) and of its entire civil enforcement office (2008-2012), said that since the 1990s corporations and environmental enforcers had become more cooperative with each other.¹⁰⁵ The more “forward-leaning” firms, he observed, will now work toward settlements to ensure a “continuing good relationship” with the EPA. Even outside actual enforcement proceedings, noted Kushner, corporate executives will now just “call up” the enforcement office; he remembered the CEO of one company initiating a meeting with him to provide an update on the company’s activities, even though no enforcement was pending against the company. Then, if and when an enforcement issue does arise for such a company, it has built up “a level of trust” with the office. Kushner named specific companies that had come to be

103. Interview with David Sarvadi, Partner, Keller & Heckman LLP.

104. Interview with Source 52, *supra* note 76.

105. This is consistent with the secondary literature on the gradual acceptance of environmental regulation within many large corporations. *See, e.g.*, MARC ALLEN EISNER, *GOVERNING THE ENVIRONMENT: THE TRANSFORMATION OF ENVIRONMENTAL REGULATION* 133-51 (2007); ANDREW J. HOFFMAN, *FROM HERESY TO DOGMA: AN INSTITUTIONAL HISTORY OF CORPORATE ENVIRONMENTALISM* (2d ed. 2001).

particularly well-regarded within the agency (e.g., by volunteering for extra monitoring as part of an EPA project to gather data on certain oil-refinery emissions). Those firms have now built relationships with the EPA that they do not want to disrupt. Of course, these companies can still violate the law, and there will still be enforcement against them, but it occurs against a backdrop of trust and good faith.¹⁰⁶ (Environmental violations, according to one classic analysis, are “usually inadvertent.”)¹⁰⁷ Similarly, a senior environmental counsel at a Fortune 100 company said that a good relationship with the EPA, built over time, is an “investment” that you may need to “cash in” later. The interviewee cited the blurry line between civil and criminal violations in environmental law and the great discretion officials have to pursue one or the other for a given course of conduct. When criminal prosecutions occur for behavior not obviously criminal, it is essentially because of a “bad relationship”—because someone at the company has “pissed someone at the agency off,” by “stonewalling,” “being an a--hole.”¹⁰⁸

The rise of these trust relationships is associated with adherence to guidance in several ways. First, a company’s general adherence to guidance, said Kushner, strengthens the trust it receives from the enforcement office.¹⁰⁹ Second, guidance can be the means by which the EPA fosters mutually trusting exchanges between the agency and firms. For example, under a policy statement known as the “audit policy,” adopted by the EPA in 1995, if companies adopt internal audit and compliance programs and self-disclose the violations discovered thereby, the EPA makes a (nominally nonbinding) promise that it will reduce penalties for those violations.¹¹⁰ A statistical study of the period 1993-2003 found that firms that engaged in such self-disclosure of Clean Air Act violations not only received reduced penalties for those violations but also enjoyed lessened regulatory scrutiny going forward (i.e., fewer inspections) even when controlling for other factors, suggesting successful investment in a larger trusting relationship.¹¹¹ The study also found that firms adopting internal audit systems had better environmental performance than otherwise comparable firms,

106. Interview with Adam Kushner, Partner, Hogan Lovells, former Dir. of Civil Enf’t, Evtl. Prot. Agency.

107. Harrington, *supra* note 90, at 32.

108. Interview with Source 119, senior environmental counsel, Fortune 100 company.

109. Interview with Adam Kushner, *supra* note 106.

110. The disclaimer of binding status for the most recent version of the policy is in Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations, 65 Fed. Reg. 19618, 19627 (Apr. 11, 2000).

111. Michael W. Toffel & Jodi L. Short, *Coming Clean and Cleaning Up: Does Voluntary Self-Reporting Indicate Effective Self-Policing?*, 54 J.L. & ECON. 609 (2011). Another study found that an earlier policy, started in 1991, that invited firms to engage in voluntary reductions of emission of certain toxic chemicals, with only an “implicit[]” offer of lessened regulatory scrutiny, did allow participating firms to reap the reward of lessened enforcement and also caused those firms to improve environmental performance. Robert Innes & Abdoul G. Sam, *Voluntary Pollution Reductions and the Enforcement of Environmental Law: An Empirical Study of the 33/50 Program*, 51 J.L. & ECON. 271, 272 (2008)

indicating that the policy does what the EPA wants it to do.¹¹² One might view the “audit policy” as an especially transparent way of conveying what Kushner said was a general tendency of the enforcement office to go easier on self-disclosed violations but to “dig in” against violations that companies did not identify,¹¹³ information disclosure being a key element of trust. Third, adherence to guidance pertaining to substantive conduct is often a condition in the EPA’s settlement offers,¹¹⁴ so guidance defines the conduct to which relationship-minded firms eager to settle are now willing to commit themselves.

The need for a good relationship in the pre-approval setting and for a good relationship in the enforcement setting may be linked. A statistical study of EPA-supervised permitting in six states under the Clean Air Act and Clean Water Act in 1990-98 found that companies with less noncompliance in their enforcement records received pre-approvals more quickly, controlling for other factors.¹¹⁵ This may further explain why regulated parties want to invest in good relationships and reputations (partly by following guidance) at the enforcement level: it may help them at the pre-approval level, particularly with respect to delay, on which agency leverage can be great.

The FDA is another agency at which regulated parties follow guidance out of concern for maintaining a relationship. A maker of drugs or devices will often need to seek pre-approvals repeatedly and will be subject to ongoing monitoring and enforcement (e.g., inspections of manufacturing practices). Daniel Carpenter, in a history of the FDA drawn from archival and statistical research, concludes that “[d]ifferent firms carry different reputations with the FDA,” with some “trusted more, others less,” a dynamic that “often leads to greater regulatory trust of larger and older firms, the companies whose histories and professionals are better known to FDA officials.”¹¹⁶ Carpenter views this as largely salutary, or at least inevitable, for “a resource-constrained and uncertain regulator is compelled to rely partially upon trust.”¹¹⁷ Taking a more negative perspective, Lars Noah cites accusations from the 1990s that the FDA retaliated against firms that did not acquiesce to its extra-legal demands, and he argues that, “[w]hether or not such charges are accurate, the perception leads companies to accede to the agency’s wishes.”¹¹⁸

Interviewees agreed that relationships mattered at the FDA—and linked the building of relationships with following guidance. A former senior official in the FDA Office of Chief Counsel said companies were afraid to challenge the agency regarding guidance because the guidance might pertain to one little issue,

112. Toffel & Short, *supra* note 111, at 637-38

113. Interview with Adam Kushner, *supra* note 106.

114. *Id.*

115. Christopher S. Decker, *Corporate Environmentalism and Environmental Statutory Permitting*, 46 J.L. & ECON. 103 (2003).

116. CARPENTER, *supra* note 43, at 663.

117. *Id.*

118. Noah, *supra* note 21, at 123-24.

and if they “raised the wrath” of the agency on that point, this might result in the agency finding some *other* problem with the company’s conduct. A company with (say) thirty approved drugs at the FDA could not afford to get “crosswise” with the agency. Industry therefore does what the agency says.¹¹⁹ According to another former senior FDA official, following guidance was helpful to firms that wanted to be proactive, particularly in seeking to escape the scrutiny of the FDA. If a company could show the agency that it was “on the right track” in an area like manufacturing, the agency would grant it relief from inspections, so as to focus resources on higher-risk firms.¹²⁰ An official at a national public interest organization observed that FDA guidance was useful in that it could move industry in a direction her organization thought better; she cited the example of how the FDA successfully used guidance to get the makers of antibiotics to revise their animal growth promotion claims (a move that helps reduce the risk of resistance to antibiotics). As to why the firms followed the guidance, she said it was partly because they anticipated an eventual statute or legislative rule to the same effect, but also because the firms were “repeat players” at the FDA, dealing with the agency on multiple issues, including pre-approvals, and needing to maintain relations at a reasonable level. The issue covered by the guidance did not itself involve pre-approvals, but the companies’ need to maintain relationships within the pre-approval context increased their willingness to follow the FDA’s wishes outside that context.¹²¹

Some interviewees, though agreeing that regulated parties *perceived* maintaining good relationships (partly by following guidance) to be important for successful dealings with the FDA, thought this perception had little to no basis in the reality of the FDA’s behavior. A partner in a large law firm and former senior federal official said that firms depended for their business on FDA approvals, and they therefore worried they had to do everything possible to maintain a positive relationship with the agency, including follow guidance; this is what companies would tell her. In reality, she contended, these fears about relationships are overblown. If a company gets into an enforcement-related dispute with the FDA, she said, the reviewers deciding pre-approvals will not even know about it. The reviewers are straight-shooters, impartial, and focused on the science. Indeed, there are examples of them granting important pre-approvals to companies even while the companies are involved in such disputes. Industry does fear that tension with the FDA on non-approval issues could “spill over” to pre-approval issues, but the fears are overblown.¹²² Similarly, Coleen Klasmeier, the head of Sidley Austin’s FDA regulatory practice, said that companies’ attitudes toward the FDA’s pre-approval process and adherence to

119. Interview with Source 83, former senior official, Office of Chief Counsel, U.S. Food & Drug Admin.

120. Interview with Source 80, *supra* note 4.

121. Interview with Source 133, official, national public interest organization.

122. Interview with Source 78, *supra* note 68.

guidance therein had become increasingly relationship-minded and “touchy-feely” in recent decades, “as if FDA approves drugs because they like you.” In truth, she insisted, companies succeed or fail because of the data in each individual application, the same “as if it were blind.”¹²³ Likewise, Richard Naples, the chief regulatory officer of the Fortune 500 medical device maker Becton Dickinson, said that while retaliation was perceived as a large risk, it was “overblown”; it did not actually happen a whole lot, and when it occurred, was usually through unconscious bias.¹²⁴

Whereas companies’ relationships to the FDA are generally a “big deal,” observed a trade association official, there is more variation when it comes to CMS; some companies have repeated and direct interactions, while others’ interactions are more attenuated.¹²⁵ But where relationships do exist at CMS, they seem to exhibit many of the same dynamics and ambiguities as at the other agencies analyzed above, including with respect to guidance. CMS stakeholders do have fears about preserving their relationships with the agency, said one healthcare industry attorney. She considered these fears “overwrought”—CMS is “not Nixonian”—but acknowledged that “other people have a different perception than me.” In any event, she did think it was important, when engaged in a discussion or dispute with CMS program personnel over adherence to guidance, to show one’s “good faith.” That meant *not* emphasizing the legal distinction between guidance (nonbinding) and legislative rules (binding), but instead defending your view on policy grounds, not just legal ones. The regulated party does not want CMS people to think it is “overly legalistic”—throwing case law at them about the guidance/rule distinction does not send a “good vibe.” The officials will reply, “You’re going to get me on a technicality? But you’re still not doing the right thing” in terms of the goals of the program and “helping patients”! (Interestingly, actually *litigating* against the agency—as distinct from engaging in outside-of-court discussions and disputes with program officials directly—does not present this problem because lawsuits are shunted off to HHS attorneys, and CMS program officials do not follow them.)¹²⁶

C. *Intrafirm Constituencies for Following Guidance*

The lion’s share of federal agency guidance pertains to firms rather than individuals, and the firm is a “they,” not an “it.” Practical day-to-day decisions about a firm’s adherence to guidance often fall to employees whose

123. Interview with Coleen Klasmeier, Head of Food, Drug and Medical Device Regulatory Practice, Sidley Austin LLP, and former attorney, Office of the Chief Counsel, U.S. Food & Drug Admin.

124. Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson and Co.

125. Interview with Source 24, *supra* note 65.

126. Interview with Source 58, healthcare industry attorney (with over fifteen years’ experience in the field).

backgrounds, socialization, or career incentives may motivate them to follow guidance more than would other people within the firm, particularly the firm's in-house counsel, to say nothing of its outside counsel. There is some evidence that this is true for regulatory affairs professionals and compliance officers. In addition, small firms who lack such specialized personnel may nonetheless rely for guidance-related decisions on outside service providers who themselves have particular capacities or motivations to follow guidance.

Begin with regulatory affairs (RA) professionals, who are prominent in FDA-regulated firms. The FDA's acquisition in 1962 of statutory authority to regulate drugs for efficacy led over the next few decades to the "credibility-based transformation of the pharmaceutical company"—a fundamental reorganization of firms around their newly central goal of maintaining credibility with the FDA.¹²⁷ One of the most important elements of this transformation was the advent and expansion of the RA department to serve as the interface between the company and the agency.¹²⁸ Destined to become "one of the most powerful offices" in the firm, the RA department would "help coordinate various members and units of the company into a unified and coherent 'face' for presentation to the FDA"; it would "reconcile conflicting claims," "preserve credibility by making sure that no [company employee] speaks too optimistically of the product," and "that compliance means the same thing to all internal arms."¹²⁹ The RA profession continues to grow, and the role of these departments has become less "paper-pushing" and more "strategic," including involvement in the early design of company products. RA professionals usually have backgrounds in science or engineering, not law.¹³⁰

In the view of Coleen Klasmeier, the head of Sidley Austin's FDA regulatory practice and formerly a career attorney in the FDA's Office of Chief Counsel, the role of RA professionals powerfully shapes how FDA-regulated companies treat guidance. RA people, she observed, see their mission as maintaining relations with the FDA. They aim to understand the agency's expectations, distribute them within the firm, and ensure compliance. They are conflict-averse and view disagreement with the agency as "failure." By contrast, said Klasmeier, lawyers are taught to believe that adversary processes are an appropriate way to make decisions. But it is the RA professionals, not the lawyers, who "own" a company's decisions about how to engage with the FDA, and the RA people see guidance as "the law," even if counsel invoke the rule/guidance distinction to say that it is not; that distinction is "not how their world operates." Klasmeier believed it would be unusual for RA people to have the ability or confidence to seek a departure from guidance from the FDA or to self-determine that the company would make such a departure. It is the lawyers

127. CARPENTER, *supra* note 43, at 646.

128. *Id.* at 644-46.

129. *Id.* at 644, 662-63.

130. Interview with Richard Naples, *supra* note 124.

who would push back and say, “I know you think FDA will not like this, but it is perfectly lawful, and we should still try to do it.” The result, given RA’s dominance of the firm-FDA interface, is that many problems with guidance are never raised or ventilated to begin with.¹³¹

Consistent with this, Daniel Troy, the general counsel of GlaxoSmithKline, observed that RA personnel were very reluctant to challenge the FDA. “What they really *have*,” he said, is their “relationship” to the agency.¹³² A partner in a large law firm healthcare practice likewise found RA professionals to be “very deferential” toward the FDA, though she also noted that, in her experience, in-house counsel *were* quite involved in the company’s processing of guidance; they would train RA personnel and would look at guidance documents in conjunction with those personnel.¹³³

Richard Naples, the chief regulatory officer of the Fortune 500 medical device maker Becton Dickinson, agreed that RA professionals like himself had a different approach and role at the FDA than did the company’s lawyers (Naples’s background is in chemistry). He and his RA colleagues would need to consult in-house counsel if they got into a dispute with an FDA reviewer and escalated the matter to a higher level within the agency, or if they had to make a call on whether something was lawful; however, these instances were “few and far between.” RA people would also consult in-house counsel to get an opinion on the meaning of a guidance document, though the RA people themselves would make the final decision. Naples explained that he generally followed guidance documents (even when the FDA had only issued them in draft). Nevertheless, he approached reviewers to seek departures from such documents from time to time. Naples noted that one should take issue with only a targeted portion of the document, on the basis of well-prepared scientific reasoning, and in a manner that avoids “tick[ing] off” the reviewer (sometimes by following the guidance in the instant proceeding while seeking a revision of it anonymously through a trade association). If the reviewer refused a departure request, explained Naples, he might then elevate the matter to a meeting between company personnel, the reviewer, and the reviewer’s boss. Naples noted that “the last thing you want to do” is to bring a lawyer to such a meeting. He had brought lawyers to only a handful of FDA meetings in his twenty-five-year career and tried to avoid doing so, for it did not lead to a constructive solution.¹³⁴ (For his

131. Interview with Coleen Klasmeier, *supra* note 123.

132. Interview with Daniel Troy, *supra* note 64.

133. Interview with Source 101, partner, large law firm healthcare practice. Another interviewee, in a line of discussion that was more about different players’ understandings of the rule/guidance distinction than about their willingness to take advantage of it and depart from guidance, said initially that lawyers and “some policy people” were more sophisticated about the distinction, but then said variation in sophistication about the rule/guidance distinction did not depend so much on people’s roles (lawyer versus RA versus compliance) as on whether the company overall was invested in public policy issues: an RA shop could be very sophisticated about the issue. Interview with Source 77, former senior official, U.S. Dept. of Health & Human Servs.

134. Interview with Richard Naples, *supra* note 124.

part, Troy, the GlaxoSmithKline general counsel, also said he would advise against bringing a lawyer to a scientific meeting: “it’s like bringing a gun to a knife fight.”¹³⁵)

RA professionals concentrated in the FDA realm are not the only intrafirm actors whose attitudes may render the firm more amenable to guidance; another is the cohort of compliance officers who now work in companies across many industries, perhaps most prominently in healthcare and finance.¹³⁶ New provisions in the U.S. Sentencing Guidelines in 1991 encouraged firms to build compliance programs, and the DOJ and other agencies have furthered the trend through enforcement activities that make the buildup of compliance infrastructure a condition of settlement in prosecution and enforcement.¹³⁷ Accordingly, “firms have gone on a hiring spree to staff compliance, with large firms adding hundreds, even thousands, of compliance officers at a time.”¹³⁸ The scope of their mission is “greater than the enforcement of law and regulation,” for they also administer “corporate ‘ethics’ policies” and guard against any kind of “‘reputation risk’” to the firm.¹³⁹ As to nuts and bolts, compliance officers assess the firm’s environment, develop internal policies accordingly, disseminate those policies within the firm (including through training sessions), monitor employees’ adherence to internal policies, investigate violations, and defend the compliance program on external review (including by regulators).¹⁴⁰

Many practitioners and proponents of compliance programs believe that compliance must break free of “law” as a defining aspect of its mission. Many compliance officers have law degrees, but a law degree is not a prerequisite for the job, and the field “may not necessarily be owned by lawyers in the future and may still be up for grabs.”¹⁴¹ In terms of organizational structure, “there is little uniformity to how corporations implement their compliance function.”¹⁴² In some firms, compliance is housed in or merged with the legal department, while in others, it is autonomous, with a chief compliance officer reporting directly to the CEO or even the board. There is a fierce controversy over whether compliance should be separate from legal.¹⁴³ Compliance officers now have their own professional association and credentialing process, and many want to have

135. Interview with Daniel Troy, *supra* note 64.

136. See Griffith, *supra* note 45, at 2099-2100, 2103-04.

137. *Id.* at 2084-92.

138. *Id.* at 2077.

139. *Id.* at 2082; see also Donald C. Langevoort, *Cultures of Compliance*, 54 AM. CRIM. L. REV. 933, 942 (2017) (stating that compliance operates on the theory that “without a values or ethics base to crowd out excess legalism in compliance, compliance programs would predictably fall short”).

140. Robert C. Bird & Stephen Kim Park, *The Domains of Corporate Counsel in an Era of Compliance*, 53 AM. BUS. L.J. 203, 214-15 (2016).

141. Michele DeStefano, *Creating a Culture of Compliance: Why Departmentalization May Not Be the Answer*, 10 HASTINGS BUS. L.J. 71, 102 (2014).

142. *Id.* at 73; see also Griffith, *supra* note 45, at 2101-02 (noting the diversity of corporate compliance structures).

143. Bird & Park, *supra* note 140, at 203-07.

their own autonomous departments.¹⁴⁴ At least two agencies, the SEC and the HHS Office of Inspector General, have recently forced misbehaving corporations to establish compliance departments separate from their legal departments.¹⁴⁵

The rising power and autonomy of compliance officers could give them authority to implement an emergent vision of “compliance” that is quite distinct from simply following law. As one scholar observes, “part of the reason that regulators have sought to separate compliance from the legal department” is that the “compliance function . . . is designed to inculcate norms of behavior that exceed narrow legal obligations.”¹⁴⁶ “The lawyers tell you whether you can do something,” said the HHS Office of Inspector General’s Chief Counsel in 2009, “and compliance tells you whether you should.”¹⁴⁷ Proponents of an autonomous compliance function argue that letting the legal department decide compliance matters will be “excessively legalistic” and “devalue the role of firm culture.”¹⁴⁸ As one corporate general counsel said of the distinction between legal and compliance departments, “Legal tells you . . . what you literally need to do to comply with the law. Compliance tells you what you should do to comply with the spirit of the law—may be more than legally required.”¹⁴⁹ One recent commentary on compliance applies this thinking to the firm-agency relationship:

In a culture of integrity, a firm establishes not only rules that mandate internal compliance with minimum regulatory requirements but also the principles and aspirations that transcend those rules and establish a values-driven organization from the newest employee to senior executives and the board of directors. . . .

Building a culture of integrity not only impacts the internal workings of the organization but also influences how firms engage with regulators and external stakeholders. Regulators, in many instances, have substantial discretion to select how and under what conditions they should apply finite resources to meet statutorily defined mandates and their own policy goals. A culture of integrity can enable a firm to benefit from this discretion, creating a self-generating cycle of collaboration between regulators and regulated firms that benefits both parties. The first step of the cycle is that firms externally signal their genuine and long-term commitment to the goals of the regulatory body. This may be accomplished by making public disclosures of firm practices and commitments through voluntary social and environmental reporting, self-reporting and self-policing, self-regulating beyond minimum requirements, and engaging in nonexploitative

144. *Id.* at 216-17; DeStefano, *supra* note 141, at 110.

145. DeStefano, *supra* note 141, at 103-04.

146. Griffith, *supra* note 45, at 2124-25.

147. Jim Edwards, *Pfizer’s Lawyers Play Musical Chairs in Wake of Bextra Settlement*, CBS NEWS (Sept. 23, 2009, 2:51 PM EDT), <https://www.cbsnews.com/news/pfizers-lawyers-play-musical-chairs-in-wake-of-bextra-settlement> [https://perma.cc/AU6U-645Y] (quoting the Chief Counsel).

148. Bird & Park, *supra* note 140, at 206 (providing the quote and discussing this point of view).

149. DeStefano, *supra* note 141, at 149 (quoting the general counsel).

Federal Agency Guidance and the Power to Bind

behavior toward regulatory mandates. Regulators, in turn, respond to the firm's commitment to regulatory goals by allocating resources away from the monitoring function and de-escalate toward a nonconfrontational posture.¹⁵⁰

To the extent that compliance officers are in a position to determine a firm's treatment of guidance, this kind of professional orientation would presumably tend to make them follow guidance rather than invoke any distinction between it and a legally binding legislative rule. Whether compliance officers are in fact in such a position varies between corporations, even within the same industry,¹⁵¹ and there is little public data on the matter.¹⁵² But there is evidence in the interviews that compliance officers at least sometimes help determine companies' attitudes toward guidance—and that agency personnel interface with compliance officers on guidance-related matters and may view those officers as a preferred interface. While there is much room for future research on compliance officers' role with respect to guidance, this evidence deserves attention given the large and growing role of compliance officers in many industries.

Among FDA-regulated firms (which employ both RA professionals and compliance officers in separate capacities),¹⁵³ a partner in a large law firm and former senior federal official observed that “culture of compliance” was the buzzword, with compliance officers comprising a whole organization of their own within the larger companies. Indeed, compliance was now a “whole industry” unto itself, often backed by corporate integrity agreements arising from enforcement actions—an industry that “glorifies compliance separate from law.” “Compliance,” explained the interviewee, does not mean “law”; it means “doing what the agency wants you to do.” “Every once in a while,” she said, compliance with guidance might be “so problematic” from a business perspective that you might then interrogate the guidance's legal justification, “but not usually.” She then gave an example of an FDA draft guidance document that she considered inconsistent with the relevant legislative rule but that industry tried to follow anyway.¹⁵⁴

As to banking, a former senior Federal Reserve official, who has counseled financial institutions, described compliance officers affectionately as “geeky”

150. Bird & Park, *supra* note 140, at 234-35.

151. *E.g.*, Interview with Source 131, *supra* note 102 (observing that, in the banking industry, there is much variation, even among banks of comparable size, on which categories of personnel—business line managers, compliance officers, in-house counsel, government or regulatory affairs officers, etc.—interface directly with the agency on matters like receiving and processing guidance).

152. Griffith, *supra* note 45, at 2100 (noting that questions about the organization and the authority of compliance officers “depend upon information that is not publicly available,” since firms “are not required to report information on compliance in their public filings,” so there can be only a “glimpse” of compliance's practice through sources like interviews and surveys).

