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FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE

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INTRODUCTION¹

Guidance—the umbrella category covering what the Administrative Procedure Act calls “general statements of policy” and “interpretative rules”—is a ubiquitous and essential feature of countless agency programs. It covers all general statements an agency issues announcing how it proposes to exercise the discretion created by its enabling statutes and legislative rules, or announcing how it interprets those enabling statutes or legislative rules.² Because guidance is not itself a legislative rule, it is conventionally said to be nonbinding—a mere tentative announcement of the agency’s current thinking about what to do in individual adjudicatory or enforcement proceedings, subject to the agency’s case-by-case discretion and regulated parties’ individual arguments for doing things differently.³ Because of this requirement to be nonbinding, guidance has been the subject of continuing controversy. The concern is that agencies in reality are not tentative or flexible when it comes to guidance but instead follow it as if it were a binding legislative rule, and regulated parties are under coercive pressure to do the same. The use of guidance as a binding norm undermines the mandate of the APA that general binding policies should be made only through the exacting procedures of legislative rulemaking, including notice and comment, in which the parties to be bound by a policy can participate in its

¹ This Report cites observations and opinions by numerous interviewees. Some of these contain praise or criticism of agency behavior. As I believe and hope will be clear from my presentation, I am often presenting interviewees’ opinions and observations as pieces of a mosaic, with findings and conclusions to be drawn from the totality of the picture, not any one piece; or I am presenting them in an effort to identify the range of possibilities, interpretations, or perspectives on a given issue. Given this, I do not necessarily mean to endorse every instance of praise or criticism in every interview citation that appears in the Report.

² The category of guidance would cover statements of this description if addressed to a generic class of regulated parties and/or to agency staff with the understanding that it would affect their activities with respect to such a generic class, and the category would even be conventionally understood to cover “opinion letters or letters of interpretation” addressed to individual regulated parties if such documents are “reasonably anticipated to have precedential effect and a substantial impact on regulated entities or the public.” Office of Management and Budget, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3435 (2007).

³ At least, general statements of policy are conventionally thought to be nonbinding; the question of whether interpretative rules are nonbinding is more uncertain. On the applicability of this Report to interpretative rules, see *infra* notes text at 33-43. For an excellent review of the case law and institutional pronouncements indicating that general statements of policy are to be nonbinding, see Ronald M. Levin, *Rulemaking and the Guidance Exemption*, Admin. L. Rev. (forthcoming 2018), manuscript (July 21, 2017) at 22-36, available at papers.ssrn.com/sol3/papers.cfm?abstract_id=2958267. Levin also makes a forceful argument that interpretive rules, on the best reading of the law (viewed in light of policy considerations), are to be nonbinding, as well. *Id.* at 65-69.

formulation before it is set in stone. Guidance, it is feared, allows the agency to make policy without the participation of those affected and then effectively to bind them.⁴

This Report finds that, while the critics are partly right in that guidance is sometimes inflexible and regulated parties are often under much pressure to follow it, this state of affairs results mainly from institutional factors that are either beyond the agencies' control or result from the agencies being cross-pressured or under-resourced or operating by inertia—not usually because the agencies are engaged in bad-faith circumvention of the APA. The problem with guidance is largely an institutional problem that calls for an institutional response, not a problem of bureaucratic bad faith that calls for accusation and blame. Much of the concern about guidance can be mitigated if agencies adopt institutional reforms in favor of flexibility, though these will have to be balanced against resource constraints and legitimate pressures on agencies from stakeholders and political overseers to provide some degree of consistency and predictability. The concern about guidance can also be mitigated if agencies voluntarily allow for public participation in its formulation, up to and including voluntarily doing notice and comment. But the tradeoffs involved in deciding whether to provide for this participation—and the potential unintended consequences of it—are sufficiently complex and variable that it would be unwise to have a government-wide requirement for notice and comment on guidance documents, unless it covers only the very most extraordinary documents.

While there is already a very substantial academic literature on guidance, it focuses almost entirely on judicial opinions and is concerned with defining the rule/guidance distinction in a manner that is tractable for courts. That literature is important for judicial decisionmaking, but it misses much about the everyday workings of guidance that pervade the administrative state, for it focuses on the tiny fraction of guidance documents that get challenged in litigation, and only on the kinds of facts about guidance that reach the courts.

My focus in this Report is different. I have sought to assess guidance's essential role and its sometime pathologies from the worm's eye view: day-to-day operations of agencies and regulated parties. My main sources are unstructured interviews with people from agencies, industry, and NGOs. In all, I interviewed 135 individuals, with the vast majority of interviews

⁴ As Michael Asimow aptly stated: "If the public is denied an advance opportunity to influence a policy statement, it should have a fair chance to persuade a decisionmaker to follow a different course when the discretionary function is actually exercised in a subsequent investigation, formal or informal adjudication, or other proceeding." Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 Duke L.J. 381, 391.

lasting for between 60 and 90 minutes each, all between September 2016 and July 2017. 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 (ACUS agency contacts and ACUS public members), asking them for names of knowledgeable people, interviewing those people, asking 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.” Because following up every single interview lead would have rapidly multiplied the interviewee pool beyond what I could manage, 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 EPA, because of the unmatched scale of its regulatory operations and its unmatched prevalence in legal controversy over both guidance and legislative rulemaking, and FDA, given its heavy reliance on guidance documents and its use of an unusually formalized process for issuing guidance).⁵ In the end, 24% of the interviewees were expert on EPA, 23% on FDA, and between 4% and 11% each on OSHA, the Department of Energy, USDA, FAA, HHS (besides FDA), and the banking regulatory agencies. (For a complete description of the study’s methods, see the Appendix. Note that, for interviewees who wished their identities to remain confidential, I have arbitrarily assigned male and female pronouns in alternating Parts of the Report—female for the Introduction and Parts II and IV and male for Parts I, III, and V—to avoid giving information on the identities of these sources.)

⁵ 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 Section B of the Appendix.

A. The Argument of the Report

Here I lay out the argument of the Report, explaining its findings part by part and showing how they fit in to larger debates on guidance and administration. (A more abridged summary of the Report’s findings can be found in Part VI, in the preamble to my proposed recommendations.)

The Report begins, in Part I, by discussing the importance of guidance. It is an essential and ubiquitous instrument of administration across numerous agencies. Officials say they cannot imagine a world without guidance. And while regulated parties are the source of complaints and concerns about guidance, it must be emphasized that much and perhaps most guidance is issued because regulated parties seek and demand it. The attractiveness of guidance to agencies and regulated parties alike is understandable. Compared with purely case-by-case adjudication or enforcement, guidance makes frontline agency decisionmakers more decisive and fast in their decisions, saving time and resources for the agency and the regulated public. It also makes agency decisionmaking more predictable, comprehensible, and uniform, shielding regulated parties against unequal treatment, unnecessary costs, and unnecessary risk. Compared with legislative rulemaking, guidance is better for dealing with conditions of uncertainty and for making agency policy comprehensible to regulated parties who lack counsel. Further—and interviewees cited this factor several times more than any other—the provision of guidance takes less time and resources than legislative rulemaking. An agency making policy through guidance gives up legally-binding status for that policy, but it simultaneously frees up resources to make more policy on more matters. (Let me note, this Report assesses how agencies do and should administer guidance, and the processes that agencies do and should follow for issuing guidance, but it takes as given the fact that agencies are proceeding by guidance, and it does *not* answer the prior question of whether an agency should proceed by guidance or instead by legislative rulemaking to begin with. Addressing that question would require a body of research—at least as extensive as the one offered here on how guidance actually works—on how legislative rulemaking actually works, and whether it could be made to move faster and more cheaply. Part I offers some suggestive evidence on how to make legislative rulemaking faster and cheaper, but no more.)

The heart of the Report—Parts II and III—confronts questions about guidance’s capacity to “bind” regulated parties and agencies themselves. These questions were the focus of one of

the principal ACUS recommendations on guidance (Recommendation 92-2)⁶ and of one of the principal ACUS reports on it, by Robert Anthony. In his report—a deep and formidable critique of agencies’ use of guidance—Anthony declared that the “capital problem” was that “agencies often inappropriately issue [guidance documents] with the intent or effect of imposing a practical binding norm upon the regulated or benefited public.”⁷ These were his twin concerns: “intent” and “effect.” He used that paired formulation repeatedly (sometimes substituting “purpose” for “intent”).⁸ But of the two, his concept of a binding “effect” was not elaborately formulated or analyzed,⁹ and it was clearly “intent” that drew most of his intellectual energy, for he believed agencies’ abuses were quite often deliberate. As he wrote in one passage of this classic work:

[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.¹⁰

⁶ Recommendation 92-2, Agency Policy Statements, 57 Fed. Reg. 30,103 (July 8, 1992).

⁷ 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, 1315 (1992) (emphasis omitted). The present Report is primarily concerned with the issues addressed by the Anthony report and by Recommendation 92-2, and also, in Part V of the present report, the public-participation issues addressed in Recommendation 76-5, Interpretive Rules of General Applicability and Statements of General Policy, 41 Fed. Reg. 56,769 (Dec. 30, 1976); Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 Mich. L. Rev. 520, 556 (1977). There have also been ACUS reports and recommendations on other aspects of the guidance phenomenon. Recommendation 2015-3, Declaratory Orders, 80 Fed. Reg. 78163 (Dec. 4, 2015); Emily S. Bremer, *The Agency Declaratory Judgment*, 78 Ohio St. L.J. (forthcoming, 2017-18), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2955214; Recommendation 2014-3, Guidance in the Rulemaking Process, 79 Fed. Reg. 35992 (June 25, 2014); Kevin M. Stack, *Preambles as Guidance*, 84 Geo. Wash. L. Rev. 1252 (2016); Recommendation 71-3, Articulation of Agency Policies, 38 Fed. Reg. 19,788 (July 23, 1973); Brice McAdoo Clagett, *Informal Action—Adjudication—Rule Making: Some Recent Developments in Federal Administrative Law*, 1971 Duke L.J. 51.

⁸ Id. at 1328, 1355-59, 1373.

⁹ The longest discussion of binding “effect” is in id. at 1358-59, where it appears to refer to situations in which an agency’s frontline decisionmakers treat a guidance document as dispositive of the questions that come before them.

¹⁰ Id. at 1360. See also E. Donald Elliott, *Re-Inventing Rulemaking*, 41 Duke L.J. 1490, 1490 (1992) (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”).

Intent was not only Anthony’s primary focus; it was also the part of his critique that made it into ACUS Recommendation 92-2, whereas the “effect” prong was deleted during the Conference’s deliberations.¹¹ The recommendation speaks in terms of *intent*, and the intent-laden term *attempt*: “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 Specifically, agencies should not *attempt* to bind affected persons through policy statements.”¹²

Anthony was correct to say that regulated parties often feel they have no practical choice but to follow a guidance document (I stress that I say *often*, not *always*). Anthony was also correct to say that such parties can be effectively shut out of all participation, for they can neither engage in notice-and-comment on the policy when it is generally formulated nor exercise any real choice or voice once the policy is applied to them individually. But I believe Anthony was mistaken to view this phenomenon primarily in terms of the agency’s “intent” to produce this unhappy outcome. Moreover, his focus on intent gave his report a tone of accusation and blame when in fact the problem of guidance is largely one of institution-level behavior that nobody fully intends: it requires an institutional-reform response rather than an indictment.

That regulated parties often (though not always) feel strong pressure to follow guidance is absolutely true, but the origins of this fact 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 are vastly beyond the control of the agency officials who are issuing a guidance document.¹³ (The pressure I am discussing here is the kind that exists when the guidance is operative, i.e., when the agency has not granted a regulated party’s request for a dispensation from the guidance. Dispensations are addressed in Part III, to be summarized a bit later.)

¹¹ Peter L. Strauss, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1488 n.74 (1992) (recalling with respect to Conference deliberations on the recommendation: “Focusing on the references to ‘independent basis’ in note 3 and Part III of Recommendation 92-2, I would argue that I won; but Professor Anthony might claim he did. What is clear is that the Recommendation applies to the situations Professor Anthony and I agree about—where the agency tries to treat its policy as an *independent* source of obligation. [Anthony’s] wish to extend the [recommendation] to ‘practical effect’—our disagreement—was in my judgment rejected”).

¹² ACUS Recommendation 92-2, point I.A (emphasis added).

¹³ Insofar as agency officials did 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 vastly beyond what officials are thinking about with respect to a guidance document.

Part II of this Report discusses four of these structural features that incentivize regulated parties to follow guidance documents when operative. 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, not from any regulatory agency.¹⁴ 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 probable 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, to get the accusation meaningfully examined and adjudicated by an official distinct from the enforcement personnel. This creates a strong incentive to avoid being accused in the first place.

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

¹⁴ The rise of compliance personnel has occurred largely in the years since Anthony wrote his report.

guidance is relatively less likely to be followed, according to interviews. I note that in all these areas, the four structural features discussed above are mostly weak or absent. This finding indicates that the pressure to follow guidance, though real, is far from universal. It is contingent on factors like pre-approval, investment in firm-agency relationships, compliance personnel cohorts, and certain structures of ex post enforcement.

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 consciously 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. That cannot be right.

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. As a former EPA program office director said in a recollection of such a scenario, “you’re aware of your leverage.”¹⁵ But this argument does not

¹⁵ Interview with Source 71, former EPA program office director. William Funk raised this issue of an agency’s subjective awareness of its structural leverage in a brief theoretical discussion: “While these general statements of policy cannot be used to bind persons, they may effectively coerce persons into compliance because of the fear of agency enforcement or adverse agency rulings in adjudications. Or, they may provide assurance of a safe harbor from enforcement to persons if they take certain actions. Thus, to an agency, if persons act on the basis of the general statements of policy, these statements may be almost as effective as legislative rules.” William Funk, *A Primer on Nonlegislative Rules*, 53 Admin. L. Rev. 1321, 1333 (2001). Funk later discussed a related point, that an agency may be subjectively aware of structural barriers to *judicial review* and consciously take advantage of them in deciding what policies to adopt through guidance: “Regulated entities, unable to obtain pre-enforcement review of a questionable nonlegislative rule, are put in the unenviable position of having to conform to the questionable rule or willfully act contrary to its terms. In many cases, the risk analysis will counsel in favor of complying with the rule,

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 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. But the courts rejected that doctrine decades ago in favor of the present “binding effect” test—a rejection that Anthony himself did not question.¹⁶

If we really want to protect regulated parties from feeling strongly pressured to follow guidance, we would have to reform quite substantially 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,¹⁷ 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.¹⁸ 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 those relationships from forming (as by rotating agency personnel), yet doing so would dramatically increase information costs to the agency,¹⁹ and might incline it to become more impersonal, exacting, and punitive.²⁰ The rise of the compliance profession has been attacked as a stealth reform imposed on corporate America by unelected and ill-informed

even when the doubts as to the lawfulness of the rule are substantial. Agencies act with the knowledge that their nonlegislative rules may escape pre-enforcement review, and they may count on the coercive (extortionate) effect of the unreviewable rule to achieve compliance even when they might be very reluctant to test the validity of their rule in an actual enforcement action.” *Id.* at 1340.

¹⁶ The only mentions of “substantial impact” in Anthony’s article are in one quotation from a long string of quotations on which he does not specifically comment, Anthony, *supra* note 7, at 1357 (quoting *Levesque v. Block*, 723 F.2d 182-83 (1st Cir. 1983)), and in a footnote where he notes the doctrine’s rejection, *id.* at 1376 n.370.

¹⁷ Richard A. Epstein, *The Permit Power Meets the Constitution*, 81 *Iowa L. Rev.* 407 (1995)

¹⁸ 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) (on the use of general permits).

¹⁹ 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”).

²⁰ If a regulator has a continuing series of interactions with a regulated party, it 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* (1992).

DOJ prosecutors,²¹ but corporate compliance programs are now the norm across many industries 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 personnel²²—these, too, have high costs and wide-ranging implications.

But if structural features will create a strong incentive to follow certain guidance whenever the guidance is operative—a point we must take as given in the short to medium term—there is still one escape hatch: the agency itself is in control of whether the guidance is operative for any particular regulated party. Per the D.C. Circuit’s test, a policy qualifies as guidance rather than a legislative rule if the agency “reserves discretion” to depart from it in any given case. As Anthony memorably phrased it, this requires the agency to keep an “open mind.” In his words: “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.”²³ ACUS Recommendation 92-2 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,” “at or before the time” when the guidance is applied to the party.²⁴ In the words of the D.C. Circuit, the guidance must not be a “binding norm” but instead leave “the agency and its decisionmakers free to exercise discretion.”²⁵ The court held that a guidance document preserved the required discretion when it ensured that “the agency’s position” on the subject matter of the guidance “remains flexible.”²⁶

²¹ Sean J. Griffith, *Corporate Governance in an Era of Compliance*, 57 Wm. & Mary L. Rev. 2075, 2117-30 (2016).

²² Rachel E. Barkow, *Overseeing Agency Enforcement*, 84 Geo. Wash. L. Rev. 1129, 1143-50 (2016).

²³ Anthony, *supra* note 7, at 1362. See also *id.* at 1329-30, 1374-75.

²⁴ ACUS Recommendation 92-2, Point II.B.

²⁵ *Center for Auto Safety v. NHTSA*, 452 F.3d 798, 806 (D.C. Cir. 2006) (quoting *CropLife Am. v. Evtl. Protection Agency*, 329 F.3d 876, 883 (D.C. Cir. 2003)).

²⁶ *Id.* at 809. For other helpful formulations of the agency’s obligation, see Anthony, *supra* note 7, at 1316 (“the agency should stand ready to entertain challenges to the [guidance] in particular proceedings to which the document may apply, and should observe a disciplined system for maintaining an ‘open mind’ when passing upon such challenges”); Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 Duke L.J. 1497, 1500 (1992) (“The essence of the agency’s duty” is “first, to allow the challenger to present a case, and second, to respond meaningfully to that case”).

Yet, in Anthony's view, the agency's mind was frequently closed, and intentionally so, though it was easy for the agency to hide this fact:

Where the [guidance document] reserves discretion to decide cases individually and to vary the standards, 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. Of course the agency heads may be genuinely uncertain about what they will want to do when cases arise. The trick is to distinguish their announcements in these situations of authentic uncertainty (as to which legislative rulemaking is not required) 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).²⁷

Thus, the focus on intent that generally informed Anthony's view of guidance was especially intense when it came to the agency's open-mindedness and flexibility (or lack thereof).

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 could have a burdensome and coercive effect on regulated parties who wanted to do things differently from the guidance. But again, I believe the focus on "intent" obscures more than it illuminates.

In Part III, I analyze the inflexibility that agencies sometimes exhibit when using guidance, and I seek to break down the reasons for this 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 of 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.²⁸

²⁷ 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).

²⁸ Anthony did briefly acknowledge that agencies might act inflexibly for reasons other than an intentional plan to bind regulated parties. Anthony, *supra* note 7, 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.

First off, we must recognize that agencies are quite often under active stakeholder pressure *to be inflexible* (a.k.a., to be consistent) and that these stakeholder pressures spring from legitimate concerns that agencies would be remiss to 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 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 to begin with.

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*.²⁹ 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

²⁹ 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, *supra* note 11, at 1472-73, 1485-86. See also John F. Manning, *Nonlegislative Rules*, 72 *Geo. Wash. L. Rev.* 893, 933-37 (2004); Thomas W. Merrill, *The Accardi Principle*, 74 *Geo. Wash. L. Rev.* 569, 598 (2006); Levin, *supra* note 3, at 28.

departure will tamp down the number of departures and make it easier to anticipate when departures may happen. In some contexts (though certainly not all), principled flexibility may be required by the APA's arbitrary-or-capricious standard, though it is not practical to think judicial enforcement will be the main driving force behind agencies' adoption of it.

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 who have especially limited time and lack fine-grained information about the matters they are reviewing. This renders departures yet harder to grant. A former senior EPA official now in private practice, reflecting on these factors, expressed frustration with EPA personnel's rigid use of guidance but did not accuse them of bad faith: “they feel stuck,” she said.³⁰ Another interviewee—a former EPA program office director—recognized that “theoretically” there was supposed to be an “out” when administering a guidance document, but concluded that “programmatic” factors “overwhelmed” that.³¹

On top of these organizational and resource-based obstacles to principled flexibility, there are additional such 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 appeals may antagonize the frontline officials, creating fears of retaliation (a fear that can still have consequences even if baseless). 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

³⁰ Interview with Source 52, partner in large law firm and former senior EPA official.

³¹ Interview with Source 71, former EPA program office director.

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.

In light of the findings in Parts II and III, what is to be done? In formulating new recommendations on agency use of guidance, we must recognize that the pressure on regulated parties to follow guidance when operative is often (though not always) substantial, but that this pressure does not arise mainly from agencies' intentional acts. 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. The implication is that being flexible in a good way requires spending resources and undertaking active managerial reform, meaning that 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 II, (b) the less it is subject to the legitimate external pressures for consistency discussed at the start of Part III, 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 III, 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 to effectively invoke the norm against the career officials and vice versa.

Part IV considers the peculiar phenomenon of deregulatory guidance, i.e., 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. If this guidance shifts the status quo in a more industry-friendly direction, one can expect regulated parties to alter their behavior so as to follow it, not because of any of the quasi-coercive structural features discussed in Part II, but simply because it is what they want to do. But 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 (i.e., so that 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 flexibility operates at the micro-level 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 seek 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 or modified at a general level. This will usually be the form of participation most suited to NGOs’ limited resources.

Part V provides a general assessment of how and whether agencies should voluntarily provide for public participation in the initial formulation and issuance of guidance documents, as distinct from providing flexibility in the documents’ on-the-ground application once issued. This

form of participation may be especially suited to regulatory beneficiaries, as noted in Part IV, but it can also be quite valuable to regulated parties and to the agency itself.

There are diverse means by which agencies can seek public input on the formulation and issuance of a guidance document. The agency can reach out individually to selected stakeholders whom it already knows; it can hold public discussions on developing the guidance at stakeholder meetings, workshops, forums, roundtables, sessions at conferences, webinars, or other such events (for which invitations will often be distributed through agency listservs); it can use an advisory committee as a channel for public participation; or it can voluntarily undertake notice and comment on a published draft of the guidance document before adopting the guidance, which is the maximal option in terms of broad, open, and impersonal participation. Note, however, that voluntary notice and comment on guidance is still usually much faster and less costly than legislative rulemaking, since it does not involve the same demands in terms of cost-benefit analytic requirements, record-building and voluminous responses to comments in contemplation of judicial review, etc.

In deciding what level of public participation to seek on the issuance of guidance—and especially in deciding whether to undertake voluntary notice and comment on it—an agency must weigh several potential benefits and costs. One potential benefit is the technical information that stakeholders may provide, which may greatly improve the guidance (e.g., by helping the agency anticipate and account for potential implementation problems). That said, broadening participation (with notice and comment being the maximum) may see diminishing returns on this front, depending on how concentrated or diffuse the actors with useful information are. If information is concentrated, then narrow outreach to a few stakeholders may provide just as good technical information at much less cost.

A second potential benefit of notice and comment on guidance is that it gives the agency better political information, that is, helps the agency anticipate which stakeholders may challenge the guidance at a political or legal level, so the agency can make a better-informed decision on whether to proceed and how, diminishing the likelihood of being overridden by Congress or the courts. That said, there is enough inertia in agency-stakeholder interactions that, if the agency refrains for seeking input and simply issues the guidance, stakeholders may acquiesce in a way they would not if the agency were openly tentative about the initiative. Tentativeness can sometimes invite resistance.

A third potential benefit of notice and comment on guidance is that it may increase the legitimacy of the guidance and of the agency itself, in the sense of giving stakeholders a sense that the agency issues guidance through a fair process in which they have “buy-in,” which may increase stakeholder willingness to cooperate with and support the agency and its program. There are at least three specific ways in which notice and comment can increase legitimacy, though each has its complications and limits. First, notice and comment can give stakeholders confidence that the agency understands and is responsive to their concerns. But this is a double-edged sword, for under some circumstances notice and comment can come to seem like an empty gesture and might therefore alienate stakeholders (e.g., if the agency rarely makes changes in response to comments, or finds the cost of giving a response to comments prohibitive). Second, notice and comment can foster legitimacy by deflecting charges that an agency is biased in terms of which voices it is willing to hear. This point seems especially important for NGOs, some of whose officials see notice and comment as leveling the playing field between them and industry. Public comment also allays the fear that lurks in officials’ minds about being accused of favoritism. Yet that very anxiety can lead agencies not only to undertake notice and comment but also to *close off* any interchanges with stakeholders that occur outside the public-comment process, which some industry representatives thought was counter-productive, since it prevents iterative and informal dialogue that may be optimal for agency learning. Third, notice and comment may increase legitimacy simply by broadening the pool of participants, as exemplified by the fact that some draft guidance documents have recently been focal points for “mass comment” campaigns sponsored by advocacy groups, rising to the tens of thousands of comments. If the rulemaking context is any guide, however, agencies have tended to ignore such mass comments, or to use them only in an opportunistic way; it is not entirely clear how agencies can use such comments meaningfully, as they are not usually written to be part of a deliberative and analytic decisionmaking process, as opposed to a plebiscitary one.

Against the potentially great yet uncertain benefits of notice and comment on guidance (technical and political information and legitimacy), one must measure the costs, in time and resources. Several interviewees pointed out that, if agency personnel responsible for guidance expend effort to seek public input on the guidance they issue, they will have less capacity to issue guidance on other subjects, leaving regulated parties adrift in some areas. One major question is whether the agency should provide a response to the comments it receives: this

renders participation more meaningful, yet it greatly increases the cost to the agency. Further, it is possible that the cost of participation may rise so high as to seriously hamper the agency's capacity to make policy at all, which may actually *delegitimize* the agency in the eyes of regulatory beneficiaries—an unintended and extremely perverse consequence.

Thus, the potential benefits and costs of notice and comment on guidance are numerous, they vary with context, and they are sometimes counter-intuitive. Notice and comment will often be worth it, but deciding whether it is involves a context-specific judgment.

For this reason, decisions about whether to seek notice and comment on guidance should be made document-by-document, or perhaps agency-by-agency, in the sense that an agency can adopt a procedural rule requiring notice and comment for an objectively-defined broad category of its guidance. But a government-wide requirement for notice and comment on anything but the very most extraordinary guidance documents would be rash.³² Making decisions on participation on a narrower basis allows for more learning about what works best, and it cabins the consequences of any decisions that do not turn out well.

Further, broad mandates for notice and comment on guidance (even if only agency-wide rather than government-wide) risk two major unintended consequences, which interviews confirm have sometimes come to pass. First, if there is an agency-wide procedural rule requiring notice and comment for a large category of guidance, and the agency lacks the resources to process all the comments it receives on all the documents, the agency may end up leaving many guidance documents in published “draft” form indefinitely, without officially adopting them. When regulated parties have incentives to comply with whatever they perceive to be the agency's wishes (as described in Part II), those parties may take a draft guidance document to be a reflection of those wishes, and they may therefore follow its content, regardless of its draft status. This outcome defeats the purpose of notice and comment. And it can actually be even worse than that. It is possible that *most* of the guidance documents left indefinitely in draft are in that state because of the agency's insufficient resources, while *some* remain indefinitely in draft because there is too much disagreement within the agency to reach a decision about which comments to accept. Regulated parties are well-advised to follow guidance that reflects the

³² The Office of Management and Budget's Good Guidance Practices, calling for pre-adoption public comment on “economically significant” guidance documents, appear to cover only a relatively tiny number of these very extraordinary documents. See *infra* text and notes 650-658.

agency's view but is held up due to lack of resources, but *not* to follow guidance that is held up because the agency cannot come to any agreed-upon view. Yet it may be difficult for regulated parties to tell what the reason is for the holdup of any particular draft. The result is that regulated parties are left guessing, which increases their decisionmaking costs and the risks they bear and un-levels the playing field among regulated competitors. In addition, indefinite draft status can prevent the agency from achieving principled flexibility in its use of guidance, since whenever the agency wants to depart from guidance, it will be tempting simply to say "it's only a draft," rather than go to the trouble of articulating the real policy reason for departing.

A second major unintended consequence that may arise from a broad mandate for notice and comment on guidance is that guidance may thereby become *so legitimate*—in the eyes of agency officials and/or stakeholders or political overseers—that it may come near to replacing legislative rulemaking altogether. This would not necessarily be a bad outcome; some critics think legislative rulemaking's process burdens have risen too high, and this would be a means of radically reducing them. I take no position on this question, but there is no doubt that it is a profound one. If we categorically adopt notice and comment for guidance on a broad basis, we may find that this profound question effectively gets decided without us thinking about it, unless we couple the participatory mandate with some safeguard to ensure that legislative rulemaking continues to be undertaken for some substantial fraction of the agency's policies.

While I advise that decisions about notice and comment on guidance should have a scope no broader than an individual agency, I am not saying that such decisions should be left to the agency itself. As we shall see, there are examples of congressional overseers and the White House putting pressure on particular agencies with respect to their participation policies for guidance, or even their participation decisions regarding individual documents. The demands of congressional overseers and the White House play a salutary role on this subject, but those demands are most likely to be well-conceived when pitched at a workable level of specificity.