153. Interview with Coleen Klasmeier, *supra* note 123 (noting the distinct roles of these personnel).

154. Interview with Source 78, *supra* note 68.

people doing “thankless” work who really tried hard to “get things right.” The interviewee said that if compliance officers see guidance from the agency, they will incorporate it into their internal policies and procedures since otherwise they would risk scrutiny from examiners that they want to avoid. If something is listed as a compliance issue in an agency bulletin, the compliance people would generally add it to their list. Many compliance officers are not lawyers, and they “don’t care” if a policy arises from guidance or a legislative rule. They want to answer the question, “what do I have to do to comply?,” and they do not care about “theory,” i.e., whether something is a rule or guidance.¹⁵⁵ According to an interviewee who held senior posts at the CFPB and other federal agencies, compliance officers at CFPB-regulated entities would be the ones paying closest attention to “what happens in the regulatory space,” including issuance of guidance. A conventional view among banking regulators was that the quality of a company’s compliance management system was the best predictor of the company’s compliance with law. The CFPB wanted a company’s compliance people to have “a seat at the table” in firm decisionmaking in order to ensure that compliance issues are considered as business choices are made.¹⁵⁶

As for healthcare insurers and providers, a healthcare industry attorney said that CMS, in dealing with regulated companies, preferred to deal with compliance officers as the agency’s interface, compared with other kinds of firm employees. Compliance officers, she noted, were far less focused on the rule/guidance distinction than outside counsel would be. Their job was to track new issuances from the agency and communicate them to whoever within the company needed to know about them. The interviewee recalled giving a lecture to an assembled group of compliance officers. The APA, she said, is “otherworldly” to these people. They were taken aback that one would even engage CMS on whether it followed the right procedures in adopting its own policies.¹⁵⁷

Beyond the distinct RA profession in the FDA approval realm and the self-identified compliance officers across multiple industries, there are other company personnel at the operations level who may be the first or only audience for guidance within their firms but are not lawyers and are not necessarily mindful of the rule/guidance distinction. The general counsel of a Fortune 500 company explained that, while her firm is subject to much guidance from

155. Interview with Source 72, *supra* note 91.

156. Interview with Source 90, *supra* note 95.

157. Interview with Source 58, *supra* note 126. Another interviewee said that, in her experience, CMS guidance was highly technical and went mainly to operations people within regulated firms, typically with an in-house attorney involved, while compliance people were relatively less involved than they would be with FDA guidance. Interview with Source 101, *supra* note 133. Another interviewee—drawing from experience with the Consumer Product Safety Commission, Department of Energy appliance standards, and the EPA’s Energy Star program—observed tension within corporations between compliance people (more conservative about adherence to guidance) and marketing people (more aggressive), though he found in-house counsel to be *more* conservative than the compliance people. Interview with Charles Samuels, Partner, Mintz Levin, and counsel, Ass’n of Home Appliance Mfrs.

multiple federal agencies regarding its products, her law department does not have anybody who systematically searches for that guidance; there is so much of it that the law department does not have the resources to find it. The intake and application of guidance is handled far more by the company's product safety, quality assurance, and regulatory staff, who are close to the operations of the company and actually make the plants work. They are the ones plugged in to the relevant agencies' output of guidance. They are not lawyers, nor are they labeled "compliance" people. They are frontline workers, part of the operations of the company. The interviewee said that, in dealing with guidance, these people would follow a "meet or exceed" standard, that they had a sense that "when the government tells you to do something, you do it," and that they tended to be rule-followers. She could not remember anyone ever coming to her and asking, "can we not follow this guidance?" It was possible that operations people did have conversations about such questions with agency personnel at the plant level, or even that they might approach some of her in-house attorneys, but she added that many operations people considered guidance-governed matters their own province, not that of the lawyers.¹⁵⁸

Because some businesses are too small to have full-time compliance or RA specialists, one might think that small businesses will follow guidance less. To some degree, that is true. However, for certain business activities covered by guidance, a small firm may contract out to a specialized service provider that gives the kind of full-time attention to the agency's utterances that a corporate compliance staff would. For example, observed a former CMS division director, physician practices usually have no in-house compliance personnel, but they commonly outsource their billing to specialized billing companies. These companies make an investment in learning the highly technical CMS guidance on Medicare billing, and they follow it. Practices' increasing reliance on these billing companies in recent years has had the effect of increasing the practices' compliance with guidance. Notably, HHS looks favorably on physician practices that have billing companies compared to those that do not.¹⁵⁹ Other intermediaries playing a similar role with respect to guidance include "technical assistance providers" helping small water utilities regulated by the EPA;¹⁶⁰ consultants known as "field men" who advise organic wholesalers regulated by the USDA;¹⁶¹ and commercial testing laboratories hired by small appliance sellers subject to the Department of Energy's energy efficiency standards.¹⁶²

158. Interview with Source 73, general counsel, Fortune 500 company.

159. Interview with Source 93, *supra* note 88.

160. Interview with Source 84, former official, Office of Water, Env'tl. Prot. Agency.

161. Interview with Miles McEvoy, *supra* note 86.

162. Interview with Charles Samuels, *supra* note 157.

D. The Prospect of a One-Off Enforcement Proceeding

Even if we put aside pre-approval requirements, relationships to the agency, and cohorts of compliance people with peculiar sensitivity to the agency, there is still one other factor potentially incentivizing compliance with guidance: the risk that the agency will sanction the regulated party *ex post* for violating the relevant statute or legislative rule in a one-off enforcement proceeding.¹⁶³ Because guidance suggests what the agency considers to be lawful (or unlawful), or announces against what conduct the agency will (or will not) enforce, a regulated party can greatly reduce the risk associated with enforcement by following guidance. One might think reducing this risk in itself creates a strong incentive to follow guidance.

But that is much too crude. In fact, the magnitude of the enforcement-based incentive to follow guidance is context-specific. The regulated party will compare the upside it sees in guidance-noncompliant behavior with the downside, which varies with four factors: (1) the probability of the agency detecting the regulated party's guidance-noncompliant conduct and initiating enforcement to begin with, (2) the potential cost of the resulting enforcement proceeding irrespective of its outcome, (3) the probability that the proceeding will result in a finding that the party violated the relevant legislative rule or statute, and (4) the potential cost of sanctions attached to that finding.

I am not saying this out of some *a priori* view of regulated parties as calculating rational actors. The factors listed above are just an assembly and analytic refinement of what many interviewees told me. Indeed, an executive at a drug manufacturer was quite explicit that, in deciding whether to follow the FDA's enforcement-related guidance, her company will do a risk calculation. They consider, on the one hand, the benefit of guidance-noncompliant behavior to their business and to the public health, and, on the other hand, the level of legal justification they feel under the legislative rule or statute ("Are we prepared to take a warning letter and defend ourselves?") and the "enforcement risk" (i.e., the "probability" of enforcement "times" the "damage" to the business in the event of enforcement).¹⁶⁴

Let us consider in turn the four factors that contribute to the downside risk of departing from guidance, with particular attention to how each of them can vary and change, making the incentives arising from one-off enforcement quite specific to context.

163. By "one-off," I mean to put aside the possibility that the enforcement proceeding could implicate a larger relationship between the regulated party and the agency—a point already discussed in Section I.B above. This Section focuses on the enforcement proceeding's consequences in isolation from any larger relationship.

164. Interview with Source 108, *supra* note 20.

1. Probability of Detection

This probability depends on many circumstances and can change over time. First, detection becomes easier, and the incentive to follow guidance stronger, the greater the agency's resources and the fewer and more visible the regulated parties. Eric Schaeffer, the former director of civil enforcement at the EPA and now head of an environmental NGO, said guidance could have a big impact in the context of a concentrated industry like makers of new mobile sources of air pollution (cars), where there is only a small number of companies, as compared with mobile sources modified in the after-market, where there are thousands of "chop shops."¹⁶⁵ When regulated entities are numerous, detection tends to be less probable, though there are means to try to make it more likely. For example, environmental regulation of stationary sources of air pollution operates on a two-tiered system where enforcement is geared toward producing information: sources must regularly self-report emissions, with self-reported violations usually subject to minor penalties, but if sources deliberately avoid or falsify reports, severe penalties like criminal prosecution are much more likely.¹⁶⁶ When it comes to Medicare, qui tam relators, whose role has increased greatly in the last two decades, provide additional eyes and ears to the DOJ and to the HHS Office of Inspector General. And HHS and its contractors also increasingly use "big data" techniques to target audits at healthcare providers who are statistical outliers in their billing behavior.¹⁶⁷ Under the Department of Energy's appliance standards program, compliance is thought to be high because the regulated firms all sell standardized products to the public, and they purchase and test each other's products to make sure no firm is getting a competitive advantage by cheating.¹⁶⁸ On occasion, a firm has caught its competitor not complying and turned that competitor in to the Department.¹⁶⁹

2. Cost of the Enforcement Proceeding Irrespective of Outcome

A regulated party with a legal theory for why its behavior violates the guidance but not the legislative rule may be vindicated once there is an actual agency adjudication of the question (or judicial review thereof). But if the adjudication process itself is costly enough, then simply following guidance may seem the better course ex ante.

165. Interview with Eric Schaeffer, *supra* note 20.

166. Wayne B. Gray & Jay P. Shimshack, *The Effectiveness of Environmental Monitoring and Enforcement: A Review of the Empirical Evidence*, 5 REV. ENVTL. ECON. & POL'Y 3, 5 (2011). On criminal prosecution for avoiding permitting (and with it, reporting), see David M. Uhlmann, *Prosecutorial Discretion and Environmental Crime*, 38 HARV. ENVTL. L. REV. 159, 200-02 (2014).

167. Interview with Source 93, *supra* note 88.

168. Interview with Andrew DeLaski, Exec. Dir., Appliance Standards Awareness Project.

169. Interview with Sources 3, 4, and 5, *supra* note 20.

The most obvious cost of a proceeding is that of being investigated and mounting a defense. Direct legal bills came up briefly in the interviews.¹⁷⁰ So did the seizure of computers and records, which by itself could put some firms out of business.¹⁷¹ So did the opportunity cost of defense. Kushner, the former EPA career official who rose to civil enforcement director, said regulated firms were under a lot of pressure to settle—“I appreciated that I had a lot of leverage when I was [at the EPA]”—partly because of legal bills but more importantly because of the distraction to the business internally; for example, fighting an enforcement action meant that “the top EHS [i.e., ‘environmental, health, and safety’] guy at a refinery” would have to focus on the litigation instead of the business’s operations.¹⁷² A former SEC official similarly cited internal disruption to the business as a major reason to avoid enforcement activity altogether, regardless of its outcome.¹⁷³

But the cost most frequently noted in the interviews was bad publicity—a cost that appears to be real in some contexts but not all. Agencies often do announce their enforcement activities to the public, naming the parties targeted, and not always with many safeguards.¹⁷⁴ But do these announcements tangibly harm the targets? Since the 1990s, there have been many statistical studies of how publicly traded companies’ stock prices react to newsbreaks of agency investigatory or enforcement actions (and also to media newsbreaks of company misconduct likely to lead to such actions). The literature indicates that when the alleged harm is to third parties who do not transact with the target company, as is usually the case in environmental regulation, the stock-price drop is of similar magnitude to the present value of government penalties and private damages and settlements to be later incurred by the company, meaning the publicity itself does not cause losses. The literature also shows, however, that when the alleged harm is to parties who do transact with the target company, as with fraud that victimizes investors or consumers or product-safety problems that harm consumers, the stock-price drop is greater—often much greater—than anticipated penalties, damages, and settlements (e.g., seven times greater in SEC accounting fraud cases). The difference, it seems, reflects the market’s expectation that consumers, investors, and other potential counterparties will lose trust in the company, be less inclined to transact with it, and demand more

170. Interview with Source 17, former official, Office of Mgmt. & Budget.

171. Interview with Source 93, *supra* note 88.

172. Interview with Adam Kushner, *supra* note 106. One interviewee briefly mentioned the power of the FDA, through litigation by DOJ, to seize products on a preliminary basis. Interview with Source 82, staff member, U.S. Congress. Obviously, this could be quite costly to the business regardless of enforcement’s ultimate outcome. But apparently the seizure power is “rarely invoked.” Bhagwat, *supra* note 19, at 1293; *see also* Noah, *supra* note 21, at 125 (noting a few examples of firm concessions in the face of seizure threats).

173. Interview with Source 19, former official, Sec. & Exch. Comm’n.

174. Nathan Cortez, *Agency Publicity in the Internet Era*, ADMIN. CONF. U.S. (Sept. 25, 2015), <https://www.acus.gov/sites/default/files/documents/agency-publicity-in-the-internet-era.pdf> [<https://perma.cc/KJ3Q-K93K>].

favorable terms to do so, thereby reducing the company's profits.¹⁷⁵ Thus, bad publicity in itself is costly to regulated parties, but mainly in areas like fraud and product safety, rather than in environmental regulation.¹⁷⁶ These statistical findings are consistent with interviewee comments that companies would follow guidance to avoid the reputational harm of a warning letter from the FDA,¹⁷⁷ or a noncompliance letter from the USDA National Organic Program,¹⁷⁸ or an enforcement proceeding by a banking regulator¹⁷⁹ or by the SEC.¹⁸⁰ SEC enforcement, noted a former official at that agency, is mutually reinforcing with bad publicity in the financial press: bad press leads to enforcement, which causes leaks, which leads to more bad press, and so forth in a vicious cycle. The commencement of an SEC investigation, she said, is "a disaster from the word 'go'" and can be nearly as bad as a judicial finding of liability.¹⁸¹

But if publicly traded firms are vulnerable to reputational harm from agency accusations in areas like fraud and product safety, this is much less clear for smaller firms. There are obviously no studies of capital-market reactions for them, and they are less likely to have brands to protect. One public interest organization official believed that sensitivity about reputation and brands

175. For a review of the literature by one of the leading economists on the topic, see Jonathan M. Karpoff, *Does Reputation Work to Discipline Corporate Misconduct?*, in THE OXFORD HANDBOOK OF CORPORATE REPUTATION (Timothy G. Pollock & Michael L. Barnett eds., 2012). The study of accounting fraud is Jonathan M. Karpoff et al., *The Cost to Firms of Cooking the Books*, 43 J. FIN. & QUANTITATIVE ANALYSIS 581 (2008). A study published after the 2012 review of market reactions to revelations of companies' use of tax shelters finds no reputational effect on stock prices, which is consistent with the rest of the literature, in that tax avoidance does not involve harm to companies' consumers, investors, or the like. John Gallemore et al., *The Reputational Costs of Tax Avoidance*, 31 CONTEMP. ACCTG. RES. 1103 (2014). Another subsequently published study finds some reputational effect of allegations of bribery, less than for fraud but more than environmental violations. Vijay S. Sampath et al., *Corporate Reputation's Invisible Hand: Bribery, Rational Choice, and Market Penalties*, 151 J. BUS. ETHICS 743 (2018).

176. It is possible that bad publicity in the environmental context could eventually affect a firm economically if the publicity operates through more contingent mechanisms like community suspicion of the firm in localities where it needs to maintain and expand its facilities. A public interest organization official cited bad publicity as a reason to comply with EPA guidance, saying it could operate at the national or local level. Interview with Source 56, official, public interest group. There is statistical support for the idea that corporations engage in cleaner environmental behavior when located in more politically engaged local communities, even controlling for other factors. Markus Kitzmueller & Jay Shimshack, *Economic Perspectives on Corporate Social Responsibility*, 50 J. ECON. LITERATURE 51, 75 (2012); see also Interview with James Conrad, Conrad Law & Policy Counsel, and former Assistant Gen. Counsel, Am. Chemistry Council (noting that the "hardest battles" for chemical manufacturers involve local-government decisions like zoning and that a firm does not want trouble with the EPA that would spill over to the local level).

177. Interview with Daniel Troy, *supra* note 64 (citing his company's practice of closely studying all FDA Office of Prescription Drug Promotion letters).

178. Interview with Jake Lewin, *supra* note 82.

179. Interview with Source 131, *supra* note 102. *But see* Interview with Source 18, *supra* note 100 (observing that the reputational harm of a public accusation of racial discrimination would cause financial institutions to change practices, but this was less true of accusations of lesser moral gravity).

180. Interview with Source 19, *supra* note 173; Interview with Source 40, former official, Sec. & Exch. Comm'n.

181. Interview with Source 19, *supra* note 173.

incentivized large firms to follow guidance, but not small ones for whom reputation did not matter.¹⁸² Then again, small firms might be less able to bear the direct costs of enforcement, such as legal bills, handing over records, etc.

Enforcement activity regardless of its outcome may also prompt follow-on lawsuits by state attorneys general or class-action plaintiffs, though their incentivizing power is uncertain. Three interviewees discussing the FDA noted that a warning letter from the agency could prompt such suits.¹⁸³ Data on their effect is limited. As for the state attorneys general, the total value of penalties they imposed on pharmaceutical firms from the takeoff of such suits in 2008 through 2015 seems large (\$3.5 billion) but is less than one-sixth of the sum of penalties imposed against the industry in that same period by the federal government.¹⁸⁴ As for class actions that follow on enforcement, there seems to be little published data.¹⁸⁵ A former senior official at the FDA Office of Chief Counsel said, regarding consumer protection suits against the food industry premised on FDA warning letters that in turn rested on noncompliance with guidance, that “the Chobanis of the world can handle these lawsuits,” but “they hurt small companies.”¹⁸⁶

Finally, especially for large firms, we must consider that the mere initiation of enforcement proceedings may severely impact individual employees of the firm in ways that give those employees an incentive, *ex ante*, to ensure the firm’s compliance with guidance. In banking, the start of an enforcement action can cause a bank to abandon whatever financial product is the target of that action, damaging the careers of whichever bank employees had developed the product. This means that bank employees are reluctant to develop new products unless there is some assurance from the agency that they are lawful, which the agency may not be willing to provide before it sees the product in action. The result is that employees hold back, following existing guidance unless the agency changes it.¹⁸⁷

182. Interview with Source 56, *supra* note 176.

183. Interview with Daniel Troy, *supra* note 64; Interview with Source 82, *supra* note 172; Interview with Source 83, *supra* note 119.

184. The calculations are based on Sammy Almashat et al., *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015*, PUBLIC CITIZEN 44 fig.11, 46 fig.13 (March 31, 2016), <https://www.citizen.org/sites/default/files/23110.pdf> [<https://perma.cc/T8DJ-YUFP>].

185. For general background on “coattails class actions,” see Howard M. Erichson, *Coattail Class Actions: Reflections on Microsoft, Tobacco, and the Mixing of Public and Private Lawyering in Mass Litigation*, 34 U.C. DAVIS. L. REV. 1 (2000); Max Minzner, *Should Agencies Enforce?*, 99 MINN. L. REV. 2113 (2015). There does not seem to be an empirical literature on this subject apart from one study of the SEC. James D. Cox & Randall S. Thomas, *SEC Enforcement Heuristics: An Empirical Inquiry*, 53 DUKE L.J. 737 (2003).

186. Interview with Source 83, *supra* note 119.

187. Interview with Source 131, *supra* note 102.

3. Probability of a Violation Being Found

A regulated party that departs from guidance and finds itself in an enforcement proceeding will have to convince the agency not to read the relevant statute or legislative rule to simply track the guidance. The prospect of doing this successfully depends upon the agency's flexibility—something that varies profoundly based on several factors, which I shall discuss in Part II below.

In addition to the agency's flexibility, another factor influencing the regulated party's prospect of success is whether, if the agency comes to an unfavorable conclusion, a court can be convinced to overturn it. This raises the question of what deference courts give guidance, and whether such deference discourages parties from departing from guidance to begin with. Although scores of my interviewees discussed reasons why regulated parties would follow guidance, only four cited the prospect of judicial deference as one such reason.¹⁸⁸ And only one of these four interviewees spoke of deference more than briefly. Further, this interviewee was the only one of the four to specifically raise the *Auer*¹⁸⁹ or *Seminole Rock*¹⁹⁰ doctrine that arguably grants agencies a kind of super-deference when interpreting their own legislative rules through vehicles like guidance. Notably, this interviewee was not a specialist on any particular agency.¹⁹¹

Considering the furious academic debate that has occurred over judicial deference and especially *Auer* in recent years, one might have expected deference to come up as a reason to follow guidance in more interviews.¹⁹² Its modest showing may be due to the fact that judicial deference to guidance is not as strong as we might assume. For one thing, agency win rates under *Auer* have fallen in recent years, so they are comparable with those under the alternative deference regime of *Chevron*, perhaps indicating that *Auer* is not some all-powerful government weapon.¹⁹³ Plus, a recent study indicates that, in the U.S. circuit courts, over half the opinions reviewing guidance documents' interpretations of statutes or legislative rules do so not under the strongly

188. Interview with Richard Stoll, Partner, Foley & Lardner LLP; Interview with Frank White, former Deputy Assistant Secretary, Occupational Health & Safety Admin., Dep't of Labor; Interview with Source 38, official, AFL-CIO; Interview with Source 68, Partner, large law firm. A fifth interviewee initially cited judicial deference to guidance as a reason for EPA-regulated parties to ensure guidance was followed in proceedings where the agency might otherwise depart from it in favor of industry (e.g., a permit proceeding). The interviewee suggested that a court hearing an NGO challenge might hold the agency to its guidance—not at all the usual posture for deference. This interviewee then said the court presumption in favor of guidance's correctness could also apply if the reviewed agency action went against the regulated party. Interview with Source 54, former official, Env'tl. Prot. Agency.

189. *Auer v. Robbins*, 519 U.S. 452 (1997).

190. *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945).

191. Interview with Source 68, *supra* note 188.

192. See Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, 16 GEO. J.L. & PUB. POL'Y 103 (2018).

193. Cynthia Barmore, *Auer in Action: Deference after Talk America*, 76 OHIO ST. L.J. 813, 827 (2015); William M. Yeatman, Note, *An Empirical Defense of Auer Step Zero*, 106 GEO. L.J. 515, 547 (2018).

deferential *Chevron* framework or the supposedly super-deferential *Auer* framework, but instead under the *Skidmore* framework, which offers the weakest deference of the three.¹⁹⁴ But I suspect the modesty of deference's role in shaping behavior is mainly due to factors besides what courts do. For parties making an initial decision whether to follow guidance, the prospect of judicial review is quite attenuated. The party's conduct may not be detected, and even if it is, sticking with the enforcement proceeding to the bitter end and then suing may not seem worth it by reason of the proceeding's costs (discussed above) or the risk of sanctions (discussed below), to say nothing of other factors shaping compliance with guidance discussed elsewhere (pre-approval, relationships, compliance personnel's commitments, and the agency's level of flexibility).

4. Cost of Sanction for a Violation

The prospect of a severe sanction for a violation, if authorized by the statute and credibly threatened by the agency, could incentivize a regulated party to follow guidance to begin with. In this scenario, the anticipated sanction is so severe that even a very low probability of being detected and losing an enforcement proceeding is too much to tolerate. Also, the regulated party knows that, if it were to depart from guidance and be hit with an enforcement proceeding, any legal arguments it might think up against the guidance's reading of the law would be practically irrelevant, because an adverse outcome is so catastrophic that one simply cannot take the risk of going to a final disposition—one must accept whatever settlement offer the agency makes.¹⁹⁵ Are any sanctions actually severe enough to trigger this scenario? If so, what are they?

The most convincing candidates are the sanctions that involve excluding the regulated party from the industry altogether, which can easily put it out of business. In the case of the power of the HHS Office of Inspector General (OIG) to exclude firms and individuals from participation in federal healthcare programs such as Medicare, the threat appears credible. In recent years the HHS OIG has annually excluded around three thousand to four thousand persons or firms (some permanently, others not).¹⁹⁶ The list of excluded entities is “peppered with the names of home health agencies and [durable medical equipment] companies.”¹⁹⁷ And while “[h]istorically” the HHS OIG has “declined to use” exclusion against hospitals because of the collateral consequences, there have been “rare exceptions” that show that the agency will

194. The data for the three deference regimes are in Yeatman, *supra* note 193, at 545-46. But since the figures for *Chevron* and *Skidmore* were obtained via sampling, one must scale them up on an approximated basis using the ratios in *id.* at 545 tbl.1.

195. Barkow, *supra* note 46, at 1148, 1163-65.

196. Judith A. Waltz & Adam Hepworth, *Medicare and Medicaid Administrative Enforcement*, in HEALTH LAW HANDBOOK 101, 105 (Alice G. Gosfield ed., 2017).

197. Jonathan Feld & Howard O'Leary Jr., *Criminal Prosecution of Hospitals: Unnecessary Treatment*, 26 HEALTH LAW 1, 1 (2014).

pull the trigger.¹⁹⁸ Hospitals that rapidly closed as a result of exclusion include Chicago’s Edgewater Medical Center in 2001 (215 beds), Miami’s South Beach Community Hospital in 2006 (146 beds), and Chicago’s Sacred Heart Hospital in 2013 (119 beds).¹⁹⁹ The closings confirm that exclusion is “an organizational death sentence.”²⁰⁰ Further, exclusion is technically available against healthcare providers for *any* false claim against the government, no matter how small.²⁰¹ While HHS’s internal guidance and practice impose the sanction far more narrowly, its technical availability confers great bargaining power on the agency.²⁰² A partner in a large law firm and former senior federal official, in explaining why companies follow guidance, said the threat of exclusion is “hanging over” every firm. HHS OIG officials, she recounted, will “yell at you in conference rooms” about “exclusion” if you don’t admit wrongdoing; “maybe” the OIG is “bluffing,” but “you can’t tell.”²⁰³ In an OIG enforcement proceeding, notes one scholar, “the agency’s guidance (i.e., whether the provider followed the guidance) will likely play a pivotal role in determining whether the law was violated,”²⁰⁴ not least because the OIG’s very power to induce settlement means that Medicare law gets made to a large degree by the OIG’s practice in settled enforcement proceedings, not by judicial pronouncements in litigation.²⁰⁵ Thus providers are incentivized to follow guidance at the outset to avoid sanctions in an adjudication that (given the threat of exclusion) they cannot practically contest. A law firm partner who deals frequently with CMS and the FDA said that she expected the HHS OIG to follow the agency’s guidance in deciding what conduct was subject to enforcement, and she then said that industry’s most serious concern was the False Claims Act—their fears very much including program exclusion.²⁰⁶

While healthcare program exclusion appears to a credible threat and an effective means to head off adjudication and incentivize regulated parties to

198. *Id.* at 1.

199. *Id.* at 6-7, 7 n.2. For the number of beds at Edgewater, see Bruce Japsen, *Edgewater Medical Center Succumbs to Financial Woes*, CHI. TRIBUNE (Dec. 7, 2001), <http://www.chicagotribune.com/news/ct-xpm-2001-12-07-0112070450-story.html>. For the number of beds at Sacred Heart, see Andrew L. Wang & Kristen Schorsch, *Sacred Heart Hospital Closes*, CRAIN’S CHI. BUS. (July 1, 2013, 7:00 AM), <https://www.chicagobusiness.com/article/20130701/NEWS03/130709987/sacred-heart-hospital-closes> [https://perma.cc/DH8J-G7QB].

200. Feld & O’Leary, *supra* note 197, at 1.

201. PARRILLO REPORT, *supra* note †, at 72 n.219.

202. Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL’Y 55, 66, 114, 132-37 (2003).

203. Interview with Source 78, *supra* note 68.

204. Krause, *supra* note 202, at 106.

205. *Id.* at 113-32.

206. Interview with Source 104, law firm partner who deals frequently with CMS and the FDA; cf. Interview with Source 101, *supra* note 133 (stating that, while exclusion is a major concern, criminal prohibitions by themselves would be enough to motivate widespread compliance with guidance).

follow guidance,²⁰⁷ we should not assume that every statute establishing this kind of exclusionary sanction necessarily creates the same kind of practical incentive. That is because, at times, extreme sanctions may be legally available to the agency but not practically available because the agency regards them as too severe to use. Indeed, the sanctions may be “politically unavailable”: to impose them would prompt a political backlash that the agency knows it cannot withstand.²⁰⁸

Besides exclusion, the sanction with greatest incentive power appears to be criminal punishment.²⁰⁹ In federal healthcare programs, the number of jail sentences—though small compared to the size of the industry—is great enough to be salient and to show that the government is not afraid to use imprisonment. In FY 2016, the results just for the nine-city DOJ-HHS “Medicare Fraud Strike Force” were 290 defendants sentenced to prison, for an average of more than four years each (over one thousand years total).²¹⁰ According to a partner in a large law firm healthcare practice, the prospect of criminal prosecution was the main reason people in the industry followed guidance (more important than exclusion, in her judgment), not least because the failure to follow guidance was a “bad fact” with respect to criminal intent.²¹¹ A former CMS division director, while viewing the need for timely payment as the immediate reason to follow guidance, said there was a “built-in level of hysteria” about healthcare program enforcement, ratcheted up by the “daily parade” of news stories about “indictments.” If a provider failed to follow clear guidance, that would be “a huge bullseye on your back” and a “strong reason for the government to proceed.”²¹²

But while the threat of criminal prosecution can encourage compliance with guidance where credible, it is not always credible. In OSHA regulation, the statute is drawn narrowly to criminalize only conduct that is “willful” and causes an employee’s death, and there have been only about twelve criminal convictions since 1970.²¹³ Environmental regulation falls between the Medicare and OSHA

207. The threat of exclusion may also be a strong incentive at other agencies, such as the FAA and the CFPB. See PARRILLO REPORT, *supra* note †, at 73 n.225.

208. Brigham Daniels, *When Agencies Go Nuclear: A Game Theoretic Approach to the Biggest Sticks in an Agency’s Arsenal*, 80 GEO. WASH. L. REV. 442, 452-54, 503-04 (2012).

209. I focus on imprisonment because fines may be indemnified by the targeted individual’s firm. Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms?*, 70 FOOD & DRUG L.J. 435, 446 (2015).

210. DEP’T OF HEALTH & HUMAN SERVS. & DEP’T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FISCAL YEAR 2016, at 10 (2017), <https://oig.hhs.gov/publications/docs/hcfac/FY2016-hcfac.pdf> [<https://perma.cc/R3T9-FZV2>].

211. Interview with Source 101, *supra* note 133; see also Krause, *supra* note 202, at 109 (“Although reliance on erroneous agency statements will not establish a defense as a matter of law, the fact that the defendant sought in good faith to comply with such advice may establish that the defendant lacked the requisite intent needed to violate the law.”).

212. Interview with Source 93, *supra* note 88.

213. Eric J. Conn & Kate M. McMahon, *OSHA Criminal Cases on the Rise*, 13 FED. EMP. L. INSIDER 2 (2016); see also Sidney A. Shapiro & Randy Rabinowitz, *Voluntary Regulatory Compliance in Theory and Practice: The Case of OSHA*, 52 ADMIN. L. REV. 97, 109 (2000) (noting, in a

extremes: formal liability is broad, tracking numerous civil violations with only a factual-knowledge requirement tacked on,²¹⁴ but the EPA and the DOJ have exercised a great deal of discretion to confine prosecutions largely to cases that have higher indicia of intent, especially those involving deception or repeat violations.²¹⁵ The result is annual incarceration years on the order of one hundred.²¹⁶

The prospect of criminal prosecution *of the firm* could also be frightening enough to encourage compliance with guidance, but again, this varies depending on the industry. After the accounting firm Arthur Andersen collapsed in the wake of its indictment in 2002, many officials came to believe that simply initiating a criminal prosecution would destroy any large company. However, it appears this is only true of firms in contexts where prosecution poses a specific threat to the firm's business model, as in the accounting industry, where companies trade on their perceived trustworthiness.²¹⁷ An empirical study found that in 2001 to 2010 the federal government obtained convictions of fifty-four publicly traded firms, of which the vast majority survived, and for the few that failed, the failure was not caused by conviction.²¹⁸ That said, where companies have Andersen-like vulnerabilities (as in finance), criminal prosecution or conviction could amount to a corporate death penalty.²¹⁹ Then again, the DOJ has become so fully committed to deferred-prosecution agreements in the finance sector that the threat may be blunted.²²⁰

Barring an Andersen-like collapse, the most visible consequences of criminally prosecuting a firm (or civilly enforcing against it) will be monetary penalties,²²¹ raising the question of whether the prospect of such penalties encourages the firm to comply with guidance. There has in fact been a huge spike

comparison of firms' willingness to take part in voluntary compliance programs under the EPA and OSHA, that criminal penalties under OSHA regulation are miniscule compared to those under the EPA); *id.* at 143-44 (noting that issuance of OSHA guidelines has not resulted in compliance with agency goals).

214. Uhlmann, *supra* note 166, at 167-71.

215. *Id.* at 193-214.

216. *Enforcement Annual Results for Fiscal Year 2016*, U.S. ENVTL. PROTECTION AGENCY (Jan. 9, 2017), <https://archive.epa.gov/epa/enforcement/enforcement-annual-results-fiscal-year-2016.html> [<https://perma.cc/9CR4-3755>] (ninety-three years for sentenced defendants); *Enforcement Annual Results for Fiscal Year (FY) 2015*, U.S. ENVTL. PROTECTION AGENCY, available at https://19january2017snapshot.epa.gov/enforcement/enforcement-annual-results-fiscal-year-fy-2015_.html [<https://perma.cc/3B7R-V9BF>]; U.S. ENVTL. PROT. AGENCY, FISCAL YEAR 2014 EPA ENFORCEMENT AND COMPLIANCE ANNUAL RESULTS 11 (Dec. 18, 2014), <https://www.epa.gov/sites/production/files/2014-12/documents/fy-2014-enforcement-annual-results-charts-12-08-14.pdf> [<https://perma.cc/3CGG-PS5R>] (providing data for FY 2010 to FY 2014).

217. Gabriel Markoff, *Arthur Andersen and the Myth of the Corporate Death Penalty: Corporate Criminal Convictions in the Twenty-First Century*, 15 U. PA. J. BUS. L. 797, 827-34 (2013).

218. *Id.* at 818-27.

219. Gregory M. Gilchrist, *The Special Problem of Banks and Crime*, 85 U. COLO. L. REV. 1, 28-32 (2014) (arguing that banks have these characteristics).

220. Markoff, *supra* note 217, at 804-12; Matthew C. Turk, *Regulation by Settlement*, 66 KAN. L. REV. 259, 264-69, 314-15 (2017).

221. There can also be corporate integrity agreements that call for expansion of internal compliance infrastructure and procedures (with possible outside monitoring) or injunctive relief.

in federal criminal fines against organizational defendants since about 2007,²²² which some interviewees picked up on.²²³

The practical incentives created by these rising penalties for large publicly traded firms are somewhat doubtful for two reasons. First, they are paid with the corporation's money, not with the money of individual executives who make decisions about corporate conduct.²²⁴ Theoretically, shareholders upset over a penalty could pressure the board to remove the responsible executives. But shareholders are often diffuse and disorganized, and even if they are not, the penalty would have to be large enough to get their attention. That brings us to the second reason: monetary penalties against large firms, though seemingly large in a newspaper headline, are often small in the context of the firm's business. Despite penalty settlements against pharmaceutical companies reaching into the billions of dollars, the sums paid are "often a manageable percentage of the revenue received from the particular product under scrutiny,"²²⁵ and "most" do "not significantly disrupt the pharmaceutical firm's operations."²²⁶ In particular, settlements for these penalties "do not make clear the economic analysis on which the payment is based," e.g., they do not break out the portion of the money that is a disgorgement of profits so that the figure could be compared with the overall profits on the product.²²⁷ In environmental regulation, a senior environmental counsel for a Fortune 100 company said that an EPA civil penalty would not be a factor for the company overall (though "maybe" it would be for the individual facility concerned, as a profit-and-loss center within the company).²²⁸ In banking regulation, said an official at a nonprofit public policy research organization (formerly a consultant in consumer finance), the monetary penalties imposed were "not material" in most cases: for a penalty to matter to a bank, it would have to be bigger than what an agency would practically impose for conduct that was arguably legal.²²⁹ In the view of former Deputy Attorney General David Ogden, large monetary penalties against corporations arise from the perverse incentives of government enforcers to rack up "publicity, stats, and big money" rather than from a serious effort to deter

222. BRANDON L. GARRETT, *TOO BIG TO JAIL: HOW PROSECUTORS COMPROMISE WITH CORPORATIONS* 5 (2014).

223. Interview with Source 17, *supra* note 170 (observing rising fines, both in headlines and for smaller firms); Interview with Source 56, *supra* note 176 (observing that "crime does not pay anymore," given the increase in penalties in areas like violations of the Clean Water Act, though not at OSHA, whose schedule of penalties remains "pitiful" even after a 2016 increase).

224. Sonia A. Steinway, *SEC "Monetary Penalties Speak Very Loudly," But What Do They Say? A Critical Analysis of the SEC's New Enforcement Approach*, 124 *YALE L.J.* 209, 222 (2014); Rodwin, *supra* note 209, at 438.

225. Kevin Outterson, *Punishing Health Care Fraud—Is the GSK Settlement Sufficient?*, 367 *NEW ENG. J. MED.* 1082, 1083 (2012).

226. Rodwin, *supra* note 209, at 438.

227. *Id.* at 444.

228. Interview with Source 119, *supra* note 108.

229. Interview with Source 131, *supra* note 102.

misconduct, which would require more onerous and risky prosecutions of individuals.²³⁰

But while the run-up in penalties has doubtful effects on large firms, we know little about whether it has also occurred in enforcement against smaller firms, and if so, whether it has serious effects on their business and incentives. That is a good topic for future research.

E. When Incentives to Follow Guidance Are Weak

If pre-approval requirements, the need to maintain relationships, the prevalence of compliance personnel, and high enforcement costs incentivize regulated parties to follow guidance, then when these factors are weak or absent, we would expect regulated parties to follow guidance less. In this Section, I explore four areas where this appears to be the case.

1. OSHA Regulation Beyond Large Firms

In contrast to the several areas where interviewees said regulated parties routinely followed guidance—such as FDA approvals, EPA licensing programs, and bank examinations—interviewees on OSHA gave, in the aggregate, a much less sanguine assessment.

Some interviewees said compliance with OSHA guidance was low, at least outside large firms. Industry safety consultant John Newquist, who worked at OSHA for twenty-nine years and rose to Assistant Administrator of Region V (headquartered in Chicago), observed that the “average” construction company or manufacturer would follow OSHA guidance “not at all.” It was “hard enough” to comply with the actual legislative rules. Companies that followed guidance were those with a high level of safety expertise; they tended to be large and to have good trade associations with high membership that disseminated the guidance, as in the case of oil refineries and chemical plants, who watched guidance closely. By contrast, a manufacturer with say “three hundred employees” would have “very little expertise.” And even some big companies did not much comply with OSHA guidance, as in food manufacturing.²³¹ Adam Finkel, who served in career positions at OSHA including regional administrator for the Rocky Mountain states, began his discussion of motives for companies to comply with guidance by saying, “often they *don’t* comply.”²³² Baruch Fellner, the founding partner of Gibson Dunn’s OSHA practice for the last twenty-seven years, observed that most employers made a good-faith effort to protect

230. JESSE EISINGER, *THE CHICKENSHIT CLUB: WHY THE JUSTICE DEPARTMENT FAILS TO PROSECUTE EXECUTIVES 200-01* (2017) (quoting former Deputy Attorney General David Ogden).

231. Interview with John Newquist, Partner, Newquist Safety, and former Assistant Reg’l Admin’r, Occupational Safety & Health Admin.

232. Interview with Adam Finkel, Senior Fellow & Exec. Dir., Program on Regulation, Univ. of Pa., and former Reg’l Admin’r, Occupational Safety & Health Admin.

employee safety in substance; however, the complex and arcane nature of OSHA rules and guidance caused most employers not to engage much with the details of those rules and guidance, treating the prospect of OSHA citations as “a cost of doing business”: “If OSHA finds me, I’ll pay the fine.” “Very few” employers, he said, had access to the kind of expertise needed for the details of OSHA rules and guidance, whether in-house or through consultants.²³³

Other interviewees said the level of employer compliance with OSHA guidance was unknown. The health and safety director of North America’s Building Trades Unions said the level of employer compliance with guidance was a “good question” and an unknown, though she cited a pending study on what the construction industry was doing with a certain set of OSHA recommended practices.²³⁴ A health and safety expert at a labor union said levels of compliance were “all over the lot” and “hard to understand” and that “we don’t have a handle on actual compliance.”²³⁵ Marc Freedman, the U.S. Chamber of Commerce’s executive director of labor law policy, in discussing controversial draft guidance on noise reduction that OSHA proposed and withdrew in 2010 to 2011 and that the Chamber opposed, thought it was “hard to say” how many employers would have taken such guidance seriously. He added “anecdotally” that “many” employers had approached the Chamber upset about the proposed guidance, fearing it was a “big ticket item.”²³⁶

Yet other interviewees talked about employers who followed guidance but indicated that their statements were not generalizable to OSHA’s vast jurisdiction. Frank White, the former deputy head of OSHA and former president of a major health, safety, and environmental (HSE) consultancy, said OSHA guidance had “pretty uniform and profound” influence on the Fortune 100 companies that made up virtually his entire clientele and that he advised them to follow it. However, he added that as companies got smaller, there was less compliance with guidance. According to White, a medium or small company acting in good faith would try to follow guidance, but even then it might not have the time or the systems in place to do it; furthermore, some employers were simply uninterested in compliance.²³⁷ Jonathan Snare, an occupational safety and health (OSH) partner at Morgan Lewis and former deputy solicitor of the Department of Labor (DOL), said that larger companies with safety staff would keep up with OSHA guidance and use it in their training. He added that he also had some experience with smaller contractors in construction, who had some

233. Interview with Baruch Fellner, Partner, Gibson, Dunn & Crutcher LLP.

234. Interview with Chris Trahan Cain, Dir. of Safety & Health, N. Am.’s Building Trades Unions, and Exec. Dir., CPWR Ctr. for Constr. Research & Training.

235. Interview with Source 113, health and safety expert, labor union.

236. Interview with Marc Freedman, Exec. Dir. of Labor Law Policy, U.S. Chamber of Commerce.

237. Interview with Frank White, *supra* note 188.

awareness of the OSHA website and would use it to some degree.²³⁸ David Sarvadi, who spent more than fifteen years as an industrial hygienist before entering law and is now a partner in Keller Heckman’s OSH practice, said his clients took guidance seriously and would ask him about it, but later in the interview, speaking about industry more generally, he said compliance would depend on the topic. He contrasted compliance on matters of substance—“if somebody will die, people care about that”—with things like “paperwork exercises.”²³⁹ Celeste Monforton, an academic and safety advocate and former OSHA legislative analyst, said that nobody looks systematically at employer compliance with OSHA guidance and that she had seen no data on it. But her sense was that employers would ignore guidance on an issue not governed by a legislative rule. However, most would make an effort to comply with a legislative rule if one was applicable, and employers would use guidance in that context—on this point, she emphasized newly promulgated legislative rules, which she noted were rare. For these, she recalled seeing employers demand guidance from OSHA, although she thought employers’ varying levels of interest in getting such guidance—or in sometimes mounting political or litigation resistance to it—had little to do with their actual probabilities of being inspected and instead depended on which of them belonged to trade associations that were raising fear about OSHA to justify their own existence to their members (more on that below).²⁴⁰

While not all these interviews are consistent, I take them in the aggregate to suggest that OSHA guidance has a substantially lower impact on regulated-party behavior, at least beyond large firms, than we have observed for several other agencies. I think this lessened impact is to be expected because the four factors discussed above in Sections I.A through I.D are weak or absent when it comes to OSHA:

First, OSHA has no pre-approval authority.

Second, OSHA does not have frequent interactions or continuing relationships with the large majority of employers. OSHA’s inspection force is so small compared to the number of employers in the twenty-nine states where it administers the OSH Act that each employer can be inspected on average something like once per century—a point cited by five interviewees.²⁴¹ On this

238. Interview with Jonathan Snare, Partner, Morgan Lewis, and former Deputy Solicitor, Occupational Safety & Health Admin., Dep’t of Labor.

239. Interview with David Sarvadi, *supra* note 103.

240. Interview with Celeste Monforton, Lecturer, Dep’t of Health and Human Performance, Tex. State Univ., and Professorial Lecturer, Milken Inst, Sch. of Pub. Health & Health Servs., George Washington Univ., and former Legislative Analyst, Occupational Safety & Health Admin., and former Policy Advisor, Mining Safety & Health Admin.

241. Calculations of the time period vary but are all on the order of a lifetime or more. Interview with Chris Trahan Cain, *supra* note 234 (140 years); Interview with Baruch Fellner, *supra* note 233 (125 years); Interview with David Sarvadi, *supra* note 103 (70 years); Interview with Jonathan Snare, *supra* note 238 (noting the “low ratio” without giving a number); Interview with Source 62, former senior official, Occupational Safety & Health Admin. (140 years).

point, Monforton drew a contrast between OSHA and the Mine Safety and Health Administration (MSHA), where she had also worked. Mines were each inspected by the MSHA four times per year, got to know their inspectors individually, and received guidance “all the time” as part of the accepted course of business. By contrast, she said, most employers never actually “meet” OSHA; they only hear about it.²⁴²

Third, whereas compliance officers or RA professionals in areas like pharmaceutical or banking regulation can constitute a force internal to the firm yet highly sensitive to the agency, companies’ compliance infrastructure for workplace safety does not necessarily fit this pattern. Outside large firms, compliance infrastructure for safety is usually thin to nonexistent. According to White, the former deputy head of OSHA and HSE consultancy president, the role of safety professionals inside corporations “fades out quickly” as they get smaller. Though it is hard to say where the exact threshold is, a full-time safety person would be “rare” in a company below 500 to 1,000 employees.²⁴³ (Note that 53% of U.S. private-sector employment is in firms with less than 500 employees.²⁴⁴) A former senior OSHA official likewise noted that many companies tasked their Human Resources personnel with handling safety even though they might have no training in it.²⁴⁵

That said, large companies do have safety departments staffed with full-time specialists. According to White, safety personnel at the facility level in a Fortune 100 company would defer to OSHA guidance and not distinguish it from a legislative rule unless they encountered a problem with it, reported the matter upward, and received authorization at the corporate level to depart.²⁴⁶ But the interviews indicate that large corporate safety departments feel some ambivalence toward OSHA guidance and may not serve as a pro-agency force as much as compliance personnel in other areas of regulation. This is because safety professionals in large corporations may feel they have—and may actually have—greater expertise in safety than OSHA does. OSHA’s recommended practices, observed the health and safety director of North America’s Building Trades Unions, did not have “much impact” on big companies because they were “ahead of OSHA” already.²⁴⁷ Fellner, the OSH founding partner at Gibson Dunn, said that, ironically, the large companies who were most sophisticated about their own workers’ safety “know more than OSHA” and therefore got more frustrated

242. Interview with Celeste Monforton, *supra* note 240.

243. Interview with Frank White, *supra* note 188. *But see* Interview with Jonathan Snare, *supra* note 238 (noting “anecdotal[ly]” that he has represented general contractors between 50 and 300 employees, most of whom have at least one full-time safety person, and some may have two or three).

244. See the figures for 2016 in *Table F. Distribution of Private Sector Employment by Firm Size Class: 1993/Q1 Through 2017/Q1, Not Seasonally Adjusted*, U.S. BUREAU OF LABOR STATISTICS (July 25, 2018), https://www.bls.gov/web/cewbd/table_f.txt [<https://perma.cc/ZJY7-QJ3Y>].

245. Interview with Source 62, *supra* note 241.

246. Interview with Frank White, *supra* note 188.

247. Interview with Chris Trahan Cain, *supra* note 234.

with the shortcomings of OSHA guidance.²⁴⁸ Likewise, White noted that large companies were more likely to have the expertise necessary to question whether OSHA guidance was right.²⁴⁹

Fourth, guidance’s limited impact in OSHA regulation may be explained by the mostly low expected costs to most employers of one-off OSHA enforcement. As already discussed, OSHA has so few inspectors that the probability of inspection for the average employer is very low, though we must qualify this by noting that large employers with many facilities have a higher probability of being inspected,²⁵⁰ as do employers subject to OSHA “emphasis programs” for selected hazards.²⁵¹ If and when inspections do happen and violations are found, the cited firm’s cost of abating the hazard can potentially be high; this depends on the technological and economic feasibility of the measures OSHA is seeking.²⁵² But monetary penalties are low. Even with an increase in 2016, said a public interest organization official, OSHA fines were still “pitiful” in comparison to those under environmental statutes like the Clean Water Act.²⁵³ Officials at Public Citizen called OSHA fines “meaningless,” often in the range of \$3,000 to \$5,000, occasionally rising to say \$200,000.²⁵⁴ White, the former deputy head of OSHA, said most citations are not litigated because it is not worth it, given the size of the fine.²⁵⁵ Also, criminal convictions are vanishingly rare for OSH violations in comparison to environmental regulation or healthcare programs.²⁵⁶ Consistent with this, the results of statistical studies asking whether OSHA inspections and penalties produce deterrence are “more mixed” compared with stronger statistical evidence of deterrence in environmental regulation, and they provide less evidence that OSHA regulation has driven the historical decline in workplace injuries and fatalities compared to stronger evidence for environmental regulation as a driver of companies’ improved environmental performance.²⁵⁷

248. Interview with Baruch Fellner, *supra* note 233.

249. Interview with Frank White, *supra* note 188.

250. *Id.*

251. Interview with Jonathan Snare, *supra* note 238.

252. Interview with Baruch Fellner, *supra* note 233.

253. Interview with Source 56, *supra* note 176; *see also* Shapiro & Rabinowitz, *supra* note 213, at 109 (old fine schedule).