B. The Scope of the Report: Two Notes

1. Policy Statements versus Interpretive Rules

This Report's scope, in its broadest definition, includes all agency statements that fall into the categories of "interpretative rules" or "general statements of policy" under § 553 of the

APA. “Interpretative rules” (which I shall call interpretive rules, following modern usage) were defined in the *Attorney General’s Manual on the Administrative Procedure Act* as “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.” “General statements of policy” (which I call policy statements, for short) were defined in the *Manual* as “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.”³³

There is general agreement that policy statements are supposed to be nonbinding on the public and on the agency, meaning regulated parties are entitled to a reasonable opportunity to contest the policy statement in general or as applied to them, in contrast to a legislative rule, which can be applied automatically.³⁴ To be sure, there is much confusion and controversy on what it practically means for a policy statement to be “nonbinding,” but there is at least agreement on what the principle is, if not on how it cashes out in day-to-day work.

As to interpretive rules, the confusion and controversy operate at a more fundamental level. There is not consensus—not among judges, not among officials, not among scholars—on whether interpretive rules are supposed to be nonbinding in the way policy statements are. Some circuit court opinions say interpretive rules are unlike policy statements in that they can be binding, but others say the opposite; the divergence is not just between circuits, but within the D.C. Circuit itself.³⁵ Among my interviewees who spoke on the subject (nearly all current or former officials), some said their agencies took the position that they could bind through interpretive rules, but more were equivocal or uncertain or rejected this view outright.³⁶ As to

³³ Attorney General’s Manual on the Administrative Procedure Act 30 n.3 (1947).

³⁴ On this general agreement, see Levin, *supra* note 3, at 18-42.

³⁵ For an excellent critical discussion of this case law, see Levin, *supra* note 3, at 42-71. Cases indicating that interpretive rules may bind include: *American Mining Congress v. MSHA*, 995 F.2d 1106, 1111 (D.C. Cir. 1993); *Syncor International Corporation v. Shalala*, 127 F.3d 90, 94-96 (D.C. Cir. 1997); *Metro. School Dist. v. Davila*, 969 F.2d 485, 493 (7th ed. 1992). The line of reasoning in these cases seems to underlie recent dicta that interpretive rules are “sometimes” final for purpose of judicial review prior to enforcement whereas policy statements can never be. *National Mining Association v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). Cases indicating that interpretive rules cannot be binding include: *Association of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 716-18 (D.C. Cir. 2015); *American Tort Reform Association v. OSHA*, 738 F.3d 387, 401, 404, 406 (D.C. Cir. 2013); *Vietnam Veterans of America v. Sec’y of the Navy*, 843 F.2d 528, 537-38 (D.C. Cir. 1988).

³⁶ The views expressed by interviewees on the binding or nonbinding status of interpretive rules—which are diverse in the aggregate and sometimes qualified in themselves—were as follows:

- Regarding EPA: An EPA official said that an interpretive rule allowed the agency to choose one reading of a statute or rule “definitively” and “generally” and to use mandatory language in a way that it could not in a policy statement (though of course the interpretive rule itself could always be changed if circumstances changed). But she added that EPA issued interpretive rules only “occasionally.” Interview with Source 99, EPA official. A second interviewee, a former senior EPA official with cross-office responsibilities, recalled the agency proceeding by interpretive rule for the specific reason that such a vehicle would be binding, though she said she only saw this

happen “once” during her tenure. Interview with Source 96, former senior EPA official with cross-office responsibilities. A third interviewee, Carrie Wehling of the EPA Office of General Counsel, distinguished between (a) non-required recommendations administered case-by-case and (b) interpretations, which she said were not case-by-case. She did not speak to the relative frequency of use of these two forms in EPA practice. Interview with Carrie Wehling, EPA Office of General Counsel. A fourth interviewee, an official at the EPA Office of General Counsel, said EPA would be “nervous” about relying on the premise that an interpretive rule could be binding, as the case law on this point was “murky.” She added that, in most instances, a guidance document consisted of a mixture of interpretive-rule material and policy-statement material that was hard to disentangle; a “pure” interpretive rule was less common. Interview with Source 61, EPA Office of General Counsel official. See also Funk, *supra* note 15, at 1332 (“general statements of policy can look like an interpretive rule, and often agencies claim both exceptions when they are challenged”). A fifth interviewee, Adam Kushner, former EPA director of civil enforcement, said the idea that interpretive rules could be binding had “never” come up in his years of EPA enforcement work. Interview with Adam Kushner, Partner, Hogan Lovells; former EPA director of civil enforcement. A sixth interviewee, a former EPA program office director, said interpretive rules were meant to be enforceable from the start but then added, “that is a legal debate.” Interview with Source 71, former EPA program office director.

- Regarding DOT: Kathryn Thomson, former general counsel of DOT, drew a distinction between policy statements and interpretive rules, saying the latter could bind. Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA.

- Regarding the Department of Education: A civil rights advocate said that a clarification of the famous 1979 “policy interpretation” of Title IX was not meant to be merely “suggestive”; rather it was understood there would be enforcement proceedings for noncompliance with it. Interview with Source 23, civil rights advocate.

- Regarding the Department of Energy: A DOE Office of General Counsel official said an interpretive rule did not involve a reservation of case-by-case discretion in the way a policy statement did. Yet, she said, she could imagine a regulated party making a successful showing that a different interpretation was necessary as to that party, e.g., because the party’s product could not possibly do something the interpretive rule assumed it could do. She could not recall this actually coming up, possibly because the enabling statute provided other safety valves for such eventualities (e.g., exception relief). Interview with Source 3, Department of Energy Office of General Counsel official.

- Regarding CFPB: A former CFPB official who represents CFPB-regulated entities said that, to her knowledge, CFPB had issued only two statements called “interpretive rules” that it asserted did not have to go through notice and comment. Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

- Regarding FDA: An FDA Office of Policy official explained that, under FDA’s Good Guidance Practices, all guidance, whether interpretive in nature or not, was uniformly treated as nonbinding on the agency and the public. For this reason, she said, the distinction between policy statements and interpretive rules did not matter much to FDA. Interview with Source 25, FDA Office of Policy official. Notably, the 1997 legislation instructing FDA to implement the Good Guidance Practices refers only to “guidance documents,” not to policy statements or interpretive rules, and says such documents “shall not create or confer any rights for or on any person” and “shall not be binding on [FDA].” 21 U.S.C. § 371(h)(1). One could argue that this legislation repeals the APA’s distinction between policy statements and interpretive rules as to FDA.

- Regarding CMS: A former CMS division director, when discussing flexibility in guidance, said CMS thought mostly in terms of interpretive rules, not policy statements, and viewed guidance as telling regulated parties how they *must* proceed. Asked whether this treatment of interpretive rules was premised on case law suggesting that interpretive rules could bind, she said “I guess” CMS thought of it that way, but really, it was a “fool’s errand” to make sense of that case law. Also, later in the interview, she made clear that CMS often did entertain requests for departures from guidance, although these had a higher chance of success if they were couched as requests for reinterpretations of the guidance, as opposed to departures outright. Interview with Source 93, former CMS division director.

- Regarding DOL: Marc Freedman, the U.S. Chamber of Commerce’s executive director of labor law policy, said the Chamber assumed that, when DOL issued guidance, it intended to make that guidance “stick”—the Department would not commit resources to issuing a document to which it would not adhere—but when asked about the theory that *interpretive status* conferred power to bind, he said that “seems academic” and did not suggest DOL was consciously operating on that theory. Interview with Marc Freedman, Executive Director of Labor Law Policy, U.S. Chamber of Commerce.

scholarship, Anthony took the position that interpretive rules could be binding, on the ground that they merely “restate[d] or explain[ed]” the content of a statute or legislative rule that was itself binding.³⁷ But other commentators have criticized that view.³⁸ The most elaborate and recent critique, by Ronald Levin, points out that treating interpretive rules in this manner effectively deprives regulated parties of the opportunity for input *both* at the stage of promulgation *and* at the stage of implementation. According to Levin, there is nothing special about the interpretive status of an agency statement that justifies shutting out input in this way. The act of interpretation is creative and discretionary,³⁹ and a premise of our adversary system is that decisionmaking on legal questions benefits from the input of affected parties.⁴⁰ Notably, Levin does not question that an interpretive rule can legitimately *contain mandatory language*, insofar as it is glossing a statute or legislative rule that is itself mandatory, but he contends that the agency is obligated to remain open-minded about departing from that interpretation in response to regulated-party input.⁴¹

My aim in this report is to study the fraught question of how agencies can appropriately issue and use statements that are supposed to be nonbinding. That is the subject that concerned Anthony in 1992, which explains why Anthony (believing interpretive rules could bind) focused his report mostly on policy statements.⁴² Indeed, Recommendation 92-2 focuses entirely on policy statement and says nothing whatever about interpretive rules. My interest in “statements that are supposed to be nonbinding” obviously covers all policy statements, but it also covers interpretive rules insofar as people believe or assume (contra Anthony) that interpretive rules are supposed to be nonbinding.

I think that my conclusions and recommendations will be helpful to any agency seeking to figure out appropriate processes and uses for statements that it recognizes are supposed to be

• Finally, a large law firm partner, not a specialist on a particular agency, said the courts and the bar generally did understand that interpretive rules could bind, and that was how most regulated entities approached the issue. Interview with Source 68, partner in large law firm.

³⁷ Anthony, *supra* note 7, at 1324. See also *id.* at 1313-14, 1323-26, 1375-78. Anthony did urge that, as a matter of good government (not law), agencies should use notice-and-comment for any interpretive rule that “would 1) extend the scope of the jurisdiction the agency in fact exercises, 2) alter the obligations or liabilities of private parties, or 3) modify the terms on which the agency will grant entitlements,” so long as the change in interpretation was “substantial” and “does not derive in an obvious way from established norms.” *Id.* at 1377-78.

³⁸ E.g., Strauss, *supra* note 11, at 1478-79.

³⁹ Levin, *supra* note 3, at 51. See also Manning, *supra* note 29, at 923-27.

⁴⁰ Levin, *supra* note 3, at 52.

⁴¹ *Id.* at 67.

⁴² Anthony, *supra* note 7, at 1326.

nonbinding. Whether these conclusions and recommendations are applicable only to policy statements or also to interpretive rules is a question for the agencies and, potentially, for the Conference. I did not focus my research on the question of whether it was sound, as an administrative matter, to confer binding status on statements couched as “interpretive.”⁴³ The question of how to issue and use statements *once* the agency decided they would be officially nonbinding was demanding enough.

A word about terminology. In this report, I frequently use the term “guidance.” In academic writing, this is an umbrella term that covers the APA § 553 categories of policy statements and interpretive rules. In common usage among agency officials and stakeholder representatives, “guidance” usually denotes agency statements that are supposed to be nonbinding, thus covering (a) policy statements and (b) interpretive rules insofar as the speaker thinks interpretive rules are nonbinding. I use the term “guidance” in this sense, that is, agency statements that are meant to be nonbinding, though the exact scope of that category may differ depending on the point of view of the agency or even the individual speaker. The point is to capture how people grapple with the practical managerial challenge of using a statement appropriately when they think it is not supposed to be binding.

2. External Guidance versus Internal Guidance

It is common to draw a distinction between guidance that is addressed internally to the agency’s own officials and guidance that is addressed externally to regulated parties, but I have put little emphasis on that distinction in this Report. Admittedly, one might think the distinction would matter, given that the legal prohibition against binding status applies only to guidance that binds regulated parties; the requirement of nonbinding status would therefore seem irrelevant to internal guidance. But that is not so. One can imagine guidance that is nominally addressed to agency officials even as it practically binds regulated parties. If a legislative rule says the agency may grant a permit upon a showing of *A* or *B*, and a guidance document binds all the agency’s adjudicators to grant the permit only upon a showing of *A* and never upon a showing of *B*, that would seem to have a binding effect on any permit applicant who wanted to show *B*. As Michael Asimow put it, a guidance document “might be addressed either to the staff or to the public

⁴³ It was not an issue that jumped out in the interviews. While a majority of the 135 interviewees discussed the issue of guidance’s binding or nonbinding effect in some way or other, only four brought up the idea that the interpretive status of guidance entailed some special power to bind.

without any real difference in impact.”⁴⁴ The key to discerning binding effect, as ever, is whether regulated parties have a “fair opportunity” to seek departure from guidance “in an agency forum that assures adequate consideration by responsible agency officials.”⁴⁵ As the Office of Management and Budget said in its 2007 Good Guidance Practices for executive agencies, guidance can be mandatory if “addressed to agency staff” *but only* if its mandatory terms “will not foreclose agency consideration of positions advanced by affected private parties.”⁴⁶ Thus, although a guidance document can bind *frontline* agency officials, avoidance of an impermissible binding effect on regulated parties would seem to require that those parties have a reasonable chance to appeal the guidance’s application to some *higher-level* official who is not bound. As James Conrad said, “just as guidance must leave regulated entities free to challenge it before the agency, a guidance must also leave agency staff *at some level in the hierarchy* free to depart from it.”⁴⁷

The focus of the Report is on how guidance affects parties outside the agency—and how agency flexibility and public participation can help to mitigate or legitimate those effects—regardless of whether the guidance is addressed internally or externally. Insofar as guidance is truly internal in the sense of having no effect on outside parties, it is beyond the scope of this Report.

⁴⁴ Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 Mich. L. Rev. 520, 556 (1977). William Funk articulated this point with respect to guidance binding on administrative law judges. William Funk, *Legislating for Nonlegislative Rules*, 56 Admin. L. Rev. 1023, 1036 (2004) (“to allow agencies to bind ALJs to the agency’s interpretations contained in nonlegislative rules would be effectively to give those interpretations binding legal effect on persons outside the agency”); *id.* at 1037-38 (“If a general statement of policy was binding upon ALJs, . . . the effect of a general statement of policy on a regulated entity would be indistinguishable from the effect of a legislative rule”).

⁴⁵ ACUS Recommendation 92-2, Point II.B. See generally Levin, *supra* note 3, at 26-36.

⁴⁶ OMB Good Guidance Practices § II(2)(h), 72 Fed. Reg. 3432, 3440 (Jan. 25, 2007) (emphasis added).

⁴⁷ James W. Conrad Jr., *Draft Guidance on the Appropriate Use of Rules Versus Guidance*, 32 ELR News & Analysis 10721, 10724 (2002) (emphasis added). The American Bar Association has recommended that regulated parties should have an “opportunity to challenge” only guidance “respecting which public reliance or conformity is intended, reasonably to be expected, or derived from the conduct of agency officials and personnel; in particular, enforcement manuals setting internal priorities or procedures rather than standards of conduct by the public are not covered [by the recommendation in favor of opportunities for challenge], whether or not they have been in fact published or otherwise made available to the public.” ABA Recommendation 120C, 118-2 Ann. Rep. A.B.A. 57-58 (Aug. 1993). How to tell whether regulated-party reliance or conformity is “reasonably to be expected” or “derived from the conduct of agency officials and personnel”—and whether enforcement manuals could never fit these descriptions—is an interesting question. A former SEC official noted that the SEC Enforcement Division “scrupulously” follows its Enforcement Manual and that defense attorneys would “often” cite it. Interview with Source 19, former SEC official.

I. THE IMPORTANCE OF GUIDANCE

Guidance is widely understood to be an essential instrument of federal administration. Agencies and stakeholders often prefer it over case-by-case adjudication or legislative rulemaking, for a variety of reasons. The result is that guidance is ubiquitous at most agencies. Though regulated parties have sometimes complained of guidance's abuse, they also very frequently demand that it be issued.

A. Reasons to Prefer Guidance to Case-by-Case Adjudication

Agency officials and stakeholder representatives gave several examples of how decentralized case-by-case adjudication or enforcement caused problems that could be solved if only the agency provided more guidance. It was clear from these interviews that guidance increases an agency program's integrity and efficiency and shields regulated parties against unequal treatment, unnecessary work, and unnecessary risk.

One example involved the USDA National Organic Program (NOP), which confers and renews accreditations for nonfederal certifying organizations who effectively decide which producers can use the USDA organic label. Guidance can help certifiers predict how NOP will apply the relevant statutes and legislative rules when making accreditation decisions. The head of NOP, Miles McEvoy, explained that, up to 2009, the program did not have the resources to provide guidance beyond published responses to individual inquiries, which he said were confusing because each answer was so specific to the question asked, and the answers did not seem to align on related topics. Also, some regulated parties accessed this system, while others did not, which was problematic. Only after a budget increase was it possible for NOP, in 2010, to publish more general, comprehensive, and integrated guidance, which McEvoy said led to much better information and clarity.⁴⁸ An official at one of the certifying organizations said that NOP's increased provision of guidance had been helpful in getting the certifiers "all on the same page," which strengthened the "integrity" of the organic label, in contrast to the previous era when there was more variation between certifiers, causing "disruptions" in the organic trade.⁴⁹

⁴⁸ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

⁴⁹ Interview with Source 114, official at an organic certifier.

Another example, highlighting how adjudication in the absence of guidance can be inefficient, comes from EPA’s administration of the Toxic Substances Control Act (TSCA), as recently amended to provide that EPA must make up-or-down decisions on whether a new chemical presents a unreasonable risk before it can be manufactured. According to Lynn Bergeson, the managing partner of the law firm Bergeson & Campbell (which has a specialization in chemical regulation), EPA frontline decisionmakers were reluctant to take responsibility for green-light decisions; there was not enough guidance on how to make the decisions, with the result that manufacturers’ applications got held up, resulting in a backlog, causing industry to go “almost berserk.”⁵⁰ In another EPA adjudicatory scheme, in which the agency decides whether to approve state agencies’ grants of permits under the Clean Water Act, the executive director of the Environmental Council of the States explained that state agencies would like to have more up-front guidance from EPA on how it decides whether to approve. As things stand, EPA staff sometimes have an “unwritten” policy view that goes against granting a permit, resulting in EPA objecting to the permit or expressing discomfort with it in a manner that delays any decision. These post-grant holdups are problematic for the state agencies because they occur after the agencies have put in a lot of work on their decisions. More clear, up-front guidance articulating EPA’s views would help.⁵¹

Further problems with guidance’s absence in case-by-case decisionmaking arise when the context is enforcement. Bergeson explained that she was working to get EPA to ease up on using enforcement as a means for policymaking under TSCA, urging the agency instead to clarify changes in its interpretations of the law prior to bringing enforcement actions premised on those changes (e.g., through a public workshop), as enforcement without this warning results in disruption and reputational injury for the target firms.⁵² In the world of FDA enforcement, Bradley Merrill Thompson, who has been counsel to trade associations dealing with FDA, urged that FDA should provide more guidance on the obligations of medical device makers. As things stand, he explained, a company can obtain guidance from FDA in the form of a confidential

⁵⁰ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell. Months after this interview, EPA announced that the caseload on this matter was “back at the baseline and now in line with the typical active workload,” in part due to a new procedural rule signed June 22, 2017. News Release, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (August 7, 2017), available at <https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews>.

⁵¹ Interview with Alexandra Dapolito Dunn, executive director, Environmental Council of the States.

⁵² Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

letter that takes about two or three months to get, but the letter has the effect of locking the company in to whatever facts the company provided in soliciting the letter. The development of the product can later get “tied up in knots” because the company does not want to take the risk of departing from the letter’s specifics (as the letter is not necessarily applicable to any other fact pattern). More general, less fact-bound guidance would address this difficulty. In the absence of more general guidance, a company not wanting to commit itself to a particular fact pattern in an FDA letter must seek (in a typical case) an opinion from outside counsel that puts together “small and remote pieces of the puzzle,” including FDA official speeches, reports to Congress, and enforcement patterns (though there is not a complete public record of these), and does effectively a risk assessment of the product seeking to imitate what FDA would do. Even with all this material, it can be difficult to provide a clear answer.⁵³

B. Reasons to Prefer Guidance to Legislative Rulemaking

Of course the advantages of guidance cited in the preceding Section could, in principle, be achieved by announcing policy through legislative rulemaking. But interviewees gave reasons why agencies and stakeholders often preferred guidance nonetheless. First, guidance is better-suited to dealing with matters that involve uncertainty, either because the general matter being regulated (or the agency’s understanding of the matter) is likely to change rapidly, or because it is difficult to anticipate particulars that might arise in individual proceedings that would justify an ad hoc adjustment.⁵⁴ Second, guidance—because it is not legally binding—can be written in language that is accessible to parties who need to know the agency’s view but lack

⁵³ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

⁵⁴ These two factors were discussed jointly in Conrad, *supra* note 47, at 10725-10726. On uncertainty in the agency’s general understanding, see Interview with Source 83, former senior FDA Office of Chief Counsel official (stating that it is sometimes hard to do legislative rulemaking in a way that keeps up with changes in science); Interview with Source 98, former EPA program office director (stating that one reason for guidance is that the agency may not know the answers, and guidance makes it easier to revise or deviate); Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney (stating guidance is appropriate in the context of rapidly evolving scientific inquiry); Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA (stating that the need to provide clarification in a rapidly evolving industry made legislative rulemaking more difficult to use). On uncertainty about variation in individual proceedings, see Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA (stating that while a certain guidance document offered enforcement leniency in exchange for firms’ devising internal audit programs and self-reporting violations, enforcement under the document still required case-to-case judgment and therefore should not have been done through legislative rulemaking).

access to counsel, such as small employers regulated by OSHA,⁵⁵ small water utilities regulated by EPA,⁵⁶ or small trucking firms regulated by FMCSA.⁵⁷

Third—and interviewees raised this factor several times more than any other—guidance takes less time and fewer resources to issue than does a legislative rule. Numerous interviewees across multiple regulatory areas stated that guidance was less time-consuming and resource-intensive than legislative rulemaking,⁵⁸ and many others viewed this disparity (or, at least, the agency’s perception of the disparity) as a cause of agency use of guidance, though the interviewees varied in the degree to which they cast the causal link as a conscious choice by agency personnel, or a less-conscious tendency to gravitate toward less-costly means when meeting demands for policymaking.⁵⁹ Even interviewees who questioned the empirical premise

⁵⁵ Interview with Chris Trahan Cain, health and safety director, North America’s Building Trades Unions; and executive director, CPWR Center for Construction Research and Training.

⁵⁶ Interview with Source 84, former EPA Office of Water official.

⁵⁷ Interview with Source 12, 13, 14, and 15, FMCSA officials.

⁵⁸ Interview with Source 103, former senior EPA Air Program office official (stating that rulemaking is unduly cumbersome, and more resource-intensive than guidance); Interview with Source 99, EPA official (stating that rulemaking takes an “excruciatingly” long time whereas the agency is “more nimble” on guidance); Interview with Source 107, former senior FDA official (saying legislative rulemaking process is very time-consuming, whereas guidance, even with voluntary notice and comment, is much more abbreviated); Interview with Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA (stating that guidance can be provided closer to “real time” than can rulemaking, which takes a long time; by the time you complete a rulemaking, “the science may have changed”); Interview with Source 27, FDA Office of Chief Counsel official (stating that whereas rulemaking was criticized for being “ossified,” it was possible to get guidance “pretty quickly”); Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions (stating a solo Fed rulemaking would take 9-18 months whereas a solo Fed guidance would take 1 month); Interview with Jean Richardson, former chair, National Organic Standards Board (stating that USDA National Organic Program guidance even with notice and comment is much faster than legislative rulemaking); Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL (stating that an advantage to the agency of guidance is that it is less cumbersome than rulemaking, which is especially cumbersome and lengthy); Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA (stating that guidance, even with notice and comment, is much faster than legislative rulemaking); Interview with Source 122, FAA Office of Rulemaking official (stating that guidance is way faster than legislative rulemaking, though it depends on the complexity of the guidance).

⁵⁹ Interview with Source 77, former senior HHS official (recalling that HHS sometimes used guidance instead of rules when there was urgent demand for policy and it was hard to get rules out quickly); Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA (stating that, if legislative rulemaking had been required for adoption of EPA’s “audit policy” offering leniency to firms that devised internal audit programs, EPA would not have adopted the policy, partly because of the process costs of rulemaking); Interview with Source 96, former senior EPA official with cross-office responsibilities (stating that, in internal EPA discussions on whether to proceed by guidance or rulemaking, one of the factors in play was the perception that rulemaking was cumbersome and guidance easier); Interview with Source 98, former EPA program office director (stating that, as a manager, he would always prefer guidance to a legislative rule, partly because it was hard to put out a rule); Interview with Carrie Wehling, EPA Office of General Counsel (observing that legislative rulemaking in the last several years has become slower and more cumbersome even to do small things, resulting in an increase in guidance); Interview with Source 18, former CFPB official (stating guidance is attractive because it is quicker than legislative rulemaking); Interview with Source 82, congressional staffer (saying FDA personnel say that legislative rulemaking is cumbersome and they will do guidance if they can); Interview with

that guidance is far more costly than legislative rulemaking acknowledged that the agency they were discussing *believed* it was, and that this belief shaped agency behavior.⁶⁰ (Process differences between legislative rulemaking and the issuance of guidance are discussed in depth in Section V.B below.)

To some degree, the time-and-resources factor is an element of the uncertainty factor discussed above. If legislative rules could be made (and amended) rapidly and cheaply, then agencies could easily use such rules even under conditions of uncertainty, since the rules could be amended easily as the agency learned more.

But the time-and-resources factor is also its own, free-standing reason to prefer guidance. Even if there is relatively little uncertainty, an agency may implement some policies by guidance simply because the cheapness of guidance increases the number of policies an agency can implement and, therefore, the degree to which it can fulfill what it considers to be its statutory mission. As one former agency general counsel said, the capacity to make legislative rules is a scarce resource, which means not all policy can be pushed through legislative rulemaking. A political appointee deciding the agency's agenda, facing short tenure and a limited discretionary budget, will be acutely aware of this.⁶¹ To be sure, an agency opting for guidance on certain policies thereby gives up legally-binding status for those policies, but as we shall see in Part II, regulated parties often have strong incentives to follow guidance regardless of its legal status. Agencies' use of guidance to expand their policymaking capacity is a practice often criticized by industry (as we shall see throughout this Report), but a great deal of policymaking is in industry's interest, either because of its substance or merely because it provides clarity.

Source 83, former senior FDA Office of Chief Counsel official (stating he appreciates why FDA likes guidance, there being several reasons, one of which is that legislative rulemaking is laborious); Interview with Source 104, law firm partner who deals frequently with FDA and CMS (saying FDA defaults to using guidance, that it is hard for FDA to get rules out, and that FDA often says rulemaking is too hard); Interview with Source 24, trade association official (stating that on the agency side the reason to proceed by guidance is to avoid red tape); Interview with Daniel Troy, General Counsel, GlaxoSmithKline (stating FDA is averse to rulemaking because they think it takes too long); Interview with Jake Lewin, President, CCOF Certification Services (stating that guidance is a legitimate process especially when you cannot practically get rules made); Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL (stating that, as rulemaking has become more difficult, complex, and rare, from a legal and political standpoint, guidance comes to substitute for rulemaking, with allegations that rulemaking is being circumvented); Interview with Source 35, AFL-CIO official (stating that guidance is necessary because rulemaking is so cumbersome and adversarial); Interview with Sources 12, 13, 14, and 15, FMCSA officials (stating the agency has some preference for guidance because it is faster than rulemaking, which has many hurdles).

⁶⁰ Interview with Coleen Klasmeier, head of Sidley Austin's FDA regulatory practice; former FDA OCC attorney; Interview with Source 20, former FDA official.

⁶¹ Interview with Source 69, former agency general counsel.

Regarding FDA, which industry has sometimes criticized for its overuse of guidance, an executive at a drug manufacturer said he could see the argument “in the abstract” for why legislative rulemaking was better, but he said sardonically that he preferred to know what FDA was thinking “rather than wait twenty years” for a legislative rulemaking to finish. Guidance, he said, is “the best you can do.”⁶²

To be sure, this attitude fatalistically accepts the extreme costliness, in time and resources, of legislative rulemaking. One might argue that legislative rulemaking can and should be made less costly, or even that agencies are systematically overestimating its actual costs. These are important questions, but they are beyond the scope of this Report. I take as given that agencies, for a variety of reasons (including the cost of rulemaking), will produce guidance, and I focus on how that guidance ought to be issued and administered.

Still—as an aside and an invitation to future research—I must note that the extreme costliness of legislative rulemaking does not appear inevitable, for some agencies or offices finish legislative rulemakings faster than others. This may seem surprising, given that agencies are generally constrained by the same notice-and-comment process and the same kind of judicial review. But as a few interviewees noted, constraints are not the whole story. There can be differences in agencies’ or offices’ affirmative motivations to get rulemaking finished, often driven by statutory and court deadlines, which, if frequent enough, can instill an agency or office with a more general capacity for speed and decisiveness.

One example is EPA’s Air Program office. A former senior EPA official with cross-office responsibilities said that that office was faster at rulemaking than EPA’s other major program offices. “The more you do rulemaking, the less you fear doing it,” he said, noting that the Air Program office did a higher volume of rules than any other, and it had routinized the process in a way the others had not.⁶³ A former senior official from the Air Program office agreed that it was faster, putting out rules in two or three years while other EPA program offices took four or five. That the Air Program office had turned itself into “a rule-writing machine” was due, he said, to the Clean Air Act amendments of 1990, which set forth a clear set of rulemakings that had to be done; the implementation process was written into the statute. He emphasized the importance of court deadlines as a driving factor, triggered by deadlines in the

⁶² Interview with Source 108, executive at a drug manufacturer.