254. Interview with Michael Carome and Sammy Almashat, *supra* note 66. OSHA’s online database of enforcement cases with \$40,000+ penalties indicates that, if one includes the twenty-one states where state agencies administer the statute, there have been seventy-one enforcement cases with initial penalties of \$200,000 or more between January 2015 and June 2017. *Enforcement Cases with Initial Penalties Above \$40,000*, OCCUPATIONAL SAFETY & HEALTH ADMIN. (Sept. 20, 2018), <https://www.osha.gov/topcases/allstates.html> [<https://perma.cc/NB5B-5ZMG>].

255. Interview with Frank White, *supra* note 188.

256. *See supra* note 213 and accompanying text.

257. James Alm & Jay Shimshack, *Environmental Enforcement and Compliance: Lessons from Pollution, Safety, and Tax Settings*, 10 FOUND. & TRENDS MICROECON. 209, 239-41 (2014) (reviewing literature). There is recent and strong evidence that OSHA achieves specific (as distinct from general) deterrence—i.e., the few individual firms that are actually hit with penalties do have fewer injuries in the future—but even that finding disappears when looking at firms with more than 250

If indeed most employers' incentives to follow OSHA guidance are relatively low, there must nonetheless be some explanation for the strong opposition that certain OSHA guidance documents have elicited, from time to time, in litigation and on Capitol Hill. To a substantial degree, it appears, this opposition is driven by industry association officials and outside counsel who believe certain OSHA guidance to be unlawful and unreasonable and not in the long-run interest of employers (after all, at least some employers *will* be cited and could be hit with substantial abatement costs, even if the probability is low *ex ante* for the large majority of employers and thus often ignored by them). Fellner—founder of Gibson Dunn's OSH practice and a leading attorney for challenges to major OSHA initiatives like ergonomics regulation²⁵⁸—explained that when OSHA guidance was opposed through litigation or congressional channels, the main actors on the employer side were associations of businesses, some regularly involved pan-industry associations and some industry-specific associations that became involved depending on the subject matter, as well as a few sophisticated individual companies. The associations, he said, would try to inform their members of OSHA's plans and solicit their support. But, he observed, it was "difficult" to "kindle" companies' interest in opposing OSHA guidance, even sophisticated companies. For trade associations to extract support from their members on such a matter was often "like pulling teeth." If the association recognized the problem but the members did not, it sometimes happened that an association would bring a challenge independently of its members or that just one or a few member companies would provide substantially all the funding for a challenge by one or a few associations. A challenge to a widely applicable OSHA policy, Fellner explained, often depended on the initiative of outside counsel: it was not necessarily "the employer going to the lawyer," but "the lawyer going to the employer." In Fellner's view, outside counsel or individual companies who initiated and took on the burden of these challenges faced a "free rider problem" in that they were providing a good—the blocking of unlawful and unreasonable regulation—whose benefits would extend far beyond the few actors who put in the effort and resources to provide the good.²⁵⁹

Significantly, this view of the relationship between trade associations and outside counsel leading the opposition to guidance, on the one hand, and employers actually subject to guidance, on the other, was shared to a substantial

employees. Amelia M. Haviland et al., *A New Estimate of the Impact of OSHA Inspections on Manufacturing Injury Rates, 1998-2005*, 55 AM. J. INDUS. MED. 964, 965 (2012).

258. E.g., *Industry Groups File Suit Against OSHA's Ergonomics Rule*, EHS TODAY (Nov. 15, 2000), https://www.ehstoday.com/news/ehs_imp_33872 [<https://perma.cc/FJ5U-49D7>] (referring to Fellner as "industry[]"s chief counsel").

259. Interview with Baruch Fellner, *supra* note 233. Compare the U.S. Chamber of Commerce labor law policy director's statement that, "anecdotally," "many" employers had approached the Chamber upset about OSHA's proposed noise reduction guidance in 2010 (later withdrawn), though it was "hard to say" how many employers in general would have taken the guidance seriously. See *supra* note 236 and accompanying text.

degree by interviewees on the non-industry side. To be sure, these non-industry interviewees had a different normative take on the phenomenon and a more jaundiced view of the motivations of the associations and outside counsel, but their basic description of associations and outside counsel taking the initiative themselves, more than reacting to the initiative of their members or clients, was similar. Monforton, the academic and safety advocate and former OSHA legislative analyst, observed that trade associations and OSHA defense firms would “stir the pot,” raising fear of an OSHA inspector “on every doorstep,” even though this was not real. Associations did this, in her view, to maintain their membership and justify their existence; it was their “business model.”²⁶⁰ Similarly, Finkel, the former OSHA regional administrator, said on the subject of employer opposition to OSHA guidance that trade associations had “incentives to pick fights” and that there was an “agency problem” between the associations and their members.²⁶¹

I should note that, assuming these interviews are accurate in indicating that the initiative lies more with trade associations than with their members in challenges to OSHA guidance, this dynamic would hardly be unique to industry. A recent study finds that institutional arrangements can produce similar dynamics between advocacy groups and the persons they represent across the political spectrum.²⁶²

2. FTC Consumer Protection

The consumer protection wing of the Federal Trade Commission (FTC) operates by bringing federal court suits and intra-agency complaints against violators of the consumer protection statutes and of the FTC’s own legislative rules. David Vladeck, the former director of the FTC Consumer Protection Bureau, expressed the view that FTC guidance is very limited as a means to change behavior of regulated parties. On this point, he drew a distinction between truly noncompliant businesses (like debt-settlement scammers) and reputable ones (like major advertising agencies or retailers). As to the debt-settlement scammers, he said, changing their behavior en masse was not possible for the FTC without legislative rulemaking. Even if the FTC issued guidance in the area, actual enforcement required violations to be proven individually in each particular proceeding. Prior to completing a rulemaking on the matter, the FTC brought enforcement suits against about twenty-five debt-settlement scammers, but these suits were “slogs,” because of the need for individualized proof that the conduct violated the act. Some of the biggest scammers were enjoined, but the chances of getting caught were “pretty low”; therefore, many other scams

260. Interview with Celeste Monforton, *supra* note 240.

261. Interview with Adam Finkel, *supra* note 232.

262. Miriam Seifter, *Second-Order Participation in Administrative Law*, 63 UCLA L.

continued. Only once it finished the rulemaking—defining what conduct violated the act in a manner that would bind the courts—could the FTC bring “quick” enforcement actions, raising the probability of liability. The rulemaking and the capacity for quick enforcement “turned the tide,” forcing the scammers to abandon their schemes.

As to the major advertising agencies and retailers, said Vladeck, guidance was still ineffective as a means of “mov[ing] the goal posts” and actually changing industry norms, since individual enforcement actions (the means through which a norm change called for by guidance would have to be enforced) tended to be winnable only against deviants who fell below an already accepted industry norm. Such suits did not suffice for doing “something aspirational.” To be aspirational, you generally need legislative rulemaking, not guidance. (Vladeck did observe an exceptional context in which FTC guidance did alter the behavior of reputable firms: the 2009 guidance on claims about products appearing in endorsements, especially through social media. But he noted that there, the guidance was only restoring a pre-existing norm that had been temporarily disrupted by the onset of product endorsements on social media. It was not creating aspirational new norms that were unfamiliar to industry.)²⁶³

Consistent with Vladeck’s view of FTC guidance’s limited efficacy, a former CFPB official who now represents CFPB-regulated entities observed that, when it comes to guidance, regulated firms in her experience generally cared what the CFPB thinks while caring little what the FTC thinks. In particular, she noted, mortgage servicers followed CFPB guidance more than they followed FTC guidance.²⁶⁴

The low impact of FTC guidance, particularly as compared with CFPB guidance, can be understood in terms of the factors discussed earlier in this Part. Whereas the CFPB has effective pre-approval leverage over many of its regulatees (particularly banks), in that the agency’s identification of problems at a bank can interfere with the bank obtaining permission to undertake a merger or expansion, the FTC does not have pre-approval authority in the area of consumer protection. In addition, the FTC Consumer Protection Bureau’s interaction with regulated parties is generally through enforcement; it does not have the kind of routinized repeat interfaces with regulated parties that forge continuing relationships in, for example, bank examination. As to mortgage servicers specifically, the CFPB has authority to conduct examinations of them, and while it selects servicers for examination based on a set of risk-based

263. Interview with David Vladeck, Professor, Georgetown Law, and former Dir., Bureau of Consumer Prot., Fed. Trade Comm’n. In addition to noncompliant firms like debt settlement scammers and reputable firms like large advertising agencies, Vladeck discussed a third kind of business—exemplified by small makers of mobile phone apps—who wanted to comply with the law insofar as they knew it, but who were generally uninformed. Enforcement actions would produce no general deterrence for these businesses, as they were diffuse and ignorant, so the best thing for the FTC to do was “outreach.”

264. Interview with Source 81, *supra* note 96.

priorities (unlike the more routinized rotating schedule employed by the OCC or the Federal Reserve for banks),²⁶⁵ the mortgage-servicing industry is subject to substantial CFPB-examination scrutiny because the great majority of its business is done by a small number of large firms.²⁶⁶ Large firms are aware that the CFPB has considered mortgage servicing a high priority for examination ever since the agency was founded;²⁶⁷ furthermore, large firms within any high-priority industry are most likely to be examined, other things being equal.²⁶⁸ Finally, in the realm of enforcement, the probability of being detected and facing agency action differs between the two agencies. The former CFPB official noted that whereas the FTC devoted only a few attorneys to mortgage-servicer cases, the CFPB had whole units dedicated to that industry.²⁶⁹

3. CFPB Regulation of Nonbank Institutions

The CFPB has jurisdiction over two kinds of institutions. The first are banks (as well as savings associations and credit unions) that have assets over \$10 billion; there are about 150 of these, covering 80% of the national banking market.²⁷⁰ The second are nonbanks, that is, companies that provide “consumer financial products or services” but do “not have a bank, thrift, or credit union charter.”²⁷¹ Nonbanks are further defined to include mortgage servicers, payday lenders, debt collectors, private education lenders, consumer reporting agencies, remittance transfer providers, and others. Altogether, they number “well over 15,000.”²⁷²

In terms of sensitivity to guidance, an interviewee who held senior posts at the CFPB and other federal agencies said that there was a major divergence between banks and nonbanks (though the interviewee also noted that among nonbanks, the relatively sophisticated firms—which were usually, though not

265. Steven Antonakes, *Prepared Remarks of CFPB Director Steven Antonakes at the Exchequer Club*, CONSUMER FIN. PROTECTION BUREAU (Feb. 18, 2015), <https://www.consumerfinance.gov/about-us/newsroom/prepared-remarks-of-cfpb-deputy-director-steven-antonakes-at-the-exchequer-club/> [<https://perma.cc/A8WG-QTCL>].

266. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-278, *NONBANK MORTGAGE SERVICERS: EXISTING REGULATORY OVERSIGHT COULD BE STRENGTHENED* 11-13 (2016).

267. Interview with Source 90, *supra* note 95.

268. An institution's market share is one of four factors deciding priority for examination. Antonakes, *supra* note 265. Another of the four factors is the size of the product market, Antonakes, *supra* note 265, and “the mortgage market is far and away the largest consumer credit market,” *Policy Priorities Over the Next Two Years*, CONSUMER FIN. PROTECTION BUREAU 9 (Feb. 25, 2016), http://files.consumerfinance.gov/f/201602_cfpb_policy-priorities-over-the-next-two-years.pdf [<https://perma.cc/ZP57-X4D2>]. The other two factors are the product's general potential for consumer harm and risks specific to the institution. Antonakes, *supra* note 265.

269. Interview with Source 81, *supra* note 96.

270. Steve Antonakes & Peggy Twohig, *The CFPB Launches Its Nonbank Supervision Program*, CONSUMER FIN. PROTECTION BUREAU (Jan. 5, 2012), <https://www.consumerfinance.gov/about-us/blog/the-cfpb-launches-its-nonbank-supervision-program> [<https://perma.cc/BH2P-6E83>].

271. *Id.*

272. Antonakes, *supra* note 265.

always, the large ones—were likely to behave more like banks).²⁷³ As to nonbanks, she explained, the “value of guidance is less.” Whereas banks generally read guidance and usually do more than read it, nonbanks are “more resistant to changing their business practices in response to guidance.” The interviewee attributed this difference to several factors, including pre-approval authority, continuous interaction and relationships, and compliance infrastructure. Nonbank business operations, she explained, are not overseen at the federal level in the same way as those of banks. Unlike banks, nonbanks are not required to apply to a federal regulator to carry out transactions that significantly impact their operations and growth plans. Such transactions include mergers and acquisitions, as well as smaller transactions which may impact the communities that they serve, such as opening or closing a branch location. Moreover, nonbanks are typically licensed at the state level, which can be difficult to track. As a result, the CFPB often has limited information about nonbank firms under its supervisory jurisdiction, particularly those with smaller market shares. Whereas banks know their regulators and seek them out, nonbanks often “hope the agency will never find them,” so they are less likely to structure their operations to meet federal compliance expectations. In other words, nonbanks are “willing to take their chances.” The interviewee also drew a contrast between banks and nonbanks in terms of “compliance culture.” Banks have “taken to heart” that they need a viable compliance program, and it is common for all but the very smallest banks to have a full-time compliance officer. Whether a nonbank has compliance personnel is “more a matter of resources”; nonbanks may say, “we don’t have the money for a compliance program.”²⁷⁴

Furthermore, all banks under CFPB jurisdiction are subject to examinations by the agency, whereas many nonbanks under the agency’s jurisdiction are not subject to examinations, only to ex post enforcement actions. When it comes to guidance, examination is more effective at getting businesses’ attention. According to a former CFPB official who represents CFPB-regulated entities, firms subject to examination “are more worried about examination than enforcement.” Those firms know the examination is “surely coming.” They will invest in compliance. By contrast, for a nonbank that is subject only to enforcement and no examination, whether guidance is followed depends on “the compliance culture of the firm,” or on whether it has private equity investors (who might insist on following guidance). Without a compliance culture or such investors, such firms may be “whistling past the graveyard” and are not worried enough to invest in compliance.²⁷⁵ The significance of examinations is of interest

273. This would particularly apply to mortgage servicing, which is a concentrated market to which the CFPB has long assigned a high priority for examination and enforcement. Interview with Source 90, *supra* note 95.

274. *Id.*

275. Interview with Source 81, *supra* note 96. An interviewee who held senior posts at the CFPB and other federal agencies noted that the CFPB selects firms for examination through a risk-

because, if sufficiently frequent, they are more likely to result in the buildup of a relationship between agency and firm than would mere enforcement.

4. Ex Post Enforcement Against Permitless Discharges Under the Clean Water Act

The Clean Water Act (CWA) generally prohibits the discharge of any pollutant into the “waters of the United States,” but the Army Corps of Engineers (Corps) can grant permits for discharges.²⁷⁶ The question of what pieces of property are “waters of the United States” and are thus covered by the CWA has been the subject of uncertainty, controversy, and litigation for decades.²⁷⁷ An owner uncertain about whether property is covered—and therefore whether development of the property requires a permit—can seek a jurisdictional determination from the Corps to get that question answered. If the answer is yes, the owner needs to go through the Corps’ permit application process in order to develop the property, and that process can be costly. If the answer is no, the owner can go ahead without a permit.²⁷⁸ Alternatively, the owner could refrain from seeking a jurisdictional determination to begin with and take the risk of developing the property amid legal uncertainty. But in that case, the EPA could bring a civil enforcement suit against the owner and, if it turns out the property is covered, obtain injunctive relief and civil penalties.²⁷⁹ Criminal penalties are also available if the defendant acted with negligence or knowledge.²⁸⁰

Thus, there are two contexts in which owners may interact with regulators: (a) the jurisdictional determination process, in which the owner seeks out the regulator in order to obtain what is essentially a pre-approval, and (b) the ex post enforcement process, in which the EPA roves the countryside in search of owners who are taking the risk of developing property without seeking assurances. The EPA and the Corps have repeatedly issued guidance on the general question of what property constitutes “waters of the United States,” which simultaneously governs both the Corps’ pre-approval decisions (jurisdictional determinations) and the EPA’s decisions about what discharges to enforce against ex post. One such guidance document was issued in 2003.²⁸¹ Then, in 2006, the Supreme

based set of priorities, meaning that some firms may be legally subject to examination but unlikely to actually see an examiner on a regular basis. But some firms, she noted, would be aware they are a high priority for examination if they are relatively large participants in an area (such as mortgage origination or servicing) that the CFPB has publicly designated high priority; these firms would not ignore guidance in the way many nonbanks might. Interview with Source 90, *supra* note 95.

276. 33 U.S.C. §§ 1311(a), 1344, 1362(7), (12) (2018).

277. See WILLIAM N. ESKRIDGE JR. & JOHN FERREJOHN, *A REPUBLIC OF STATUTES: THE NEW AMERICAN CONSTITUTION* 254-66 (2010).

278. See *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 136 S. Ct. 1807, 1812 (2016).

279. *Id.* § 1319(b), (d).

280. *Id.* § 1319(c).

281. The guidance is appended to Advance Notice of Proposed Rulemaking on the Clean Water Act Regulatory Definition of “Waters of the United States,” 68 Fed. Reg. 1991, 1995 (Jan. 15, 2003).

Court handed down a splintered decision in *Rapanos v. United States* that threw the meaning of “waters of the United States” into even greater uncertainty.²⁸² The EPA and the Corps reacted by issuing guidance in June 2007 (modified in December 2008) that identified large categories of property as falling into a grey area for which officials would have to apply a fact-intensive test on whether the property’s waters had a “significant nexus” with “traditional navigable water.”²⁸³ During the Obama administration, the EPA proposed a modification to the guidance but withdrew it, then went through a full legislative rulemaking to clarify the matter, only to have the rule blocked in court as the administration was near its end.²⁸⁴

As explained by an attorney at an environmental NGO, the impact of guidance on CWA administration, relative to what a legislative rule could do, depends on whether the context is pre-approval or ex post enforcement. The “day to day administration” of the Act “in the back-and-forth between owners and the Corps”—that being jurisdiction determinations and permitting—“might not be all too different” if the policies to be implemented by the Corps appeared in guidance or in a legislative rule. But in ex post enforcement—when an owner has decided to make discharges without seeking the prior assurance of a jurisdictional determination—“then the absence of a [legislative] rule has a real effect.” According to the attorney, there had been “a lot of indication” during both the Bush and Obama administrations that the EPA and the Corps were focusing enforcement suits on property not in the grey area. But a legislative rule could have eliminated the grey area: it could be “categorical and guaranteed,” and it would often be the exclusive focus of the judge deciding the enforcement suit (whereas guidance would have at most persuasive power, and then only “maybe”).²⁸⁵

In other words, guidance can be about as impactful as a legislative rule when the context is pre-approval, since there the regulated party has sought out the agency and is seeking to get the agency’s assent. But in ex post enforcement, the agency bears the burden of building its case from the ground up. That case is already built automatically if the agency has a legislative rule to rely upon, thereby allowing a large number of easy suits to be brought rapidly, increasing the probability of detection and deterrence. But this is not possible if the agency has only guidance in hand, since then it must work up each case individually,

282. 547 U.S. 715 (2006).

283. U.S. ENVTL. PROT. AGENCY & U.S. ARMY CORPS OF ENG’RS, CLEAN WATER ACT JURISDICTION FOLLOWING THE U.S. SUPREME COURT’S DECISION IN *RAPANOS V. UNITED STATES & CARABELL V. UNITED STATES* (2008); U.S. ENVTL. PROT. AGENCY & U.S. ARMY CORPS OF ENG’RS, CLEAN WATER ACT JURISDICTION FOLLOWING THE U.S. SUPREME COURT’S DECISION IN *RAPANOS V. UNITED STATES & CARABELL V. UNITED STATES* (2007).

284. See CLAUDIA COPELAND, CONG. RESEARCH SERV., R43455, EPA AND THE ARMY CORPS’ RULE TO DEFINE “WATERS OF THE UNITED STATES” 1-2, 14-15 (2017).

285. Interview with Source 97, attorney at an environmental NGO; see also Interview with Source 96, *supra* note 74 (stating that using guidance for CWA coverage would have less effect than a legislative rulemaking, and it was hard to say how much weight it would have).

reducing the number of cases it can bring overall. This can mean a low probability of detection for regulated parties if they are numerous, as they are in the CWA context, thus reducing incentives to comply. (It also seems reasonable to assume that the target class for enforcement—owners who opt against seeking jurisdictional determinations from the Corps—constitutes a self-selected group whose members tend not to have repeated interactions with or strong relationships to the Corps or the EPA.)

One refinement of this analysis is in order: if you want to strengthen an ex post enforcement regime, you can achieve some (though not all) of the benefit of a legislative rule if you replace a guidance document with a clearer guidance document. Although a clearer guidance document will not bind the courts in the way a legislative rule would, it can reduce the agency's internal processing times in deciding which cases to initiate, thereby allowing more cases to be brought, with some increase in detection and deterrence. The reverse happened in the wake of *Rapanos*, when the EPA and the Corps in 2007 issued guidance that recognized larger grey areas and called for more fact-intensive individualized determinations in those grey areas before enforcement could be initiated. As the EPA's Director of Water Enforcement wrote in an internal email in 2008, the agency lacked "sufficient resources" to make these determinations, "thereby reducing oversight and increasing incentives for noncompliance."²⁸⁶ The goal of the Obama administration's proposed modification of the guidance was to narrow (though it could not eliminate) some areas of uncertainty, thereby redressing the "systemic underenforcement" of the CWA that had prevailed since the 2007 guidance, according to an official at a public interest group.²⁸⁷

II. Agency Flexibility and Inflexibility

While many regulated parties have strong incentives to follow guidance when it is operative, the agency can decide whether it should be operative or not in any given case. At the request of a regulated party, agency officials can decide to depart from the guidance. If officials maintain a reasonably open mind in deciding whether to do so, then we would not say that regulated parties are "bound," notwithstanding all the incentives described in Part I.

This Part explains why agencies sometimes do not keep an open mind—why they are sometimes inflexible in their use of guidance. As discussed in the Introduction, inflexibility usually does not connote some bad intent on the part

286. Memorandum: Decline of Clean Water Act Enforcement Program from Majority Staff, H. Comm. on Oversight & Gov't Reform, and Majority Staff, H. Comm. on Transp. & Infrastructure, to Rep. Henry A. Waxman, Chairman, H. Comm. on Oversight & Government Reform, and Rep. James L. Oberstar, Chairman, H. Comm. on Transp. & Infrastructure 6 (Dec. 16, 2008), <http://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/20081216113810.pdf> [<https://perma.cc/L594-4VFG>] (quoting staff notes on an Email from Mark Pollins, Dir. of Water Enf't, Evtl. Prot. Agency, to Randy Hill, Dir. of Civil Enf't, Evtl. Prot. Agency (Feb. 26, 2008)).

287. Interview with Source 56, *supra* note 176.

of the agency to use guidance improperly. Rather, as Section II.A explains, agencies are often under legitimate pressures to be consistent: regulated entities want a level playing field and predictability; NGOs and members of Congress are on the lookout for improper special treatment of industry players; and officials themselves fear that a few departures will make it impossible not to grant more, opening the floodgates. Theoretically, as discussed in Section II.B, the agency can remain flexible while meeting these legitimate demands by adopting *principled flexibility* as its approach: making departures but explaining them in a transparent manner and applying their reasoning to all like cases going forward. Yet, as Section II.C shows, principled flexibility is unfortunately hard to implement, especially because reason-giving is often costly. And there are yet other organizational obstacles to flexibility of any kind, principled or not, as noted in Section II.D. These factors, along with those in Sections II.A and II.C, probably explain most of the inflexibility we observe. Such factors operate without any official bad faith: agencies would be remiss to ignore the legitimate demands described in Section II.A, and the pathologies noted in Sections II.C and II.D are matters of resource poverty, inertia, or lack of managerial initiative.

That said, it is possible for agencies to be inflexible because personnel are committed to the substantive content of the guidance, as discussed in Section II.E. This motivation for inflexibility is the most problematic: if an agency wants to shut off consideration of alternatives to a policy simply because it thinks the policy is right, that is the classic case for legislative rulemaking.

A. Legitimate Pressures for Consistency

1. Industry Preferences for Consistency

If an agency behaves flexibly and grants an individual firm's request for a departure from guidance, that firm will be happy. But *other* firms in the industry—the competitors of the firm that obtained the departure—may not be happy. They may see themselves being put at a competitive disadvantage, and they may criticize and oppose the agency directly about that. Plus, in a broader view, departures can weaken regulated firms' sense that they are operating on a level playing field and their confidence that they can predict the agency's behavior. This can make them more defensive and less cooperative in dealing with the agency, which can reduce compliance and make the agency's work more difficult. Moreover, agency inconsistency makes it harder for companies' compliance officers and counsel to maintain credibility with their own companies and clients, which can further weaken compliance. Altogether, these industry preferences (and industry pressures) are substantial and legitimate

reasons weighing against departures from guidance in agency officials' minds, potentially rendering their use of guidance more inflexible.²⁸⁸

Consider EPA enforcement, for which guidance is key on multiple levels. EPA program offices issue guidance regarding means of compliance; that guidance colors the judgment of the enforcement office and often helps decide what conduct that office will demand of a defendant firm as a condition of settlement.²⁸⁹ Furthermore, the enforcement office's own guidance provides a predictable framework for deciding what civil penalties and other sanctions to impose on a firm and what conduct to punish.²⁹⁰

Eric Schaeffer, who served in a career position as the EPA's Director of Civil Enforcement from 1997 to 2002 and now heads an environmental NGO, said that the agency can use guidance to "demonstrate a level playing field" among firms in the regulated industry. "Despite" the APA's requirement that an agency using guidance must exercise discretion, "industry does not want discretion"—it "wants a level playing field." In a negotiation arising from an enforcement proceeding, if the EPA seeks something from the firm as a condition of settlement, the firm asks, "will you require this of everyone else [in the industry]?"²⁹¹

Similarly, Adam Kushner, who served in several career positions including Director of Civil Enforcement at the EPA from 2008 to 2012 and is now a partner at Hogan Lovells, observed that if an agency in an enforcement proceeding departs from guidance in a way that favors the target firm, other firms that previously were targeted and settled will say the shift is unfair because it puts them at a competitive disadvantage. (Note that settlements, administrative and judicial, are matters of public record, so competing firms can monitor each other's deals.) The EPA's resources are limited, so it cannot find all the violations itself—"you need industry to identify the pollution for you." Therefore, the enforcement office must get firms to come "to the table" if they have "screwed up," which "is common." Firms are more likely to disclose their violations to the EPA and settle—reducing the agency's search and litigation costs—if they (a) can predict, in advance of admitting what they have done, the penalties and sanctions they will bear and (b) believe that coming clean and settling will not put them at a competitive disadvantage with respect to firms who did similar things. "If you're not consistent and fair, [industry] won't come to the table." Kushner recounted that as enforcement director he would tell

288. Kagan observed similar linkages between industry competition, agency rigidity, and compliance in his study of the Nixon wage-price freeze, although he was focusing on the interpretation and application of regulations instead of guidance documents. KAGAN, *supra* note 54, at 76-77. For statistical studies indicating the value for compliance of clarity and consistency in regulation, see Peter J. May & Robert S. Wood, *At the Regulatory Front Lines: Inspectors' Enforcement Styles and Regulatory Compliance*, 13 J. PUB. ADMIN. RES. & THEORY 117 (2003); and Soren C. Winter & Peter J. May, *Motivation for Compliance with Environmental Regulations*, 20 J. POL'Y ANALYSIS & MGMT. 675 (2001).

289. Interview with Adam Kushner, *supra* note 106.

290. *Id.*

291. Interview with Eric Schaeffer, *supra* note 20.

companies, “you may not like the civil penalty policy,” and even if you believe the policy is “arbitrary,” “at least it’s applied the same across all cases”—“equal arbitrariness” for everybody who has come before you. Industry, he said, “gets that.”²⁹²

One guidance document that Schaeffer and Kushner helped administer—the EPA “audit policy” originating in 1995 that offered reduced penalties to companies who built internal audit programs and disclosed violations discovered through them²⁹³—appeared to work according to the principles of enforcement that Schaeffer and Kushner discussed. According to a statistical study of 1993 to 2003, firms that took advantage of the audit policy needed fewer inspections (saving government resources) and had better environmental performance even when controlling for other factors, indicating that a company’s internal program, presumably adopted in reliance on the audit policy, actually caused better performance.²⁹⁴

As to the FDA, interviewees expressed similar views about industry’s preference for consistency and predictability in guidance. Coleen Klasmeier, the head of Sidley Austin’s FDA regulatory practice and a former FDA Office of Chief Counsel attorney, said that, in her experience, it was “far more common” for the complaint of industry to be that an FDA reviewer was *not* following guidance than that the reviewer was following it too closely. Industry, she said, just wants “certainty” and a “level playing field.”²⁹⁵ Similarly, a former senior FDA official observed that, although some guidance had to be flexible because science is changing, “flexibility” is not a “primary interest” for pharmaceutical companies; instead they “want certainty”—“tell me what to do, and I’ll do it.” Guidance provides the certainty that investors want.²⁹⁶ Another food and drug industry attorney said that, while a business might sometimes seek flexibility in guidance, it would want the FDA to be inflexible (and would complain to the agency accordingly) if the company had followed guidance while its competitor was not doing so. (He pointed out that, despite the confidentiality of FDA proceedings, companies had ways of finding out if their competitors were enjoying departures from guidance, e.g., the information might come out in

292. Interview with Adam Kushner, *supra* note 106. To be sure, Kushner noted some points on which there might be variation between firms, particularly if (a) the agency was newly addressing a problem and wanted to land one settlement quickly, as an example to the rest of industry, in which case greater leniency might induce one early settlement, or (b) there is new learning about relevant technology after some firms have settled on a certain issue but before others have done so on that same issue. Kushner added that, even when firms asked for treatment specific to their situations, the EPA might still insist on certain control technologies or other arrangements in the interest of evenness with prior settlements. *Id.*

293. Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations, 65 Fed. Reg. 19617 (Apr. 11, 2000).

294. Michael W. Toffel & Jodi L. Short, *Coming Clean and Cleaning Up: Does Voluntary Self-Reporting Indicate Effective Self-Policing?*, 54 J.L. & ECON. 609 (2011).

295. Interview with Coleen Klasmeier, *supra* note 123.

296. Interview with Source 110, *supra* note 62.

public review documents or via disclosures in litigation.²⁹⁷) Consistent with all this, it seems that the FDA itself does not perceive industry to be clamoring for flexibility. When asked about inflexibility in guidance, an FDA Office of Policy official said that the main issue with guidance at the FDA was not industry complaining about inflexibility, but rather industry being confused and critical about the FDA's use of *draft* guidance.²⁹⁸

We also see an industry preference for consistency in the views expressed by the Senior Director, Regulatory Affairs, of the Association of Home Appliance Manufacturers regarding the Department of Energy's regulations on energy efficiency for appliances. This official explained that, although the Department's guidance does not necessarily have the force of law, in practice, industry treats it as if it does and the Department consistently relies on its guidance. She was supportive of this approach. When discussing departures from guidance, she emphasized those that the agency makes on a public, wholesale basis for all firms (saying she had no observations of ad hoc company-specific flexibility), and she said all guidance ought to be general and public. If guidance is not public and general, then firms are not operating on a level playing field, and that can be a disadvantage to all firms in the long run. Overall, she said, for the regulatory program to be successful, stakeholders had to be able to rely upon the public guidance; otherwise, the guidance process would become "useless" and "meaningless."²⁹⁹ (One might interpret this interviewee's view as being distinctly that of a *trade association*, aiming to represent the common interests of all industry firms, rather than the view of an actual individual firm, but even if that is the case, the fact that agencies so frequently deal with industry via trade associations means that agencies will quite often hear the strong preference those associations express for a level playing field.)

That firms may not seek (and may even oppose) departures from guidance makes sense when we consider that quite often, a firm cares more about getting *some* answer about how to proceed investment-wise than about the particular answer it gets. A former CMS division director said that, in his experience, healthcare providers were more interested in knowing what the rule is than in trying to get a more advantageous rule; their main fear is finding out they will not be reimbursed for an investment they have already made.³⁰⁰ Similarly, James Conrad, a regulatory consultant and formerly an attorney at the American Chemistry Council, said that, for industry, what is most important is "certainty"—"you just want an answer." A firm wants to avoid investing in

297. Interview with Source 92, *supra* note 61.

298. Interview with Source 25, official, Office of Pol'y, U.S. Food & Drug Admin. FDA draft guidance is discussed in the PARRILLO REPORT, *supra* note †, at 171-79. Another example is the USDA National Organic Program, the very purpose of which is to preserve the integrity of the USDA organic label by maintaining a consistent standard for organic production. See PARRILLO REPORT, *supra* note †, at 96 n.319.

299. Interview with Source 105, Senior Dir., Regulatory Affairs, Ass'n of Home Appliance Mfrs.

300. Interview with Source 93, *supra* note 88.

something and then having to switch later on.³⁰¹ Insofar as firms make investment decisions in reliance upon guidance, those investments can turn them into partisans for future adherence to the guidance.

Inconsistency or unpredictability in agency use of guidance can especially be a problem for industry compliance officers and industry counsel, for it may diminish their credibility with their own companies or clients, weakening industry compliance overall. A senior environmental counsel at a Fortune 100 company cited instances where the EPA has issued guidance announcing that some matter is a “low priority” for enforcement. Although one would think industry people would be happy with that guidance, said the interviewee, “I’m not,” because with such guidance, “I can’t tell [my company] that rules are rules.” Other companies will react to such guidance by saying, “okay, it’s a low priority [for the agency], so we won’t do it [i.e., won’t comply].” If a compliance person does not take this attitude, then he or she is put in the position of creating a competitive disadvantage for his or her own firm. Such indefiniteness is therefore bad for compliance, said the interviewee. Recalling discussions of this question at meetings of Fortune 500 industry compliance personnel, the interviewee estimated that companies were split about evenly in their view on whether these indefinite announcements about “low priorities” in enforcement were even desirable.³⁰²

Similarly, in the banking sector, an official at a nonprofit public policy research organization, who was previously a consultant and product manager in consumer finance, observed that business line people in banks were not “anti-regulation” or “pro-regulation” but rather “pro-clarity” and “pro-consistency”: they say, “Tell [me] what I can do and can’t do, and I’ll devise a business model within that.” It drives the business line people “crazy” when a bank compliance officer or in-house lawyer answers their questions by saying, with guidance in hand, “it depends.”³⁰³ Klasmeier, the head of Sidley’s FDA regulatory practice, warned that the use of guidance on legal requirements (as distinct from scientific matters) breeds “nihilism” and “cynicism” within industry regarding compliance. It was hard for a lawyer to get a commercial organization to comply without “something specific to point to,” like a sixty-five miles-per-hour speed limit, as compared to the “uncertainty” that she believed characterized too great a portion of FDA guidance.³⁰⁴

When it comes to guidance, industry complains about inconsistency not only from one company to another, but also across different geographic areas and across different agencies that regulate the same subject matter. The animating factor here, one assumes, is that there are economies of scale when it comes to compliance, which firms cannot exploit if they are denied uniformity.

301. Interview with James Conrad, *supra* note 176.

302. Interview with Source 119, *supra* note 108.

303. Interview with Source 131, *supra* note 102.

304. Interview with Coleen Klasmeier, *supra* note 123.

An official at the FDA Office of Regulatory Affairs, which supervises the agency's field inspectors, said the office hears complaints about variability across parts of the country, say from a single company that operates in multiple locations. These complaints can prompt the FDA to do an internal review of its guidance.³⁰⁵ Officials at Airlines for America, the principal airline trade association, said there was a general concern about consistency among FAA inspectors.³⁰⁶ In banking, where a single firm may be regulated simultaneously by several different agencies, the companies want "uniform answers" and "consistency." Agencies like OCC, the Federal Reserve, and FDIC respond to this demand by producing a large amount of their guidance in consultation with each other, often through an interagency working group to formulate a document. The CFPB has joined these efforts when consumer protection issues are involved.³⁰⁷

2. Demands for Consistency by NGOs, the Media, and Congress

The criticism and antagonism that an agency may suffer for making ad hoc departures from guidance arise not only from industry but also from NGOs, the media, and Congress. That is because an individualized departure from guidance can potentially be viewed as some kind of special favor, carrying an implication of impropriety. This perception may be entirely unwarranted on the particular facts, but it draws force from a legitimate general concern about ad hoc departures from ordinary policy and unequal treatment of regulated parties. In any event, the criticism will happen. The media can be expected to play up allegations of favoritism and impropriety because of their newsworthiness. NGOs and members of Congress may have various motives for criticizing: they may think the guidance appropriately stringent in substance and see departures as lamentable efforts to undermine it, or they may view the agency (or the larger presidential administration) as an adversary who deserves to be sharply questioned. But whatever the actual motives, it is the appearance (at least) of inconsistency and special treatment that gives the criticism its resonance. To be sure, agencies vary in how much attention is paid to their activities by nonindustry groups, by the media, and by congressional overseers. But the more such attention they get, the more they have another reason to protect themselves from potential criticism by adhering to guidance.³⁰⁸

305. Interview with Source 28, official, Office of Regulatory Affairs, U.S. Food & Drug Admin.

306. Interview with Sources 64, 65, 66, officials, Airlines for Am.

307. Interview with Source 90, *supra* note 95.

308. As Kagan wrote in his study of the Nixon wage-price-freeze, a "regulatory program" is "more likely to maintain a relatively stringent stance" when, among other things, it "experiences high public visibility" and "is confronted with a more balanced pressure group structure," i.e., when it faces more (and more diverse) pressure groups than just an industry trade association. KAGAN, *supra* note 54, at 68; see also *id.* at 13, 77. Anthony noted briefly that agency staff might adhere rigidly to guidance because doing so made them "relatively invulnerable to criticism" and to "disapproval for

This dynamic seems strong at the EPA—unsurprisingly, as that agency faces an especially diverse assembly of interest groups and is highly visible to the media and Congress. A partner in a large law firm and former senior EPA official said that, in his experience, the EPA was quite often inflexible on guidance, to his frustration, and he gave three reasons for this inflexibility: (a) the agency desired to be fair, and to be perceived as fair; (b) agency officials were driven by fear or concern about being criticized by congressional overseers, inspectors general, etc., and uniform adherence to guidance provided a shield against accusations of favoritism; and (c) a departure from guidance would usually require some kind of sign-off from a political appointee, which meant that responsibility would have to be taken by officials with relatively high visibility to Congress, the media, etc. For a single company to ask for a one-off departure from a guidance document was “essentially an exception request,” and officials would be concerned about accusations of “favoritism” or a “special deal,” with the main audience being Congress—any deviation from existing policy is fodder for oversight—and also the media. Even if the proceeding in which the departure occurred were not public, word of it would sometimes be let slip by EPA staff (especially if they distrusted the political appointee making the decision), or, “stupidly,” by the company benefiting from the departure. And even if the official decisionmaker was a career official, that person would check with the political appointee above him or her regarding the departure as a matter of self-protection. The interviewee made clear that all these incentives for inflexibility could operate quite independently of what any official thought about the guidance’s substance and the merits of the departure request. Officials might even tell the requesting party, “You’re right, but there’s nothing I can do for you.” The officials “feel stuck.”³⁰⁹ A senior environmental counsel at a Fortune 100 company expressed a similar view. Seeking a favorable departure from guidance from the EPA, he said, was hardly “worth the time and effort.” The agency’s inflexibility arose from an “unhealthy symbiotic relationship” between the agency, NGOs, and Congress, which instilled in EPA officials a “fear” of being considered wrong and getting “pilloried.” The mentality was to fear and avoid second-guessing by Congress, NGOs, or local community groups—to avoid being asked, why did you allow a departure “here and not there?”³¹⁰ Consistent with this, several interviewees cited NGOs’ tendency to challenge

departing from established positions,” but he did not elaborate on these points, e.g., did not say who the sources of the criticism or disapproval might be. Anthony, *supra* note 15, at 1364.

309. Interview with Source 52, *supra* note 76.

310. Interview with Source 119, *supra* note 108; *see also* Interview with David Hawkins, Dir. of the Climate Program, Nat. Res. Def. Council, and former Assistant Admin’r, Air Program Office, Env’tl. Prot. Agency (stating that one of the three causes of the EPA’s tendency to adhere to guidance was congressional scrutiny, along with fear of litigation challenges and agency political leadership’s commitment to the guidance’s substance). Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

one-off departures from EPA guidance, whether in intra-agency proceedings,³¹¹ EPA-supervised state agency proceedings,³¹² or litigation.³¹³

For an NGO perspective on this dynamic, consider the views of Andrew DeLaski, executive director of the Appliance Standards Awareness Project, the principal NGO dealing with federal regulation of the energy efficiency of appliances, which is administered by the Department of Energy. On whether he expects the Department to adhere to its guidance, he said, “yes, I presume these are the rules,” even if they do not technically have the “force of law.” Any variance from the guidance in an individual case, he believed, would amount to a “modification” of the guidance. If such modification were made without transparency, “that would bother me.” It would create an appearance of “special treatment,” an “unlevel playing field,” and a “fairness problem,” which could undermine the “standing and integrity of the program” in the eyes of the public and of policymakers. “I don’t want the program to get a black eye.” DeLaski was acutely aware that one-off departures could raise the ire of competitors of the benefiting firm, and he saw this as raising bigger dangers. He drew an analogy to an incident (not directly involving a guidance document, at least at first) in which refrigerator manufacturers discovered that one of their competitors was opportunistically administering a required energy-efficiency test less stringently than they were, upon which they “cried bloody murder.” The Department redressed this unfairness by issuing guidance to ensure uniform administration of the procedure. Had the Department failed to ensure uniformity in this way, said DeLaski, the disadvantaged manufacturers might have sought redress at the political level, and the unfairness could have been used as a rationale for deregulation. While DeLaski recognized that guidance sometimes had to be changed in contexts where legislative rulemaking was impractical, he wanted all changes to be public, transparent, and generally applicable, with reasons stated, thus allowing watchdog groups like his own to play a role and also protecting competitors and the program’s integrity.³¹⁴

3. Fear That Inconsistency Will Open the Floodgates

If an agency accedes to one firm’s request for a departure from guidance, many firms may object that this amounts to ad hocery and unfairness, as discussed in Section II.A.1 above. But some firms (perhaps some of the same ones!) may view the grant as an opening to seek similar special dispensations for their own benefit. It is easy to laugh about the industry opportunism evident here. A food and drug attorney, when asked whether he wanted the FDA to be more flexible on guidance, wryly replied, “Depends on my client and what they

Agency. 311. Interview with Source 103, former senior official, Air Program Office, Envntl. Prot.
 312. Interview with Source 128, employee, environmental NGO.
 313. Interview with Source 54, *supra* note 188.
 314. Interview with Andrew DeLaski, *supra* note 168.

want.”³¹⁵ But again, a demand for the same favorable treatment that your competitor received springs from a legitimate concern about fairness. That legitimate concern makes it hard for agencies to ignore such follow-on requests. Yet addressing them is both costly and dangerous to the agency—costly because the entreaties take up officials’ scarce time and multiply the possibilities for accusations of the kind described in Sections II.A.1 and II.A.2 above, and dangerous because, if the agency fails to draw the line and acquiesces in the rising tide of exception requests, it risks ending up with guidance that no longer has any meaning or usefulness. It is no surprise that some agencies act inflexibly from the outset, to avoid opening the floodgates to more entreaties.³¹⁶

This issue loomed large in interviews about HHS. According to a former CMS division director, the making of an exception for one healthcare provider will prompt follow-up requests from others, for “there are no secrets”: word that the agency made an exception will get out somehow. Because exceptions produce follow-on requests, initial requests are resisted by CMS career officials. They often fall on “deaf ears.” The officials believe that “saying ‘no’ to everybody is fair,” and they find guidance easier to administer if they are consistent—they will not have to spend time going to meetings to hear “hard luck stories.” In contrast to the career people, CMS political appointees are less worried about administrative problems that will arise from inviting other providers to ask for exceptions, so they are somewhat more likely to grant exceptions, although the fact that political appointees rely upon briefing from the career staff means even they usually go along with the staff’s wish to follow guidance.³¹⁷ Similarly, a former HHS Office of General Counsel official said that one reason for the difficulty of getting departures from guidance at CMS was that, although a healthcare provider’s attorney would strive to define the client’s departure request as being unique, there really were no unique situations; there would always be some other provider who would want the same dispensation. Hence officials faced with such requests felt concern about having to make a call that could potentially pertain to a large number of providers, which raised a fear of having to generalize.³¹⁸ A former senior HHS official said that, when officials at the Department are asked to make a departure from guidance, they want to be fair, and they ask themselves, “do we really want to give an answer to this one firm, without putting all firms on notice?” They could address this concern by undertaking a general clarification of the guidance. But that takes resources, which may be too much to spend if they are not getting this same question repeatedly. The result may be that the agency does nothing in response to the request.³¹⁹

315. Interview with Source 92, *supra* note 61.

316. *See supra* note 292.

317. Interview with Source 93, *supra* note 88.

318. Interview with Source 67, former official, Office of Gen. Counsel, U.S. Dep’t of Health & Human Servs.

319. Interview with Source 77, *supra* note 133.

We see similar reactions at other agencies. Frank White, the former deputy head of OSHA and former president of a major HSE consultancy, characterized OSHA as generally skeptical of requests for departures from guidance, in part because, if the agency grants one, other employers will ask, “why can’t we do that, too?” The dispensation may end up governing the whole industry.³²⁰ At the FDA, observed the chief regulatory officer of a Fortune 500 medical device maker, reviewers and their bosses are “thoughtful” but “cautious” about making exceptions to guidance, as they are mindful of precedent and want to avoid a “slippery slope.”³²¹ At the EPA, a former senior official in the Air Program Office, when discussing flexibility in guidance, recalled being in charge of several innovation task forces in which he tried to help regulated firms obtain agency assurance that alternative means they proposed for compliance with regulations (using new technology) would be acceptable to the agency. The EPA’s Office of General Counsel was concerned that, if the agency allowed one firm to use an alternative approach, it would become harder to say “no” to other firms seeking other departures. The Office of General Counsel, he said, tried to “rein me in.”³²²

B. Principled Flexibility: A Good Solution, in Principle

In principle, the problems described in the preceding Section can be largely overcome if the agency engages in *principled flexibility*. By this, I mean that agency officials make departures from guidance, but for each departure, they give a written explanation that is accessible to other agency officials and to regulated parties, with the understanding that the exception thereby becomes generally applicable to like facts going forward. The departure explanations form a body of rationally evolving precedent that informs future decisions about departure requests.³²³ (Obviously this description is an ideal type: an agency could approach this ideal to varying degrees depending on the proportion of departures that get explanations, the depth and quality of those explanations, the care with which they are consulted in the future, etc.).