⁶³ Interview with Source 96, former senior EPA official with cross-office responsibilities.

statute, meaning the office did not wait for consensus before acting, in the way that other offices did.⁶⁴

Another part of the bureaucracy that does legislative rulemaking relatively quickly is CMS. A law firm partner who works frequently with CMS and FDA said that, whereas FDA often used guidance when he believed it should have used legislative rulemaking, CMS was much better about this; it was “more comfortable” with doing rules. One important reason, he said, was that CMS was subject to statutory deadlines for many of its rules and simply had to get them out. The experience of regularly having to meet these deadlines gave CMS a higher “comfort level” with overriding controversy and just going ahead with a rule; its personnel were willing to disagree with unhappy stakeholders and say “sue me,” with an understanding that the disagreement was not to be taken personally. Even when making policy on matters not subject to a statutory deadline, CMS would sometimes make policies on those matters and tack them on to the rules that were deadline-driven.⁶⁵

All that said, organizations like the EPA Air Program office and CMS appear to be exceptional, and, even at those organizations, legislative rulemaking takes large amounts of time and resources in an absolute sense. Reducing the cost of legislative rulemaking is potentially a worthy mission for the future, but for now, we have little choice but to recognize guidance’s relative attractiveness and think about how it should be issued and administered.

C. The Ubiquity of Guidance

Given that it is often more attractive than pure case-by-case adjudication or legislative rulemaking, agencies use guidance very frequently and regard it as essential to their missions. A former senior HHS official said it would be “impossible” to operate Medicare without guidance.⁶⁶ A former senior FDA official said, “I cannot imagine a world without guidance.”⁶⁷ Guidance is “the bread and butter of agency practice,” said an EPA official.⁶⁸ Providing it is an

⁶⁴ Interview with Source 103, former senior EPA Air Program office official.

⁶⁵ Interview with Source 104, law firm partner who deals frequently with CMS and FDA.

⁶⁶ Interview with Source 77, former senior HHS official.

⁶⁷ Interview with Source 80, former senior FDA official.

⁶⁸ Interview with Carrie Wehling, Office of General Counsel, EPA.

“essential responsibility,” said a former OSHA official.⁶⁹ Observers predicted that, if anything, the role of guidance would grow in the future, as regulation becomes more performance-based: when no particular means of compliance is specified in the legislative rule, regulated parties will want the agency to suggest one.⁷⁰

There is no comprehensive compilation of guidance, but everyone agrees its volume is oceanic.⁷¹ Its provision is a “big part” of EPA operations in the aggregate, said an EPA official.⁷² Medicare’s legislative rules are “the tip of the iceberg,” said a former senior HHS official, and guidance is the iceberg.⁷³ Nobody really knows the volume of agencies’ guidance, said a trade association official, but it is orders of magnitude greater than that of legislative rules.⁷⁴

D. Stakeholders’ Demand for Guidance

It also seems that, for most regulated parties most of the time, guidance is a much-needed resource that they would not want to do without—and may actively demand.⁷⁵ Without guidance, said Charles Samuels, counsel to the home appliance manufacturers’ association, we would be “cast adrift” in terms of what the agency regulating us thinks.⁷⁶ Even interviewees who mounted very substantial critiques of what they considered the abuse of guidance recognized that much guidance was nonetheless essential. Marc Freedman, the U.S. Chamber of Commerce’s executive director of labor law policy, went into depth on what he considered OSHA’s improper use of guidance but readily acknowledged that businesses sometimes demanded guidance and that it was quite reasonable for the agency to provide it to clarify vague

⁶⁹ Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

⁷⁰ Interview with Source 122, FAA Office of Rulemaking official; Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

⁷¹ Strauss, *supra* note 11, at 1468-69; 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*].

⁷² Interview with Source 61, EPA Office of General Counsel official.

⁷³ Interview with Source 77, former senior HHS official.

⁷⁴ Interview with Source 2, trade association official.

⁷⁵ On the point that guidance’s function is largely to provide assurances that benefit regulated parties, meaning that a focus on complaints or litigation about guidance may mislead as to its aggregate effects, see Strauss, *supra* note 11, esp. 1474-75, 1483.

⁷⁶ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

legislative rules (the problem being if guidance effectively changed the legislative rules).⁷⁷ A congressional staffer noted that even those who argued that FDA improperly over-used guidance on some subjects simultaneously wanted the agency to issue *more* guidance *faster* on other subjects.⁷⁸ Anthony himself acknowledged, if only very briefly, that guidance “generally serves the important function of informing staff and the public about agency positions, and in the great majority of instances is proper and indeed very valuable.”⁷⁹

Indeed, it will often be harder for an agency *not* to issue guidance than to issue it, since refraining from issuing guidance may require remaining resolutely silent in the face of regulated parties’ entreaties for clarification. When regulated firms come to EPA saying they are confused and need something explained, said a former program office director at the agency, “EPA’s instinct is to answer the question.”⁸⁰ Once the agency starts answering questions, it is hard to keep those answers secret. The same interviewee gave an example of how EPA clarificatory letters could be obtained by a regulated party through the Freedom of Information Act.⁸¹ Another former EPA program office director recalled that, once his office began issuing such individualized answers in the form of letters, those letters got “passed around” among industry, and parties besides the addressees began to rely upon them.⁸² And once guidance is being provided to individuals who seek it, the agency begins to see that it would be more efficient and fair to provide that guidance in the form of more general public documents. A former SEC official recalled that, decades ago, he spent 30 hours per week on “phone duty,” answering the inquiries of regulated parties who called in. The giving of advice in this ad hoc manner by individual staff members, he said, was inferior to the provision of general guidance, toward which the SEC more recently shifted. More general guidance was better because ad-hoc advice-giving led to inconsistency between answers, ate up more staff time, and created an unlevel

⁷⁷ Interview with Marc Freedman, Executive Director of Labor Law Policy, U.S. Chamber of Commerce.

⁷⁸ Interview with Source 82, congressional staffer. See also Interview with Source 25, FDA Office of Policy official (acknowledging that FDA does not provide as much guidance as industry would like). But see Interview with Source 73, general counsel of Fortune 500 company (arguing that really his industry’s preference is for legislative rulemaking, which is easier to find out about, and does a better job of providing guardrails in which to act, so industry can gear up for compliance).

⁷⁹ Anthony, *supra* note 7, at 1317.

⁸⁰ Interview with Source 71, former EPA program office director.

⁸¹ *Id.*

⁸² Interview with Source 98, former EPA program office director.

playing field among regulated parties, some of whom phoned while others did not.⁸³ Thus, unless an agency shuts itself off from stakeholder demands, or foregoes obvious means to increase efficiency and fairness, it is going to end up issuing guidance.

II. 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) intra-firm constituencies for compliance beyond legal requirements, and (D) the risks associated with one-off enforcement. The Part concludes (in Section 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 or reimbursement, etc.⁸⁴ The strength of the incentive varies with four factors.

⁸³ Interview with Source 46, former SEC official. See also Asimow, *supra* note 4, at 388 (noting that guidance “permits everyone who must deal with the agency equal access to vital information, thus diminishing the advantage held by experienced professionals or former agency staff members”). See also Interview with Source 40, former SEC official (describing SEC efforts to make guidance more generally available and transparent so as to provide more equal access for regulated parties).

⁸⁴ The strong incentive that regulated parties have to follow guidance in a pre-approval regime is briefly discussed by Anthony, *supra* note 7, at 1340, and by Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 Yale L.J. 782, 803-04 (2010). For an in-depth theoretical treatment of how pre-approval regimes generally give agencies more leverage over regulated parties than do ex post enforcement regimes, see Ashutosh Bhagwat, *Modes of Regulatory Enforcement and the Problem of Administrative Discretion*, 50 Hastings L.J. 1275 (1999). 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). Bhagwat makes a brief reference to FDA guidance but

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 pre-application 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.⁸⁵ 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 re-applying successfully after its initial application is denied, which cost includes any non-reusable investment made in that initial application. If the re-application requires a costly redo of the initial submission, or worse, investment in a different product or service to begin with, 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, or if agency delay is subject to a time limit or efficacious complaint system, or if the agency must decide requests in a queue. But

only to say that FDA has sometimes resisted providing it in clear form, *id.* at 1325-26 & n.156, not that FDA's preapproval authority renders its guidance practically binding.

⁸⁵ For an argument that USDA has chosen not to scrutinize license renewal applications for regulated parties' noncompliance under the Animal Welfare Act, thus causing a pre-approval scheme to operate as if it were an ex post enforcement scheme, see Delcianna J. Winders, *Administrative License Renewal and Due Process—A Case Study*, 47 Fla. L. Rev. (forthcoming 2018), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2952062. See also *People for the Ethical Treatment of Animals v. USDA*, 861 F.3d 502 (4th Cir. 2017) (upholding the approach discussed by Winders).

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.

A classic pre-approval regime is the statutory requirement that drugs and medical devices be approved by FDA as safe and effective before marketing. Consistent with this, interviewees observed that FDA's published guidance documents have extremely strong influence on how drug and device makers go about designing studies and, concomitantly, how they go about designing 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.⁸⁶ Given the nature of premarket approval, explained one food and drug industry attorney when discussing conformity to guidance, an applicant must anticipate how FDA thinks; it would be “foolish” to proceed with an application without following the agency's guidance.⁸⁷ 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 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 FDA would not accept this protocol “before I spent \$100 million on it!”⁸⁸ 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.⁸⁹ The general counsel of GlaxoSmithKline stated that, especially on pre-market approvals (as compared with other dealings between drugmakers and the agency), if FDA says, “jump,” you ask, “how

⁸⁶ For an argument that 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 Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 Neb. L. Rev. 89, 122-24, 130-37 (2014) [hereinafter Noah, *Governance*]. For additional discussion of FDA extraction of concessions by way of its licensing powers, see Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 Wis. L. Rev. 873, 876-84 (1997) [hereinafter Noah, *Arm-Twisting*].

⁸⁷ Interview with Source 92, food and drug industry attorney. The interviewee added that one could go to FDA before submitting the application and “work something out” beforehand regarding departure from guidance; on that process, see Part III below.

⁸⁸ Interview with Source 110, former senior FDA official.

⁸⁹ Interview with Source 20, former FDA official.

high?”⁹⁰ When 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 pre-market approval (as distinct from other FDA-industry interactions), companies will always follow the draft’s contents, with almost no exception, because pre-market approval decisions are discretionary and the draft represents FDA’s latest thinking on the matter. It would be “folly” not to follow it.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 FDA holding high leverage over industry because the context was pre-market approval. It is on *post*-approval industry activities, they said, that industry compliance becomes a serious problem.⁹²

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 FDA to decide an application is still variable enough that observers think following guidance significantly helps a firm get more quickly to market.⁹³ 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 FDA has great discretion on matters like delay; companies will follow guidance to get their applications approved faster.⁹⁴ Another former

⁹⁰ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

⁹¹ Interview with Source 24, trade association official. I found additional evidence for guidance’s peculiar force in pre-market approval in: Interview with Source 78, partner in large law firm and former senior federal official (noting that, while exclusion from Medicare is always hanging over drugmakers’ heads, pre-market approval issues are what cause companies to follow guidance all the time on a day-to-day basis); Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney (noting firms know they must follow certain FDA guidance if it is in a licensing situation, since otherwise they will jeopardize the license); Interview with Source 108, executive at a drug manufacturer (stating that whether to depart from guidance in the absence of a prior assurance from FDA depends on a risk-based calculation that is very situation-dependent but noting that, in the specific context of pre-market approval, it would be a pretty high risk to depart); Interview with Source 82, congressional staffer (stating that guidance in the pre-market approval context gets close to the same level of compliance as a legislative rule, given the investments involved, while there is maybe a little less compliance with guidance in the post-approval context).

⁹² Interview with Michael Carome, Director, and Sammy Almashat, Research Associate, Public Citizen Health Research Group.

⁹³ 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. Poli. Sci. 98 (2011).

⁹⁴ Interview with Source 78, partner in large law firm and former senior federal official.

senior FDA official likewise said that on pre-market review the reason to follow guidance is to obtain approval faster.⁹⁵

As a former senior FDA official noted, agency personnel will engage in presubmission 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 FDA's published guidance documents, which the agency cites and always follows in these communications, albeit with some latitude for interpretation.⁹⁶ And even with this back-and-forth, 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.⁹⁷ 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 EPA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a maker of pesticides cannot sell a new product until it obtains registration from EPA, which requires showing, by way of scientific studies, that the product is not unreasonably risky. 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 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, since the office can more easily evaluate a submission that does follow the guidance, so the manufacturer will obtain approval quicker. Industry thus cares intensely about this pre-registration 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

⁹⁵ Interview with Source 80, former senior FDA official.

⁹⁶ Interview with Source 110, former senior FDA official.

⁹⁷ Interview with Source 20, former FDA official.

review every 15 years, but even then, if 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 EPA wants something, the manufacturer is in a strong position to say, “thanks, we’re not interested.” The incentive is no longer there.⁹⁸

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 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.⁹⁹

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. Whatever that office says, observed a partner in a 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 by itself puts at risk the company’s investment. 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

⁹⁸ Interview with Source 41, EPA official.

⁹⁹ Interview with Source 96, former senior EPA official with cross-office responsibilities.

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 EPA relatively hard in a way that the automakers are not willing to push EPA regarding tailpipe emission certifications.¹⁰⁰

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. A certifier that fails to get or maintain accreditation is out of business. As noted by a former chair of NOP’s National Organic Standards Board (NOSB), the five-year renewal process involves an in-depth audit in which NOP goes over 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 NOP expects. The legislative rules and the audit are complicated enough that NOP will inevitably find some noncompliance that it will tell the certifier to correct. Though 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.¹⁰¹ 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,¹⁰² and (b) NOP, upon finding noncompliance within that process, will give the certifier time to correct it.¹⁰³ Thus, this is not quite like FDA, where an applicant defying guidance risks being denied outright and unable to sell its product.¹⁰⁴ The certifier departing from guidance is not immediately at risk of outright shutdown but will have a chance to come into compliance if NOP should insist upon the course outlined in the guidance.¹⁰⁵ However, explained the former NOSB chair, initial noncompliance findings can lead to incremental sanctions short of losing accreditation, like fines.¹⁰⁶ Plus, noted the president of a

¹⁰⁰ Interview with Source 52, partner in large law firm and former senior EPA official.

¹⁰¹ Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

¹⁰² 7 CFR § 205.510(c)(2).

¹⁰³ 7 CFR § 205.507(a).

¹⁰⁴ Of course the difference between FDA and 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.

¹⁰⁵ 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, risking denial of accreditation, which can take away “your ability to function.” Interview with Jake Lewin, President, CCOF Certification Services.

¹⁰⁶ Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

large certifier, the noncompliance warning itself can have collateral consequences like bad publicity.¹⁰⁷ Faced with this mix of incentives—and given the sense among certifiers that the integrity of organic food is their common endeavor with NOP¹⁰⁸—certifiers have strong reason to follow guidance. NOP’s top official noted certain guidance documents about which certifiers were complaining even as they complied with them “reluctantly.”¹⁰⁹ 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.¹¹⁰

Beyond permission to sell a product or provide a service, the incentives of pre-approval also kick in when a regulated party seeks money from the government. When it comes to Medicare reimbursement, a former CMS division director said 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 HHS Office of Inspector General or 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. Non-payment, she said, is the “scenario feared” by healthcare providers and is independent of the False Claims Act (which, she acknowledged, is “also very scary”).¹¹¹ 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.¹¹²

¹⁰⁷ Interview with Jake Lewin, President, CCOF Certification Services.

¹⁰⁸ Interview with Jake Lewin, President, CCOF Certification Services; Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

¹⁰⁹ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA. Within the overall mix of incentives, accreditation is said to be “pretty significant” and a “big deal.” Interview with Jake Lewin, President, CCOF Certification Services.

¹¹⁰ Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

¹¹¹ Interview with Source 93, former CMS division director.

¹¹² Interview with Source 24, trade association official.

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, if a regulated party wins the trust and confidence of the agency—that is, builds a reputation with the agency for generally seeking in good faith to comply and cooperate—then the agency is likely to (a) reduce its scrutiny of the regulated party, thus diminishing the chance of the agency finding arguably noncompliant conduct to begin with, and also diminishing the process costs borne by the regulated party of being scrutinized or investigated, and (b) give the regulated party the benefit of the doubt if and when the agency does discover arguably noncompliant conduct, by interpreting that conduct as relatively less deserving of adverse consequences (e.g., as accidental rather than deliberate).¹¹³

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 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*

¹¹³ Treatments of agency-regulatee relationships in the literature, from which this discussion draws, include: Carpenter, *supra* note 19, at 662-84; Winston Harrington, *Enforcement Leverage When Penalties Are Restricted*, 37 J. Public Economics 29 (1988); David P. McCaffrey, Amy E. Smith, and Ignacio J. Martinez-Moyano, "Then Let's Have a Dialogue"; *Interdependence and Negotiation in a Cohesive Regulatory System*, 17 J. Pub. Admin. Res. & Theory 307 (2006), esp. *id.* at 323.

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 toward, 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 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 to 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 to 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, say, three weeks, empowered to inspect whatever internal documents they want and 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.¹¹⁴ 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

¹¹⁴ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

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 weighing on the bank’s ability to obtain the agency approval that is required to engage in certain expansionary activities, such as opening new branches or undertaking a merger.¹¹⁵ 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. OCC covers nationally-chartered banks; the Federal Reserve covers state-chartered banks that are members of the Federal Reserve System, and also bank holding companies; FDIC covers state-chartered banks that are not members of the Federal Reserve System; and CFPB covers large banks (national or state) for consumer protection issues. 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 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 multi-week 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.¹¹⁶ 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.¹¹⁷ To give one example cited by an interviewee: CFPB made certain demands on a bank, the bank disagreed, and OCC then said it would not allow the bank to grow until it settled with CFPB, on the ground

¹¹⁵ Interview with Source 51, Federal Reserve official.

¹¹⁶ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

¹¹⁷ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

that a dispute with CFPB over bad consumer practices would undermine the bank's safety and soundness.¹¹⁸

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 should follow it or have a compelling reason why not; 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.¹¹⁹ 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 good faith—that you are trying 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."¹²⁰

¹¹⁸ Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

¹¹⁹ 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.

¹²⁰ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions. Another interviewee, who held senior posts at 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

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.¹²¹ Another former CFPB official, who now counsels CFPB-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’re 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.”¹²² (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 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.¹²³)

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.

she was somewhat more qualified in characterizing its level of influence. When guidance is issued, she said, most banks accept that the issuing agenc(ies) expect 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, person who held senior posts at CFPB and other federal agencies.

¹²¹ Interview with Source 18, former CFPB official.

¹²² Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

¹²³ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

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. If (say) 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).¹²⁴

While banking is an especially strong example, the link between relationships and guidance comes up at other agencies, notably EPA. For one thing, a regulated party may face EPA pre-approval requirements on a repeated basis, meaning the incentives associated with pre-approvals per se are coupled with the incentives associated with maintaining a trusting relationship to 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 the agency has so few inspectors in proportion to its jurisdiction that each employer regulated by OSHA can be inspected only once every 70 years on average. But, he noted, 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).¹²⁵ The same dynamic operates elsewhere at EPA. A partner in a large law firm and former senior EPA official said that regulated parties wanted to maintain a good relationship with EPA whenever they had continuing need for pre-

¹²⁴ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

¹²⁵ Interview with David Sarvadi, Partner, Keller Heckman.

approvals. She cited, *inter alia*, automakers seeking tailpipe emission certifications and electrical utilities seeking approvals for modifications to facilities and selection of fuels.¹²⁶

But it is not just within pre-approval regimes that regulated parties feel a need to maintain relationships with 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 EPA's air enforcement division (2003-08) and of its entire civil enforcement office (2008-12), said that since the 1990s corporations and environmental enforcers had become more cooperative with each other. (This is consistent with a secondary literature on the gradual acceptance of environmental regulation within many large corporations.¹²⁷) The more "forward-leaning" firms, he observed, will now work toward settlements to ensure a "continuing good relationship" with 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 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 EPA that they do not want to disrupt. Of course, these companies can still violate and there will still be enforcement against them, but it occurs against a backdrop of trust and good faith.¹²⁸ (Environmental violations, according to one classic analysis, are "usually inadvertent.")¹²⁹ Similarly, a senior environmental counsel at a Fortune 100 company said that a good relationship with 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

¹²⁶ Interview with Source 52, partner in large law firm and former senior EPA official.

¹²⁷ 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).

¹²⁸ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

¹²⁹ Harrington, *supra* note 113, at 32.

essentially because of a “bad relationship”—because someone at the company has “pissed someone at the agency off,” by “stonewalling,” “being an a--hole.”¹³⁰

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.¹³¹ Second, guidance can be the means by which EPA fosters mutually trusting exchanges between the agency and firms. For example, under a policy statement known as the “audit policy,” adopted by EPA in 1995, if companies adopt internal audit and compliance programs and self-disclose the violations discovered thereby, EPA makes a (nominally nonbinding) promise that it will reduce penalties for those violations.¹³² A statistical study of the period 1993-2003 found that firms that engaged in such self-disclosure of Clean Air Act violations not only got 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. The study also found that firms adopting internal audit systems had better environmental performance than otherwise comparable firms, indicating that the policy does what EPA wants it to do.¹³³ 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,¹³⁴ information disclosure being a key element of trust. Third, adherence to guidance pertaining to substantive conduct is often a condition in EPA’s settlement offers,¹³⁵ 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

¹³⁰ Interview with Source 119, senior environmental counsel at a Fortune 100 company.

¹³¹ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

¹³² 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 (April 11, 2000).

¹³³ Michael W. Toffel & Jodi L. Short, *Coming Clean and Cleaning Up: Does Voluntary Self-Reporting Indicate Effective Self-Policing?*, 54 J. Law & 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. Law & Econ. 271, 272 (2008).

¹³⁴ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

¹³⁵ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

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.¹³⁶ 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.

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 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.” Carpenter views this as largely salutary, or at least inevitable, for “a resource-constrained and uncertain regulator is compelled to rely partially upon trust.”¹³⁷ Taking a more negative perspective, Lars Noah cites accusations from the 1990s that 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.”¹³⁸

Interviewees agreed that relationships mattered at 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, 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 FDA could not afford to get “crosswise” with the agency. Industry therefore does what the agency says.¹³⁹ 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 FDA; if a company could show the agency that it was “on the

¹³⁶ Christopher S. Decker, *Corporate Environmentalism and Environmental Statutory Permitting*, 46 J. Law & Econ. 103 (2003).

¹³⁷ Carpenter, *supra* note 19, at 663.

¹³⁸ Noah, *Governance*, *supra* note 86, at 123-24.

¹³⁹ Interview with Source 83, former senior FDA Office of Chief Counsel official.

right track” in an area like manufacturing, the agency would grant it relief from inspections, so as to focus resources on higher-risk firms.¹⁴⁰ 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 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 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 FDA’s wishes outside that context.¹⁴¹

Some interviewees, though agreeing that regulated parties *perceived* maintaining good relationships (partly by following guidance) to be important for successful dealings with FDA, thought this perception had little to no basis in the reality of 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 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 FDA on non-approval issues could “spill over” to pre-approval issues, but the fears are overblown.¹⁴² Similarly, Coleen Klasmeier, the head of Sidley Austin’s FDA regulatory practice, said that companies’ attitudes toward FDA’s pre-approval process and adherence to

¹⁴⁰ Interview with Source 80, former senior FDA official.

¹⁴¹ Interview with Source 133, official at national public interest organization. One other interviewee stated that, if following FDA guidance involves minor annoyance, a company will go along, because, as an FDA-regulated entity, it does not want to antagonize the agency. Because the firm has so many interactions with the regulator, it does not want to poke the regulator in the eye. But if guidance created a strong problem for the firm’s business, there might be more willingness to challenge the agency. Interview with Source 82, congressional staffer.

¹⁴² Interview with Source 78, partner in large law firm and former senior federal official.

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.”¹⁴³ 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.¹⁴⁴

Whereas companies’ relationships to 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.¹⁴⁵ 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. You do not want CMS people to think you are “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 the CMS program officials do not follow them.)¹⁴⁶

I did not have a chance during interviews to get deep into questions about the importance (or not) of relationships and their connection (if any) to guidance at the USDA National Organic

¹⁴³ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney.

¹⁴⁴ Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson and Company.

¹⁴⁵ Interview with Source 24, trade association official.

¹⁴⁶ Interview Source 58, healthcare industry attorney (with over 15 years’ experience in the field).

Program or the Department of Energy appliance standards program. But I was told that, at NOP, a certifier's performance on one audit helps determine how frequently the agency will come back for future audits,¹⁴⁷ and that, at DOE, a company that is "known to be a problem" will get more enforcement attention.¹⁴⁸

C. Intra-Firm 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 on a firm's adherence to guidance often fall to employees whose 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 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. 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 FDA.¹⁴⁹ 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.¹⁵⁰ 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 "make sure that compliance means the same thing to all internal arms."¹⁵¹ The RA profession continues to grow, and the role of these departments has become less "paper-pushing"

¹⁴⁷ Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

¹⁴⁸ Interview with Andrew DeLaski, Executive Director, Appliance Standards Awareness Project.

¹⁴⁹ Carpenter, *supra* note 19, at 646.

¹⁵⁰ Carpenter, *supra* note 19, at 644-46.

¹⁵¹ Carpenter, *supra* note 19, at 644, 662-63

and more “strategic,” including involvement in the early design of company products. RA professionals usually have backgrounds in science or engineering, not law.¹⁵²

In the view of Coleen Klasmeier, the head of Sidley Austin’s FDA regulatory practice and formerly a career attorney in 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 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 FDA, and the RA people see guidance as “the law,” no matter 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 FDA or to self-determine that the company would make such a departure. It is the lawyers 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.¹⁵³

Consistent with this, Daniel Troy, the general counsel of GlaxoSmithKline, observed that RA personnel were very reluctant to challenge FDA. “What they really *have*,” he said, is their “relationship” to the agency.¹⁵⁴ A partner in a large law firm healthcare practice likewise found RA professionals to be “very deferential” toward 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.¹⁵⁵

¹⁵² Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson and Company.

¹⁵³ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney.

¹⁵⁴ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

¹⁵⁵ Interview with Source 101, partner in large law firm healthcare practice. Another interviewee, in a line of discussion that was more about different players’ understanding 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 HHS official.

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 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 were to get into a dispute with an FDA reviewer and escalate the matter to a higher level within the agency, or if they had to make a call on whether something was lawful, but 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 did follow guidance documents (even when FDA had only issued them in draft) but that he did approach reviewers to seek departures from such documents from time to time, noting 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 to avoid "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 bring a lawyer to such a meeting; he had brought lawyers to only a handful of FDA meetings in his 25-year career; and he tried to avoid bringing lawyers to meetings, for it did not lead to a constructive solution.¹⁵⁶ (For his 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."¹⁵⁷)

RA professionals concentrated in the FDA realm are not the only intra-firm 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. New provisions in the U.S. Sentencing Guidelines in 1991 encouraged firms to build compliance programs, and DOJ and other agencies have furthered the trend through their enforcement activities, making the buildup of compliance infrastructure a condition of settlement in prosecution and enforcement.¹⁵⁸ Accordingly, "firms have gone on a hiring spree to staff compliance, with large firms adding hundreds, even thousands, of compliance

¹⁵⁶ Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson and Company.

¹⁵⁷ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

¹⁵⁸ Griffith, *supra* note 21, at 2084-92.

officers at a time.”¹⁵⁹ 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.¹⁶⁰ As to nuts and bolts, compliance officers assess the firm’s environment, develop internal policies accordingly, disseminate those policies within the firm (including training sessions), monitor employees’ adherence to internal policies, investigate violations, and defend the compliance program from external review, including by regulators.¹⁶¹

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.”¹⁶² In terms of organizational structure, “there is little uniformity to how corporations implement their compliance function.”¹⁶³ 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.¹⁶⁴ Compliance officers now have their own professional association and credentialing process, and many want to have their own autonomous departments.¹⁶⁵ 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.¹⁶⁶

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.”¹⁶⁷ “The lawyers tell you whether you can do

¹⁵⁹ Griffith, *supra* note 21, at 2077.

¹⁶⁰ Griffith, *supra* note 21, at 2082. See also Donald C. Langevoort, *Cultures of Compliance*, 54 Am. Crim. L. Rev. 933, 942 (2017) (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”).

¹⁶¹ 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).

¹⁶² Michele DeStefano, *Creating a Culture of Compliance: Why Departmentalization May Not Be the Answer*, 10 Hastings Bus. L.J. 71, 102 (2014).

¹⁶³ DeStefano, *supra* note 162, at 73; see also Griffith, *supra* note 21, at 2101-02.

¹⁶⁴ Bird & Park, *supra* note 161, at 203-07.

¹⁶⁵ DeStefano, *supra* note 162, at 110; Bird & Park, *supra* note 161, at 216-17.

¹⁶⁶ DeStefano, *supra* note 162, at 103-04.

¹⁶⁷ Griffith, *supra* note 21, at 2124-25.

something,” said the HHS Inspector General’s Chief Counsel in 2009, “and compliance tells you whether you should.”¹⁶⁸ 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.”¹⁶⁹ 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.”¹⁷⁰ 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 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.¹⁷¹

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 have a tendency 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,

¹⁶⁸ Quoted in Jim Edwards, *Pfizer’s Lawyers Play Musical Chairs in Wake of Bextra Settlement*, CBS News, Sept. 23, 2009, available at <https://www.cbsnews.com/news/pfizers-lawyers-play-musical-chairs-in-wake-of-bextra-settlement>.

¹⁶⁹ Quoted in Bird & Park, *supra* note 161, at 206 (discussing this point of view).

¹⁷⁰ Quoted in DeStefano, *supra* note 162, at 149.

¹⁷¹ Bird & Park, *supra* note 161, at 234-35.

even within the same industry,¹⁷² and there is little public data on the matter.¹⁷³ 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),¹⁷⁴ 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.¹⁷⁵

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

¹⁷² E.g., Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry (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).

¹⁷³ Griffith, *supra* note 21, at 2100 (noting that questions about the organization and 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).

¹⁷⁴ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC official (noting the distinct roles of these personnel).

¹⁷⁵ Interview with Source 78, partner in large law firm and former senior federal official.

since otherwise they would run the risk of 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.¹⁷⁶ According to an interviewee who held senior posts at 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. 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.¹⁷⁷

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 Administrative Procedure Act, 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.¹⁷⁸

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

¹⁷⁶ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

¹⁷⁷ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

¹⁷⁸ Interview Source 58, healthcare industry attorney (with over 15 years’ experience in the field). 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, partner in large law firm healthcare practice. Another interviewee—drawing from experience with CPSC, Department of Energy appliance standards, and EPA’s Energy Star program—observed there was a tension within corporations between compliance people (more conservative about adherence guidance) and marketing people (more aggressive), though he found in-house counsel to be on the conservative side, even more so than the compliance people. Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

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 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.¹⁷⁹

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.¹⁸⁰ Other intermediaries playing a similar role with respect to guidance include "technical assistance providers" helping small water

¹⁷⁹ Interview with Source 73, general counsel of Fortune 500 company.

¹⁸⁰ Interview with Source 93, former CMS division director.

utilities regulated by EPA;¹⁸¹ consultants known as “field men” who advise organic wholesalers regulated by USDA;¹⁸² and commercial testing laboratories hired by small appliance sellers subject to the Department of Energy’s energy efficiency standards.¹⁸³

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.¹⁸⁴ Because guidance suggests what the agency considers to be lawful (or unlawful), or announces what conduct the agency will (or will not) enforce against, 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 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

¹⁸¹ Interview with Source 84, former EPA Office of Water official.

¹⁸² Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

¹⁸³ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

¹⁸⁴ 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 B above. This Section focuses on the enforcement proceeding’s consequences in isolation from any larger relationship.

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” (that is, the “probability” of enforcement “times” the “damage” to the business in the event of enforcement).¹⁸⁵

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:

1. Probability of Detection

This probability depends on many circumstances and can change over time. To start with, 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 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.”¹⁸⁶ 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 in which 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.¹⁸⁷ 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 by which they target audits at healthcare providers who are statistical outliers in their billing behavior.¹⁸⁸ Under the

¹⁸⁵ Interview with Source 108, executive at a drug manufacturer.

¹⁸⁶ Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA.

¹⁸⁷ Wayne B. Gray & Jay P. Shimshack, *The Effectiveness of Environmental Monitoring and Enforcement: A Review of the Empirical Evidence*, 5 *Review of Environmental Economics and Policy* 3, 5 (2011). On criminal prosecution for avoiding permitting (and with it reporting), see David M. Uhlmann, *Prosecutorial Discretion and Environmental Crime*, 38 *Harv. Environmental L. Rev.* 159, 200-02 (2014).

¹⁸⁸ Interview with Source 93, former CMS division director.

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.¹⁸⁹ It has happened that a firm catching its competitor not complying will turn that competitor in to the Department.¹⁹⁰

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*.

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.¹⁹¹ So did the seizure of computers and records, which by itself could put some firms out of business.¹⁹² 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 EPA]”—partly because of legal bills but more importantly because of the distraction to the business internally, e.g., fighting an enforcement action meant “the top EHS guy at a refinery” would have to focus on the litigation instead of the business’s operations.¹⁹³ A former SEC official similarly cited internal disruption to the business as a major reason to avoid enforcement activity to begin with, regardless of its outcome.¹⁹⁴

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

¹⁸⁹ Interview with Andrew DeLaski, Executive Director, Appliance Standards Awareness Project.

¹⁹⁰ Interview with Sources 3, 4, and 5, Department of Energy Office of General Counsel officials.

¹⁹¹ Interview with Source 17, former OMB official.

¹⁹² Interview with Source 93, former CMS division director.

¹⁹³ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA. One interviewee briefly mentioned the power of FDA, through litigation by DOJ, to seize products on a preliminary basis. Interview with Source 82, congressional staffer. 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 84, at 1293. See also Noah, *Governance*, *supra* note 86, at 125 (noting a few examples of firm concessions in the face of seizure threats).

¹⁹⁴ Interview with Source 19, former SEC official.

activities to the public, naming the parties targeted, and not always with many safeguards.¹⁹⁵ 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 (a) 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, but (b) 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 favorable terms to do so, thereby reducing the company's profits.¹⁹⁶ Thus, bad publicity in itself is costly to regulated parties, but mainly in areas like fraud and product safety, rather than environmental regulation.¹⁹⁷ These statistical findings are

¹⁹⁵ Nathan Cortez, Agency Publicity in the Internet Era, Report to the Administrative Conference of the United States (Sept. 25, 2015).

¹⁹⁶ 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 Journal of Financial and 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 Gallemler et al., *The Reputational Costs of Tax Avoidance*, 31 Contemporary Accounting Research 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*, Journal of Business Ethics, published online July 11, 2016.

¹⁹⁷ 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 at a 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 Journal of Economic Literature 51, 75 (2012). See also Interview with James Conrad, Conrad Law and Policy Counsel; formerly Assistant General Counsel at the American Chemistry Council (noting the "hardest battles" for chemical manufacturers involve local-government decisions like zoning and that a firm does not want trouble with EPA that would spill over to the local level).

consistent with interviewee comments that companies would follow guidance to avoid the reputational harm of a warning letter from FDA,¹⁹⁸ or a noncompliance letter from the USDA National Organic Program,¹⁹⁹ or an enforcement proceeding by a banking regulator,²⁰⁰ or by the SEC.²⁰¹ 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.²⁰²

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 incentivized large firms to follow guidance, but not small ones, for whom reputation did not matter.²⁰³ 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 FDA noted that a warning letter from the agency could prompt such suits.²⁰⁴ 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 the sum of penalties imposed against the industry in that same period by the federal government.²⁰⁵ As for class actions that follow on

¹⁹⁸ Interview with Daniel Troy, General Counsel, GlaxoSmithKline (citing his company’s practice of closely studying all FDA OPDP letters).

¹⁹⁹ Interview with Jake Lewin, President, CCOF Certification Services.

²⁰⁰ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry. Compare Interview with Source 18, former CFPB official (observing that 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).

²⁰¹ Interview with Source 19, former SEC official; Interview with Source 40, former SEC official.

²⁰² Interview with Source 19, former SEC official.

²⁰³ Interview with Source 56, official at a public interest group.

²⁰⁴ Interview with Daniel Troy, General Counsel, GlaxoSmithKline; Interview with Source 82, congressional staffer; Interview with Source 83, former senior FDA Office of Chief Counsel official.

²⁰⁵ Calculations based on Sammy Almashat et al., *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015* (March 31, 2016), at 43 (fig. 11), 45 (fig. 13).

enforcement, there seems to be little published data.²⁰⁶ A former senior official at the FDA Office of Chief Counsel said, regarding consumer protection suits against the food industry premised on FDA warnings letters that in turn rested on noncompliance with guidance, “the Chobanis of the world can handle these lawsuits,” but “they hurt small companies.”²⁰⁷

Finally, especially as to 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 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.²⁰⁸

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 III 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

²⁰⁶ 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).

²⁰⁷ Interview with Source 83, former senior FDA Office of Chief Counsel official.

²⁰⁸ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

guidance, only four cited the prospect of judicial deference as one such reason.²⁰⁹ 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* or *Seminole Rock* 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.²¹⁰

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. 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.²¹¹ 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 deferential *Chevron* framework or the supposedly super-deferential *Auer* framework, but instead under the *Skidmore* framework, which offers the weakest deference of the three.²¹² 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

²⁰⁹ Interview with Source 68, partner in a large law firm; Interview with Source 38, AFL-CIO official; Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL; Interview with Richard Stoll, Partner, Foley and Lardner. 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 EPA official.

²¹⁰ Interview with Source 68, partner in a large law firm.

²¹¹ William M. Yeatman, *An Empirical Defense of Auer Step Zero*, 106 Geo. L.J. (forthcoming 2018), manuscript at 55, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2831651; Cynthia Barmore, *Auer in Action: Deference after Talk America*, 76 Ohio State L.J. 813, 827 (2015).

²¹² The data for the three deference regimes are in Yeatman, *supra* note 211, at 51. 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 25.

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.²¹³ 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 HHS Office of Inspector General’s power to exclude firms and individuals from participation in federal healthcare programs such as Medicare, the threat appears credible. In recent years HHS OIG has annually excluded around 3,000 to 4,000 persons or firms (some permanently, others not).²¹⁴ The list of excluded entities is “peppered with the names of home health agencies and [durable medical equipment] companies.”²¹⁵ And while “[h]istorically” HHS OIG has “declined to use” exclusion against hospitals, given the collateral consequences, there have been “rare exceptions” showing the agency will pull the trigger.²¹⁶ 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).²¹⁷ The closings confirm that exclusion is “an organizational death sentence.”²¹⁸

²¹³ Barkow, *supra* note 22, at 1148, 1163-65.

²¹⁴ Judith A. Waltz & Adam Hepworth, *Medicare and Medicaid Administrative Enforcement*, 2017 Health L. Handbook 4 (May 2017), text at note 13.

²¹⁵ Jonathan Feld & Howard O’Leary Jr., *Criminal Prosecution of Hospitals: Unnecessary Treatment*, 26 Health Lawyer 1, 1 (2014).

²¹⁶ *Id.* at 1.

²¹⁷ *Id.* at 6-7 & n.2. For the number of beds at Edgewater, see Bruce Japsen, *Edgewater Medical Center Succumbs to Financial Woes*, Chicago Tribune, Dec. 7, 2001. For the number of beds at Sacred Heart, see Andrew L. Wang & Kristen Schorsch, *Sacred Heart Hospital Closes*, Crain’s Chicago Business, July 1, 2013.

²¹⁸ Feld & O’Leary, *supra* note 215, at 1.

Further, exclusion is technically available against healthcare providers for *any* false claim against the government, no matter how small.²¹⁹ While HHS’s internal guidance and practice impose the sanction far more narrowly, its technical availability confers great bargaining power on the agency.²²⁰ 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” OIG is “bluffing,” but “you can’t tell.”²²¹ 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,”²²² not least because OIG’s very power to induce settlement means that Medicare law gets made to a large degree by OIG’s practice in settled enforcement proceedings, not by judicial pronouncements in litigation.²²³ Thus are providers incentivized to follow guidance to begin with, 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 FDA said she expected HHS OIG to follow the agency’s guidance in deciding what conduct was subject to enforcement, and she then said industry’s most serious concern was the False Claims Act, very much including program exclusion.²²⁴

²¹⁹ As relevant to the False Claim Act, the Secretary’s permissive exclusion authority under 42 U.S.C. § 1320a can be invoked whenever “the Secretary determines [that the defendant] has committed an act,” 42 U.S.C. § 1320a-7(b)(7), violating either 42 U.S.C. § 1320a-7a (the Civil Monetary Penalties Act) or 42 U.S.C. § 1320a-7b (prohibiting inter alia false claims, fraud, and kickbacks). A single claim in violation of either provision is therefore sufficient under the statute to trigger exclusion. See 42 U.S.C. § 1320a-7a(i)(2) (defining a “claim” as “an application for payments for items and services under a Federal health care program”); 42 U.S.C. § 1320a-7b(a) (imposing liability for “any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program”). The regulations implementing the Secretary’s exclusion authority do not provide further restrictions. The regulation implementing 42 U.S.C. § 1320a-7a permits the “OIG [to] exclude any individual or entity that it determines has committed *an* act described in section 1128A of the Act.” 42 C.F.R. § 1001.901(a). Similarly, the regulation implementing 42 U.S.C. § 1320a-7b permits “the OIG [to] exclude any individual or entity that it determines has committed *an* act described in section 1128B(b) of the Act.” 42 C.F.R. § 1001.951(a).

²²⁰ Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J. Law & Policy 55, 66, 114, 132-37 (2003).

²²¹ Interview with Source 78, partner in large law firm and former senior federal official.

²²² Krause, *supra* note 220, at 106.

²²³ Krause, *supra* note 220, at 113-32.

²²⁴ Interview with Source 104, law firm partner who deals frequently with CMS and FDA. Compare Interview with Source 101, partner in large law firm healthcare practice (stating that, while exclusion is a major concern, criminal prohibitions by themselves would be enough to motivate widespread compliance with guidance).

While healthcare program exclusion appears to be credible as a threat and effective as a means to head off adjudication and incentivize regulated parties to follow guidance,²²⁵ 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.²²⁶

Besides exclusion, the sanction with greatest incentive power appears to be criminal punishment.²²⁷ 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 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 1,000 years total).²²⁸ 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.²²⁹ 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

²²⁵ The threat of exclusion may also be a strong incentive at other agencies. An FAA official, discussing air carriers’ receptivity to guidance, said that “certificate action”—the power to suspend or revoke a carrier’s license to fly—was “the club” that “drives and motivates behavior.” Interview with Source 10, FAA official. An interviewee who held senior posts at CFPB and other federal agencies, explaining banks’ acceptance that they had to take guidance seriously, noted that charter revocations for banks were rare, but they did happen. Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

²²⁶ 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). If the agency has the power to exclude and shut down regulated parties but never actually pulls the trigger, there is a looming question as to whether (a) the regulated parties so fear exclusion that they always satisfy the agency or (b) the agency so fears the blowback from imposing exclusion that it engages in lax enforcement. For a series of case studies of threatened use of extreme sanctions in environmental regulation that (on my reading) reflect an enduring ambiguity as to how much the regulated parties fear the sanction and how much the agency fears pulling the trigger, see Brigham Daniels, *Environmental Regulatory Nukes*, 2013 Utah L. Rev. 1505.

²²⁷ 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).

²²⁸ Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2016 at 10 (January 2017).

²²⁹ Interview with Source 101, partner in large law firm healthcare practice. See also Krause, *supra* note 220, at 109.

follow clear guidance, that would be “a huge bullseye on your back” and a “strong reason for the government to proceed.”²³⁰

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 1970.²³¹ Environmental regulation falls between the Medicare and OSHA extremes: formal liability is broad, tracking numerous civil violations with only a factual-knowledge requirement tacked on,²³² but EPA and 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.²³³ The result is annual incarceration years on the order of 100.²³⁴ Even within a single regulatory area, criminal prosecution’s role can vary over time. According to one account, the willingness of DOJ to seek criminal penalties against executives of financial institutions fell considerably between the dot-com bust of 2001-02 and the financial crisis of 2008.²³⁵

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

²³⁰ Interview with Source 93, former CMS division director.

²³¹ Eric J. Conn & Kate M. McMahon, *OSHA Criminal Cases on the Rise*, Federal Employment Law Insider (February 2016). See also Sidney A. Shapiro & Randy Rabinowitz, *Voluntary Regulatory Compliance in Theory and Practice: The Case of OSHA*, 52 Admin. L. Rev. 97 (2000) (noting, in a comparison of firms’ willingness to take part in voluntary compliance programs under EPA and OSHA, that criminal penalties under OSHA regulation are miniscule compared to those under EPA); id. at 143-44 (noting that issuance of OSHA guidelines has not resulted in compliance with agency goals).

²³² Uhlmann, *supra* note 187, at 167-71.

²³³ Uhlmann, *supra* note 187, at 193-214.

²³⁴ Enforcement Annual Results for Fiscal Year 2016, available at <https://www.epa.gov/enforcement/enforcement-annual-results-fiscal-year-2016> (93 years for sentenced defendants); Enforcement Annual Results for Fiscal Year (FY) 2015, available at https://19january2017snapshot.epa.gov/enforcement/enforcement-annual-results-fiscal-year-fy-2015_.html; Fiscal Year 2014 EPA Enforcement and Compliance Annual Results at 11 (Dec. 18, 2014), available at <https://www.epa.gov/sites/production/files/2014-12/documents/fy-2014-enforcement-annual-results-charts-12-08-14.pdf> (providing data for FY 2010 to FY 2014).

²³⁵ Jesse Eisinger, *The Chickenshit Club: Why the Justice Department Fails to Prosecute Executives* (2017).

perceived trustworthiness.²³⁶ An empirical study found that in 2001-2010 the federal government obtained convictions of 54 publicly-traded firms, of which the vast majority survived, and for the few that failed, the failure was not caused by conviction.²³⁷ That said, where companies have Andersen-like vulnerabilities (as in finance), criminal prosecution or conviction could amount to a corporate death penalty.²³⁸ Then again, DOJ has become so fully committed to deferred-prosecution agreements in the finance sector that the threat may be blunted.²³⁹

Barring an Andersen-like collapse, the most visible consequences of criminally prosecuting a firm (or civilly enforcing against it) will be monetary penalties,²⁴⁰ 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 in federal criminal fines against organizational defendants since about 2007,²⁴¹ which some interviewees picked up on.²⁴²

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.²⁴³ 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

²³⁶ Gabriel Markoff, *Arthur Andersen and the Myth of the Corporate Death Penalty: Corporate Criminal Convictions in the Twenty-First Century*, 15 U. Penn. J. Business L. 797, 827-34 (2013).

²³⁷ Markoff, *supra* note 236, at 818-27.

²³⁸ 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).

²³⁹ Markoff, *supra* note 236, at 804-12; Matthew C. Turk, *Regulation by Settlement*, 66 U. Kansas L. Rev. (forthcoming), manuscript at 5-9, 45 (April 17, 2017), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2954047.

²⁴⁰ There can also be corporate integrity agreements that call for expansion of internal compliance infrastructure and procedures (with possible outside monitoring) or injunctive relief.

²⁴¹ Brandon L. Garrett, *Too Big to Jail: How Prosecutors Compromise with Corporations* 5 (2014).

²⁴² Interview with Source 17, former OMB official (observing rising fines, both in headlines and for smaller firms); Interview with Source 56, official at public interest organization (observing that "crime does not pay anymore," given increase in penalties in areas like the Clean Water Act, though not at OSHA, whose schedule of penalties remains "pitiful" even after a 2016 increase).

²⁴³ Sonia A. Steinway, *SEC "Monetary Penalties Speaks 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 227, at 438.

manageable percentage of the revenue received from the particular product under scrutiny,”²⁴⁴ and “most” do “not significantly disrupt the pharmaceutical firm’s operations.”²⁴⁵ 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.²⁴⁶ 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).²⁴⁷ 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.²⁴⁸ 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 misconduct, which would require more onerous and risky prosecutions of individuals.²⁴⁹

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. Here I explore four areas where this appears to be the case: FTC consumer

²⁴⁴ Kevin Outterson, *Punishing Health Care Fraud—Is the GSK Settlement Sufficient?*, 367 *New England Journal of Medicine* 1082, 1083 (2012).

²⁴⁵ Rodwin, *supra* note 227, at 438.

²⁴⁶ Rodwin, *supra* note 227, at 444.

²⁴⁷ Interview with Source 119, senior environmental counsel at a Fortune 100 company.

²⁴⁸ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

²⁴⁹ Quoted in Eisinger, *supra* note 235, at 200-01.

protection, CFPB regulation of nonbank institutions, enforcement of the Clean Water Act against permitless discharges, and OSHA regulation beyond large employers.

1. FTC Consumer Protection

The consumer protection wing of the 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 did bring enforcement suits against about 25 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,” and therefore many other scams 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 to “move the goal posts” and actually change 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 preexisting 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.)²⁵⁰

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 CFPB thinks while caring little what FTC thinks. In particular, she noted, mortgage servicers followed CFPB guidance more than they followed FTC guidance.²⁵¹

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 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 (say) bank examination. As to mortgage servicers specifically, CFPB has authority to conduct examinations of them, and while it selects servicers for examination based on a set of risk-based priorities (unlike the more routinized rotating schedule employed by OCC or the Federal Reserve for banks),²⁵² 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,²⁵³ and large firms are aware that CFPB has considered mortgage servicing a high priority for examination ever since the agency was founded,²⁵⁴ and further that large firms within any high-priority industry are most

²⁵⁰ Interview with David Vladeck, Professor, Georgetown Law; former Director, Bureau of Consumer Protection, FTC. Apart from noncompliant firms like debt settlement scammers and reputable firms like large advertising agencies, Vladeck also 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 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.”

²⁵¹ Interview with Source 81, former CFPB official who represents CFPB-regulated firms.

²⁵² Steven Antonakes, *Prepared Remarks of CFPB Director Steven Antonakes at the Exchequer Club* (Feb. 18, 2015), <https://www.consumerfinance.gov/about-us/newsroom/prepared-remarks-of-cfpb-deputy-director-steven-antonakes-at-the-exchequer-club/>.

²⁵³ Government Accountability Office, *Nonbank Mortgage Servicers: Existing Regulatory Oversight Could Be Strengthened*, GAO-16-278 (March 2016), at 11-13.

²⁵⁴ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

likely to be examined, other things being equal.²⁵⁵ 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 FTC devoted only a few attorneys to mortgage servicer cases, the CFPB had whole units dedicated to that industry.²⁵⁶

2. 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. The second are nonbanks, that is, companies providing “consumer financial products or services” but do “not have a bank, thrift, or credit union charter.”²⁵⁷ 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.”²⁵⁸

In terms of sensitivity to guidance, an interviewee who held senior posts at CFPB and other federal agencies said 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 always, the large ones—were likely to behave more like banks).²⁵⁹ 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 banks’. Unlike banks, nonbanks are not required to apply to a federal regulator to carry out transactions that significantly impact their operations and growth

²⁵⁵ An institution’s market share is one of four factors deciding priority for examination. Antonakes, *supra* note 252. Another of the four factors is the size of the product market, Antonakes, *supra* note 252, and “the mortgage market is far and away the largest consumer credit market,” CFPB, *Policy Priorities Over the Next Two Years*, at 9 (Feb. 25, 2016), http://files.consumerfinance.gov/f/201602_cfpb_policy-priorities-over-the-next-two-years.pdf. The other two factors are the product’s general potential for consumer harm and risks specific to the institution. Antonakes, *supra* note 252.

²⁵⁶ Interview with Source 81, former CFPB official who represents CFPB-regulated firms.

²⁵⁷ Steve Antonakes & Peggy Twohig, *The CFPB Launches Its Nonbank Supervision Program* (Jan. 5, 2012), <https://www.consumerfinance.gov/about-us/blog/the-cfpb-launches-its-nonbank-supervision-program>.

²⁵⁸ Antonakes, *supra* note 252.

²⁵⁹ This would particularly apply to mortgage servicing, which is a concentrated market to which CFPB has long assigned a high priority for examination and enforcement.

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” and so 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.”²⁶⁰

It should also be noted that 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, when it comes to 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.²⁶¹ The significance of examinations is of interest because, if sufficiently frequent, they are more likely to result in the buildup of a relationship between agency and firm than is mere enforcement.

²⁶⁰ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

²⁶¹ Interview with Source 81, former CFPB official who represents CFPB-regulated entities. An interviewee who held senior posts at CFPB and other federal agencies noted that CFPB selects firms for examination through a risk-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 CFPB has publicly designated high priority; these firms would not ignore guidance in the way many nonbanks might. Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

3. 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 can grant permits for discharges.²⁶² 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. An owner uncertain about whether property is covered—and therefore whether (say) 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. 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, 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. Criminal penalties are also available if the defendant acted with negligence or knowledge.²⁶³

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. 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 EPA’s decisions about what discharges to enforce against ex post. One such guidance document was issued in 2003.²⁶⁴ Then, in 2006, the Supreme 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.²⁶⁵ 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

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

²⁶³ 33 U.S.C. § 1319(c), (d).

²⁶⁴ Joint Memorandum, 68 Fed. Reg. 1991 (Jan. 15, 2003).

²⁶⁵ 547 U.S. 715 (2006).

“traditional navigable water.”²⁶⁶ During the Obama administration, 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.

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 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”).²⁶⁷

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, 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

²⁶⁶ Clean Water Act Jurisdiction Following the U.S. Supreme Court’s Decision in Rapanos v. United States & Carabell v. United States (June 5, 2007); Clean Water Act Jurisdiction Following the U.S. Supreme Court’s Decision in Rapanos v. United States & Carabell v. United States (Dec. 2, 2008).

²⁶⁷ Interview with Source 97, attorney at an environmental NGO. See also Interview with Source 96, former senior EPA official with cross-office responsibilities (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).

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 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 the benefit of a legislative rule if you replace a less-clear guidance document with a more-clear guidance document. Though a more-clear 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 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 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.”²⁶⁸ 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.²⁶⁹

4. 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 29 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

²⁶⁸ Email from Mark Pollins to Randy Hill (Feb. 26, 2008), quoted in Memorandum from Majority Staff, Committee on Oversight and Government Reform, to Chairman Henry A. Waxman, Re: Decline of Clean Water Act Enforcement Program (Dec. 16, 2008), available at <http://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/20081216113810.pdf>.

²⁶⁹ Interview with Source 56, official at a public interest group.

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 “300 employees” would have “very little expertise.” And even some big companies did not much comply with OSHA guidance, as in food manufacturing.²⁷⁰ 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.”²⁷¹ Baruch Fellner, the founding partner of Gibson Dunn’s OSH practice for the last 27 years, observed that most employers made a good-faith effort to protect employee safety in substance but that 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.²⁷²

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.²⁷³ 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.”²⁷⁴ 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 2010-11 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.”²⁷⁵

²⁷⁰ Interview with John Newquist, Partner, Newquist Safety; former assistant regional administrator, OSHA.

²⁷¹ Interview with Adam Finkel, Senior Fellow and Executive Director, Program on Regulation, University of Pennsylvania; former regional administrator, OSHA.

²⁷² Interview with Baruch Fellner, Partner, Gibson Dunn.

²⁷³ Interview with Chris Trahan Cain, health and safety director, North America’s Building Trades Unions; and executive director, CPWR Center for Construction Research and Training.

²⁷⁴ Interview with Source 113, health and safety expert at a labor union.

²⁷⁵ Interview with Marc Freedman, Executive Director of Labor Law Policy, U.S. Chamber of Commerce.

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, but he added that as companies got smaller, there was less compliance with guidance. According to White, a medium or small company if 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; and some employers were simply uninterested in compliance.²⁷⁶ Jonathan Snare, an OSH partner at Morgan Lewis and former deputy solicitor of DOL, said that larger companies with safety staff would keep up with OSHA guidance and use it in their training, adding that he also had some experience with smaller contractors in construction, who had some awareness of the OSHA website and would use it to some degree.²⁷⁷ David Sarvadi, who spent more than 15 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, and he drew a contrast between compliance on matters of substance—“if somebody will die, people care about that”—and things like “paperwork exercises.”²⁷⁸ 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, though 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

²⁷⁶ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

²⁷⁷ Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL.

²⁷⁸ Interview with David Sarvadi, Partner, Keller Heckman.

associations that were raising fear about OSHA to justify their own existence to their members (more on that below).²⁷⁹

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 A through 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 29 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.²⁸⁰ On this 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 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.²⁸¹

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

²⁷⁹ Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

²⁸⁰ Calculations of the time period vary but are all on the order of a lifetime or more. Interview with Chris Trahan Cain, health and safety director, North America's Building Trades Unions; and executive director, CPWR Center for Construction Research and Training (140 years); Interview with Baruch Fellner, Partner, Gibson Dunn (125 years); Interview with David Sarvadi, Partner, Keller Heckman (70 years); Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL (noting “low ratio” without giving a number); Interview with Source 62, former senior OSHA official (140 years).

²⁸¹ Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

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.²⁸² (Note that 53% of U.S. private sector employment is in firms under 500.²⁸³) A former senior OSHA official likewise noted that many companies tasked their HR people with handling safety even though they might have no training in it.²⁸⁴

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.²⁸⁵ 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.²⁸⁶ 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 with the shortcomings of OSHA guidance.²⁸⁷ Likewise, White noted that large companies were more likely to have the expertise necessary to question whether OSHA guidance was right.²⁸⁸

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

²⁸² Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL. Compare Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL (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).

²⁸³ See the figures for 2016 in “Table F: Distribution of private sector employment by firm size class: 1993/Q1 through 2016/Q1, not seasonally adjusted,” U.S. Bureau of Labor Statistics, National Business Employment Dynamics Data by Firm Size Class, available at <https://www.bls.gov/bdm/bdmfirmsize.htm>.

²⁸⁴ Interview with Source 62, former senior OSHA official.

²⁸⁵ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL

²⁸⁶ Interview with Chris Trahan Cain, health and safety director, North America’s Building Trades Unions; and executive director, CPWR Center for Construction Research and Training.