If principled flexibility can actually be implemented (and there are major challenges to doing so, discussed in Sections II.C and II.D below), it serves as a good response to the legitimate pressures for consistency that an agency faces. As to the fear that departures will reduce agency predictability and make regulated parties less cooperative, the obligation to give public reasons will restrain officials from making many departures, thus preserving a good deal of stability. Moreover, while some departures would still be made, the growing body of precedent would reduce uncertainty about what they would be. As to the

320. Interview with Frank White, *supra* note 188.

321. Interview with Richard Naples, *supra* note 124.

322. Interview with Source 103, *supra* note 311.

323. My formulation of principled flexibility is inspired by the works of Robert Kagan and Peter Strauss, as noted *supra* note 54.

concern that departures would unlevel the playing field among competitors, the incentive that reason-giving creates for moderate stability would, again, be helpful. And the general applicability of all exceptions to like facts on a prospective basis would reduce unfairness. As for accusations of favoritism and impropriety, the publication of explanations renders accusations of back-room deals less plausible, and the general applicability of the exception makes favoritism less feasible. Further, as DeLaski noted, public reasons and generality help preserve a regulatory program's "standing and integrity" and make it easier for a wider range of stakeholders to weigh in, reducing their suspicion and alienation.³²⁴ Finally, as to the risk of inviting follow-on requests, the public explanations provide a means for the agency to cabin the exception, e.g., by emphasizing unusual aspects of the requesting party's situation. As a former EPA program office director said, you "explain an exception" in order to avoid "opening the floodgates."³²⁵ A former EPA official likewise said the agency would gather specific information on a requesting party's situation to "avoid opening the floodgates" to others asking for the same treatment.³²⁶

The factors that counsel an agency to engage in principled flexibility are not just the political and organizational pressures documented in Section II.A, but also, to at least some degree, legal pressures. If the guidance pertains to agency adjudicatory proceedings, then, if any adjudicatory orders have actually been issued in accordance with the guidance, a subsequent departure from the guidance would require a reasoned explanation, because any departure from adjudicatory precedent is subject to the APA's prohibition against decisionmaking that is "arbitrary" or "capricious."³²⁷ David Hawkins, former head of the EPA's Air Program office, said the agency's latitude diminished as more adjudicatory decisions were made under a guidance document, and if there were then a departure from the guidance (and from the prior adjudications), stakeholders would say, "We'll sue you if you have no justification for this." Such litigation risk, said Hawkins, was one of the main reasons the EPA adhered to guidance.³²⁸ This raises the question of whether the agency would face the risk of a lawsuit if it departed from a guidance document prior to there being any adjudicatory orders under it.³²⁹ Leading commentators have argued that a

324. See *supra* text at note 314.

325. Interview with Source 98, former program office director, U.S. Env'tl. Prot. Agency.

326. Interview with Source 54, *supra* note 188.

327. 5 U.S.C. § 706(2)(A) (2018). On the agency's obligation to explain departures from its own adjudicatory precedents, see *Atchison, Topeka, & Santa Fe Railway Co. v. Wichita Board of Trade*, 412 U.S. 800, 806-09 (1973) (Marshall, J., plurality opinion).

328. Interview with David Hawkins, *supra* note 310. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization. See also Interview with Source 93, *supra* note 88 (noting the litigation risk of an arbitrary-or-capricious challenge if an agency made an exception to guidance).

329. The absence of any adjudications is hardly unheard of: in some of the contexts described in Part I where the incentives to follow guidance are strong, it may be that all regulated firms follow the guidance and thus never force an adjudication.

guidance document *should* have the same status as an adjudicatory order for purposes of the agency’s obligation to explain subsequent departures, but they do not cite direct authority for this actually being the law.³³⁰ D.C. Circuit case law on the question is not entirely clear.³³¹

But even if the doctrine does require a reasoned explanation for departing from a guidance document, we should not exaggerate the effect of legal pressures in getting agencies to adopt principled flexibility. The prohibition against unexplained departures from guidance (which exists at least when there have been prior adjudications tracking the guidance) is likely to be underenforced. Departures from guidance requested by regulated parties will favor those parties, and if the agency grants one without explanation, the plaintiff would have to be a disadvantaged competitor or a regulatory beneficiary, who will not always come forward. And even if a departure from guidance disfavors the regulated party that is the subject of the adjudication, that party may have various incentives to refrain from suing, which may track the incentives not to rock the boat described in Part I.³³² Further, a great deal of guidance pertains not to adjudicatory decisions but to enforcement decisions—a species of agency action that is presumptively committed to the agency’s discretion and not subject to judicial review at all.³³³

Therefore, insofar as agencies adopt principled flexibility, it will, to a great degree, be organizational and political factors that drive them to it, not just legal ones. But even if the threat of an actual lawsuit is not looming, the inclination of some agencies (or at least their lawyers) to adopt principled flexibility is probably shaped by the general importance of reason-giving in the legal culture of the federal administrative state. An attorney at the EPA Office of General Counsel said that, although guidance is not binding on the agency, deviating requires a “rationale.”³³⁴ A former agency general counsel declared that, in general, “if you make an exception,” you “need a principled reason” for why the present case is different. “You can’t depart without justification of the deviation,” and the justification you give ought to alter the guidance “for everybody.”³³⁵

Consistent with these kinds of views, several agencies prefer to frame flexibility on guidance as *reinterpretation* of the guidance document, rather than

330. For arguments that guidance should have this status, see Manning, *supra* note 18, at 933-37; and Strauss, *Rulemaking Continuum*, *supra* note 2, at 1472-73, 1485-86. For an argument coming nearer to the idea that guidance *does* have this status, see Thomas W. Merrill, *The Accardi Principle*, 74 GEO. WASH. L. REV. 569, 598 (2006).

331. See *Friends of Blackwater v. Salazar*, 691 F.3d 428, 435 (D.C. Cir. 2012) (“Whether an agency must account for a departure from a prior non-binding statement of intent is not entirely clear.”); PARRILLO REPORT, *supra* note †, at 105 n.352.

332. See also Section II.D.1 *infra* (discussing additional concerns about retaliation).

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

334. Interview with Source 61, official, Office of Gen. Counsel, U.S. Envtl. Prot. Agency.

335. Interview with Source 69, former agency gen. counsel.

as an outright *departure* from it.³³⁶ Interpretation by its nature cabins the exception-making process and forces it into a reasoning idiom, e.g., by encouraging the official to look to the guidance’s purpose. According to a former CMS division director, if you can, you should couch your request for an exception as an interpretation of the guidance, because if you argue that the guidance is “flat out wrong” and “bad policy,” your “odds” of winning an exception “go way down.”³³⁷ A former HHS Office of General Counsel official went farther, observing that no CMS employee would simply say, “you need not follow the guidance because it’s not binding”; instead, officials would proceed either by giving an interpretation of the guidance or by actually amending it.³³⁸ Richard Stoll, of Foley and Lardner, said that at the EPA, a regulated party’s “best” strategy was to “distinguish” a guidance document rather than actually challenge it.³³⁹ A former senior FDA official warned that you were not living in the “real world” if you said to the FDA, “this guidance is wrong, we’ll do it differently, do you agree?” Instead, you should seek flexibility through interpretation.³⁴⁰ Jonathan Snare, the former deputy solicitor of the DOL, said that while OSHA sometimes will accept proposals for outright departures from guidance, flexibility is usually couched as an interpretation or application of the guidance in light of some unanticipated circumstance.³⁴¹

C. Organizational and Resource-Based Obstacles to Principled Flexibility

Despite its promise as a means to reconcile the agency’s legal obligation to be flexible with legitimate pressures on the agency to be consistent, principled flexibility is an expensive, logistically challenging process to carry out and manage. Here we consider those expenses and challenges—and how the inability to address them may cause the agency to fall back on inflexibility. I should emphasize, the problems described in this Section—which involve agencies sometimes being inflexible because they lack the resources and internal structures to engage in much deliberation on proposed departures from guidance—underscore that these agencies take the view that any flexibility must be principled. That view is laudable. The trouble is that the deliberation and explanation required by principled flexibility can be hard to undertake, so agencies may default to inflexibility.

336. Cf. KAGAN, *supra* note 54, at 105 (noting that flexibility in the Nixon wage-price freeze was conceived of as interpretation).

337. Interview with Source 93, *supra* note 88.

338. Interview with Source 67, *supra* note 318.

339. Interview with Richard Stoll, *supra* note 188.

340. Interview with Source 110, *supra* note 62.

341. Interview with Jonathan Snare, *supra* note 238.

1. Cost of Evaluating Departures in the First Instance

An agency, in deciding how to formulate a guidance document in the first place, must figure out specific courses of conduct that would (at least probably) fulfill the general requirements of a statute or legislative rule. Figuring this out requires time and money. The agency may need to find and synthesize studies and data, or produce its own studies and data, on questions like the means of reducing power plant emissions, the kind of equipment that makes a car more crash-worthy, the likelihood that incentive payments to bank employees will push them to commit fraud, etc. Costly research may likewise be necessary whenever the agency decides whether a course of conduct *different from* the guidance would still fulfill the statute or legislative rule.

Often these costs are borne to a large degree by the regulated party who seeks the departure from the guidance. In other words, the agency will entertain a request for departure so long as the regulated party makes its case. The very cost of making the case has the effect of inducing many regulated parties to follow the guidance by default. For example, an advisory circular issued by the FAA purports to set forth *one way* of complying with a legislative rule, said an official at the airlines' trade association, but the circular "instantly" becomes the "most attractive" means of compliance because, in order to do something different, the regulated entity would have to make a showing that its alternative path is compliant, effectively "redoing" all the research and testing the FAA had done but for a different course of action. Thus, while a circular is officially just "*a*" means of compliance, it often becomes "*the*" means of compliance.³⁴² As FAA officials said, following guidance is "the easy way."³⁴³ Similarly, a former EPA program office director said that one does what the agency suggests "if it seems halfway reasonable," since merely coming up with an alternative is costly.³⁴⁴ The imperative under principled flexibility to make departure decisions applicable to similar situations going forward may render any individual firm reluctant to invest in justifying a departure, as its competitors may then free-ride off its effort.

Interviewees differed on whether this practical incentive for regulated parties not to seek departures amounted, in itself, to an unacceptable kind of inflexibility. A trade association official said that following guidance was a "fast track" to obtaining the agency's approval, which he considered a "legal grey zone" in terms of whether regulated entities were effectively coerced.³⁴⁵ Former

342. Interview with Source 66, official, Airlines for Am.

343. Interview with Sources 8, 9, and 10, *supra* note 20; *see also* Interview with Kathryn Thomson, Partner, Morrison & Foerster, and former general counsel, U.S. Dep't of Transp., and former chief counsel, Fed. Aviation Admin. (stating that the FAA makes departures from guidance, but they can be really time-consuming).

344. Interview with Source 71, former program office dir., U.S. Envtl. Prot. Agency; *see also* Interview with Source 79, former senior official, U.S. Envtl. Prot. Agency (noting that the cost of showing an alternative to be compliant creates an incentive to follow guidance).

345. Interview with Source 2, official, trade association.

senior Department of Transportation (DOT) official Neil Eisner, however, noted that agencies inevitably lacked the resources to identify *all* acceptable means of compliance, but that was no reason they should not help regulated parties by identifying *some* acceptable means, even if this inevitably created some practical incentive to follow the course the agency identified.³⁴⁶ That said, it is surely an important exercise of power when the agency opts to enshrine one means of compliance in a guidance document rather than another means, since the various means on the menu may have different costs and benefits for different stakeholders. As a former senior EPA official noted, the alternatives from which the agency chooses in formulating guidance may consist of (say) pollution-control technologies that are sold by different companies: for the company whose method is selected, the guidance serves as a kind of “advertisement.”³⁴⁷

But even if we accept that a regulated party should bear the burden of making the case for departure, a good deal of expense will still fall on the agency itself. This is because agencies cannot and do not take at face value a regulated party’s case for departure. According to a former EPA program office director, there will be some distrust between the agency and a regulated party seeking to diverge from guidance. The party is asking for a “break,” and officials will fear they are not getting the whole story of what the consequences would be. The officials will feel they have to do some investigation of their own.³⁴⁸ Similarly, Frank White, the former deputy head of OSHA and HSE consultancy president, noted that when a company asks OSHA for an assurance that some departure from guidance is acceptable, the officials are concerned about the risk that, in the narrow setting of a meeting with company representatives, they cannot be sure if the relevant factual questions about safety have been answered correctly. They fear missing something and being blamed if an accident occurs.³⁴⁹ Hence, officials feel they must either do more investigation independently, or simply reject the request.

The costs to the agency of investigating and weighing requests for departures can be significant, and they compete with other resource demands on the agency. Reopening an issue, observed a trade association official, involves a serious commitment of time and personnel in the face of other priorities, so there is institutional reluctance to go back over existing guidance.³⁵⁰ An EPA Office of Water official said it was a “work prioritization issue” whether his outfit could respond to stakeholders asking for revisions to guidance.³⁵¹ Lynn Bergeson, the

346. Interview with Neil Eisner, consultant, and former Assistant Gen. Counsel for Regulation and Enf’t, U.S. Dep’t of Transp.; see also Strauss, *Rulemaking Continuum*, *supra* note 2, at 1481 (arguing that it is more appropriate to frame guidance as saving money for regulated parties who follow it than as imposing a cost on those who seek alternatives, given that the agency is under no obligation to provide any guidance in the first place).

347. Interview with Source 79, *supra* note 344.

348. Interview with Source 71, *supra* note 344.

349. Interview with Frank White, *supra* note 188.

350. Interview with Source 2, *supra* note 345.

351. Interview with Source 42, official, Office of Water, U.S. Env’tl. Prot. Agency.

managing partner of Bergeson & Campbell, which specializes in chemical regulation, said resources were a “huge issue” in determining whether officials in the EPA’s FIFRA and TSCA offices would be flexible on guidance.³⁵² Indeed, deciding departures from guidance can take up so many resources that some regulated parties may strategically exploit this fact to interfere with the agency’s operations. David Hawkins, the former head of the EPA’s Air Program office, recalled that during his tenure, one of the automakers filed several requests for clarification per month, to keep the office staff busy with the company’s agenda and keep them “off task.”³⁵³

The ratio of agency resources to the volume of work is key in determining how much the agency can really deliberate on individualized requests for departures. Resources determine how much time the agency can spend on a request, and, as Robert Kagan writes, “the crush of time forces the decision maker into a stereotyped search for solutions to the problem” and into “selective perception of the situation,” not appreciating all the subtleties and equities.³⁵⁴ If decisions to which the guidance pertains are high in volume, said a former EPA program office director, “you just cannot treat every case as unique,” for then it would be “impossible to do the work.”³⁵⁵ At the FDA, a former senior official in the Office of Chief Counsel said that the ratio of agency employees and resources to the volume of applications was a factor in making the Office of New Drugs (OND) relatively more flexible on guidance than the Office of Generic Drugs (OGD). The OGD had to approve an order of magnitude more applications than the OND each year. Although a given drugmaker would often deal repeatedly with the same few officials at OGD in application after application (thus creating a relationship), there was comparatively little time for interaction and deliberation *on any single application*. By contrast, at the OND, there could be far more time spent in back-and-forth on a particular application. Time for interaction on a particular application was key to getting more flexibility on that application. The interviewee added that the difference in levels of flexibility between the OND and the OGD was also caused by a difference in the nature of the two offices’ work: the OND dealt with brand new clinical data, whereas the OGD’s decisionmaking is more “mechanical” by nature. Despite this, he said, the OGD’s work still involved matters of judgment that would benefit from greater flexibility if only the OGD were resourced and managed to provide it. He believed that the OGD had gone too far in the direction of a “checklist” approach.³⁵⁶

352. Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell, P.C.

353. Interview with David Hawkins, *supra* note 310. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

354. KAGAN, *supra* note 54, at 132. On the tradeoff between speed and fact-finding procedure, see *id.* at 107, 129.

355. Interview with Source 71, *supra* note 344.

356. Interview with Source 83, *supra* note 119. It should be noted that another interviewee said that the OGD tended to be flexible (without drawing a direct comparison to the OND),

The inflexibility that tends to come with high volume and a consequent “checklist” approach helps explain why the Obama administration was forced to undertake a very official and public effort to alter the guidance on the Clean Water Act’s coverage (an effort that attracted intense political resistance and eventually forced the administration to rely exclusively on legislative rulemaking to try to make the changes it sought).³⁵⁷ Whether a piece of property is covered by the Clean Water Act is decided by the Army Corps of Engineers through a jurisdictional determination (JD).³⁵⁸ The Corps must issue JDs on the order of forty-five thousand per year.³⁵⁹ To implement guidance on such a high volume of determinations, explained an official at an environmental NGO, it is necessary to reduce the guidance to a checklist to render it usable by the Corps’ large number of field personnel. The Corps did this for the guidance that was handed down during the Bush administration; Corps staff would complete a form also available to the property owner applying for the JD. When the Obama administration came to power, it wanted to change the Corps’ approach to JDs.³⁶⁰ In a different context, the administration might have been able to do so through informal flexibility without officially altering the guidance document; in some contexts, agency leadership’s issuance of a mere *draft* guidance document can alter the behavior of front-line officials and regulated parties, who get the signal that the draft reflects the current leadership’s real wishes.³⁶¹ But when the Obama administration issued its draft guidance on the Clean Water Act, the behavior of frontline Corps personnel did not change, according to the environmental NGO official. The checklist form, still reflecting the Bush-era guidance, made their behavior sticky. Had deviations occurred, the checklist format would have made them plain, and any of the numerous property owners with stakes in the matter might have blown the whistle.³⁶² Thus, once again, volume tends to keep agency personnel in compliance with officially existing guidance.

2. Cost of Obtaining High-Level Approval for Departures

Another key factor limiting agencies’ practical capacity to evaluate potential departures from guidance is that high-level officials usually must be

but he added that he was not speaking from “very deep knowledge” about the OGD, as most of his company’s dealings were with OND. Interview with Source 108, *supra* note 20. Another interviewee said his impression was that the OGD was more flexible than the OND, but he added that his impression might be “colored” by the fact that he dealt mostly with the OGD and not the OND. Interview with Source 92, *supra* note 61. On the importance of face-to-face interaction between officials and regulated parties in diminishing legalistic stringency, see KAGAN, *supra* note 54, at 138, 151-52.

357. See COPELAND, *supra* note 284, at 1.

358. See U.S. Army Corps of Eng’rs v. Hawkes Co., 136 S. Ct. 1807, 1812 (2016).

359. Calculation based on Clean Water Rule: Definition of “Waters of the United States,” 80 Fed. Reg. 37054, 37065 (June 29, 2015).

360. Interview with Source 97, *supra* note 285.

361. See PARRILLO REPORT, *supra* note †, at 171-79 (discussing draft guidance at the FDA).

362. Interview with Source 97, *supra* note 285.

involved in the process. The OMB’s Good Guidance Practices say that “[a]gency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.”³⁶³ The FDA definitely requires this,³⁶⁴ and officials confirm the requirement is followed on the understanding that the employee must go up one level to his or her boss.³⁶⁵ As for the EPA, a partner in a large law firm and former senior EPA official said that an exception to guidance would need signoff from a senior person, usually a political appointee, or a career official who would check with the relevant political appointee for self-protection.³⁶⁶ A former EPA official said that frontline staff would not do a “stretch” argument on their own and would check with their superiors.³⁶⁷ And of course, if a regulated firm seeks a departure from frontline personnel and gets nowhere, its only hope is to elevate the matter to higher-level officials and entreat them to override the frontline staff.

High-level officials, when asked to sign off on a departure and especially when asked to overturn a lower-level decision denying a departure, typically do not have the time to deliberate very deeply on the request. Appealing upward through the FDA’s internal hierarchy, warned the former senior Office of Chief Counsel official, was difficult because higher-level officials had “even less time” than the low-level ones who just denied the request.³⁶⁸ When a firm seeks a departure from guidance from frontline officials, said a regulatory policy executive at a drug manufacturer, the firm will usually get no response (because even the frontline people don’t have enough time). Then, if one appeals up the chain, one deals with people who are “very busy” and one is basically “begging” them for a departure; one needs to be “reasonable” and “polite.”³⁶⁹ A former HHS Office of General Counsel official said seeking departures from CMS was very challenging in part because an official high enough to have the requisite authority would have “limited time.”³⁷⁰ Bergeson, managing partner of Bergeson & Campbell, said regarding flexibility in guidance that senior officials at the EPA might not be aware of problems three levels below them; they were “busy.”³⁷¹

At the EPA, explained the large-firm partner and former senior EPA official cited earlier, who went into depth on the process, a company could try to elevate a particular issue to a higher level of the agency by seeking a meeting with a political appointee, which would usually be an audience for up to one hour to

363. OMB Good Guidance Practices § II(1)(b), 72 Fed. Reg. 3440 (Jan. 25, 2007), *see also* Strauss, *Rulemaking Continuum*, *supra* note 2, at 803-05 (urging that guidance be binding on low-level officials, with higher-level officials given authority to make departures if reasoned).

364. 21 C.F.R. § 10.115(d)(3) (2018).

365. Interview with Source 25, *supra* note 298.

366. Interview with Source 52, *supra* note 76.

367. Interview with Source 54, *supra* note 188.

368. Interview with Source 83, *supra* note 119.

369. Interview with Source 109, regulatory policy executive, drug manufacturer.

370. Interview with Source 67, *supra* note 318.

371. Interview with Lynn Bergeson, *supra* note 352.

“make your pitch,” but the kinds of issues that deserve such elevation, given how busy political appointees are, are only those that involve “programmatic risk,” i.e., decisions whose outcome could alter large numbers of other decisions or otherwise disrupt the agency’s operations. An individual interpretation of a guidance document would not meet this threshold, so a meeting would “very seldom” be possible. Instead the company would ask the frontline official to talk to the high-level official, but in that case, one can never be sure how the staff will represent your position to the boss.³⁷²

Two additional interviewees on the EPA emphasized not just high-level officials’ limited time, but also their limited information. A former EPA program office director explained that, although higher-level officials were more mindful than frontline officials of a policy’s broad consequences for industry, they knew less about technical matters and were likely to defer to lower-level officials on those. In an example that takes this point to an extreme, the interviewee mentioned that he had seen people get denied by a frontline official and then go directly to the White House, which is “the stupidest thing” for actually getting the outcome you want, since at the White House you’re “almost guaranteed to get someone who has no idea what you’re talking about.” Nonetheless, he observed, going to the White House was “surprisingly common.” In his own experience running a program office, he said it was impossible to overturn the decisions of one’s staff routinely. Rather, one should overturn the staff only on a decision that had “programmatic impact,” that is, would “damage” or “disrupt” the program itself. If he merely thought a decision was wrong, in the sense of being different from the one he would’ve reached, that was not enough.³⁷³ Another interviewee, also a former EPA program office director, said that in reviewing the individualized forms of written guidance that his staff provided (which I assume would have included any materials that reinterpreted or altered preexisting guidance), he found he had “no independent ability” to know if the staff had gotten the right answer; he just deferred to the staff and signed off. To try to control the staff’s decisionmaking on such matters would have taken up too much of his time and that of other senior managers, given other things they had to do, especially legislative rulemaking.³⁷⁴

Because resource-constrained agencies find it difficult to allocate the amount of employee time and energy to individualized requests for departures that would allow for principled flexibility in dealing with them, the best bet for a regulated party is often to find *other* regulated parties who want the same kind of departure and band together with them. Such collective action can convince the agency that the matter is worth substantial staff time and resources, which a

372. Interview with Source 52, *supra* note 76; *see also* Interview with Richard Stoll, *supra* note 188 (stating that while a regulated party entreating the EPA on any matter may attempt to elevate the matter above the lowest level in the office hierarchy, such elevation is rarely successful, and that elevation would be even rarer regarding a departure from guidance).

373. Interview with Source 71, *supra* note 344.

374. Interview with Source 98, *supra* note 325.

one-off departure request is not. According to a former CFPB official, an individual financial institution seeking a departure from guidance “won’t get anywhere” with the CFPB; the institution must go through the trade association and may need to pressure the CFPB for years.³⁷⁵ Bergeson said that if a client were having difficulty obtaining a departure from guidance, she would advise the client to “band together” with others (e.g., by going to the trade association) because proceeding “one-off” is “ineffectual”—the EPA could not spend too much time and money on a request for just one firm.³⁷⁶ The large-firm partner and former senior EPA official cited earlier likewise stated that, although an individual departure from guidance would not warrant elevation to a political appointee at the EPA, it might if a trade association leaned on the agency.³⁷⁷ Note also that, as between industry players, proceeding collectively may address the free-rider problem by which any individual firm is discouraged from investing in arguing for a departure decision that its competitors might then exploit for themselves.