²⁸⁷ Interview with Baruch Fellner, Partner, Gibson Dunn.

²⁸⁸ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

higher probability of being inspected,²⁸⁹ as do employers subject to OSHA “emphasis programs” for selected hazards.²⁹⁰ 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.²⁹¹ 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.²⁹² Officials at Public Citizen called OSHA fines “meaningless,” often in the range of \$3,000 to \$5,000, occasionally rising to say \$200,000.²⁹³ 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.²⁹⁴ Also, criminal convictions are vanishingly rare for OSH violations in comparison to environmental regulation or healthcare programs.²⁹⁵ 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.²⁹⁶

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

²⁸⁹ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

²⁹⁰ Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL.

²⁹¹ Interview with Baruch Fellner, Partner, Gibson Dunn.

²⁹² Interview with Source 56, official at a public interest organization. See also Shapiro & Rabinowitz, *supra* note 231, at 109 (old schedule).

²⁹³ Interview with Michael Carome and Sammy Almashat, Health Research Group, Public Citizen. OSHA’s online database of enforcement cases with \$40,000+ penalties indicates that, if one includes the 21 states where state agencies administer the statute, there have been 71 enforcement cases with initial penalties of \$200,000 or more between January 2015 and June 2017. Enforcement Cases with Initial Penalties Above \$40,000, <https://www.osha.gov/topcases/allstates.html>.

²⁹⁴ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

²⁹⁵ See *supra* text and accompanying note 231.

²⁹⁶ James Alm & Jay Shimshack, *Environmental Enforcement and Compliance: Lessons from Pollution, Safety, and Tax Settings*, 10 *Foundations and Trends in Microeconomics* 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 greater than 250 employees. Amelia M. Haviland et al., *A New Estimate of the Impact of OSHA Inspections on Manufacturing Injury Rates, 1998-2005*, 55 *Am. J. Industrial Medicine* 964 (2012).

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 regulation²⁹⁷—explained that when OSHA guidance was opposed through litigation or congressional channels, the main actors on the employer side were associations of businesses, some pan-industry that were regularly involved and some industry-specific that became involved depending on the subject matter, plus 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.²⁹⁸

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 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

²⁹⁷ E.g., *Industry Groups File Suit Against OSHA's Ergonomics Rule*, EHS Today, Nov. 15, 2002 (referring to Fellner as “industry’s chief counsel”).

²⁹⁸ Interview with Baruch Fellner, Partner, Gibson Dunn. 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* text and accompanying note 275.

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.”²⁹⁹ 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.³⁰⁰

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 institutional arrangements that can produce similar dynamics between advocacy groups and the persons they represent across the political spectrum.³⁰¹

III. 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 II.

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 of the agency to use guidance improperly. Rather, as Section 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

²⁹⁹ Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

³⁰⁰ Interview with Adam Finkel, Senior Fellow and Executive Director, Program on Regulation, University of Pennsylvania; former regional administrator, OSHA.

³⁰¹ Miriam Seifter, *Second-Order Participation in Administrative Law*, 63 UCLA L. Rev. 1333, 1338-52 (2016).

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 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 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 D: officials' antagonism when challenged, superiors' incentives to back their subordinates, the counter-intuitive nature of the rule/guidance distinction, and the fact that some bureaucratic task environments are not conducive to cooperation with regulated parties. These factors, along with those in Sections A and 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 A, and the pathologies noted in Sections C and 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 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. Notably, the commitment to guidance's substance is often concentrated among the political appointees or the career officials but not both, suggesting that the one could check the other's inflexibility.

Before we proceed, I should note that this Part analyzes agency flexibility as a matter of practical bureaucratic operations—an approach that contrasts with that of the courts in litigation challenging guidance for impermissible binding status. The courts, when evaluating flexibility, focus mainly on the text of a guidance document and whether it avoids mandatory wording (“must,” “shall,” etc.) and contains wording allowing for departures. Indeed, convincing a court to invalidate a guidance document based on evidence of its rigid *implementation*, when its *text* suggests discretion will be preserved, is quite difficult, for it presents factual questions about on-the-ground bureaucratic behavior in a context (administrative law) where discovery is limited.³⁰²

³⁰² Regarding limits on discovery, see Richard J. Pierce Jr., *Administrative Law Treatise* § 11.6 (2010).

As noted by Bradley Merrill Thompson, counsel to medical-device-maker associations, 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.”³⁰³ 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.³⁰⁴ Nor is FDA the only agency that is careful in its drafting. 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.³⁰⁵ Officials at FAA and the Department of Energy were likewise mindful that mandatory language had to be avoided.³⁰⁶ Eric Schaeffer, former director of EPA civil enforcement and head of an environmental NGO, said that EPA’s “OGC knows to put in boilerplate” disclaiming mandatory status, which would “usually satisfy a court.”³⁰⁷

The courts’ focus on the text of guidance documents may reflect judges’ sense of their own institutional competence: judges are better at examining documents than at evaluating the behavior of complex bureaucratic institutions, especially when such evaluation might require discovery against the federal government.³⁰⁸ Here in this Report, we are not bound by judicial limits, and so we can embark on a richer exploration of agency (in)flexibility than appears in the case law.

³⁰³ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

³⁰⁴ Interview with Source 108, executive at a drug manufacturer.

³⁰⁵ Interview with Carrie Wehling, Office of General Counsel, EPA; Interview with Source 99, EPA official.

³⁰⁶ Interview with Sources 3, 4, and 5, Department of Energy Office of General Counsel officials; Interview with Sources 8, 9, and 10, FAA officials.

³⁰⁷ Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA.

³⁰⁸ Cf. Levin, *supra* note 3, at 71 (“lawyers and judges depend heavily on judicial case law in defining the proper uses and abuses of guidance documents, but courts may not always have enough information or perspective to assess the elusive variables that bear on ‘practical binding effect.’ The questions that may arise include: Under what circumstances has an agency offered the addressees of a guidance document a meaningful opportunity to contest it? . . . How much influence may the document exert over agency staff or the public without being characterized as exerting ‘practical binding effect?’”).

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 got 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, as well as 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.³⁰⁹

Consider EPA enforcement, for which guidance is key on multiple levels. EPA program offices issue guidance regarding means of compliance, and 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.³¹⁰ Further, the enforcement office's own guidance provides a predictable framework for deciding what civil penalties and other sanctions to impose on a firm for what conduct.³¹¹

³⁰⁹ 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: "representatives of the regulated entities, while seeking accommodative rulings for themselves, exerted cross-checking pressures"; "Businesses were alert to, and argued against, concessions to their competitors and suppliers"; "formal equality of treatment [of regulated entities], most easily symbolized by completely stringent rules, was assumed to be a quid pro quo that had to be paid [by the agency] to win compliance." Kagan, *supra* note 29, 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. Public Admin. Research & Theory 117 (2003); Soren C. Winter & Peter J. May, *Motivation for Compliance with Environmental Regulations*, 20 J. Policy Analysis & Mgmt. 675 (2001).

³¹⁰ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

³¹¹ *Id.*

Eric Schaeffer, who served in a career position as EPA’s director of civil enforcement (1997-2002) and now heads an environmental NGO, said 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 EPA seeks something from the firm as a condition of settlement, the firm asks, “will you require this of everyone else [in the industry]?”³¹²

Similarly, Adam Kushner, who served in several career positions including civil enforcement director at EPA (2008-12) 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.) 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 EPA and settle—reducing the agency’s search and litigation costs—if they can (a) 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 competitors 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 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’s come before you. Industry, he said, “gets that.”³¹³

³¹² Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA.

³¹³ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA. 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, EPA might still insist on certain control technologies or other arrangements in the interest of evenness with prior settlements. *Id.*

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 them³¹⁴—appeared to work according to the principles of enforcement that Schaeffer and Kushner discussed. According to a statistical study of the period 1993-2003, firms that took advantage of the audit policy needed fewer inspections (saving government resources) and had better environmental performance even controlling for other factors, indicating that a company’s internal program, presumably adopted in reliance on the audit policy, actually caused better performance.³¹⁵

As to 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.”³¹⁶ 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.³¹⁷ Another food and drug industry attorney said that, while a business might sometimes seek flexibility in guidance, it would want 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 public review documents or via disclosures in litigation.³¹⁸) Consistent with all this, it seems FDA itself does not perceive industry to be clamoring for flexibility. When asked about inflexibility in guidance, an FDA Office of Policy official said the main issue with guidance at FDA was not industry complaining about inflexibility, but rather industry being

³¹⁴ Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations, 65 Fed. Reg. 19,627 (2000).

³¹⁵ Michael W. Toffel & Jodi L. Short, *Coming Clean and Cleaning Up: Does Voluntary Self-Reporting Indicate Effective Self-Policing?*, 54 J. Law & Econ. 609 (2011).

³¹⁶ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney.

³¹⁷ Interview with Source 110, former senior FDA official.

³¹⁸ Interview with Source 92, food and drug industry attorney.

confused and critical about FDA’s use of *draft* guidance (a subject I discuss in Subsection V.D.2 below).³¹⁹

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.”³²⁰ (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

³¹⁹ Interview with Source 25, FDA Office of Policy official. 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. Organic producers can choose whether to be certified by one USDA-regulated certifier or another. As an official at one certifier put it, it was not good for the program if the producers were “forum shopping” for more lenient certifiers, and NOP guidance could help prevent that by reducing variation among the certifiers, thereby creating an “even playing field” among them. Interview with Source 114, official at an organic certifier. Yet, noted the former chair of the National Organic Standards Board, there could be legitimate reasons for the agency to be flexible on guidance, such as variations in agriculture across geographic regions, and NOP did manage to provide thoughtful flexibility on such matters. But to do that, it had to “overcome” its “real fear” of “accusations of favoritism.” Due to competition among certifiers, if one seemed to have more dispensations from NOP than another, producers might gravitate to that certifier. Certifiers themselves could “get angry” over “inconsistency.” Interview with Jean Richardson, former Chair, National Organic Standards Board, USDA.

³²⁰ Interview with Source 105, Senior Director, Regulatory Affairs, Association of Home Appliance Manufacturers.

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.³²¹ 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 something and then having to switch later on.³²² 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 be a problem especially 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 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.³²³

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 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,

³²¹ Interview with Source 93, former CMS division director.

³²² Interview with James Conrad, Conrad Law and Policy Counsel; formerly Assistant General Counsel at the American Chemistry Council.

³²³ Interview with Source 119, senior environmental counsel at a Fortune 100 company.

“it depends.”³²⁴ 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 65 mile per hour speed limit, as compared to the “unclarity” that she believed characterized too great a portion of FDA guidance.³²⁵

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. 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 FDA to do an internal review of its guidance.³²⁶ Officials at Airlines for America, the principal airline trade association, said there was a general concern about consistency among FAA inspectors.³²⁷ 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 inter-agency working group to formulate a document. CFPB has joined these efforts when consumer protection issues are involved.³²⁸

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

³²⁴ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

³²⁵ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney.

³²⁶ Interview with Source 28, official at Office of Regulatory Affairs, FDA.

³²⁷ Interview with Sources 64, 65, 66, officials at Airlines for America.

³²⁸ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

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 non-industry 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.³²⁹

This dynamic seems strong at 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, 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,

³²⁹ 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 29, 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 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 7, at 1364.

“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/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.”³³⁰ A senior environmental counsel at a Fortune 100 company expressed a similar view. Seeking a favorable departure from guidance from 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?”³³¹ Consistent with this, several interviewees cited NGOs’ tendency to challenge one-off departures from EPA guidance, whether in intra-agency proceedings,³³² EPA-supervised state agency proceedings,³³³ or litigation.³³⁴

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, 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

³³⁰ Interview with Source 52, partner in large law firm and former senior EPA official.

³³¹ Interview with Source 119, senior environmental counsel at a Fortune 100 company. See also Interview with David Hawkins, director, climate program, Natural Resources Defense Council; former Assistant Administrator, Air Program Office, EPA (stating that one of the three causes of 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.

³³² Interview with Source 103, former senior official at EPA Air Program Office.

³³³ Interview with Source 128, employee at environmental NGO.

³³⁴ Interview with Source 54, former EPA official.

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.³³⁵

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 Subsection 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, asked whether he wanted FDA to be more flexible on guidance, wryly replied, “Depends on my client and what they want.”³³⁶ 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 Subsections 1 and 2 above, and dangerous because, if the agency fails to

³³⁵ Interview with Andrew DeLaski, executive director, Appliance Standards Awareness Project.

³³⁶ Interview with Source 92, food and drug industry attorney. A senior environmental counsel at a Fortune 100 company amusedly observed that industry talks about how the agency should be flexible, then “in the same breath” demands consistency: companies want “flexibility when it helps them” and “consistency when it helps them.” Interview with Source 119, senior environmental counsel at a Fortune 100 company. The president of an organic certifier regulated by the USDA National Organic Program said he was ambivalent about maintaining the generality and clarity of guidance, on the one hand, and having opportunities for individual tailoring, on the other. Interview with Jake Lewin, President, CCOF Certification Services.

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.³³⁷

This issue loomed large in interviews on 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.³³⁸ 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.³³⁹ 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.³⁴⁰

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

³³⁷ See also *supra* note 309.

³³⁸ Interview with Source 93, former CMS division director.

³³⁹ Interview with Source 67, former HHS Office of General Counsel official.

³⁴⁰ Interview with Source 77, former senior HHS official.

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.³⁴¹ At 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.”³⁴² At 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. 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. OGC, he said, tried to “rein me in.”³⁴³

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.³⁴⁴ (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 C and 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

³⁴¹ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

³⁴² Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson and Company.

³⁴³ Interview with Source 103, former senior EPA Air Program Office official.

³⁴⁴ My formulation of principled flexibility is inspired by the works of Robert Kagan and Peter Strauss, as noted in *supra* note 29.

will restrain officials from making many departures, thus preserving a good deal of stability; and while some departures would still be made, the growing body of precedents would reduce uncertainty about what they would be. As to the 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 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.³⁴⁵ 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."³⁴⁶ 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.³⁴⁷

The factors that counsel an agency to engage in principled flexibility are not just the political and organizational pressures documented in Section 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."³⁴⁸ David Hawkins, former head of 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."

³⁴⁵ See *supra* text at note 335.

³⁴⁶ Interview with Source 98, former EPA program office director.

³⁴⁷ Interview with Source 54, former EPA official.

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

Such litigation risk, said Hawkins, was one of the main reasons EPA adhered to guidance.³⁴⁹ 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.³⁵⁰ Leading commentators have argued that a 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.³⁵¹ D.C. Circuit case law on the question is not entirely clear.³⁵²

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 under-enforced. 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

³⁴⁹ Interview with David Hawkins, director, climate program, Natural Resources Defense Council; former Assistant Administrator, Air Program Office, EPA. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization. See also Interview with Source 93, former CMS division director (noting litigation risk of an arbitrary-or-capricious challenge if agency made exception to guidance).

³⁵⁰ The absence of any adjudications is hardly unheard of: in some of the contexts described in Part II where the incentives to follow guidance are strong, it may be that all regulated firms follow the guidance and thus never force an adjudication.

³⁵¹ For arguments that guidance should have this status, see Strauss, *supra* note 11, at 1472-73, 1485-86; Manning, *supra* note 29, at 933-37. 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).

³⁵² In one case, the D.C. Circuit said that, while a “pattern” of adjudications under a certain guidance document “might give rise to an obligation to explain a sudden reversal,” the document at issue was, in itself, “too vague to impose a duty of explanation standing alone,” *Vietnam Veterans of America v. Secretary of the Navy*, 843 F.2d 528, 539 (D.C. Cir. 1988), which seems to leave open the question of whether a less-vague guidance document could by itself impose such an obligation. In another case, the D.C. Circuit seemed to proceed on the premise (which it did not question) that a guidance document could impose an obligation to explain a departure, though it concluded on the merits that the agency’s adjudicatory decision was not in fact a departure. *Community for Creative Non-Violence v. Lujan*, 908 F.2d 992, 995-96 (D.C. Cir. 1990). In a later case, the D.C. Circuit said that two “policy statements” by FERC had “no precedential effect” and “no precedential value,” though it also said (apparently without making any distinction) that the statements were not “binding precedent” and had “no binding effect.” *Panhandle Eastern Pipe Line Company v. FERC*, 198 F.3d 266, 269-70 (D.C. Cir. 1999). The court was unclear as to whether, by “precedential,” it meant: (a) absolutely prohibiting departures in future cases or (b) imposing an obligation to explain departures in future cases. Also, the “policy statements” at issue were of a peculiar variety: they were adjudicatory orders that were yet to become final when they were mooted by a settlement. Later still, the D.C. Circuit suggested that agencies within adjudicatory proceedings have *some* explanatory obligation with respect to guidance when it held that “[i]f . . . the agency changes its policy statement before the [adjudication] is complete, it must explain why the pending [adjudication] should be decided on the basis of the old versus the new policy.” *Consolidated Edison Company of New York v. FERC*, 315 F.3d 316, 323 (D.C. Cir. 2003).

adjudication, that party may have various incentives to refrain from suing, which may track the incentives not to rock the boat described in Part II.³⁵³ 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.³⁵⁴

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.”³⁵⁵ 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.”³⁵⁶

Consistent with these kinds of views, several agencies prefer to frame flexibility on guidance as *reinterpretation* of the guidance document, rather than as an outright *departure* from it.³⁵⁷ 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.”³⁵⁸ 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.³⁵⁹ Richard Stoll, of Foley and Lardner, said that at EPA a regulated party’s “best” strategy was to “distinguish” a guidance

³⁵³ See also the concerns about retaliation discussed in Subsection III.D.1 *infra*.

³⁵⁴ Heckler v. Chaney, 470 U.S. 821 (1985).

³⁵⁵ Interview with Source 61, EPA Office of General Counsel official.

³⁵⁶ Interview with Source 69, former agency general counsel.

³⁵⁷ Cf. Kagan, *supra* note 29, at 102 (noting that flexibility in the Nixon wage-prize freeze was conceived of as interpretation).

³⁵⁸ Interview with Source 93, former CMS division director.

³⁵⁹ Interview with Source 67, former HHS Office of General Counsel official.

document rather than actually challenge it.³⁶⁰ A former senior FDA official warned that you were not living in the “real world” if you said to FDA, “this guidance is wrong, we’ll do it differently, do you agree?” Instead you should seek flexibility through interpretation.³⁶¹ Jonathan Snare, the former deputy solicitor of 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.³⁶²

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.

1. Resources and Time Needed to Evaluate Departures

Coming to a defensible decision on whether a specific course of conduct fulfills the requirements of a more general legislative rule or statute can be costly in time and money. It may involve—to give a few examples—scientific or mechanical engineering research, predictive judgments about employee behavior and the rate of workplace accidents, assessments of how much a certain combination of training and incentives raises the likelihood of financial institution employees engaging in fraud, etc. Such determinations are exactly what an agency needs to make in deciding what should be the content of guidance in the first place—and also in deciding whether a proposed departure from guidance is acceptable.

³⁶⁰ Interview with Richard Stoll, Partner, Foley and Lardner.

³⁶¹ Interview with Source 110, former senior FDA official.

³⁶² Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL.

Often these costs are borne to a large degree by the regulated party who seeks the departure. 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 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.³⁶³ As FAA officials said, following guidance is "the easy way."³⁶⁴ Similarly, a former EPA program office director said you do what the agency suggests "if it seems halfway reasonable," since merely coming up with an alternative is costly.³⁶⁵

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.³⁶⁶ Former senior 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.³⁶⁷ 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

³⁶³ Interview with Source 66, official at Airlines for America.

³⁶⁴ Interview with Sources 8, 9, and 10, FAA officials. See also Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA (stating that FAA makes departures from guidance but they can be really time-consuming).

³⁶⁵ Interview with Source 71, former EPA program office director. See also Interview with Source 79, former senior EPA official (noting that the cost of showing an alternative to be compliant creates an incentive to follow guidance).

³⁶⁶ Interview with Source 2, trade association official.

³⁶⁷ Interview with Neil Eisner, consultant; former Assistant General Counsel for Regulation and Enforcement, DOT. See also Strauss, *supra* note 11, at 1481 (arguing 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).

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.”³⁶⁸

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.³⁶⁹ 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.³⁷⁰ Hence officials feel they must either do more investigation independently, or simply reject the request.³⁷¹

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.³⁷² 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.³⁷³ Lynn Bergeson, the managing partner of Bergeson & Campbell, which has a specialization in chemical regulation, said

³⁶⁸ Interview with Source 79, former senior EPA official.

³⁶⁹ Interview with Source 71, former EPA program office director.

³⁷⁰ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

³⁷¹ Besides this, there is another argument against agency passivity regarding departures from guidance: the more officials passively rely on industry initiative in deciding what departures to make, they more they may give an advantage to the subset of firms with the capacity to identify and argue for alternative courses of conduct. Kagan, *supra* note 29, at 16 (noting that more sophisticated firms are more in a position to take advantage of regulatory flexibility). That said, principled flexibility can mitigate this problem by ensuring that, once a departure from guidance is approved, it is disseminated to all regulated parties, consistent with protection of confidential business information. E.g., FAA has a process for doing this. Interview with Sources 8, 9, 10, FAA officials.

³⁷² Interview with Source 2, trade association official.

³⁷³ Interview with Source 42, EPA Office of Water official.

resources were a “huge issue” in determining whether officials in EPA’s FIFRA and TSCA offices would be flexible on guidance.³⁷⁴ 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 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.”³⁷⁵

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.³⁷⁶ 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.”³⁷⁷ At FDA, a former senior official in the Office of Chief Counsel said 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). OGD had to approve an order of magnitude more applications than 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 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 OND and OGD was also caused by a difference in the nature of the two offices’ work: OND dealt with brand new clinical data, whereas OGD’s decisionmaking is more “mechanical” by nature. Despite this, he said, OGD’s work still involved matters of judgment that would benefit from greater flexibility if only OGD

³⁷⁴ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

³⁷⁵ Interview with David Hawkins, director, climate program, Natural Resources Defense Council; former Assistant Administrator, Air Program Office, EPA. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

³⁷⁶ Kagan, *supra* note 29, at 132. On the tradeoff between speed and fact-finding procedure, see *id.* at 107, 129.

³⁷⁷ Interview with Source 71, former EPA program office director.

were resourced and managed to provide it. He believed OGD had gone too far in the direction of a “checklist” approach.³⁷⁸

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). 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). The Corps must issue JDs on the order of 50,000 per year.³⁷⁹ 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; it was manifested in a form that was filled out by Corps staff and 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.³⁸⁰ In a different context, the administration might have been able to do so through informal flexibility without officially altering the guidance document; as we shall see, 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.³⁸¹ 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

³⁷⁸ Interview with Source 83, former senior FDA Office of Chief Counsel official. It should be noted that another interviewee said that OGD tended to be flexible (without drawing a direct comparison to OND), but he added that he was not speaking from “very deep knowledge” about OGD, as most of his company’s dealings were with OND. Interview with Source 108, executive at a drug manufacturer. Another interviewee said his impression was that OGD was more flexible than OND, but he added that his impression might be “colored” by the fact that he dealt mostly with OGD and not OND. Interview with Source 92, food and drug industry attorney. On the importance of face-to-face interaction between officials and regulated parties in diminishing legalistic stringency, see Kagan, *supra* note 29, at 138, 151-52.

³⁷⁹ Calculation based on Clean Water Rule: Definition of “Waters of the United States,” 80 Fed. Reg. 37054, 37065 (2015).

³⁸⁰ Interview with Source 97, attorney at environmental NGO.

³⁸¹ See *infra* Subsection V.D.2.

owners with stakes in the matter might have blown the whistle.³⁸² Thus, once again, volume tends to keep agency personnel in compliance with officially-existing guidance.

Another key factor limiting agencies' practical capacity to evaluate potential departures from guidance is that high-level officials usually have to be involved in the process. OMB's Good Guidance Practices say that "[a]gency employees should not depart from significant guidance documents without appropriate justification and supervisory approval."³⁸³ FDA definitely requires this,³⁸⁴ and officials confirm the requirement is followed, on the understanding it means the employee must go up one level, to his/her boss.³⁸⁵ As to 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.³⁸⁶ A former EPA official said that frontline staff would not do a "stretch" argument on their own and would check with their superiors.³⁸⁷ 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 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 your request.³⁸⁸ When you seek a departure from guidance from frontline officials, said a regulatory policy executive at a drug manufacturer, you will usually get no response (because even the frontline people don't have enough time), and then if you appeal up the chain, you are dealing with people who are "very busy" and you are basically "begging" them; you need to be "reasonable" and "polite."³⁸⁹ A former HHS Office of General Counsel official said seeking departures from CMS was very

³⁸² Interview with Source 97, attorney at environmental NGO.

³⁸³ OMB Good Guidance Practices, § II(1)(b), 72 Fed. Reg. 3440 (2007). See also Strauss, *supra* note 11, at 1483 (urging that guidance be binding on low-level officials, with higher-level officials given authority to make departures if reasoned).

³⁸⁴ 21 CFR § 10.115(d)(3).

³⁸⁵ Interview with Source 25, FDA Office of Policy official.

³⁸⁶ Interview with Source 52, partner in large law firm and former senior EPA official.

³⁸⁷ Interview with Source 54, former EPA official.

³⁸⁸ Interview with Source 83, former senior FDA Office of Chief Counsel official.

³⁸⁹ Interview with Source 109, regulatory policy executive at a drug manufacturer.

challenging in part because an official high enough to have the requisite authority would have “limited time.”³⁹⁰ Bergeson, managing partner of Bergeson & Campbell, said regarding flexibility in guidance that senior officials at EPA might not be aware of problems three levels below them; they were “busy.”³⁹¹

At 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 “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 be possible “very seldom.” Instead the company would ask the frontline official to talk to the high-level official, but in that case, you can never be sure how the staff will represent your position to the boss.³⁹²

Two additional interviewees on 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

³⁹⁰ Interview with Source 67, former HHS Office of General Counsel official.

³⁹¹ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

³⁹² Interview with Source 52, partner in large law firm and former senior EPA official. See also Interview with Richard Stoll, Partner, Foley and Lardner (stating that while a regulated party entreating 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); Kagan, *supra* note 29, at 138-39 (noting that higher-level decisionmakers, pressed for time, may turn away requests for advice from lower-level ones).

thought a decision was wrong, in the sense of being different from the one he would've reached, that was not enough.³⁹³ 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.³⁹⁴

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 one-off departure request is not. According to a former CFPB official, if you’re an individual financial institution seeking a departure from guidance, you “won’t get anywhere” with CFPB; you need to go through the trade association, and may need to pressure CFPB for years.³⁹⁵ Bergeson said that, if a client were having difficulty obtaining a departure from guidance, she would advise the client to “band together” with others, as by going to the trade association, since proceeding “one-off” is “ineffectual,” since EPA could not spend too much time and money on a request for just one firm.³⁹⁶ 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 EPA, it might if a trade association leaned on the agency.³⁹⁷

2. 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

³⁹³ Interview with Source 71, former EPA program office director.

³⁹⁴ Interview with Source 98, former EPA program office director.

³⁹⁵ Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

³⁹⁶ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

³⁹⁷ Interview with Source 52, partner in large law firm and former senior EPA official.

“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*. While 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,³⁹⁸ attorney Charles Samuels, counsel to the home appliance manufacturers’ trade association, noted that, while DOE *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.³⁹⁹

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 that when a frontline official departing from guidance goes to check with his/her supervisor (as required), this also entails documenting the departure.⁴⁰⁰ 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.⁴⁰¹ 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.⁴⁰² Regarding OSHA, Celeste Monforton, the academic and safety advocate and former OSHA legislative analyst, said we just don’t know how much OSHA personnel are departing from guidance (e.g., how frequently inspectors are being flexible in

³⁹⁸ Interview with Andrew DeLaski, executive director, Appliance Standards Awareness Project.

³⁹⁹ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

⁴⁰⁰ Interview with Source 25, FDA Office of Policy official.

⁴⁰¹ Interview with Source 80, former senior FDA official.

⁴⁰² Interview with Richard Naples, Chief Regulatory Office, Becton, Dickinson, and Company.

setting up abatement plans with employers, which would most likely happen if there were complex equipment), because there is no database of such departures.⁴⁰³

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, 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.⁴⁰⁴

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, one way or other.

1. Officials’ Antagonism to Being Challenged

If a frontline official has 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 provide that a regulated party can complain to higher-level officials; for example, FDA says, “If you believe . . . that someone at FDA treated a guidance document as a binding requirement, you should contact that person’s supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest

⁴⁰³ Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

⁴⁰⁴ Interview with Sources 8, 9, 10, FAA officials.

supervisor.”⁴⁰⁵ However, interviewees said that regulated parties at 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 II.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 on 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 in his experience FDA reviewers showed very little flexibility on guidance and 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 get one person as reviewer over and over.⁴⁰⁶ A former senior FDA Office of Chief Counsel official concurred that, in the device area, companies “don’t want to rock the boat.”⁴⁰⁷ William Schultz, former FDA Deputy Commissioner for Policy, said companies were “very shy” about complaining about the review functions of 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/her.⁴⁰⁸ On the drugs side, Daniel Troy, the general counsel of GlaxoSmithKline, gave the example that his company was deep into respiratory treatments; FDA had only one respiratory office, and “we can’t make them mad,” though the company could have a constructive scientific dialogue with them.⁴⁰⁹ According to an executive at a drug manufacturer, appealing up the chain after receiving a negative response or

⁴⁰⁵ 21 C.F.R. § 10.115(o).

⁴⁰⁶ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

⁴⁰⁷ Interview with Source 83, former senior FDA Office of Chief Counsel official.

⁴⁰⁸ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁴⁰⁹ Interview with Daniel Troy, general counsel, GlaxoSmithKline.

no response 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.⁴¹⁰

Some interviewees observed that, while retaliation was widely feared, it was not as common as, 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 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.”⁴¹¹ Troy, of GlaxoSmithKline, said there was a perception that FDA would retaliate, and “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.⁴¹²

The fear of retaliation extends from pre-market review to enforcement and inspections, where there is also repeat play. An official at FDA’s Office of Regulatory Affairs, which oversees the inspectors, said 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.⁴¹³ Troy, general counsel of GlaxoSmithKline, said you have to be really careful with appeals within FDA, because all the companies are “repeat players,” and you 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.⁴¹⁴ 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/her, if they needed to deal with the official again down

⁴¹⁰ Interview with Source 108, executive at a drug manufacturer.

⁴¹¹ Interview with Richard Naples, Chief Regulatory Officer, Becton Dickinson.

⁴¹² Interview with Daniel Troy, general counsel, GlaxoSmithKline.

⁴¹³ Interview with Source 28, official at FDA Office of Regulatory Affairs.

⁴¹⁴ Interview with Daniel Troy, general counsel, GlaxoSmithKline.

the road. He recalled that, during his tenure at FDA, he would urge public audiences of stakeholders to tell him if they thought they were not being treated fairly, but 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 frustrating, he said, because if FDA had received more complaints, it would have enabled the agency to train its employees better.⁴¹⁵

Some interviewees pointed out ways in which FDA was addressing, or might address, the fear of retaliation. The drug manufacturer executive cited FDA’s formalization of a “Dispute Resolution Process” in recent years, saying the formality had made escalation “more accessible” and reduced companies’ fear.⁴¹⁶ The official at FDA’s Office of Regulatory Affairs noted the office now had an ombuds to help with the matter.⁴¹⁷ (There are also ombuds at other components of FDA.) William Schultz, former FDA Deputy Commissioner for Policy, suggested perhaps FDA could periodically solicit companies for anonymous feedback to see whether they thought reviewers were treating guidance flexibly.⁴¹⁸

Beyond 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.⁴¹⁹ Lynn Bergeson, managing partner of Bergeson & Campbell, said that appealing within EPA on behalf of a client expends some of the law firm’s “political capital.”⁴²⁰ 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.”⁴²¹ In banking regulation, a former CFPB official said that if a bank sought a departure from guidance in the

⁴¹⁵ Interview with Source 80, former senior FDA official.

⁴¹⁶ Interview with Source 108, executive at a drug manufacturer. 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 and Regulatory Science* 697 (2016).

⁴¹⁷ Interview with Source 28, official at FDA Office of Regulatory Affairs.

⁴¹⁸ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁴¹⁹ Interview with Source 71, former EPA program office director.

⁴²⁰ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

⁴²¹ Interview with Source 77, former senior HHS official.

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.⁴²²

The most common remedy for this problem is for companies to seek assurances regarding departures from guidance anonymously, often through 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 FDA, could give examples of the problem, but with company and product names removed.⁴²³ 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.⁴²⁴ 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.⁴²⁵

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,

⁴²² Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

⁴²³ Interview with Richard Naples, Chief Regulatory Officer, Becton Dickinson.

⁴²⁴ Interview with Source 80, former senior FDA official.

⁴²⁵ Interview with Source 69, former agency general counsel.

as it might be in the case of an appellate court reviewing a trial court. Regarding FDA, the agency's former Deputy Commissioner for Policy, William Schultz, said it was "hard" for an FDA manager not to support the reviewers under his/her supervision; "it's not like an appellate judge overturning a trial judge."⁴²⁶ Bradley Merrill Thompson, counsel to device makers' trade associations, noted that when a higher-level FDA official reviewed his/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.⁴²⁷ 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 regulated parties "work through channels" and give frontline officials a chance to correct themselves. (He added that "many" supervisors at EPA took the same approach.) Further, he noted, there was just a limit to how much a supervisor feels he/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.⁴²⁸ 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."⁴²⁹

Second, higher-level officials are concerned about maintaining the credibility of their own frontline officials vis-a-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."⁴³⁰ The former EPA program office director said you must give your subordinates an "envelope" in which to operate freely, and not

⁴²⁶ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁴²⁷ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

⁴²⁸ Interview with Source 71, former EPA program office director. See also Interview with Richard Stoll, Partner, Foley and Lardner (noting that at EPA superiors tend to back their subordinates, so you "rarely" get success by going up the agency hierarchy).

⁴²⁹ Interview with Source 93, former CMS division director.

⁴³⁰ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

second-guess them simply because you would've made a different decision, "especially if you are supervising supervisors."⁴³¹

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.⁴³² (An alternative strategy would be to prohibit frontline staff from departing from guidance, so that departure decisions would be made in the first instance at the higher level, without the baggage of reviewing somebody's decision below; but this presents obvious resource and bottleneck problems.)

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/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 FDA ombuds could play the role.⁴³³

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 counter-intuitive to many people, and it can be counter-intuitive to 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 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

⁴³¹ Interview with Source 71, former EPA program office director.

⁴³² Interview with Source 69, former agency general counsel.

⁴³³ Interview with Source 83, former senior FDA Office of Chief Counsel official.

“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 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.⁴³⁴ Similarly, a former senior FDA Office of Chief Counsel official said that, although he “loved” the people at 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 non-mandatory language throughout such documents, the rule/guidance distinction was “lost on people” at 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.”⁴³⁵ (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,⁴³⁶ and another former FDA official said senior officials would view guidance as more fluid than would frontline staff.⁴³⁷)

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.⁴³⁸ A former EPA program office director said the tendency to treat guidance as mandatory had to do with 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.⁴³⁹ 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.⁴⁴⁰ In banking regulation, an

⁴³⁴ Interview with Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA.

⁴³⁵ Interview with Source 83, former senior FDA Office of Chief Counsel official.

⁴³⁶ Interview with Source 83, former senior FDA Office of Chief Counsel official.

⁴³⁷ Interview with Source 20, former FDA official.

⁴³⁸ Interview with Source 77, former senior HHS official.

⁴³⁹ Interview with Source 71, former EPA program office director.

⁴⁴⁰ Interview with Neil Eisner, consultant; former Assistant General Counsel for Regulation and Enforcement, DOT.

interviewee who held senior posts at 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.⁴⁴¹ 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.⁴⁴²

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 FDA and CMS said that, of the two, FDA was more flexible on guidance, which he attributed in part to the fact that while CMS was focused on business and payment issues, FDA was focused on science, and “science means dialogue.”⁴⁴³ 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, 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 FDA would consider an alternative means of compliance.⁴⁴⁴ A congressional staffer observed the same distinction, with FDA more flexible on scientific than policy matters.⁴⁴⁵

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 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

⁴⁴¹ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁴⁴² Interview with Source 51, Federal Reserve official.

⁴⁴³ Interview with Source 101, partner in large law firm healthcare practice.

⁴⁴⁴ Interview with Source 20, former FDA official.

⁴⁴⁵ Interview with Source 82, congressional staffer.

particular, there is a striking distinction, across multiple areas of regulation, between program offices and enforcement offices.

Several interviewees with diverse perspectives agreed that EPA's civil enforcement office adheres more closely to guidance than do 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 A above, which have peculiar power in the realm of enforcement. As former EPA civil enforcement directors Eric Schaeffer and Adam Kushner stated, adherence to guidance levels the playing field for industry, which is what industry generally wants. Further, as Kushner emphasized, consistent application of guidance provides the predictability of penalties and the insurance against competitive disadvantage that are necessary to solve the special challenge facing the enforcement office: it must coax otherwise hard-to-detect violators to come forward, disclose their violations, and settle.⁴⁴⁶

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. Kushner himself 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.⁴⁴⁷ From the opposite perspective, a former senior official in 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, in which 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 furthered flexibility in shaping and using guidance after the

⁴⁴⁶ See *supra* text at notes 310-315.

⁴⁴⁷ Interview with Adam Kushner, Partner, Hogan Lovells, former director of civil enforcement, EPA.

rule's promulgation. The enforcement office, by contrast, needed to "hit" its "numbers," he said.⁴⁴⁸

Two other interviewees with yet other perspectives confirmed the distinction. Lynn Bergeson, managing partner of Bergeson & Campbell, said the EPA enforcement office's inflexibility on its penalty guidance was a point "of unique frustration" that "we all whine about."⁴⁴⁹ The executive director of the Environmental Council of the States said the enforcement office was most strict in its adherence to guidance of any component of EPA headquarters: "they don't mess around."⁴⁵⁰

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 Department of Justice were less flexible regarding guidance than CMS or program offices at FDA; he attributed the difference to the fact that regulated firms had a more personal relationship with CMS and FDA.⁴⁵¹ Looking at 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 the public, and less flexibility in components related to advertising and promotion, which were more adversary.⁴⁵²

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 was the least flexible of these. DEA conceives of itself as a criminal law enforcement agency, but some legitimate industries are partly regulated by DEA because their medicinal or chemical products can be used to make illegal drugs (especially meth). DEA has a tendency to view regulated parties through the lens of criminal law enforcement rather than administrative law.⁴⁵³

⁴⁴⁸ Interview with Source 103, former senior official in EPA's Air Program office.

⁴⁴⁹ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

⁴⁵⁰ Interview with Alexandra Dapolito Dunn, executive director, Environmental Council of the States.

⁴⁵¹ Interview with Source 104, law firm partner who deals frequently with CMS and FDA.

⁴⁵² Interview with Source 108, executive at a drug manufacturer. Another interviewee likewise observed that 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 FDA official.

⁴⁵³ Interview with James Conrad, Conrad Law and Policy Counsel; formerly Assistant General Counsel at the American Chemistry Council.

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.⁴⁵⁴ Woodcock, the director of FDA's Center for Drug Evaluation and Research, observed that the Office of Generic Drugs had difficulty with the distinction before she established an Office of Generic Drug Policy (a "policy shop") within 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 OGD, both through general training and through 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 the grassroots," that is, embedded within the particular office, as distinct from CDER's overall policy shop, which provides a "final common pathway" for all decisions that come out of OGD and the other components of CDER 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.⁴⁵⁵

At 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 OGC often tells agency personnel that guidance is nonbinding, he has not observed any training of personnel on the issue.⁴⁵⁶ But another EPA Office General Counsel official said that OGC 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.⁴⁵⁷

⁴⁵⁴ Interview with Source 25, FDA Office of Policy official; Interview with Source 31, FDA Center for Devices and Radiological Health official.

⁴⁵⁵ Interview with Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA, plus follow-up email exchange.

⁴⁵⁶ Interview with Source 70, EPA Office of General Counsel official.

⁴⁵⁷ Interview with Source 61, EPA Office of General Counsel official.

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. The other reasons for inflexibility discussed earlier in this Part can be explained as reactions to legitimate pressures for consistency that involve hard tradeoffs among competing rule-of-law values (Section A) or as the result of organizational problems and resource constraints that agencies may be able to overcome only with creative new managerial efforts or more money (Sections C and D). Not so with the agency's commitment to guidance's substance. This is the most questionable reason for inflexibility, and it is therefore the one that agencies are most obligated to avoid and resist, 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 both. This raises the possibility that, if a norm against substance-driven 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) 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 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.”⁴⁵⁸ 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.⁴⁵⁹ At 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 “political appointees.” Hawkins gave the example of a public memo he sent to the Air Program office

⁴⁵⁸ Interview with Source 77, former senior HHS official.

⁴⁵⁹ Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

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 which EPA had previously been laissez-faire.⁴⁶⁰ Richard Stoll, of Foley and Lardner, stated that, although 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 RCRA’s boiler and industrial furnace rules. In apparent response to the lobbying, EPA issued a guidance document that some of the regional offices began telling companies to follow, until EPA backed down in the face of a judicial challenge. He also noted that, where 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.⁴⁶¹ 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.”⁴⁶²

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.⁴⁶³ Likewise, a former CMS division director said 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.⁴⁶⁴ This is not to say that career officials writing guidance always feel closely committed to it. Richard Stoll, of Foley and Lardner, recalled dealing with a career official at EPA who had written key guidance on boilers and industrial furnaces under RCRA and “took all the calls” from stakeholders about

⁴⁶⁰ Interview with David Hawkins, director, climate program, Natural Resources Defense Council; former Assistant Administrator, Air Program Office, EPA. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization.

⁴⁶¹ Interview with Richard Stoll, Partner, Foley and Lardner.

⁴⁶² Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

⁴⁶³ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green. See also Interview with Source 112, former senior FDA career official (noting that, for a disease-specific guidance document, the FDA review division applying the document would have been involved in writing the document).

⁴⁶⁴ Interview with Source 93, former CMS division director.

departures from and interpretations of the document he had written: he “leaned left but was reasonable.”⁴⁶⁵

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 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.⁴⁶⁶ Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice and a former FDA Office of Chief Counsel attorney, recounted that after 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. 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.⁴⁶⁷ 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 allow reactions to flow in from stakeholders and Congress. He would then sign off at what he considered “the proper stage of policy evolution.”⁴⁶⁸

⁴⁶⁵ Interview with Richard Stoll, Partner, Foley and Lardner.

⁴⁶⁶ Interview with Source 19, former SEC official.

⁴⁶⁷ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney.

⁴⁶⁸ Interview with Source 69, former agency general counsel.

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 said 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 on 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.⁴⁶⁹

IV. 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 benefits regulated parties, as by binding the agency not to enforce against them, or 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 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.⁴⁷⁰ More recently, in *General Electric Company v. EPA*, the same court struck down 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.”⁴⁷¹ Despite the fact that the challenger

⁴⁶⁹ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

⁴⁷⁰ *Community Nutrition Institute v. Young*, 818 F.2d 943, 948 (D.C. Cir. 1987).

⁴⁷¹ *General Electric Co. v. EPA*, 290 F.3d 377, 384 (D.C. Cir. 2002). See also *United States v. Texas*, 809 F.3d 134, 171-76 (5th Cir. 2015), *aff’d* by an equally divided court, 136 S. Ct. 2271 (2016).

was not even a regulatory beneficiary but a company seeking permission from 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.

Though counter-intuitive 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.⁴⁷² The flipside of the courts’ approach is that even 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. 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.”⁴⁷³ An official at 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.⁴⁷⁴ At 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.⁴⁷⁵

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

⁴⁷² 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. Strauss, *Publication Rules*, *supra* note 71, at 817; Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 Cornell L. Rev. 397, 420-24 (2007); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 Texas L. Rev. 331, 344 (2011). 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, *supra* note 3, at 32-33. 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, some way or other, in deregulatory agency decisionmaking.

⁴⁷³ 21 C.F.R. § 10.115(d)(1), (3).

⁴⁷⁴ Interview with Source 28, Official at FDA Office of Regulatory Affairs.

⁴⁷⁵ Interview with Source 99, EPA official.

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.”⁴⁷⁶ 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.”⁴⁷⁷ More generally, “many securities law practitioners and their clients consider no-action letters a source of de facto law.”⁴⁷⁸

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

⁴⁷⁶ Funk, *supra* note 15, at 1335.

⁴⁷⁷ 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, former SEC official (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).

⁴⁷⁸ Nagy, *supra* note 477, at 924-25.

enforcement action would have been lawful and appropriate, though the agency would have gone easier on a less-sophisticated company.⁴⁷⁹

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.”⁴⁸⁰ 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” and 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.”⁴⁸¹

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%” but “not 100%.”⁴⁸² An EPA official commenting on guidance for how to do FIFRA applications said it came with the “caveat” that EPA could change its mind, though she said the agency would not “deviate cavalierly.”⁴⁸³

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 orders⁴⁸⁴—the consultant on that project 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.”⁴⁸⁵

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

⁴⁷⁹ Interview with Neil Eisner, consultant; former Assistant General Counsel for Regulation and Enforcement, DOT.

⁴⁸⁰ OSHA Field Operations Manual (Aug. 2, 2017), ABSTRACT-3.

⁴⁸¹ Interview with Baruch Fellner, Partner, Gibson Dunn.

⁴⁸² Interview with Source 119, senior environmental counsel at Fortune 100 company.

⁴⁸³ Interview with Source 41, EPA official.

⁴⁸⁴ ACUS Recommendation 2015-3, 80 Fed. Reg. 78163 (2015).

⁴⁸⁵ Emily S. Bremer, *The Agency Declaratory Judgment*, 78 Ohio St. L.J. (forthcoming, 2017-18), manuscript at 13, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2955214.

the goal that cases like *Community Nutrition Institute* sought to pursue—that is, to allow beneficiaries of regulation a voice in agencies’ deregulatory decisions.⁴⁸⁶ 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.⁴⁸⁷ 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 III, 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 micro-level. This is perhaps most common in some parts of environmental regulation: interviewees gave examples of NGOs taking part in disputes about guidance in informal conversations at the EPA Air Program office regarding industry requests for departures;⁴⁸⁸ in EPA-supervised state agency permit proceedings under the Clean Air Act;⁴⁸⁹ and in EPA proceedings on whether to override state permits under that same act.⁴⁹⁰ But in

⁴⁸⁶ 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 Strauss, *Publication Rules*, *supra* note 71, at 817; Mendelson, *supra* note 472, at 420-24; Seidenfeld, *supra* note 472, at 344. Further, Mendelson argues 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 472, at 438-44. Levin argues that regulatory beneficiaries have such a right under existing law. Levin, *supra* note 3, at 33 n.157.

⁴⁸⁷ 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).

⁴⁸⁸ Interview with Source 103, former senior official at EPA Air Program Office.

⁴⁸⁹ Interview with Source 128, employee at environmental NGO.

⁴⁹⁰ Interview with David Hawkins, director, climate program, Natural Resources Defense Council; former Assistant Administrator, Air Program Office, EPA. Like interviewees in this study generally, Hawkins was speaking for himself and not on behalf of any organization. See also Interview with Source 54, former EPA official (discussing NGO judicial challenges to EPA permit proceedings and the role of guidance therein).

many regulatory areas, NGOs will play little to no role in individual proceedings. They may lack any legal right to get involved, may lack the resources to contest or even find out about the proceedings, and 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.⁴⁹¹ 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.⁴⁹²

V. PUBLIC PARTICIPATION IN ISSUANCE OF GUIDANCE

Because the factors discussed in Parts III and IV will sometimes prevent regulated parties and regulatory beneficiaries from benefiting from flexibility on guidance at the implementation phase, it is natural to ask whether this problem could be mitigated by inviting them to participate at an earlier stage—to ask for their input when guidance is formulated and issued, at a general level, in the first place. Part IV set forth an argument in favor of such participation for regulatory beneficiaries, and this Part will evaluate the idea more broadly, for both regulatory beneficiaries and regulated parties, with attention to how participation should be implemented.

Section A notes there are many different levels at which participation can occur, e.g., the agency may reach out to handpicked stakeholders, may set up a broader stakeholder meeting, may proceed through an even broader advisory-committee process, or (the broadest option) undertake voluntary notice and comment on a draft of the guidance document. As noted in

⁴⁹¹ On limits of NGOs' monitoring capacities, with respect to rulemaking, guidance, and judicial review, see Mendelson, *supra* note 472, at 424, 430.

⁴⁹² Interview with Neil Eisner, consultant; former Assistant General Counsel for Regulation and Enforcement, DOT.

Section B, notice and comment on a guidance document is *not* the same as legislative rulemaking; it is less costly in a variety of ways. Section C then examines the benefits and costs of notice and comment for guidance, emphasizing how they vary greatly depending on context. Notice and comment will often be worth it, but it is hard to state generally when.

I conclude in Section D by considering the wisdom of a government-wide requirement of notice and comment for a large category of guidance documents. I take the view that such a mandate, if extended beyond the most extraordinary guidance documents, would be unwise, not only because of the variability discussed in Section C, but also because of certain risks on which Section D goes into depth, particularly (i) the danger that a resource-strapped agency facing such a broad mandate may leave guidance indefinitely in published draft form, defeating the purpose of public comment and—insofar as regulated parties face the strong incentives to follow guidance noted in Part II—placing those parties in a difficult and confused position; and (ii) the possibility that a strong mandate for public comment on guidance could have the effect of legitimating a wholesale shift away from legislative rulemaking—an outcome that might be good or bad, but in any event profound enough that we must debate it on a higher plane than that of talking about guidance.

Before we begin, some background is in order regarding participation in the formulation of guidance at FDA, an agency that plays an especially prominent role in this Part. FDA operates under a set of Good Guidance Practices (GGPs), which are procedural rules initially adopted by the agency in early 1997,⁴⁹³ specifically authorized and required by Congress later that year,⁴⁹⁴ and then repromulgated, without fundamental changes, in 2000.⁴⁹⁵ Under the GGPs, FDA generally conducts pre-adoption notice and comment for all its “Level 1” guidance documents, which are defined broadly as those that “(i) Set forth initial interpretations of statutory or regulatory requirements; (ii) Set forth changes in interpretation or policy that are of more than a minor nature; (iii) Include complex scientific issues; or (iv) Cover highly controversial issues.”⁴⁹⁶ This notice-and-comment mandate—unusual among agencies in its breadth and specific statutory basis—does not exhaust FDA’s means for investing guidance with

⁴⁹³ 62 Fed. Reg. 8961 (1997). The notice and comment provision appears in *id.* at 8968.

⁴⁹⁴ 111 Stat. 2296, 2368 (1997), codified in 21 U.S.C. § 371(h). The quotation is from § 371(h)(1)(C)(i).

⁴⁹⁵ 65 Fed. Reg. 56468 (2000), codified mainly in 21 C.F.R. § 10.115.

⁴⁹⁶ 21 C.F.R. § 10.115(c)(1). For guidance other than “Level 1,” FDA also invites public comment, post-adoption. 21 C.F.R. § 10.115(g)(4)(C). More generally, FDA is willing to receive comments on any guidance document at any time. 21 C.F.R. § 10.115(g)(5).

stakeholder input, but the mandate does mean that FDA has arguably the richest experience of any agency with public participation on guidance, illuminating a host of advantages and challenges that come with it.

A. Diverse Means of Stakeholder Participation

Although a guidance document can remain an intra-agency secret until the day it becomes official,⁴⁹⁷ agencies frequently seek outside input on such documents before making them operative. Agencies typically have discretion to decide the form and amount of that input. It can range from confidential targeted outreach to public meetings to advisory-committee proceedings to the solicitation of public comment.⁴⁹⁸

The most confined sort of participation is targeted outreach to stakeholders whom the agency selects. Such contacts have been noted in the literature by Nina Mendelson, who argues that they are likely to be predominantly with industry rather than other stakeholders⁴⁹⁹—a point for which the interviews offer some support, though it is fragmentary and mixed. At FDA, officials will sometimes hold meetings on formulation of guidance (prior to publication of a draft) with industry players, including trade associations, individual companies, or physician groups, all of which are subject to a general FDA meeting-disclosure policy.⁵⁰⁰ Officials at Public Citizen said they had never given, nor tried to give, this kind of pre-draft input, but they guessed FDA had such interchanges with industry.⁵⁰¹ At EPA, said an Office of General Counsel official, if the reach of the guidance document was relatively narrow, the agency might just do targeted outreach to industry and environmental groups.⁵⁰² In administering the Safe Drinking Water Act (SDWA), for which the states are co-regulators, EPA may send the draft document to all the state governments,⁵⁰³ or to (say) a half-dozen states that know the issue.⁵⁰⁴

⁴⁹⁷ According to an official at a public interest organization working on immigrants' rights, his group had no forewarning of DHS's Deferred Action for Childhood Arrivals until it was made official on June 15, 2012; it was "the best-kept secret in town," the DHS Secretary was secretive about it, and key House and Senate staff had no warning. Interview with Source 45, official at public interest organization working on immigrants' rights.

⁴⁹⁸ See generally Interview with Source 61, EPA Office of General Counsel official (stating that the development of each guidance document involves "some level" of outreach).

⁴⁹⁹ Mendelson, *supra* note 472, at 427-28.

⁵⁰⁰ Interview with Source 24, trade association official. This is, of course, in addition to FDA's routinized taking of public comment on guidance once it is published in draft. See *infra* text at notes 659-662.

⁵⁰¹ Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group.

⁵⁰² Interview with Source 61, EPA Office of General Counsel official.

⁵⁰³ Interview with Carrie Wehling, EPA Office of General Counsel official.

⁵⁰⁴ Interview with Source 84, former EPA Office of Water official.

According to Lynn Thorp of Clean Water Action, the office administering SDWA is keen to get diverse stakeholder feedback and will ask the public-health NGOs it knows for help in finding *other* public-health NGOs.⁵⁰⁵ OSHA sends drafts of guidance documents to “key players,”⁵⁰⁶ and has made alliances with industry associations on certain guidances, such as the National Staffing Association (for temps).⁵⁰⁷ An interviewee who held senior posts at CFPB and other federal agencies said that the banking regulatory agencies, in formulating guidance, would often reach out to trade associations to say, “help us understand Topic X better,” as these associations are able to gather information from their members, and the agencies have found that bank trade association members may be more willing to share operational information with the government when they can do so without the risk that it will draw regulatory scrutiny, e.g., when it is aggregated with information collected from a number of institutions without identifying any. To balance the industry perspective; the banking agencies reach out to the main consumer protection groups in the same way.⁵⁰⁸ A former senior Federal Reserve official said that, before issuing a guidance document, he might phone people at some financial institutions, on a confidential basis (not for them to report up the chain within their institutions), to ask them if he was missing any implications the guidance would have.⁵⁰⁹ An official at a nonprofit public policy research organization said that, relative to CFPB, prudential banking regulatory agencies like the Fed were, in his experience, not proactive in seeking non-industry input (though they were always receptive to meetings when he sought them).⁵¹⁰

A broader form of participation on guidance’s development consists of more capacious stakeholder meetings, workshops, forums, roundtables, discussions at conferences, or webinars; these vary in their breadth of participation and how much they satisfy stakeholders. According to Lynn Bergeson, managing partner of Bergeson & Campbell (which has a specialization in chemical regulation), EPA “often” does stakeholder meetings related to guidance when administering TSCA, FIFRA, and parts of the Air Program, which are valuable, though they are usually in DC (unless it is a huge initiative with meetings around the country) and thus limited to

⁵⁰⁵ Interview with Lynn Thorp, Campaigns Director, Clean Water Action.

⁵⁰⁶ Interview with Adam Finkel, Senior Fellow and Executive Director, Program on Regulation, University of Pennsylvania; former regional administrator, OSHA.

⁵⁰⁷ Interview with Source 36, AFL-CIO official.

⁵⁰⁸ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁵⁰⁹ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

⁵¹⁰ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

attracting “beltway people” and trade associations, although EPA tries hard to “grow” the group of stakeholders, e.g., through webinars.⁵¹¹ A former EPA Office of Water official observed that the agency conducted public meetings, call-in sessions, and webinars on the formulation of guidance under SDWA, though he had observed some controversy (e.g., with a major trade association) over whether full-blown notice and comment was needed for certain guidance.⁵¹² FDA, for its part, sometimes obtains early input on guidance through a public meeting, noted a trade association official.⁵¹³ According to an FDA Office of Policy official, the agency has held workshops on guidance, pre-draft and post-draft.⁵¹⁴ CMS, said a partner in a large law firm healthcare practice, takes input on guidance at policy forums, though it could do more.⁵¹⁵ CFPB, observed an official at a nonprofit public policy research organization, was more proactive than the prudential banking regulators in seeking out non-industry input, including from consumer and research groups, e.g., through roundtables.⁵¹⁶

Advisory committees are potentially a venue through which stakeholders can help to develop or amend guidance. A striking example is the National Organic Standards Board (NOSB), which advises the USDA National Organic Program on the regulation of organic certifiers. The NOSB has been a focal point in the development of high-stakes NOP guidance on the question of how frequently certifiers must undertake costly peer evaluations of their inspectors in the field. As recounted by former NOSB chair Jean Richardson, NOP asked NOSB to address this question, and NOSB took public comment on it. NOSB then recommended that evaluations be every 3-5 years, but NOP eschewed this advice and wrote the guidance to suggest inspections every year, then sent some actual noncompliance warnings that tracked the guidance. Certifiers were dismayed, and they and other stakeholders used NOSB proceedings to express themselves, and the NOSB ultimately engaged in dialogue with NOP to seek a modification of

⁵¹¹ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell. See also Interview with Source 61, EPA Office of General Counsel official (noting public meetings and webinars).

⁵¹² Interview with Source 84, former EPA Office of Water official.

⁵¹³ Interview with Source 24, trade association official. This is, of course, in addition to FDA’s routinized taking of public comment on guidance once it has been published in draft.

⁵¹⁴ Interview with Source 25, FDA Office of Policy official. See also Interview with Source 31, official at FDA Center for Devices and Radiological Health (noting stakeholder meetings on guidance).