3. Cost of Recording and Disseminating Departure Decisions

On top of the logistical challenge of deliberating on requests for departures from guidance, principled flexibility also requires the agency to ensure that reasoned decisions on those departures are recorded and disseminated. First off, this means deciding what constitutes a “departure decision” for purposes of principled flexibility. There is so much communication between agency officials and regulated parties regarding guidance, much of it oral, that some of it will have to be considered *de minimis*. Defining what is *de minimis* is a bit of a challenge in itself. For example, Andrew DeLaski, the executive director of the Appliance Standards Awareness Project, said he hoped the Department of Energy was being public and transparent about all departures from guidance.³⁷⁸ But attorney Charles Samuels, counsel to the home appliance manufacturers’ trade association, noted that, while the Department of Energy *is* more formal than other agencies in its communications regarding guidance, there are still oral conversations between the agency and industry in the nature of “can you explain this to me?,” which are couched as involving interpretations of the guidance, not waivers of it.³⁷⁹

Assuming that a more-than-*de-minimis* universe of departures can be defined, there is the task of documenting those departures and recording explanations for them, however cursory (e.g., they might briefly reference other exceptions made earlier and justified at greater length). Agencies seem to vary as to whether they document departures. An FDA Office of Policy official noted

375. Interview with Source 81, *supra* note 96.

376. Interview with Lynn Bergeson, *supra* note 352.

377. Interview with Source 52, *supra* note 76.

378. Interview with Andrew DeLaski, *supra* note 168.

379. Interview with Charles Samuels, *supra* note 157.

that when a frontline official departing from guidance goes to check with his or her supervisor (as required), this also entails documenting the departure.³⁸⁰ But it is not clear how much these decisions are disseminated. According to a former senior FDA official, if a firm succeeds in obtaining a departure from guidance in one meeting on one matter with some FDA officials, that does not necessarily benefit other stakeholders who were not at the meeting, and might not help the firm in dealing with other FDA personnel in the future.³⁸¹ Richard Naples, the chief regulatory officer at Becton Dickinson, said a company could have a departure from guidance memorialized so that it could be invoked in future proceedings; otherwise, it could not be if the staff changed.³⁸² Regarding OSHA, Celeste Monforton, the academic and safety advocate and former OSHA legislative analyst, said the degree to which OSHA personnel are departing from guidance (e.g., how frequently inspectors are being flexible in setting up abatement plans with employers, which would most likely happen if there were complex equipment) is unknown because there is no database of such departures.³⁸³

The dissemination of information about departures beyond the firm has to be structured to protect confidential business information. This is especially important because departures from guidance are often premised on regulated firms using new technologies, which may be proprietary. Some agencies have established mechanisms for doing this. For example, the FAA negotiates departures from guidance premised on new technology through an “issue paper process” that protects proprietary information. Once the use of the new technology reaches a certain level of maturity, the agency publishes a “policy statement” that provides a template for how to use the new technology, for the benefit of the whole industry, without revealing proprietary information.³⁸⁴

D. Organizational and Resource-Based Obstacles to Any Kind of Flexibility

Besides the logistical challenges to setting up a regime of principled flexibility, discussed above, there are several additional factors that help determine the degree to which an agency using guidance shows any kind of flexibility, whether or not that flexibility is coupled with principled explanations forming a body of precedent. An agency striving for flexibility will have to manage each of these factors in some fashion.

380. Interview with Source 25, *supra* note 298.

381. Interview with Source 80, *supra* note 4.

382. Interview with Richard Naples, *supra* note 124.

383. Interview with Celeste Monforton, *supra* note 240.

384. Interview with Sources 8, 9, 10, *supra* note 20.

1. Fear that Challenges May Damage Relationships with Officials

If a frontline official has the authority to consider a regulated party's request for a departure from guidance but rejects it, the regulated party can appeal to a higher-level official to get the rejection overturned. Further, if a frontline official adheres to guidance with improper rigidity, some agencies (such as the FDA) provide that a regulated party can complain to higher-level officials.³⁸⁵ However, interviewees said that regulated parties at the FDA and sometimes elsewhere were reluctant to go up the chain of command for fear of antagonizing the officials whose decisions they sought to override, particularly when they knew they would have to deal repeatedly with those same officials. This issue is similar to the point discussed in Section I.B above about how regulated parties' investment in relationships with individual officials may incentivize them to follow guidance, except that here we are talking about incentives to refrain from appealing the denial of a departure, not about incentives to follow guidance in the first instance.

Concerns about antagonizing officials were most prominent in interviews about the FDA. Bradley Merrill Thompson, counsel to associations of device-makers and author of the petition that helped prompt reform of FDA guidance practices in the 1990s, said that in his experience FDA reviewers showed very little flexibility on guidance. Moreover, he found that companies were extremely reluctant to go over the reviewers' heads, since this was unlikely to produce a positive result and would irritate the reviewer, possibly affecting the decision on the application at issue and future ones. For many kinds of products, there were only a handful of reviewers assigned, so it was not unusual to repeatedly have the same reviewer.³⁸⁶ A former senior FDA Office of Chief Counsel official concurred that, in the device area, companies "don't want to rock the boat."³⁸⁷ William Schultz, former FDA Deputy Commissioner for Policy, said companies were "very shy" about complaining about the review functions of the FDA, because individual reviewers had so much power. Companies knew they might see the same reviewer again on another matter and did not want to mess up their relationship with him or her.³⁸⁸ On the drugs side, Daniel Troy, the general counsel of GlaxoSmithKline, gave the example that his company was deep into respiratory treatments; the FDA had only one respiratory office, and "we can't make them mad," though the company could have a constructive scientific dialogue with them.³⁸⁹ According to an executive at a drug manufacturer, appealing up the chain after receiving a negative response or no response

385. *E.g.*, 21 C.F.R. § 10.115(o) (2018) (noting the FDA procedure).

386. Interview with Bradley Merrill Thompson, *supra* note 20.

387. Interview with Source 83, *supra* note 119.

388. Interview with William Schultz, Partner, Zuckerman Spaeder LLP, and former Deputy Comm'r for Policy (1994-98), U.S. Food & Drug Admin., and former Gen. Counsel (2011-2016), U.S. Dep't of Health & Human Servs.

389. Interview with Daniel Troy, *supra* note 64.

regarding departure from guidance involved the risk of antagonizing the frontline official, adding that one had to be “upfront” with the official about the escalation.³⁹⁰

Some interviewees observed that, while retaliation was widely feared, it was not as common or took a different form than was widely understood. As to devices, Richard Naples, the chief regulatory officer at device maker Becton Dickinson, said escalation had to be carried out in a manner to preserve the company’s relationship with the reviewer, given that the firm would need approval of many products over the long run. Preserving the relationship meant being careful to treat the reviewer with respect and working openly with the reviewer on every step of the escalation, including arranging a joint meeting with the reviewer and the reviewer’s boss. “Retaliation,” said Naples, is “widely” perceived as a “large risk” at the FDA, but he considered the fear “overblown.” Retaliation “doesn’t actually happen a whole lot,” and when it does, it is usually through “unconscious bias.”³⁹¹ Troy, of GlaxoSmithKline, said there was a perception that the FDA would retaliate. He noted that “there is some of that”—a “few” people do retaliate—but the perception was “stronger than the reality.” The issue, he explained, is not “deliberate” retaliation but “unconscious” retaliation—that the official you seek to override “may not cut you a break” in the future. The fear of *unconscious* retaliation, said Troy, was not exaggerated.³⁹²

The fear of retaliation extends from premarket review to enforcement and inspections, where there is also repeat play. An official at the FDA’s Office of Regulatory Affairs, which oversees the inspectors, said that regulated firms did fear “retribution” from the inspectors and were therefore reluctant to complain up the chain of command. The idea of complaining “scared” firms because they knew they would see the inspector again.³⁹³ Troy, general counsel of GlaxoSmithKline, said that regulated companies have to be really careful with appeals within the FDA, because all the companies are “repeat players” who want to avoid antagonizing not only the reviewers but also the inspectors, as whoever inspects your facility this year might also do so in the future.³⁹⁴ A former senior FDA official said regulated firms dealing with reviewers or inspectors feared that if they said something negative about an official, including on rigid adherence to guidance, it would harm their relationship with him or her if they needed to deal with the official again down the road. He recalled that, during his tenure at the FDA, he would urge public audiences of stakeholders to tell him if they thought they were not being treated fairly. Nevertheless, he found that people were “afraid” to report because of the idea of “negative repercussions”: only a couple of complaints would come in per year. This was

390. Interview with Source 108, *supra* note 20.

391. Interview with Richard Naples, *supra* note 124.

392. Interview with Daniel Troy, *supra* note 64.

393. Interview with Source 28, *supra* note 305.

394. Interview with Daniel Troy, *supra* note 64.

frustrating, he said, because if the FDA had received more complaints, it would have enabled the agency to train its employees better.³⁹⁵

Some interviewees pointed out ways in which the FDA was addressing, or might address, the fear of retaliation. The drug manufacturer executive cited the FDA's formalization of a "Dispute Resolution Process" in recent years, saying the formality had made escalation "more accessible" and reduced companies' fear.³⁹⁶ An official at the FDA's Office of Regulatory Affairs noted that the office now had an ombuds to help with the matter.³⁹⁷ (There are also ombuds at other components of the FDA.) William Schultz, former FDA Deputy Commissioner for Policy, suggested that perhaps the FDA could periodically solicit companies for anonymous feedback to see whether they thought reviewers were treating guidance flexibly.³⁹⁸

Beyond the FDA, interviews indicated some concern among regulated parties about relationships and repeat play, if not outright retaliation. A former EPA program office director said that a company deciding whether to appeal an official's denial of a proposed departure would "absolutely" consider damage to their relationship with the official as part of the calculus, though some officials are more likely than others to take it personally.³⁹⁹ Lynn Bergeson, managing partner of Bergeson & Campbell, said that appealing within the EPA on behalf of a client expends some of the law firm's "political capital."⁴⁰⁰ A former senior HHS official said that for a firm wanting a departure from guidance, a "key" consideration was whether the matter was worth "making a fuss about": the firm knew it would deal repeatedly with the agency and had to "pick [its] battles" and would think about its "long-term relationship" to the agency. Companies were concerned that raising a fuss frequently would be viewed as "negative."⁴⁰¹ In banking regulation, a former CFPB official said that if a bank sought a departure from guidance in the course of an examination, it would go first to the examiner, and if that were unsuccessful, over the examiner's head to the examiner-in-charge, but such a move was "delicate," because "ticking off" the examiner could have "bad consequences." There were further rungs of the agency's hierarchical ladder one might climb, but that runs the risk of "damaging" one's relationship to the agency.⁴⁰²

The most common remedy for this problem is for companies to seek assurances regarding departures from guidance anonymously, often through

395. Interview with Source 80, *supra* note 4.

396. Interview with Source 108, *supra* note 20; *see also* Khushoo Sharma et al., *An FDA Analysis of Formal Dispute Resolution in the Center for Drug Evaluation and Research: 2003 Through 2014*, 50 THERAPEUTIC INNOVATION & REG. SCI. 697 (2016) (examining the dispute resolution process of the FDA's Center for Drug Evaluation and Research).

397. Interview with Source 28, *supra* note 305.

398. Interview with William Schultz, *supra* note 388.

399. Interview with Source 71, *supra* note 344.

400. Interview with Lynn Bergeson, *supra* note 352.

401. Interview with Source 77, *supra* note 133.

402. Interview with Source 81, *supra* note 96.

trade associations. Naples, the chief regulatory officer of Becton Dickinson, said that a company, if worried about “ticking off” an FDA reviewer, might follow the problematic guidance in a particular application proceeding but also seek, through the trade association, to urge the agency to rethink the guidance’s application. The trade association, in its communications with the FDA, could give examples of the problem, but with company and product names removed.⁴⁰³ Similarly, a former senior FDA official said firms could effectively complain about rigid adherence to guidance if they proceeded through a trade association that could “mask” their identity.⁴⁰⁴ A former agency general counsel, discussing how to avoid a chilling effect on firms seeking departures, said, “that’s why God invented trade associations”—to avoid “jeopardy to the relationship” between individual firms and the agency.⁴⁰⁵

2. Superiors’ Institutional Motivations to Affirm Subordinates

Because higher-level officials are the ones who must decide whether to overturn frontline officials’ refusals to depart from guidance—and who must hear complaints about frontline officials being overly rigid—it matters whether these higher-level officials are more or less inclined to back the frontline officials. Interviewees identified certain organizational motivations that higher-level officials had to affirm their subordinates, independent of the merits of the question.

First, higher-level officials have to work with, rely upon, and retain their subordinates and therefore cannot take too great a risk of alienating them. Those institutional needs have to be considered in any decision on overturning a subordinate’s decisions. It cannot just be the merits, as it might be in the case of an appellate court reviewing a trial court. Regarding the FDA, the agency’s former Deputy Commissioner for Policy, William Schultz, said that it was “hard” for an FDA manager not to support the reviewers under his or her supervision; “it’s not like an appellate judge overturning a trial judge.”⁴⁰⁶ Bradley Merrill Thompson, counsel to device makers’ trade associations, noted that when a higher-level FDA official reviewed his or her subordinates’ decisions, the official was “not like” an appellate judge, who operates “external[ly]” to the trial court whose decision is under review. It was difficult to hire FDA reviewers, explained Thompson, as they were not well-paid. Higher-level officials did not want to “drive out” the reviewers by embarrassing them.⁴⁰⁷ A former EPA program office director recalled that he refused to listen to entreaties to overturn his subordinates unless the regulated party had first checked with the lower-level official and tried to get the decision changed there; it was imperative that

403. Interview with Richard Naples, *supra* note 124.

404. Interview with Source 80, *supra* note 4.

405. Interview with Source 69, *supra* note 335.

406. Interview with William Schultz, *supra* note 388.

407. Interview with Bradley Merrill Thompson, *supra* note 20.

regulated parties “work through channels” and give frontline officials a chance to correct themselves. (He added that “many” supervisors at the EPA took the same approach.) Further, he noted, there was just a limit to how much a supervisor feels he or she can overturn staff; if you do it in one instance, you become, for that reason alone, less likely to do it in the next instance.⁴⁰⁸ Similarly, a former CMS division director observed that political appointees, reviewing a request to depart from guidance, would “usually” follow the briefing from staff opposing departure, in part because they “don’t want to undermine the confidence of their subordinates.”⁴⁰⁹

Second, higher-level officials are concerned about maintaining the credibility of their own frontline officials vis-à-vis external audiences, including industry. In explaining why FDA managers backed their reviewers, Thompson specifically noted that they wanted to be supportive on an “external-facing issue” like requests for departures from guidance and wanted to avoid “castigating” subordinates in view of the “outside world.”⁴¹⁰ The former EPA program office director said you must give your subordinates an “envelope” in which to operate freely, and not second-guess them simply because you would have made a different decision, “especially if you are supervising supervisors.”⁴¹¹

Against this background, one former agency general counsel said political appointees had to make an effort to “show” stakeholders that they were willing to overrule the staff. He suggested that a political appointee refrain from signing off on guidance in the first place, instead having the staff issue it on their own responsibility, which would make it less difficult for the appointee to depart in the future.⁴¹²

A possible way to mitigate this problem is to have frontline officials’ inflexibility on guidance dealt with by a higher-level official *who is not their own boss*. A former FDA Office of Chief Counsel official recognized that a director of an FDA center would want to back his or her own subordinates, but things could differ when someone from the Chief Counsel’s office became involved laterally. He explained how, in his time in the Office of Chief Counsel, he would resolve disputes and correct misimpressions about guidance in parts of the agency that were separate from his own. To be sure, he noted, he was doing all this “ad hoc”; “not everyone knew to call me.” He suggested that FDA ombuds could play the role.⁴¹³

408. Interview with Source 71, *supra* note 344; *see also* Interview with Richard Stoll, *supra* note 188 (noting that EPA superiors tend to back their subordinates, so one “rarely” succeeds by going up the agency hierarchy).

409. Interview with Source 93, *supra* note 88.

410. Interview with Bradley Merrill Thompson, *supra* note 20.

411. Interview with Source 71, *supra* note 344.

412. Interview with Source 69, *supra* note 335.

413. Interview with Source 83, *supra* note 119.

3. Understanding of Rule/Guidance Distinction Is Not Intuitive

The distinction between legislative rules and guidance—that some policies are to be followed absolutely while others are to be followed unless you hear a good argument otherwise—is counterintuitive to many people, including some agency employees. Because this distinction is not something that people understand automatically, whether they actually grasp and apply it can vary with their professional background.

Several interviewees agreed that the rule/guidance distinction was more easily understood by lawyers than by people of other professional backgrounds. Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research, said a "pitfall" of using guidance was the difficulty of making sure the staff understood that it was nonbinding; she and others were "always having to correct [staff members] on that." It was a challenge, she said, to "get that level of sophistication" into all the staff. The scientists who largely populate the FDA were "not great" at seeing the distinction, as compared to lawyers. The difference between legal and scientific backgrounds was "very significant" in whether people grasped the distinction, she said.⁴¹⁴ Similarly, a former senior FDA Office of Chief Counsel official said that, although he "loved" the people at the FDA and thought they did "great work," they were mostly "nonlawyers" and did not "appreciate" the difference between legislative rules and guidance. Notwithstanding the notices of nonbinding status emblazoned on all FDA guidance documents and the use of nonmandatory language throughout such documents, the rule/guidance distinction was "lost on people" at the FDA. During his tenure, he recalled, he "often" had to remind agency officials not to enforce guidance as a rule, having conversations about the matter "about twice a month"; it was a "never ending issue."⁴¹⁵ (This seems to be a matter of how rank-and-file personnel are socialized before they arrive at the agency and not of the "tone at the top" at the agency; the Office of Chief Counsel official said that an FDA center director would understand the distinction in a way lower-level nonlawyers would miss,⁴¹⁶ and another former FDA official said senior officials would view guidance as more fluid than would frontline staff.⁴¹⁷)

Interviewees on other agencies also said lawyers were more likely to get the distinction than other agency personnel. A former senior HHS official said some in the Department "really don't get" the difference between rules and guidance. The lawyers were more sophisticated about it, but the "line level people" who interfaced with industry were less so.⁴¹⁸ A former EPA program office director said the tendency to treat guidance as mandatory had to do with

414. Interview with Janet Woodcock, Director, Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin.

415. Interview with Source 83, *supra* note 119.

416. *Id.*

417. Interview with Source 20, *supra* note 63.

418. Interview with Source 77, *supra* note 133.

the fact that the implementers were not lawyers. If lawyers were involved in implementation, they would know to treat guidance as a kind of burden-shifting mechanism: the regulated party can do things differently if it shows the alternative is still compliant.⁴¹⁹ Former senior DOT attorney Neil Eisner said that whether an agency respected the principle that guidance was nonbinding may depend partly on the status of lawyers within the agency.⁴²⁰ In banking regulation, an interviewee who held senior posts at the CFPB and other federal agencies said that, although the banking regulators emphasized to their examiners that guidance was not a rule, he was not sure that everybody understood the enforcement implications of this difference, as there were thousands of examiners across the banking agencies, many of them not lawyers.⁴²¹ But not all observers had the same view. A Federal Reserve official observed that, in his experience, the Fed's examiners did appreciate the distinction.⁴²²

Interestingly, there was a divergence among the interviewees on just what the effect of a scientific background was on agency employees' understanding of the rule/guidance distinction. As noted above, Woodcock viewed the distinction as a lawyerly concept that scientists were less suited to grasp, as did the FDA Office of Chief Counsel official. But others saw science as having a different valence. A partner in a large law firm healthcare practice who deals extensively with the FDA and CMS said that, of the two, the FDA was more flexible on guidance, which he attributed in part to the fact that while CMS was focused on business and payment issues, the FDA was focused on science, and "science means dialogue."⁴²³ Indeed, one might argue that the scientific method—which calls for a skeptical, questioning, inductive, and constantly self-revising attitude toward knowledge—could be quite consistent with empirically minded flexibility in policy. Consistent with this idea, a former FDA official said that, in his experience, the FDA was relatively less flexible on guidance on matters of public policy like promotion or marketing than on matters of science: the more "purely scientific" the matter, the more the FDA would consider an alternative means of compliance.⁴²⁴ A congressional staffer observed the same distinction, with FDA more flexible on scientific than policy matters.⁴²⁵

4. Nature of Relationships to Stakeholders May Affect Flexibility

Flexibility happens (or fails to happen) in the context of an interaction between agency officials and regulated party personnel. The way in which these

419. Interview with Source 71, *supra* note 344.

420. Interview with Neil Eisner, *supra* note 346.

421. Interview with Source 90, *supra* note 95.

422. Interview with Source 51, *supra* note 92.

423. Interview with Source 101, *supra* note 133.

424. Interview with Source 20, *supra* note 63.

425. Interview with Source 82, *supra* note 172.

groups of people are accustomed to interact can influence whether guidance is flexibly applied. Their patterns of interaction vary depending on the component of the agency and the nature of its work. In particular, there is a striking distinction, across multiple areas of regulation, between program offices and enforcement offices.

Several interviewees with diverse perspectives agreed that the EPA's civil enforcement office adheres more closely to guidance than do the EPA's program offices. To a large degree, this is probably due to the legitimate pressures in favor of consistency that I discussed in Section II.A above, which have enhanced power in the realm of enforcement.⁴²⁶ But apart from these legitimate pressures for consistency, there appears to be another reason for the enforcement office's closer adherence to guidance: enforcement people are not socialized to the kind of routine cooperative give-and-take with industry that program offices have on matters like rulemaking. Adam Kushner himself, the former director of the EPA's civil enforcement office, pointed this out. The program offices have more "affinity" with industry than does the enforcement office because the program offices *must* interact with industry in order to move their business forward, particularly to finish rulemakings that will (ideally) not be challenged in court. This attitude carried over to the program offices' provision of guidance, which Kushner viewed as mostly (though not entirely) an effort to make legislative rules more "comfortable" for industry and avoid conflict with industry.⁴²⁷ From the opposite perspective, a former senior official in the EPA's Air Program office said essentially the same thing. This official, in discussing why his office was more flexible than the enforcement office, spoke of the "collaborative process" that was established between the officials and stakeholders, mainly through the task of rulemaking, where officials engaged in "shuttle diplomacy" among industry players and NGOs in a manner that helped "mutual understanding" among the different sides and made litigation less likely. Further, the program office people, as the ones who developed the rule with industry, had a deeper appreciation of industry's challenges and frustrations, which increased flexibility in shaping and using guidance after the rule's promulgation. The enforcement office, by contrast, needed to "hit" its "numbers," he said.⁴²⁸

Two other interviewees with yet other perspectives confirmed the distinction. Lynn Bergeson, managing partner of Bergeson & Campbell, said that the EPA enforcement office's inflexibility on its penalty guidance was a point "of unique frustration" that "we all whine about."⁴²⁹ The executive director of the Environmental Council of the States said the enforcement office was the

426. See *supra* text at notes 289-294.

427. Interview with Adam Kushner, *supra* note 106.

428. Interview with Source 103, *supra* note 311.

429. Interview with Lynn Bergeson, *supra* note 352.

strictest in its adherence to guidance of any component of the EPA headquarters: “they don’t mess around.”⁴³⁰

A similar divergence between enforcement and program functions is evident in healthcare regulation. One law firm partner observed that the HHS Office of Inspector General and the DOJ were less flexible regarding guidance than CMS or program offices at the FDA; he attributed the difference to the fact that regulated firms had a more personal relationship with CMS and the FDA.⁴³¹ Looking at the FDA’s internal components, a drug company executive observed more flexibility on guidance in the review divisions, which were devoted to the essentially collaborative mission of getting drugs out to the public, and less flexibility in components related to advertising and promotion, which were more adversarial.⁴³²

And in the world of chemical manufacturing, James Conrad, an industry consultant who has represented chemical manufacturers in dealings with several different agencies, observed that the Drug Enforcement Administration (DEA) was the least flexible of these. The DEA conceives of itself as a criminal law enforcement agency, but some legitimate industries are partly regulated by the DEA because their medicinal or chemical products can be used to make illegal drugs (especially methamphetamine). Thus, the DEA tends to view regulated parties through the lens of criminal law enforcement rather than administrative law.⁴³³

5. Training to Be Flexible

Whether or not officials have professional backgrounds or day-to-day interactions suited to flexibility, one might be able to make them more flexible through training. Multiple FDA officials said preventing reviewers from treating guidance as binding was a matter of training the reviewers in the various centers on the rule/guidance distinction.⁴³⁴ Woodcock, the director of the FDA’s Center for Drug Evaluation and Research (CDER), observed that the Office of Generic Drugs (OGD) struggled with the distinction before she established an Office of Generic Drug Policy (a “policy shop”) within the OGD within the last five years. This policy shop, staffed partly by lawyers, has been tasked with not letting guidance be treated as binding at the OGD through both general training and ad hoc input to frontline officials in the event of industry complaints. Woodcock believed that, in order for this kind of initiative to be effective, it had to be “at

430. Interview with Alexandra Dapolito Dunn, Exec. Dir., Env’tl. Council of the States.

431. Interview with Source 104, *supra* note 206.

432. Interview with Source 108, *supra* note 20. Another interviewee likewise observed that the FDA’s enforcement components were more rigid in using guidance but attributed the difference to the greater geographic dispersion of these components and the consequent need to control them. Interview with Source 107, former senior official, U.S. Food & Drug Admin.