⁵¹⁵ Interview with Source 101, partner in large law firm healthcare practice

⁵¹⁶ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

the guidance.⁵¹⁷ NOP ultimately granted this, backing off its every-year stance.⁵¹⁸ In general, although NOP routinely takes public comment on guidance documents directly, stakeholders can also submit comments on a routine basis through the NOSB’s proceedings (on guidance among other topics), and those NOSB proceedings see a higher volume of comments than do the solicitations by NOP on guidance directly.⁵¹⁹ This can make NOSB *the* venue for public input on NOP guidance. Richardson said the board was unlike other advisory committees she had sat on elsewhere in the government, because the organic community was so deeply engaged—a level of input that was “almost ridiculous,” with something like 2,000 written submissions and two full days of “open mic” at every public meeting, with a lot of this participation being on guidance, as in the example above.⁵²⁰ Jake Lewin, president of a large certifier, said NOP was good at listening to public comment through the NOSB channel.⁵²¹

USDA NOP is not the only program in which an advisory committee serves as a conduit for stakeholder participation on guidance. Several committees at EPA play this role, including in the offices administering the SDWA,⁵²² and FIFRA.⁵²³ OSHA’s National Advisory Committee is asked to review some guidance,⁵²⁴ as are some FDA advisory committees.⁵²⁵

Generally, the broadest and most impersonal means of participation in the issuance of guidance is solicitation of public comment. The agency can do this through its own website, as the FAA normally does for many of its advisory circulars.⁵²⁶ Or it be done through the Federal Register and the [regulations.gov](https://www.regulations.gov) website, as with FDA.⁵²⁷ Other agencies alternate between these venues depending on the document. EPA uses one or the other and opts for the Federal Register the more (a) the guidance is highly significant, (b) the demand for the guidance allows

⁵¹⁷ Interview with Jean Richardson, former chair, National Organic Standards Board, USDA.

⁵¹⁸ NOP 2027, Instruction: Personnel Performance Evaluations, NOP 2027 (Effective March 6, 2017), available at <https://www.ams.usda.gov/sites/default/files/media/2027.pdf>

⁵¹⁹ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

⁵²⁰ Interview with Jean Richardson, former chair, National Organic Standards Board, USDA.

⁵²¹ Interview with Jake Lewin, President, CCOF Certification Services.

⁵²² Interview with Lynn Thorp, campaigns director, Clean Water Action (noting role of National Drinking Water Advisory Council in issuance of guidance, as well as ad hoc working groups and advisory committees).

⁵²³ Interview with Source 41, EPA official (noting role of the FIFRA Scientific Advisory Panel, whose reports effectively serve as a kind of guidance for agency and industry on emergent scientific questions).

⁵²⁴ Interview with Source 36, AFL-CIO official.

⁵²⁵ E.g., Interview with Source 30, official at FDA Center for Biologics Evaluation and Research (noting guidance may go through an advisory committee).

⁵²⁶ Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA; Interview with Sources 64, 65, and 66, officials at Airlines for America.

⁵²⁷ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

for the additional time that Federal Register publication requires, (c) the likely level of public interest in the guidance warrants Federal Register publication, and (d) the affected community cannot be easily reached through means other than the Federal Register.⁵²⁸

The pros and cons of soliciting public comment on guidance will be the focus of the rest of this Part. In figuring out these pros and cons, we must remember that the baseline is not necessarily zero public participation. It is, rather, the less-elaborate but sometimes effective forms of participation just discussed.

B. Burden of Public Comment on Guidance Less Than Legislative Rulemaking

If the agency is going to solicit public comment on guidance, why not just go the whole nine yards and proceed by legislative rulemaking, thus getting the benefit of legally-binding force? The reason is that the actual taking of public comment is only a fraction of the burden that legislative rulemaking imposes, and even if one focuses on the taking of comment alone, it is often less burdensome for guidance than for rulemaking. Thus, for most agencies at least, “notice-and-comment guidance” is considerably faster and less expensive than notice-and-comment rulemaking.

In discussing why legislative rulemaking takes the amount of time and resources that it does, interviewees prominently cited five aspects of the process, all of which are either absent or less costly when the process is voluntary notice and comment for guidance. In roughly descending order of prominence, the factors were: (1) mandates for cost-benefit analysis; (2) the prospect of judicial review and the consequent need to build a record and respond to comments; (3) the actual taking of comments; (4) technical challenges in drafting; and (5) dealing with stakeholders mobilized by the agency proceedings.

1. Mandates for Cost-Benefit Analysis

Before significant legislative rules can be proposed or finalized by executive agencies, they are reviewed by the President’s Office of Management and Budget to ensure, inter alia, that the agency engaged in appropriate cost-benefit analysis. OMB also reviews executive agencies’

⁵²⁸ Email from Carrie Wehling, Office of General Counsel, EPA.

“significant” guidance documents.⁵²⁹ The relevant Executive Order’s definition of “significant” is, in many ways, open-ended.⁵³⁰ According to an official at EPA’s Office of General Counsel, the decision on which guidance documents to submit to OMB for review is made at the senior management level of the agency, by political appointees, and the handling of the question changes depending on who is in the relevant agency-manager and OMB positions.⁵³¹

Generally, interviewees thought OMB review was less likely for guidance than for legislative rules and, when it occurred, less time-consuming. A former senior official at EPA’s Air Program office said he thought OMB review of guidance took less time than of legislative rules.⁵³² Lynn Thorp of Clean Water Action observed that OMB scrutiny of EPA guidance was less than that for legislative rules.⁵³³ A former senior FDA official noted that OMB was not much engaged with the agency’s day-to-day scientific guidance,⁵³⁴ while a former senior FDA career official said many FDA guidance documents did not go through OMB at all.⁵³⁵ William Schultz, former HHS General Counsel, in discussing differences between the notice-and-comment process for rulemaking and the notice-and-comment process for guidance, cited OMB

⁵²⁹ Peter R. Orszag, Director, OMB, Memorandum for the Heads and Acting Heads of Executive Departments and Agencies: Guidance for Regulatory Review (March 4, 2009) (stating that, during the period 1993-2007, “OIRA reviewed all significant proposed or final agency actions, including significant policy and guidance documents” and that “[s]uch agency actions and documents remain subject to OIRA’s review under Executive Order 12866”). See also Anthony, *supra* note 7, at 1318 n.23 (quoting Memorandum from the Vice President to the Heads of Executive Departments and Agencies on the Regulatory Review Process (March 22, 1991): “The Administration has consistently interpreted the Executive Order [on regulatory review] to include all policy guidance that affects the public”).

⁵³⁰ Executive Order 12866, § 3(f) (“‘Significant regulatory action’ means any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.”).

⁵³¹ Interview with Carrie Wehling, Office of General Counsel, EPA.

⁵³² Interview with Source 103, former senior official at EPA Air Program Office.

⁵³³ Interview with Lynn Thorp, campaigns director, Clean Water Action. A somewhat more qualified view appeared in Interview with Source 96, former senior EPA official with cross-office responsibilities (stating that, in internal agency deliberations on whether to proceed by rulemaking or guidance, there was a perception that guidance may be easier to get through OMB, but interviewee was not sure that was true anymore, though historically people perceived it to be true).

⁵³⁴ Interview with Source 107, former senior FDA official.

⁵³⁵ Interview with Source 112, former senior FDA career official. See also Interview with Source 24, trade association official (stating that FDA legislative rules would go through OMB “always,” but guidance “not necessarily”).

delays, which he said can be severe.⁵³⁶ Daniel Troy, general counsel of GlaxoSmithKline and former chief counsel of FDA, said one reason for FDA personnel’s preference for guidance over legislative rulemaking was that it avoided OMB review.⁵³⁷ At USDA NOP, which does notice and comment on “most” of its guidance,⁵³⁸ the head of the program cited OMB review as one of a few factors that makes legislative rulemaking generally slower than guidance.⁵³⁹ Richardson, the former chair of the National Organic Standards Board, said legislative rulemaking was greatly delayed by agency economic analysis in contemplation of OMB review, which was not done for guidance; and whereas OMB was a focal point for private lobbying regarding legislative rules, causing further delay, this was not true of guidance. The result was that legislative rulemaking took “much longer” than guidance even when the latter went through public comment.⁵⁴⁰ At DOT, said the former general counsel Kathryn Thomson, guidance, even with public comment, was “much faster” than legislative rulemaking, mainly because it was not necessary to do cost-benefit analysis in contemplation of OMB review; OMB would accept a fast process for guidance more than it would for a legislative rule.⁵⁴¹ At the Department of Energy appliance standards program, recalled a former Department division director, OMB could delay or accelerate legislative rulemaking depending on the administration’s calendar and politics, but guidance was not subjected to OMB review.⁵⁴²

In banking regulation, where most of the agencies are independent and therefore not subject to OMB review, economic analysis can still cause legislative rulemaking to take longer than guidance, as such analysis may be required on some matters by statute or agency practice.⁵⁴³ An interviewee who held senior posts at CFPB and other federal agencies said that at the independent banking agencies (i.e., those not funded with tax revenues and not subject to OMB

⁵³⁶ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁵³⁷ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

⁵³⁸ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA (noting that “most” guidance is “Level 1” under the NOP’s guidance practices, for which NOP does notice and comment).

⁵³⁹ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

⁵⁴⁰ Interview with Jean Richardson, former chair, National Organic Standards Board, USDA. See also Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA (noting that internal USDA economic analysis, though valuable, takes time and is a reason why legislative rulemaking takes longer than guidance).

⁵⁴¹ Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA.

⁵⁴² Interview with Michael McCabe, former division director, Department of Energy.

⁵⁴³ On statutory requirements, see David W. Perkins & Maeve P. Carey, Cost-Benefit Analysis and Financial Regulator Rulemaking, CRS Report R44813, at 7-8 (April 12, 2017).

review), where cost-benefit analysis may be required by statute, that analysis would be done for legislative rulemaking but not for guidance, which helped explain why the former took longer.⁵⁴⁴ A former senior Federal Reserve official noted that, while the Fed’s legislative-rulemaking-specific cost-benefit analysis was “sometimes a bit skippy,” the CFPB did voluminous cost-benefit analysis, because of its fear of D.C. Circuit case law striking down SEC action for violating cost-benefit requirements.⁵⁴⁵

2. Building a Record and Responding to Comments in Anticipation of Judicial Review

The advent of “hard look” judicial review in the 1970s, ratified by the Supreme Court in *State Farm*,⁵⁴⁶ pushed agencies to develop voluminous administrative records to support their legislative rules and to devote countless hours to writing long preambles responding minutely to public comments. An EPA official—in comparing legislative rulemaking (which he said took an “excruciatingly” long time) with guidance (on which he said the agency was “much more nimble”)—said that a “huge” difference between the two was the time spent developing the administrative record and replying to comments, both of which he placed under the heading of “judicial review accountability,” that is, the agency’s “fear” of investing in a legislative rule only to have it struck down in court. EPA lawyers, he explained, were “vigilant” about ensuring that the administrative record was “all there,” including the development of supporting documents, with all data gathered and analyzed, which took a “ton of time.” Likewise, lawyers were vigilant in making sure the agency accounted for all comments. By contrast, “very little” of this was required for EPA guidance. There might be some accompanying materials, but it was “very rare” to do a full supporting foundation, in part because much of the necessary information would already have been gathered for a prior relevant legislative rulemaking, or would have bubbled up from the implementation process for that prior legislative rule. And even if EPA took public comment on a guidance document and responded (which it sometimes did), “we’re coasting along the surface” compared to what is done for a legislative rulemaking preamble.⁵⁴⁷ A former senior official at the EPA Air Program Office concurred that, for guidance, supporting material did not need to be gathered because it had already been assembled in prior legislative

⁵⁴⁴ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁵⁴⁵ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

⁵⁴⁶ *Motor Vehicle Manufacturers’ Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

⁵⁴⁷ Interview with Source 99, EPA official.

rulemakings, and public comments did not need to be addressed at the same level of detail as for legislative rulemaking.⁵⁴⁸

There is a similar dynamic at FDA, which has a policy of taking public comment on a very large proportion of its guidance documents.⁵⁴⁹ A former senior FDA official explained the difference. Legislative rulemaking required support for everything in the record and a time-consuming response to comments, and the costs of this process had been part of the agency's drive since the 1990s to rely more upon guidance, for which the process, even with public comment, was much more "abbreviated." Whereas legislative rules were "law" and had to be supported, the agency in issuing guidance felt more free not to develop a voluminous record, and the comments on guidance did not require the kind of response that was required on legislative rules. The fact that FDA was sued much more on legislative rules than on guidance, he said, was surely part of this.⁵⁵⁰ Similarly, a congressional staffer observed that, although FDA took public comment on guidance, it generally did not give any response to comments, meaning there was not the same kind of "*State Farm* obligation" as for legislative rulemaking, and so the process did not ensure the same careful consideration of stakeholder views.⁵⁵¹ A former senior FDA official thought the lack of a requirement to respond to comments was a crucial and salutary feature of FDA's process for guidance: if you required a preamble, you might as well do legislative rulemaking, and the whole thing would become "unworkable."⁵⁵² A former senior FDA career official, discussing the difference between legislative rulemaking and guidance, said responding to all substantive comments in a rulemaking in writing for publication added "significantly" to the time spent.⁵⁵³ Overall, said an FDA Office of Chief Counsel official, whereas legislative rulemaking was criticized for being "ossified," it was possible to issue guidance "pretty quickly."⁵⁵⁴

⁵⁴⁸ Interview with Source 103, former senior EPA Air Program Office official. But see Interview with Source 96, former senior EPA official with cross-office responsibilities (noting that for one proposed guidance document—defining Clean Water Act jurisdiction—much technical work was done in support of it, and also for the later legislative rulemaking).

⁵⁴⁹ On FDA's policy, see *infra* text at notes 659-666.

⁵⁵⁰ Interview with Source 107, former senior FDA official.

⁵⁵¹ Interview with Source 82, congressional staffer.

⁵⁵² Interview with Source 110, former senior FDA official.

⁵⁵³ Interview with Source 112, former senior FDA career official. See also Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16) (citing response to comments as one reason legislative rulemaking is slower than guidance at FDA).

⁵⁵⁴ Interview with Source 27, FDA Office of Chief Counsel official.

Elsewhere, too, the research and analytic demands are less for guidance than for legislative rulemaking. At OSHA, said the former deputy solicitor of DOL, guidance was faster than legislative rulemaking in part because of judicial decisions requiring that the agency in each rulemaking make a showing of significant risk and technological and economic feasibility.⁵⁵⁵ By contrast, headquarters might have a regional office draft a guidance document, noted John Newquist, a former assistant administrator of OSHA's Region V (headquartered in Chicago).⁵⁵⁶

3. Taking Comment in Itself

The actual publication of the draft rule/guidance and the taking of comments on it (as distinct from the work of responding to those comments) takes time and effort in itself, but this time and effort did not figure nearly as prominently in the interviews as did cost-benefit analysis, record-building, or responding to comments. And in any event, the burden of taking comment per se tends to be less for guidance documents than for legislative rules. At the banking agencies, said an interviewee who held senior posts at CFPB and other federal agencies, the comment period tends to be shorter for guidance, and the comments fewer.⁵⁵⁷ The comment period was also said to be shorter for guidance at the USDA National Organic Program,⁵⁵⁸ and in EPA clean water regulation.⁵⁵⁹ Comments were said to be less voluminous on guidance compared to legislative rules at FDA.⁵⁶⁰

4. Drafting Challenges

Legislative rules are typically harder to draft than guidance, which adds further to the time and resources they demand. Because legislative rules are mandatory, said an EPA official, you "sweat each detail," seeking to account for all factors and contingencies, since once the rule is promulgated, "we can't go back to it for 15 years." Guidance, he said, does not involve the same sweating of details.⁵⁶¹ As to FDA, a former senior career official there said that, in writing guidance, you need not be as careful on wording as on a legislative rule, because the language is not binding and is described as reflecting the current thinking of the agency; you are therefore

⁵⁵⁵ Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL.

⁵⁵⁶ Interview with John Newquist, Partner, Newquist Safety; former assistant regional administrator, OSHA.

⁵⁵⁷ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁵⁵⁸ Interview with Jake Lewin, President, CCOF Certification Services.

⁵⁵⁹ Interview with Lynn Thorp, campaigns director, Clean Water Action.

⁵⁶⁰ Interview with Source 107, former senior FDA official.

⁵⁶¹ Interview with Source 99, EPA official.

more free to put in details, use narrative form, Q&A form, and plain language, since the document is not “set in stone.” He recalled one subject on which he and his colleagues initially sat down to write a legislative rule and found it impossible to start with “codified language,” given the complexity of the matter; he therefore suggested handling the problem by writing guidance, as a “dry run,” before drawing up binding requirements.⁵⁶² In banking regulation, an interviewee who held senior posts at CFPB and other federal agencies said that guidance was “easier” to write and could be written “faster” than a legislative rule because “you don’t need to nail everything down,” as the aim is to warn regulated parties to pay attention to certain risks, not prescribe mandatory requirements.⁵⁶³

5. Dealing with Mobilized Stakeholders

The length, officially-binding status, and public salience of legislative rulemaking make it a focal point for the mobilization of interest groups to pressure the agency and enlist political allies in Congress, the White House, and elsewhere.⁵⁶⁴ This, in turn, makes legislative rulemaking expensive to the agency in terms of political capital. An official at a public interest organization working on immigrants’ right said that, in his experience seeking favorable policies from DHS, he had found that legislative rulemaking tended to “exhaust all [the agency’s] political capital,” more than issuing guidance did. Legislative rulemaking allowed time for the opponents of an initiative to marshal their forces. If an agency and its stakeholder allies sought to proceed by legislative rulemaking, he said, they were “declaring a grand war” and had to be prepared for greater opposition.⁵⁶⁵ A former Department of Energy division director, explaining why there was “no comparison” between the processes for legislative rulemaking and guidance, emphasized that the “politics” of the former process “slowed it down,” for whenever the proceeding seemed to veer in a direction that one interest group did not like, that group would marshal evidence and political support to stop the process, enlisting friendly members of Congress or the White House.⁵⁶⁶ With respect to the USDA National Organic Program, the

⁵⁶² Interview with Source 112, former senior FDA career official.

⁵⁶³ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁵⁶⁴ Raso, *supra* note 84, at 799-800; William F. West, *Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis*, 64 *Public Admin. Rev.* 66, 72-73 (2004).

⁵⁶⁵ Interview with Source 45, official at public interest organization working on immigrants’ rights.

⁵⁶⁶ Interview with Michael McCabe, former division director, Department of Energy.

president of an organic certifier, in discussing factors that slowed legislative rulemaking, immediately cited the agency’s internal process for economic analysis (not applicable to guidance), which he said could become a “pawn” in political clashes between different parts of the industry, in which members of Congress might be involved.⁵⁶⁷

C. Benefits and Costs of Notice and Comment for Guidance

Given that public comment on guidance is not nearly as burdensome as for legislative rulemaking, the question of whether to take such comment—instead of opting for no participation or one of the lesser forms of participation noted in Section A—turns on the benefits and costs. The benefits most prominently mentioned by interviewees were that public comment can provide the agency with better technical and political information and can vest the agency’s policymaking with more legitimacy, inducing stakeholders to “buy in.” The costs are time and resources, possibly sapping the agency’s capacity to provide guidance in the first instance. Below, I evaluate how these benefits and costs vary across agencies and contexts, with particular attention to how the benefits, while undoubtedly real in some circumstances, cannot always be counted on.

1. Benefits: Better Technical Information?

An oft-cited reason for taking public comment on guidance is that industry people and other stakeholders outside the agency have information that could lead to better policy design, e.g., about unforeseen implementation problems.⁵⁶⁸ A former senior Federal Reserve official said it was wrong to issue guidance without prior public comment, because “nobody is that smart.” That is, no agency knows enough to design guidance without first getting outside perspectives on how the policy will actually work. Public comment, he said, really helps make “better policy.”⁵⁶⁹ A former senior FDA official emphasized that FDA often had a lack of understanding of how things worked internally at regulated companies, and for those instances,

⁵⁶⁷ Interview with Jake Lewin, President, CCOF Certification Services.

⁵⁶⁸ This is a classic reason given for the taking of comment on legislative rulemaking. Michael A. Livermore et al., *Computationally Assisted Regulatory Participation*, 93 Notre Dame L. Rev. (forthcoming 2018), manuscript at 7, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2970222 (reviewing literature).

⁵⁶⁹ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

the agency's practice of taking comment could fill knowledge gaps and have a real impact.⁵⁷⁰ Jonathan Snare, former deputy solicitor of DOL, said notice and comment could help with the problem that OSHA sometimes did not understand how a guidance document would practically impact employers.⁵⁷¹ Kathryn Thomson, former general counsel of DOT, said the agency's practice of often taking public comment on guidance made the agency's approaches "smarter" and "better informed."⁵⁷² According to Charles Samuels, who represents the appliance manufacturers' trade association before the Department of Energy, notice and comment improves the quality of guidance.⁵⁷³

But this rationale for public comment must be scrutinized, particularly because the agency could sometimes acquire most or all of the knowledge gained through public comment through a cheaper, faster, and more targeted form of outreach, perhaps bilateral conversations or stakeholder meetings. According to a former agency general counsel, you should do notice and comment on guidance only if you think a lot of people will be interested and you will get a lot of good input. As a counter-example, he recalled how he represented a trade association for an industry consisting of a small number of large companies with concentrated expertise. The association met with agency officials to provide input on a guidance document. In that meeting-room, he said, "you had the benefit of all the intelligence you'd have gotten" through full-blown notice and comment, meaning that such expanded participation would have been a "waste."⁵⁷⁴ Similarly, a senior environmental counsel at a Fortune 100 company said that while public comment on EPA guidance could lead to a "better product," it was not always necessary.⁵⁷⁵ Targeted outreach sometimes tells you all you need to know. The general counsel of a Fortune 500 company, expressing frustration that agency officials often wrote impractical guidance documents, meaning they did not really understand what the regulated companies were doing, said industry people would react by thinking, "If only [the officials] had called a few of us!"⁵⁷⁶

⁵⁷⁰ Interview with Source 80, former senior FDA official. See also Interview with Source 109, regulatory policy executive at a drug manufacturer (making similar point).

⁵⁷¹ Interview with Jonathan Snare, Partner, Morgan Lewis; former Deputy Solicitor (for OSHA), DOL.

⁵⁷² Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA.

⁵⁷³ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

⁵⁷⁴ Interview with Source 69, former agency general counsel.

⁵⁷⁵ Interview with Source 118, senior environmental counsel at a Fortune 100 company.

⁵⁷⁶ Interview with Source 73, general counsel to Fortune 500 company.

What is public comment's marginal contribution to the agency's knowledge beyond what it would glean from, say, a stakeholder meeting? Discussing this point, Lynn Bergeson, managing partner of Bergeson & Campbell, who deals especially with the EPA offices on TSCA and FIFRA, observed that, whereas a stakeholder meeting would normally be located in DC and attract trade associations, national NGOs, and associations of state agencies, it would usually not include parties outside DC: regional stakeholder groups, state agencies without DC associations (or not aligned with their DC associations), mid-sized businesses, or start-ups. These same kinds of stakeholders were also less likely to be on EPA's listservs, meaning they could miss guidance that was published for comment only on the EPA website and announced on the listservs, as distinct from the Federal Register, which they were less likely to miss.⁵⁷⁷

The agency has to ask itself how much it would learn from otherwise-excluded stakeholders like those listed above. That will depend on the particular matter at issue. The question will never be fully answerable; indeed, the answer will have to be somewhat arbitrary, for the agency must guess about the existence of knowledge it has not yet sought.⁵⁷⁸ The question bears some similarity to the one addressed in a recent study by Cynthia Farina and her colleagues, about when an agency that is already engaged in notice-and-comment rulemaking through the Federal Register should seek input from people who would not comment without prompting. Farina et al. argue that the agency should not seek more participation simply for participation's sake. "Many (perhaps most) rulemakings do not need more public participation—or don't need it enough to justify the expenditure of resources required to get participation of value. The topics are too specialized, technical, or narrow to generate public interest or the affected stakeholder groups are already participating in the conventional process."⁵⁷⁹ Instead the agency should seek broader participation when it has reason to think otherwise-silent parties possess useful "situated knowledge," that is, "information about impacts, problems, enforceability, contributory causes, unintended consequences, etc. that is known by the commenter because of lived experience in the complex reality into which the proposed regulation would be introduced."⁵⁸⁰ Farina et al. give the example of small-business truck

⁵⁷⁷ Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell.

⁵⁷⁸ For discussion of this challenge in agency decisionmaking generally, see Jacob Gersen & Adrian Vermeule, *Thin Rationality Review*, 114 Mich. L. Rev. 1355, 1388-93 (2016).

⁵⁷⁹ Cynthia R. Farina et al., *Rulemaking vs. Democracy: Judging and Nudging Public Participation That Counts*, 2 Mich. J. Environmental & Admin. Law 123, 147 (2012).

⁵⁸⁰ Id. at 148.

drivers affected by DOT policy regarding on-board recorders of hours of service, or travelers with disabilities affected by DOT policy on accessibility of air travel facilities.

While efforts to glean knowledge from a broader range of participants are worthy, we should not be overly sanguine in our hope that agency policymaking will be seriously influenced by stakeholders who are not already somehow known to the agency. Even in full-blown legislative rulemaking, there is reason to doubt this happens. By the time a notice of proposed rulemaking is published, the agency has usually made a significant investment in the version of the policy set forth in the notice, and changes occurring as a result of input during the comment period tend to be incremental. Only prior to the notice is the policy truly plastic, and while the agency often takes a great deal of stakeholder input in the pre-notice phase, that input necessarily comes from parties whom agency officials already know to call up, or who already inhabit the agency's listservs, or who already attend the relevant conferences, etc., as distinct from the more diffuse regulated public that keeps tabs on the Federal Register. Because of this, genuine influence on rulemaking in its more plastic phase is largely confined to the "usual suspects."⁵⁸¹

2. Benefits: Better Political Information?

Besides technical information to improve the guidance document's policy design, public comment can also reveal political information that increases the agency's chance of winning any kind of political or legal controversy or negotiation over the guidance.⁵⁸² According to Thomson, the former DOT general counsel, notice and comment on guidance served as a means to "test the political waters," allowing the agency to anticipate "hurdles" and identify which stakeholders would "push back." This information would give the agency a better idea on whether to move forward on the policy at all, or whether legislative rulemaking would be

⁵⁸¹ West, *supra* note 564, at 70-74. For more on this dynamic, see Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 Duke L.J. 1321, 1366-69, 1380-83 (2010); Richard Stoll, *Effective EPA Advocacy* 73 (2d ed. 2014); Elliott, *supra* note 10, at 1492-93. Cf. Keith Naughton et al., *Understanding Commenter Influence During Agency Rule Development*, 28 *Journal of Policy Analysis & Management* 258 (2009) (finding substantial commenter influence at the *advance* notice of proposed rulemaking stage). That said, part of the reason for the rigidity of a notice of proposed rulemaking is that the agency fears any major change would result in judicial invalidation for lack of sufficient notice, West, *supra* note 564, at 73, so perhaps the unavailability of pre-enforcement judicial review for most guidance documents could render published draft guidance more plastic than an NPRM, giving more practical openness to the commenting process for guidance than we find for legislative rules.

⁵⁸² Cf. Livermore et al., *supra* note 568, at 8 (reviewing literature), on rulemaking. See also Farina et al., *supra* note 579, at 138 (noting that the existence of mass comment on a rulemaking can itself be a signal to the agency's political appointees regarding the politics surrounding the policy, if not its substance).

necessary. In taking comment on guidance, she said, DOT wanted to find out where the “landmines” were.⁵⁸³ According to James Conrad, the regulatory consultant, EPA uses public comment on guidance to “smoke out opposition” while the agency can still respond, and to make an informed decision on whether to fight for the policy.⁵⁸⁴

While notice and comment can serve this function well, it can also backfire. The key point is that agency policy and industry behavior involve a certain amount of inertia. If the agency springs new guidance on industry without public comment, one possibility is that industry will fight back and bring political or legal pressure to get the guidance withdrawn or invalidated, in which case the agency would have been better off seeking public comment in the first place, so it could have backed off and avoided a costly fight, or better-prepared itself for combat, or reached a compromise before the atmosphere was poisoned.⁵⁸⁵ But alternatively, if the agency springs new guidance without public comment, the forces of inertia might cause industry simply to go along with it, because the cost of compliance is not quite worth the fight.⁵⁸⁶ Charles Samuels, a partner at Mintz Levin who deals with guidance at the Department of Energy, Consumer Product Safety Commission, and EPA, explained that if the agency reveals its plan before making it operative, that may open the way for industry to make a political attack on the policy, perhaps enlisting Congress to bring pressure. But if the agency makes the guidance final immediately upon revealing it, industry may let it go.⁵⁸⁷ Getting operative guidance rolled back can be harder than fighting a proposal that is tentative by its own terms. Being tentative can invite resistance.

3. Benefits: More Legitimacy?

Broad participation through notice and comment may increase the legitimacy of the document and of the agency itself, that is, the degree to which stakeholders view the agency as making policy by a fair process in which they have some buy-in, which may incline them to be

⁵⁸³ Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA.

⁵⁸⁴ Interview with James Conrad, Conrad Law and Policy Counsel; formerly Assistant General Counsel at the American Chemistry Council.