433. Interview with James Conrad, *supra* note 176.

434. Interview with Source 25, *supra* note 298; Interview with Source 31, official, Ctr. For Devices & Radiological Health, U.S. Food & Drug Admin.

the grassroots”—that is, embedded within the particular office, not within CDER’s overall policy shop, which provides a “final common pathway” for all decisions that come out of the OGD and other CDER components but is not actually embedded within any of those components. In undertaking an initiative like getting guidance to be nonbinding, she said, it was necessary to designate specific people as responsible for the initiative and to hold them accountable.⁴³⁵

At the EPA, there appears to be some variation in whether the rule/guidance distinction is part of the training of employees who will apply guidance documents. One EPA Office General Counsel official said that, although the Office of General Counsel often tells agency personnel that guidance is nonbinding, he has not observed any training of personnel on the issue.⁴³⁶ But another EPA Office General Counsel official said that the Office of General Counsel had done some trainings for program offices on certain guidance documents, which do involve the point that decisionmakers are not bound to follow the guidance.⁴³⁷

E. Inflexibility by Reason of Agency Commitment to Guidance’s Substance

This Part so far has catalogued the numerous reasons why an agency might behave inflexibly regardless of the substantive content of a guidance document, but it is also possible for an agency to follow guidance inflexibly because officials are committed to the guidance’s substantive content. In other words, they think the guidance contains the right policy and therefore should not be open to question. From the perspective of the Administrative Procedure Act and the values behind legislative rulemaking, this is the most problematic reason for inflexibility on guidance. If an agency thinks a policy must be rigidly followed and reconsideration foreclosed simply because the policy is right, that is the archetypal scenario calling for legislative rulemaking. Agencies ought to resist inflexibility of this kind, including by expending the resources and taking the managerial initiative necessary to ensure principled flexibility.

Is this prescription utopian? Commitment to guidance’s substance is the most problematic reason to be inflexible, but is it not also the *strongest* reason to be inflexible? Urging agencies to preserve open-mindedness precisely in the cases where they most strongly believe they are right may seem like a hopeless call for self-denial, unless we think bureaucrats are angels.

There is some truth to this counsel of despair, but it is not as hopeless as it seems. The agency is a “they,” not an “it.” Insofar as substantive commitment drives an agency’s rigid adherence to guidance, that commitment sometimes emanates from the political appointees or from the career officials but not from both. This raises the possibility that, if a norm against substance-driven

435. Interview with Janet Woodcock, *supra* note 414.

436. Interview with Source 70, official, Office of Gen. Counsel, Env’tl. Prot. Agency.

437. Interview with Source 61, *supra* note 334.

inflexibility is recognized, the political appointees can invoke that norm to check the behavior of the career officials and vice versa. And that is to say nothing of the possibility that external overseers (congressional committees or inspectors general or the OMB) can invoke the norm.

Before proceeding, I should emphasize two points. First, some of the interviewee comments cited below directly indicate that a substantive commitment to guidance's substance drove an agency to be inflexible or otherwise to circumvent notice and comment, but most of them indicate merely that substantive commitment was *one factor* counseling adherence to guidance, which could in principle drive the agency to the point of close-minded inflexibility, even if it did not actually get there. Second, while commitment to guidance's substance is the most problematic reason for an agency to be inflexible, we must see this reason in perspective. It comes up in several interviews, but not a great number, and it proves to be only one of the many reasons for inflexibility identified throughout this Part. This indicates that, if and when we observe inflexibility on the part of an agency, we should *not* presume, without further evidence, that it is due to agency personnel's belief that the guidance's substantive content is right. There are so many other potential causes.

Consider first interviewees' comments on inflexibility driven by commitment to guidance's substance on the part of political appointees. There was often ambiguity in these comments about just how explicitly the appointees conveyed a preference for rigid adherence to the officials implementing the guidance; sometimes, at least, it seems implementing officials adhere to guidance out of sensitivity to political appointees' perceived wishes without receiving direct orders on the point. According to a former senior HHS official, if something is a "top tier policy priority" for the "leadership" of the agency, that will influence what officials do regarding departures from guidance, "how they posture," and how they try to make the guidance "effectively binding."⁴³⁸ A former CFPB official said that officials' willingness to give assurances about whether a departure from guidance would be acceptable depends on several factors, one of which is the "attitude" of the agency's "leadership," that is, the official's "sense" of what the political leaders care about; this changes the official's "comfort level" with giving assurances about departures.⁴³⁹ At the EPA, David Hawkins, the former head of the Air Program office, said the tendency to adhere to guidance and to precedent was driven by the risk of an arbitrary-or-capricious judicial challenge, by congressional scrutiny, and—of interest to us here—by the agency's policy in favor of what the guidance says, usually meaning the preference of "political appointees." Hawkins gave the example of a public memo he sent to the Air Program office staff, without notice and comment, whereby he proposed giving a "harder look" on approvals of state implementation plans under the Clean Air Act regarding acid rain—an issue on

438. Interview with Source 77, *supra* note 133.

439. Interview with Source 81, *supra* note 96.

which the EPA had previously been *laissez-faire*.⁴⁴⁰ Richard Stoll, of Foley and Lardner, stated that, although the EPA was generally flexible on guidance when presented with the right data, there were instances of inflexibility caused by “political pressure from the top.” He cited an instance in which the Administrator was lobbied for tougher treatment of industry under the Resource Conservation and Recovery Act’s boiler and industrial furnace rules. In an apparent response to the lobbying, the EPA issued a guidance document that some of the regional offices began telling companies to follow until the EPA backed down in the face of a judicial challenge. He also noted that, where the EPA had a clear goal from the top like promotion of wind and solar power, it would show less flexibility and construe ambiguities in guidance in the direction of that policy view.⁴⁴¹ Lynn Bergeson, managing partner of Bergeson & Campbell, in discussing EPA adherence to guidance, noted that some policies were “driven” by “supercharged political appointees” and reflected the values of “the current administration.”⁴⁴²

Now consider what interviewees said about inflexibility driven by commitment to guidance’s substance on the part of career officials. In some cases, interviewees did not cast career officials as being self-consciously rigid or committed, but instead as having a less-conscious attachment to a policy because they had helped to develop it. According to Thompson, counsel to device-maker trade associations, FDA reviewers were inflexible on guidance for several reasons, including that they “often” had “helped write” it, meaning they had a “sense of ownership” of it.⁴⁴³ Likewise, a former CMS division director said that CMS career officials usually preferred to adhere to guidance, for a variety of reasons, one of which was that they had a “sense of ownership” of it because they had “often” helped to write it.⁴⁴⁴ This is not to say that career officials writing guidance always feel closely committed to it. Richard Stoll, of Foley & Lardner, recalled dealing with a career official at the EPA who had written key guidance on boilers and industrial furnaces under the Resources Conservation and Recovery Act and “took all the calls” from stakeholders about departures from and interpretations of the document he had written: he “leaned left but was reasonable.”⁴⁴⁵

Other interviewees recalled career officials being more self-conscious in seeking to get their favored policies implemented through adherence to guidance. Regarding the SEC, a former official said that career staff, who write and have final approval on much guidance, were relatively less receptive than political

440. Interview with David Hawkins, *supra* note 310. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

441. Interview with Richard Stoll, *supra* note 188.

442. Interview with Lynn Bergeson, *supra* note 352.

443. Interview with Bradley Merrill Thompson, *supra* note 20; *see also* Interview with Source 112, former senior career official, U.S. Food & Drug Admin. (noting that, for a disease-specific guidance document, the FDA review division applying the document would have been involved in writing the document).

444. Interview with Source 93, *supra* note 88.

445. Interview with Richard Stoll, *supra* note 188.

appointees to requests for departures from guidance because of the “strong views” those staff members held. The staff, he said, had a “long term plan” of how SEC regulation should operate that they sought to articulate through a variety of agency communications even as political appointees came and went.⁴⁴⁶ Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice and a former FDA Office of Chief Counsel attorney, recounted that after the FDA in 2006 issued the Physician Labeling Rule (telling drug makers what prescribing information to include in their applications for pre-market approval), the agency rapidly issued about twenty guidance documents, which everybody knew would have to be followed because of pre-approval incentives.⁴⁴⁷ This stream of guidance was perceived by many as an “end run” by FDA career officials around the actual legislative rule approved by the Bush-era OMB.⁴⁴⁸ To give another example, a former agency general counsel recalled that the career officials at his agency would try to get higher-level officials to sign off on guidance documents in a way they hoped would “bind” those officials and get them “committed” to policies articulated in the documents that the career officials thought were “the right answer.” In this way, the career officials sought to get the policy as “definite” as it could be. The interviewee admired these career officials for being “highly motivated” and “trying to do what is right,” but he also believed they failed to acknowledge “competing considerations” and did not see the “larger” consequences of the paths they sought to take. He therefore resisted signing off on guidance proposed by the staff, instead forcing them to issue it on their own responsibility so that he could allow the policy to develop experimentally and reactions to flow in from stakeholders and Congress. He would then sign off at what he considered to be “the proper stage of policy evolution.”⁴⁴⁹

It is also possible for agency inflexibility to arise from the demands of the “regulatory environment”—a more amorphous source of substantive commitment than identifiable political appointees or career officials, but a source of such commitment nonetheless. A former senior Federal Reserve official who has counseled financial institutions said that agency officials’ willingness to depart from guidance depended partly on “the regulatory environment,” which, he noted, was more intense in the present era than it had been in, say, the year 2000. Scrutiny of banking regulation was high from external institutions like Congress and public interest groups. The banking regulators were under significant stress to prevent another financial meltdown. In this environment, he judged, banks could get approval for a departure if they were saying compliance was operationally unworkable or would create some *other* risk, but not if they were saying the guidance was bad policy or challenging the guidance itself.⁴⁵⁰

446. Interview with Source 19, *supra* note 173.

447. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

448. Interview with Coleen Klasmeier, *supra* note 123.

449. Interview with Source 69, *supra* note 335.

450. Interview with Source 72, *supra* note 91.

III. Deregulatory Guidance and Regulatory Beneficiaries

The courts have made clear that a guidance document cannot bind regulated parties. They have also said that a guidance document cannot bind the agency itself, and this principle obtains even when the agency is binding itself in a manner that favors regulated parties, as by binding the agency not to enforce against them or by binding the agency to grant them permits. In *Community Nutrition Institute v. Young*, the D.C. Circuit struck down FDA guidance on the levels of food contaminants below which the agency would not bring enforcement actions against food producers, saying that the FDA had impermissibly “bound itself” to the guidance in a manner that prevented notice-and-comment participation by people who might be harmed by contaminated food.⁴⁵¹ More recently, in *General Electric Company v. EPA*, the same court invalidated EPA guidance on how companies should seek approval of methods for cleanup of certain toxic substances, in part because the document impermissibly “appears to bind the Agency to accept applications” using a certain toxicity factor, implying “that the use of that value will not be questioned” in the agency’s decision process for granting permission: “an applicant reasonably could rely upon that implication.”⁴⁵² Despite the fact that the challenger was not even a regulatory beneficiary but a company seeking permission from the EPA—that is, the very kind of party that could *benefit* from such a safe harbor—the court viewed this as a reason to find the guidance binding and therefore unlawful.⁴⁵³

Though counterintuitive and sometimes criticized, this line of case law—effectively outlawing absolute safe harbors in guidance documents—goes to a legitimate concern. If it were possible for an agency to bind itself through a guidance document so long as the policy therein was permissive rather than mandatory toward regulated parties, the effect would be to exempt much of deregulation from the requirements of legislative rulemaking and from direct participation by the beneficiaries of regulation and the NGOs who seek to represent their interests.⁴⁵⁴ The implication of the courts’ approach is that even

451. *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 948 (D.C. Cir. 1987).

452. *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 384 (D.C. Cir. 2002); *see also Texas v. United States*, 809 F.3d 134, 171-76 (5th Cir. 2015), *aff’d by an equally divided court*, 136 S. Ct. 2271 (2016) (invalidating a guidance document on the ground that it effectively bound the agency to grant applications from immigrants who met certain criteria).

453. *General Electric Co.*, 290 F.3d at 384.

454. The problem of deregulatory guidance and regulatory beneficiaries has been analyzed mainly with respect to the practical availability of judicial review, for if regulated parties follow safe-harbor guidance, there will never be an enforcement proceeding in which the guidance could be tested. Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 420-24 (2007); Seidenfeld, *supra* note 14, at 344; Strauss, *Publication Rules*, *supra* note 2, at 817. In a critique of *Community Nutrition*, Ron Levin argues that, when an agency deregulates through guidance that is permissive toward regulated parties, non-regulated interested persons deprived of a notice-and-comment rulemaking proceeding in which to comment on the deregulatory policy have no legal right to force notice-and-comment rulemaking yet would be able to submit a petition for rulemaking to have the guidance document changed, to which the agency would be legally bound to respond. Levin,

when a regulated party follows guidance to the letter, that cannot be a legal guarantee that it has complied with the law. This principle is widely recognized across agencies. The FDA announces that its guidance documents “do not legally bind the public or FDA” and that “FDA employees” can “depart from guidance documents” if they have “appropriate justification and supervisory concurrence.”⁴⁵⁵ An official at the FDA’s Office of Regulatory Affairs (which oversees inspectors) cautioned that even if a firm does follow guidance, that is not a guarantee that it has complied with the statute.⁴⁵⁶ At the EPA, an official recognized that it would be unlawful for guidance to create an absolute safe harbor; she explained how the agency instead used “weaselly words” like “highly likely” instead.⁴⁵⁷

That said, the prohibition against legally impregnable safe harbors in itself probably does not much determine the practical reliability of guidance. As William Funk writes, even though the case law encourages agencies to write guidance documents with “caveats” disclaiming any guarantees, “[a]s a practical matter, . . . the agency ‘winks’; that is, it lets it be understood that you can rely on the policy statement and avoid enforcement if you act in conformance with the policy statement.”⁴⁵⁸ This is indeed how some agencies operate, particularly regarding individualized forms of guidance on which the receiving party is especially likely to rely. At the SEC, for example, official legal reliability is weak, but *de facto* reliability is strong. A regulated party who requests and receives a no-action letter from a division of the SEC regarding the permissibility of some transaction “can consider the letter a promise that the division staff will not bring that particular transaction to the Commission’s attention for enforcement action,” although this promise does not amount to much legally: it “probably would not constitute a basis for legal estoppel.” Nonetheless, regulated parties “highly value no-action letters, undoubtedly because the Commission appears to have *never* proceeded against the recipient of a no-action letter who acted in good faith on the letter’s advice.”⁴⁵⁹ More generally, “many

supra note 6, at 305-06. As Levin acknowledges, this is not the course taken by the D.C. Circuit or other courts (though the Supreme Court has yet to weigh in). Whatever the correct legal doctrine, the approach I propose at the end of this Part is a means of achieving the functional goal that Levin and the *Community Nutrition* court seem to share: allowing regulatory beneficiaries a voice, in some way or another, in deregulatory agency decisionmaking.

455. 21 C.F.R. § 10.115(d)(1), (3) (2018).

456. Interview with Source 28, *supra* note 305.

457. Interview with Source 99, *supra* note 20.

458. Funk, *Primer*, *supra* note 18, at 1335.

459. Donna M. Nagy, *Judicial Reliance on Regulatory Interpretations in SEC No-Action Letters: Current Problems and a Proposed Framework*, 83 CORNELL L. REV. 921, 943 (1998) (emphasis added) (analyzing 17 C.F.R. § 202.1 and related provisions); *see also* Interview with Source 19, *supra* note 173 (stating that she was not aware of any instance in which a no-action letter was not honored in the enforcement context, although the agency might aggressively distinguish a no-action letter).

securities law practitioners and their clients consider no-action letters a source of de facto law.”⁴⁶⁰

At DOT, Neil Eisner, the former Assistant General Counsel for Regulation and Enforcement, said that, notwithstanding guidance’s lack of binding legal effect on the agency, he could not recall the Department ever, in an enforcement context, going back on any of the numerous guidance documents that were issued from headquarters. DOT officials’ reticence to go back on guidance, he explained, was not because they believed themselves legally constrained from doing so but because defeating reliance on guidance would not be good government practice. That said, he believed the agency did need to be practically willing to go back on guidance in the event of rogue behavior by field personnel (though such situations, he noted, were “not common”). For example, when a field inspector provided guidance to a company that was more industry-friendly than, and contrary to, guidance issued in writing by a headquarters official designated to do so by agency regulation, headquarters stopped him, and if the company (which was sophisticated and should have known better) had acted on this bogus guidance, an enforcement action would have been lawful and appropriate, though the agency would have gone easier on a less-sophisticated company.⁴⁶¹

At OSHA, the Field Operations Manual, which covers matters like what civil penalties an inspector should impose on an employer, states that its contents “are not enforceable by any person or entity against the Department of Labor or the United States.”⁴⁶² Yet Baruch Fellner, the founding partner of Gibson Dunn’s OSH practice, observed that if OSHA field personnel deviated from the Field Operations Manual in a manner unfavorable to an employer (say, on levels of penalties), the employer could contest the citation and “hold [OSHA’s] feet to the fire” to make it follow the Manual. The higher levels of the agency passing on contested citations were consistent in following the Manual “to the extent humans can be consistent.”⁴⁶³

Of course, the fact that guidance’s doubtful legal protection can translate into strong practical protection, as with SEC no-action letters or DOT headquarters guidance or the OSHA Manual, does not mean it will always do so. It is a matter of the agency’s organizational and political choices, which can vary. EPA guidance appears somewhat less practically reliable. A senior environmental counsel to a Fortune 100 company said that EPA guidance would protect you against enforcement “98%” of the time but “not 100%.”⁴⁶⁴ An EPA official commenting on guidance for how to do FIFRA applications said it came

460. Nagy, *supra* note 459, at 924-25.

461. Interview with Neil Eisner, *supra* note 346.

462. OCCUPATIONAL SAFETY & HEALTH ADMIN., FIELD OPERATIONS MANUAL, at ABSTRACT-3 (2017).

463. Interview with Baruch Fellner, *supra* note 233.

464. Interview with Source 119, *supra* note 108.

with the “caveat” that the EPA could change its mind, though she said the agency would not “deviate cavalierly.”⁴⁶⁵

While it might well be better government practice for agencies to provide more legally ironclad bases for reliance—ACUS has recommended as much by urging agencies to make greater use of binding declaratory orders⁴⁶⁶—the consultant on that recommendation acknowledged that technically-nonbinding guidance documents “[m]ore often than not . . . meet the immediate needs of both agencies and regulated parties, furnishing reliable guidance with little burden imposed upon the agency.”⁴⁶⁷

Taking as given the now-prevailing view that guidance cannot impose officially binding limits on regulation, we should ask whether this mandate for nonbinding status actually serves the goal that cases like *Community Nutrition Institute* sought to pursue—that is, to allow beneficiaries of regulation a voice in agencies’ deregulatory decisions.⁴⁶⁸ The reaction of agencies to cases like *Community Nutrition Institute* has often been not to do legislative rulemaking (which surely would allow regulatory beneficiaries a voice) but instead to disclaim more strongly the binding status of guidance.⁴⁶⁹ Assuming *arguendo* that we should take those disclaimers at face value, what is the good they do for regulatory beneficiaries? Presumably the disclaimers render the deregulatory guidance nonbinding, meaning the agency must be flexible in administering it—that is, not automatically give industry the benefit of a lighter regulatory touch in every inspection, permit application, etc. But as we saw in Part II, what animates agency flexibility day-to-day is that regulated parties in individual enforcement and adjudicatory proceedings—or in individual entreaties in anticipation of such proceedings—ask the agency to make departures. It is the agency’s responsiveness to these micro-requests that largely constitutes flexibility. But when guidance is deregulatory, who plays the role of the request-making company? Even if the agency would be responsive and flexible *if asked*, who will do the asking?

It is not as if every regulatory enforcement action or permit proceeding has an NGO on the other side seeking more stringent treatment of the industry party. To be sure, sometimes an NGO is present at the microlevel. This is perhaps most common in some parts of environmental regulation: interviewees gave examples

465. Interview with Source 41, official, Env’tl. Prot. Agency.

466. ACUS Recommendation 2015-3, 80 Fed. Reg. 78163 (Dec. 16, 2015).

467. Emily S. Bremer, *The Agency Declaratory Judgment*, 78 OHIO ST. L.J. 1169, 1180-81 (2017).

468. My discussion here is partly inspired by a line of scholarship on a distinct but related issue: whether and how regulatory beneficiaries can obtain judicial review of deregulatory guidance documents. See Mendelson, *supra* note 454, at 420-24; Seidenfeld, *supra* note 14, at 344; Strauss, *Publication Rules*, *supra* note 2, at 817. Furthermore, Mendelson argues that we should seek to ensure regulatory beneficiaries’ participation in guidance development by conferring on them a right to petition agencies to revise or repeal guidance documents. Mendelson, *supra* note 454, at 438-44. Levin argues that regulatory beneficiaries have such a right under existing law. Levin, *supra* note 6, at 306 n.200.

469. E.g., Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation: CNI v. Young and the Aflatoxin Dance*, 44 ADMIN. L. REV. 131, 153 (1992).

of NGOs taking part in disputes about guidance in informal conversations at the EPA Air Program office regarding industry requests for departures,⁴⁷⁰ in EPA-supervised state agency permit proceedings under the Clean Air Act,⁴⁷¹ and in EPA proceedings on whether to override state permits under that same act.⁴⁷² But in many regulatory areas, NGOs will play little to no role in individual proceedings. They may lack any legal right to get involved, or they may lack the resources to contest or even find out about the proceedings, or the proceedings may be confidential and/or involve rapid settlements. Thus, NGOs will often have no opportunity to press for flexibility case-by-case.

In these areas, a better means of ensuring the salutary goal of *Community Nutrition Institute* is to allow regulatory beneficiaries and NGOs an opportunity to contest the agency's use of the guidance document wholesale, not retail. This is the means of participation most commensurate with NGOs' limited resources and the practical inability of some of them to monitor anything more than the most salient things an agency does.⁴⁷³ Eisner said that, during his tenure at DOT, he never heard of an NGO becoming involved in an individual adjudication or enforcement action, but he had certainly seen NGOs get involved in legislative rulemakings and in participatory processes that DOT voluntarily undertook when issuing guidance documents. The best time for NGOs to get involved, he observed, was when guidance was first issued, not when it was individually applied.⁴⁷⁴

Agencies do sometimes invite stakeholder participation on a wholesale basis when formulating and adopting certain guidance documents. They do so by various means, up to and including a kind of "rulemaking lite," in which the guidance is posted in draft for public comment before it reaches final form and becomes agency policy. Such participatory processes are costly to the agency and can delay the provision of guidance, so they must be employed advisedly. How to assess the costs and benefits of this participation, and whether and when to invite it, are questions that I address in depth elsewhere.⁴⁷⁵ For our purposes, suffice it to say that if guidance promises to have significant deregulatory effects, that is one of the strongest factors counseling in favor of soliciting public participation before the document is adopted.

470. Interview with Source 103, *supra* note 311.

471. Interview with Source 128, *supra* note 312.

472. Interview with David Hawkins, *supra* note 310; *see also* Interview with Source 54, *supra* note 188 (discussing NGO judicial challenges to EPA permit proceedings and the role of guidance therein). Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

473. On limits of NGOs' monitoring capacities, with respect to rulemaking, guidance, and judicial review, *see* Mendelson, *supra* note 454, at 424, 430.

474. Interview with Neil Eisner, *supra* note 346.

475. PARRILLO REPORT, *supra* note †, at 137-86; Nicholas R. Parrillo, *Should the Public Get to Participate Before Federal Agencies Issue Guidance? An Empirical Study*, 71 ADMIN. L. REV. (forthcoming 2019).

IV. Conclusion

Guidance is ubiquitous and essential, yet controversial. Debate on the subject would be more realistic and productive if it occurred at a lower temperature, less charged with insinuations of bad faith and more oriented toward institutional reform. Complaints about guidance do have a genuine basis, in that regulated parties are often under strong practical pressure to follow it, and agencies sometimes do not afford the flexibility that is legally required in using it. But the pressure to follow guidance originates mainly from structural features of modern regulation that are beyond the control of officials who issue and use guidance. And the main reasons why officials act rigidly in using guidance are, first, that other stakeholders cross-pressure them to act with consistency (which itself serves rule-of-law values) and, second, that officials find it hard to overcome unintended bureaucratic pathologies. Thus, it is possible to acknowledge and explain most of the problems with coercive guidance without resorting to accusations that officials are deliberately trying to circumvent the guarantees of the Administrative Procedure Act. In terms of reform, we might in the long term consider altering structural features of regulation that strongly incentivize regulated parties to follow agency wishes short of law, but in the short term, the most promising route is to undertake managerial reforms that foster flexibility on the front lines. But we must recognize that these reforms take up scarce agency resources and managerial energy, so they will need to be traded off against competing demands—and also against competing values like consistency and predictability.