⁵⁸⁵ E.g., Nina A. Mendelson, *Should Mass Comments Count?* 2 Mich. J. Environmental & Admin. L. 173, 181 (2012) (example of this kind of scenario involving the Coast Guard).

⁵⁸⁶ Raso, *supra* note 84, at 799.

⁵⁸⁷ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

more cooperative with and supportive of the agency.⁵⁸⁸ A former senior Federal Reserve official said that taking comment on guidance, even if the agency does not follow the comments, “adds legitimacy.”⁵⁸⁹ According to a former senior EPA official with cross-office responsibilities, “we gained more legitimacy” by doing notice and comment on significant guidance.⁵⁹⁰ In this Subsection, I will consider three specific mechanisms by which public comment can foster legitimacy, and I note potential limitations on each.

The first mechanism by which notice and comment on guidance may promote legitimacy is by creating a sense that the agency is responsive to stakeholders, fostering mutual trust among stakeholders and the agency. Samuels believed that notice and comment could be helpful “if you want to build consensus” on guidance.⁵⁹¹ Richard Naples, the chief regulatory officer of Becton Dickinson, observed that the FDA’s policy of taking public comment on a large category of its guidance documents allowed for a “meaningful dialogue” with regulated firms.⁵⁹² An official at a national public interest organization said that FDA accepted his organization’s comments “not infrequently,” and he found the agency “responsive.”⁵⁹³ Regarding the USDA National Organic Program, the president of one certifier found NOP, despite his disagreements with the agency, to have an “open mind” and to be “fairly responsive” and “fairly reasonable” regarding comments on guidance.⁵⁹⁴ An official at another certifier, describing NOP’s notice and comment process for guidance, said that NOP might not incorporate all changes the certifiers wanted, but had an “open ear,” resulting in an “overall positive experience.”⁵⁹⁵

But it is possible for stakeholders to view the agency’s solicitation of public comment on guidance as a formal gesture without substance, in which case notice and comment does not

⁵⁸⁸ Cf. Livermore et al., *supra* note 568, at 8-9 (on rulemaking).

⁵⁸⁹ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

⁵⁹⁰ Interview with Source 96, former senior EPA official with cross-office responsibilities.

⁵⁹¹ Interview with Charles Samuels, Partner, Mintz Levin (counsel to the Association of Home Appliance Manufacturers).

⁵⁹² Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson, and Company.

⁵⁹³ Interview with Source 133, official at national public interest organization.

⁵⁹⁴ Interview with Jake Lewin, President, CCOF Certification Services.

⁵⁹⁵ Interview with Source 114, official at an organic certifier. Other interviewees’ assessments were more middling or mixed. Officials at Public Citizen thought FDA’s level responsiveness to their comments was variable, and that it was hard to explain why it varied. Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group. Daniel Troy, general counsel of GlaxoSmithKline, found FDA’s responsiveness to comment “quite variable.” Interview with Daniel Troy, General Counsel, GlaxoSmithKline. Richard Stoll thought that, regarding public comment on guidance, EPA was very responsive when it came to technical or factual issues, but on major policy issues (such as defining Clean Water Act jurisdiction), “you won’t get anywhere,” because the political appointees want to do things a certain way. Interview with Richard Stoll, Partner, Foley and Lardner.

nurture legitimacy and may breed cynicism and alienation. This reaction may turn on several factors, including how often the agency actually makes changes based on comments and whether the agency issues a written response to comments (which agencies often do *not* do for guidance, by reason of prohibitive cost, as I shall discuss in the next Subsection). At EPA, said former civil enforcement director Eric Schaeffer, now head of an environmental NGO, officials sometimes undertook notice and comment on guidance “just to cover themselves,” which left stakeholders “frustrated.” He noted that sometimes the agency took comment on guidance without giving a response, simply announcing the final guidance without acknowledging changes or why they were made, which he considered “irritating” and “insulting.”⁵⁹⁶ An executive at an environmental services firm said that one EPA office with which he frequently dealt took public comment on guidance but did not actually pay attention to the input, which was frustrating to regulated firms.⁵⁹⁷ A former EPA official said “nobody has faith” that EPA is actually looking at the comments submitted on guidance. He generally had not seen more than minor changes to a guidance document as a result of notice and comment. The exercise felt like the agency was doing notice and comment just to say they’d done it—“check the box.” That said, the interviewee later cited one document, the 2011 guidance on Best Available Control Technology to reduce CO₂ from bioenergy production, that he thought well-received because there had been “a lot” of public participation in its formulation and EPA had “listened to both sides.”⁵⁹⁸ Meanwhile, at FDA, a former official there said a major disadvantage of guidance, compared to legislative rulemaking, was that FDA generally gives no written response to comments, thereby cutting out a “huge” part of the process of agency-industry dialogue. In cases where industry comments do not get incorporated into the guidance document, “nobody knows” why. More generally, said the interviewee, FDA’s preference for guidance over legislative rulemaking “reduces industry acceptance” of FDA policy.⁵⁹⁹ As for OSHA, said U.S. Chamber of Commerce executive director of labor law policy Marc Freedman, public comment on guidance

⁵⁹⁶ Interview with Eric Schaeffer, Executive Director, Environmental Integrity Project; former director of civil enforcement, EPA. But see *supra* text at note 547, 639 (other interviewees stating that EPA usually does give some response to public comment on guidance).

⁵⁹⁷ Interview with Source 106, executive an at environmental services company.

⁵⁹⁸ Interview with Source 54, former EPA official.

⁵⁹⁹ Interview with Source 20, former FDA official.

was “rare,” and Freedman said he never saw the agency under the Obama administration make a change in response to a Chamber comment: “I’m jaded about this.”⁶⁰⁰

The second mechanism by which notice and comment on guidance can enhance legitimacy is by deflecting charges of selectivity, favoritism, or bias regarding whose voices the agency hears. In contrast to targeted outreach (in which the agency handpicks its interlocutors) or stakeholder meetings (whose attendance may depend on which stakeholders are engaged enough to be on the right listserv or travel to DC), notice and comment is the most general, open, and impersonal means of seeking participation.

NGO representatives considered the openness of notice and comment on guidance to be an important means of leveling the playing field with industry. An official at a national public interest organization that seeks to influence FDA guidance said that the “formal mechanism” of notice and comment was “really beneficial” to his organization, because his organization did not have the same “intimate” lobbying relationship with FDA that industry players had, nor the resources to “always be there all the time” the way industry could be.⁶⁰¹ Notably, the openness of notice and comment can be valuable to non-industry groups even if they never actually submit a comment in a specific proceeding. Andrew DeLaski, executive director of the Appliance Standards Awareness Project (ASAP), which advocates for energy efficiency in appliances and has the Department of Energy’s appliance standards as a major area of focus, stated that his group had never actually commented on a Department guidance document. However, noted DeLaski, his group was aware of the Department’s practice of generally posting guidance documents for public comment before finalizing them, and his group did monitor those drafts. Guidance documents were potentially concerning to his group, for a business seeking guidance might be “testing” for a “loophole” in a legislative rule, and a guidance document could be an “implicit weakening” or “backdoor loosening” of the rule. In the event that such concerns arose, the Department’s transparent process meant that ASAP could object. This, said DeLaski, was an improvement over the less transparent, more ad hoc approach to guidance that the Department

⁶⁰⁰ Interview with Marc Freedman, Executive Director of Labor Law Policy, U.S. Chamber of Commerce. Baruch Fellner, founding partner of Gibson Dunn’s OSH practice, had a similar view of OSHA’s taking of meetings with stakeholders: he found them “more C.Y.A. than substantive,” meaning the agency wanted to be able to say it engaged in stakeholder dialogue, but did not actually listen to stakeholder views, such that guidance’s ultimate content was predictable: “I haven’t seen them have an epiphany moment” in which they change their mind about a guidance document’s content. Interview with Baruch Fellner, Partner, Gibson Dunn.

⁶⁰¹ Interview with Source 133, official at national public interest organization.

had followed before it adopted notice and comment circa 2009. In addition, the opportunity to monitor and comment (even if never exercised) gave DeLaski “some confidence” that all regulated firms were getting the same answer to the same question, which he considered important for the integrity and political standing of the program.⁶⁰²

Notice and comment on guidance also allays the anxiety that officials themselves feel that someone may accuse them of being cozy with industry or improperly influenced.⁶⁰³ That anxiety can be quite real.⁶⁰⁴ The general counsel of a Fortune 500 company, bemoaning the fact that agency officials writing guidance had too little understanding of internal regulated-firm operations, thought it valuable for officials to attend industry conferences, but said that officials were concerned about “being caught” in such settings.”⁶⁰⁵ Frank White, the former deputy head of OSHA and former president of an HSE consultancy, observed that OSHA, when making any kind of contact with stakeholders on the formulation of guidance, was “very sensitive” about meeting with employers without labor representatives being present. Indeed, White said that, in his private practice representing employers, he would try to team up with labor representatives and bring them along to meetings with OSHA to make the officials “more comfortable.” Notice and comment rulemaking, he noted, provided this comforting balance “automatically.”⁶⁰⁶ So, of course, would notice and comment on guidance.

Yet ironically, the very openness, transparency, and impersonality of notice and comment arguably detracts from some stakeholders’ capacity to contribute to agency policy and their sense of “buy-in.” An example is FDA. While FDA’s procedures contemplate that the agency will take public comment on guidance documents once they are published in draft form, the procedures also say the agency “can seek or accept early input” on guidance prior to formulating or publishing a draft.⁶⁰⁷ In fact, the procedures say that anyone outside FDA “can submit drafts

⁶⁰² Interview with Andrew DeLaski, executive director, Appliance Standards Awareness Project. That said, DeLaski did not have a problem with notice and comment occurring through the Department’s website and listserv, rather than the Federal Register, since the website and listserv probably reached all the players who would have anything to add in this technical area. *Id.*

⁶⁰³ Cf. Mendelson, *supra* note 472, at 424-33 (arguing that targeted outreach tends to advantage industry over beneficiaries).

⁶⁰⁴ Cf. West, *supra* note 564, at 70 (discussing agency officials’ concerns about ex parte contacts in the legislative rulemaking process).

⁶⁰⁵ Interview with Source 73, general counsel at Fortune 500 company.

⁶⁰⁶ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL.

⁶⁰⁷ 21 C.F.R. § 10.115(g)(1)(i).

of proposed guidance documents for FDA to consider.”⁶⁰⁸ Yet it proves difficult, as a political matter, for FDA to sustain—alongside notice and comment—the kind of fluid, intimate, informal dialogue contemplated by this provision. Naples, Becton Dickinson’s chief regulatory officer, explained that, while he supported the FDA’s notice-and-comment policy and believed it had done much good, it also had unfortunately resulted in FDA having less interaction with industry than it should prior to publishing a draft guidance document, due to agency personnel’s “fear of favoritism” and the sense of FDA lawyers that such pre-draft contacts were somehow inappropriate despite being expressly permitted by agency procedures; consumer and patient groups would criticize the contacts as “dirty” and as conduits for “undue influence.” FDA feared the appearance of working too closely with industry. This limitation on dialogue was unfortunate because “guidance needs science,” and “the companies have the science.” For officials to formulate draft guidance in ignorance of industry knowledge was inefficient and ended up creating more work later in the process.⁶⁰⁹ Other interviewees agreed that, despite FDA’s extraordinary commitment to notice and comment on guidance, genuine communication between agency and industry could be blocked by political fear of operating outside that process. Bradley Merrill Thompson, counsel to device-maker trade associations, said that FDA’s failure to communicate with industry on a pre-draft basis was a continuing problem and was currently (as of October 2016) at a “low point,” in part because Commissioner Robert Califf, having been subjected to “absurd” accusations about coziness with industry during his confirmation hearings, was “sensitive” about the matter.⁶¹⁰ Relatedly, Daniel Troy, general counsel of GlaxoSmithKline, said that while he recalled a few times when a trade association submitted draft guidance documents to the agency (as the FDA procedures expressly permit), “politics these days” were “very challenging” for that kind of submission. It “looks like capture.”⁶¹¹ An FDA Office of Policy official confirmed that the agency “rarely” sees industry submit draft guidance.⁶¹² Janet Woodcock, Director of FDA’s Center for Drug Evaluation and Research, likewise said outside submissions of draft guidance were “very uncommon,” partly because

⁶⁰⁸ 21 C.F.R. § 10.115(f)(3).

⁶⁰⁹ Interview with Richard Naples, chief regulatory officer, Becton, Dickinson, and Company.

⁶¹⁰ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

⁶¹¹ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

⁶¹² Interview with Source 25, FDA Office of Policy official.

parties might fear an “appearance of impropriety,” though she thought industry had many ways to participate besides this.⁶¹³

A similar dynamic may occur at parts of EPA. An executive at an environmental services firm said that, while EPA over the last few decades had increasingly sought public comment on drafts of guidance documents, the agency was decreasingly receptive to input from industry prior to any version of guidance being published. He regarded this as unfortunate, because input outside of notice and comment on a particular draft was more “free flow” and “back and forth” and was thus more informative to the agency. By the time a draft was formulated and published, he noted, EPA would already be “defensive” about the draft.⁶¹⁴ This interviewee’s observation is consistent with academic literature on legislative rulemaking indicating that, although a draft rule is supposed to be the focal point for agency-stakeholder dialogue, the agency’s very act of preparing the draft and achieving internal agreement on it causes the agency to become more invested in the draft’s content and less willing to make changes.⁶¹⁵

The third mechanism by which notice and comment on guidance could increase legitimacy is by simply getting a larger number and wider range of stakeholders (especially regulatory beneficiaries) to participate. In particular, public comment on guidance makes guidance susceptible to the same kinds of “mass comment campaigns” that have become a salient (if statistically rare) feature of legislative rulemaking. For example, searches of the [regulations.gov](http://www.regulations.gov) website yield approximately fifty draft guidance documents that EPA chose to publish for public comment through the Federal Register in the period 2011-2014,⁶¹⁶ and of these, eight were subject to mass-comment campaigns yielding at least 5,000 comments each, with five that exceeded 40,000 comments.⁶¹⁷ These avalanches of comments might serve as

⁶¹³ Interview with Janet Woodcock, Director, FDA Center for Drug Evaluation and Research. See also Interview with Source 80, former senior FDA official (noting FDA sometimes encourages submission of draft guidance and that it has happened); Interview with Source 20, former FDA official (noting that in some instances industry does submit draft guidance while in others it seeks influence by more indirect means; and that in any case the agency tends to “hunker down” and stop communicating with stakeholders at some point in the formulation process before publishing a draft).

⁶¹⁴ Interview with Source 106, executive at an environmental services company.

⁶¹⁵ West, *supra* note 564, at 72. Compare Naughton et al., *supra* note 581 (finding more influence at the *advance* notice of proposed rulemaking stage).

⁶¹⁶ Note these searches would not pick up guidance documents that EPA published for public comment on its own website.

⁶¹⁷ For each of these eight documents, one can calculate a very rough number of mass-comment-campaign comments by going to the webpage for the document’s docket folder and subtracting the count of unique comments appearing in the parenthetical after the “Comments (View All)” heading from the count of total comments under the heading “Comments Received*.” But note the difference will not exclude comments that were part of a mass-

prima facie evidence that notice and comment is making the formulation of guidance more legitimate in a democratic sense—in terms of the mass public’s sense of ownership of what the agency does.

But some scholars of legislative rulemaking—where mass comment has been studied for several years—have argued that, if we operate from a conception of democratic legitimacy befitting administrative policymaking, the value of mass comments is dubious. As noted by Farina and her colleagues, “high-volume commenting almost always stems from action campaigns by one or more advocacy groups.” The “primary purpose of the [groups’] campaigns,” say Farina et al., “is persuasive, not educational,” based on appeals to emotion, hyperbolic language, and “selective deployment of facts.” The comments arising from the campaigns do not fit the paradigm of deliberative democracy—pluralist and open yet also evidence-based and rational—that has historically characterized agency policymaking, as distinct from a raw plebiscitary model of policy choice. Treating commenting as a plebiscite is dubious for the additional reason that comments are not a representative sample of the population or electorate.⁶¹⁸ In fact, as Nina Mendelson has said, comments from the mass public often state

comment campaign insofar as the individual commenters personalized their comments. On the tendency to “slightly personalize” comments in mass-comment campaigns, see Farina et al., *supra* note 579, at 141. The eight documents, with counts, are:

- Draft Guidance on Identifying Waters Protected by the Clean Water Act, EPA-HQ-OW-2011-0409 (230,625 minus 3,878 equals 226,747).
- UIC Permitting Guidance for Oil and Gas Hydraulic Fracturing Activities Using Diesel Fuels—Draft, EPA-HQ-OW-2011-1013 (97,147 minus 2,732 equals 94,415).
- Updates to Protective Action Guides Manual: Protective Action Guides (PAGs) and Planning Guidance for Radiological Incidents, EPA-HQ-OAR-2007-0268 (68,350 minus 2,213 equals 66,137).
- Benefits of Neonicotinoid Seed Treatments to Soybean Production Docket Fold, EPA-HQ-OPP-2014-0737 (41,571 minus 938 equals 40,633). (This document is an assessment of the benefits of certain seed treatments to soybean production, conducted as part of EPA’s “periodic review of pesticide registrations.” The notice inviting comment, posted October 22, 2014, is prefaced with the word “Guidance.”)
- Solicitation of Public Comments re: Guidance on Improving EPA Review of Appalachian Surface Coal Mining Operations Under CWA, NEPA and EJ Executive Order, EPA-HQ-OW-2010-0315 (63,601 minus 810 equals 62,791).
- Notice of availability of the 2012 Recreational Water Quality Criteria, EPA-HQ-OW-2011-0466 (10,513 minus 218 equals 10,295).
- Consideration of Spray Drift in Pesticide Risk Assessment, EPA-HQ-OPP-2013-0676 (5,596 minus 118 equals 5,478).
- Pesticides; Consideration of Volatilization in Pesticide Risk Assessment: Notice of Availability and Request for Comment, EPA-HQ-OPP-2014-0219 (15,442 minus 18 equals 15,424).

Examples of mass public comment on guidance documents have been noted previously in the literature, going back as far as 2003. E.g., Mendelson, *supra* note 472, at 432.

⁶¹⁸ Farina et al., *supra* note 579, at 137-45. See also Michael Herz, “Data, Views, or Arguments”: A Ruminant, 22 Wm. & Mary Bill of Rights Journal 351, 371 (2013) (noting consensus among scholars that legislative rulemaking is not plebiscitary).

value choices rather than make evidence-based arguments, and agencies “generally appear to be impatient with and unresponsive to value-based commenting.”⁶¹⁹ Indeed, agencies may be “overwhelmed and annoyed” by masses of comments that are costly to process yet seemingly of little use in decisionmaking, meaning the campaigns can even backfire in winning agency assent.⁶²⁰ Or if agencies do embrace mass comments, they are opportunistic about it: “When [the agencies’] conclusion has strong support in the [mass] comments they tend to note that fact, and when it does not they tend to glide over it.”⁶²¹ If mass comment continues to grow, we may be headed toward one of two problematic outcomes: agencies’ unresponsive or opportunistic treatment of mass comments will aggravate public cynicism, or the agencies will be forced to adopt more of a plebiscitary approach to policymaking, which is not something for which notice and comment is designed or suited.⁶²²

4. Costs: Expenditure of Time and Resources

Notice and comment on guidance will take agency resources and cause some delay, compared with narrower and less-formal means of taking input. Public comment on guidance, said a former agency general counsel, was “usually a good investment,” but came at “some cost.”⁶²³ Samuels, counsel to the home appliance manufacturers’ association, noted that it takes “manpower.”⁶²⁴ According to an EPA official, one of EPA’s criteria for whether to take public comment on guidance was the need for speed: if the guidance was needed right away, that was a reason to forego comment.⁶²⁵ A former senior EPA official with cross-office responsibilities said a drawback of notice and comment on guidance was the processing time.⁶²⁶ An interviewee who held senior posts at CFPB and other federal agencies said the targeted outreach to industry trade associations, public interest groups, and consumer advocates that was common for banking

⁶¹⁹ Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-Mail*, 79 *Geo. Wash. L. Rev.* 1343, 1367 (2011).

⁶²⁰ Herz, *supra* note 618, at 373.

⁶²¹ Herz, *supra* note 618, at 372. For an argument that the FCC genuinely took account of public sentiment expressed in mass comments in the net neutrality rulemaking, see Lauren Moxley, *E-Rulemaking and Democracy*, 68 *Admin. L. Rev.* 661 (2016).

⁶²² Livermore et al., *supra* note 568, at 14. Mendelson argues that the most rational and defensible agency approach to mass comment is to treat it as an invitation to further assessment or deliberation. Mendelson, *supra* note 619, at 1371-79.

⁶²³ Interview with Source 69, former agency general counsel.

⁶²⁴ Interview with Charles Samuels, Partner, Mintz Levin.

⁶²⁵ Interview with Source 99, EPA official.

⁶²⁶ Interview with Source 96, former senior EPA official with cross-office responsibilities.

agencies formulating guidance was “much faster” than the process that banking agencies would typically undertake when they did voluntary notice and comment on guidance (that is, administering a public notice and comment period, making an appropriate record of the comments received, and publishing the outcome).⁶²⁷ A former senior Federal Reserve official who has counseled financial institutions said he thought CFPB ought to undertake notice and comment on guidance more, estimating it would add three to five months to the process for a given document.⁶²⁸

The cost of notice and comment in time and money presents a tradeoff: it will delay issuance of the guidance at issue and possibly also burn up agency resources that could be used to produce guidance on yet other subjects. Since much guidance responds to industry demand for clarity, this is a tradeoff for industry, as well. A former CFBP official who represents CFPB-regulated entities put the “tradeoff” thus: “industry wants input,” but it also “wants guidance,” and more input means less guidance.⁶²⁹ An executive at a drug manufacturer warned that adding more process for FDA guidance would make the agency less inclined to issue it and slow things down; industry needed to know what the agency was thinking.⁶³⁰ John Newquist, the former assistant administrator of OSHA’s Region V (headquartered in Chicago), said the agency would benefit from more stakeholder input on guidance, but he said this risked making the issuance of guidance more like legislative rulemaking, which at OSHA is notoriously slow and onerous, and if that happened, you would never have any guidance.⁶³¹ Celeste Monforton, the academic and safety advocate and former OSHA legislative analyst, said that OSHA guidance was high in volume, diverse, and often based on local conditions, meaning that putting most of it out for comment was not feasible: “industry just wants the answer.”⁶³² An official at a nonprofit public policy research organization, formerly a consultant and product manager in the consumer finance industry, said that a well-run banking regulatory agency should be interested in seeking a broad range of outside viewpoints, but you cannot really force an agency to care about such input, and adding process burdens to the issuance of guidance risked taking away the value of guidance,

⁶²⁷ Interview with Source 90, person who held senior posts at CFPB and other federal agencies.

⁶²⁸ Interview with Source 72, former senior Federal Reserve official who has counseled financial institutions.

⁶²⁹ Interview with Source 81, former CFPB official who represents CFPB-regulated entities.

⁶³⁰ Interview with Source 108, executive at a drug manufacturer.

⁶³¹ Interview with John Newquist, Partner, Newquist Safety; former assistant regional administrator, OSHA.

⁶³² Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA.

that is, the capacity to change industry behavior for the better through informal nudging based on agency judgment.⁶³³ A former HHS Office of General Counsel official, while urging that CMS do notice and comment for more of its guidance, said he recognized that this had to be traded off against the fact that more process would slow things down, especially since it was already hard to get guidance out of CMS to begin with.⁶³⁴

When it comes to the time and resources spent on notice and comment, a key variable is whether the agency opts to issue a written response to the comments (the written response, in the context of legislative rulemaking, being one of the costliest elements of the process). A former agency general counsel, while declaring notice and comment usually a good investment for guidance, said it was “key” that there was no obligation to respond to the comments—a point he said kept down process costs more than any other factor, including the absence of OMB review.⁶³⁵ Consider FDA, which does not obligate itself to give any response to comments on guidance and generally gives none.⁶³⁶ When FDA first adopted its policy in favor of notice and comment on guidance in the 1990s, recalled a former senior official there, personnel were “often unhappy” with the policy, and it was “key” for obtaining their “buy-in” that the policy did not require a response to comments like that required for legislative rulemaking.⁶³⁷ William Schultz, who served as FDA Deputy Commissioner for Policy in 1994-98, recalled that the agency’s centers were “upset” about the new policy, and the staff feared that the new policy would “really impede” their work; the absence of a response requirement, he said, was important for “selling” the policy to the staff.⁶³⁸ Meanwhile, at EPA, officials usually *do* give a response to comments on guidance,⁶³⁹ though much less in-depth than for legislative rulemaking.⁶⁴⁰ DOT and the

⁶³³ Interview with Source 131, official at nonprofit public policy research organization, formerly consultant and product manager in consumer finance industry.

⁶³⁴ Interview with Source 67, former HHS Office of General Counsel official.

⁶³⁵ Interview with Source 69, former agency general counsel.

⁶³⁶ Interview with Source 24, trade association official; Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group; Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green.

⁶³⁷ Interview with Source 107, former senior FDA official.

⁶³⁸ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁶³⁹ Interview with Richard Stoll, Partner, Foley and Lardner.

⁶⁴⁰ See *supra* text at note 547.

USDA National Organic Program also give responses when they do take notice and comment on guidance.⁶⁴¹

Ironically—but crucially—the costs of notice and comment can rise high enough that such participation comes to be viewed as an obstacle to agency policymaking, which in turn delegitimizes the entire agency policymaking process in the eyes of some stakeholders. In other words, notice and comment becomes, not a costly investment in legitimacy, but a factor that kills legitimacy, at least for part of the community. At OSHA, said one AFL-CIO official, employers had succeeded over the years in “shutting down” legislative rulemaking, to the point where promulgating a major rule can take 10 to 20 years.⁶⁴² This comment is consistent with academic work indicating that, particularly at OSHA, judicial review imposed process costs that dramatically slowed legislative rulemaking in the course of the 1970s and 1980s.⁶⁴³ Efforts in recent years to beef up the process for issuing OSHA guidance and thereby make it more like legislative rulemaking, argued the AFL-CIO official, would make it “not feasible to run the government.”⁶⁴⁴ The whole challenge to guidance, said a second AFL-CIO official, was an “industry-generated” effort to get OSHA to “stop doing its job.”⁶⁴⁵ The first AFL-CIO official did not see notice and comment on guidance as a good-faith effort to broaden participation at a procedural level, but instead as a disguised substantive attack on workplace safety regulation per se. “The objection” to guidance, he said, “is not really about process but substance.” It was an effort to weigh down guidance with the same “baggage” as legislative rulemaking, out of a substantive objection “to all government regulation.”⁶⁴⁶ Even lesser forms of participation were subject to this critique. If OSHA held a stakeholder meeting on a guidance document, said the second AFL-CIO official, “it would be a disaster,” opening the way for industry associations to try to “shut down” the initiative through “scare tactics” and the invocation of “extreme” fact situations.⁶⁴⁷ “If you create an event,” said a third AFL-CIO official, “you create a target.”⁶⁴⁸

⁶⁴¹ Interview with Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA; Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

⁶⁴² Interview with Source 36, AFL-CIO official.

⁶⁴³ Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 Duke L.J. 1385, 1387-88, 1392-93, 1400-03 (1991).

⁶⁴⁴ Interview with Source 36, AFL-CIO official.

⁶⁴⁵ Interview with Source 35, AFL-CIO official.

⁶⁴⁶ Interview with Source 36, AFL-CIO official.

⁶⁴⁷ Interview with Source 35, AFL-CIO official.

⁶⁴⁸ Interview with Source 37, AFL-CIO official.

Given AFL-CIO officials' view of notice and comment on guidance as favoring industry, one might think that, if OSHA were to incur the cost of offering such process on a guidance document, the agency would increase its credibility with employer groups whom the AFL-CIO often opposes. But that is hardly guaranteed. Marc Freedman, the U.S. Chamber of Commerce's executive director of labor law policy, recounted how OSHA in October 2010 made the rare move of seeking public comment on a draft guidance document, this one pertaining to occupational noise exposure. The document favored expansive engineering controls that would be costly to employers compared with the alternative of personal protective equipment. The Chamber thought the new policy required legislative rulemaking and was unsound as a matter of substance. It commissioned an economic analysis for its comment, which it expected would have no impact on OSHA, and submitted a preliminary comment on Jan. 18, 2011, pending full comments to come in March. But suddenly, on Jan. 19, 2011, OSHA withdrew the draft. Freedman, who attributed the withdrawal at least in part to intervention by OMB (which he said had not heard of the guidance before it was published), said the whole episode "made us suspicious of OSHA guidance going forward."⁶⁴⁹ In other words, Freedman's view that the draft contained broad and wrongheaded policy and was an inappropriate use of guidance offset any increased credibility that OSHA might have hoped to achieve by voluntarily taking public comment on the initiative.

D. Should Notice and Comment Be Required for Guidance?

The preceding Section indicates that the benefits of notice and comment on guidance (though hardly certain) may be substantial enough to offset the costs in many situations. If notice and comment is worth it for at least some guidance, that raises the question of whether whole agencies, or even the entire government, should have policies requiring its use. This Section considers that question. I begin by noting several existing models for requiring notice and comment, with particular attention to one in which a single agency adopts an agency-wide mandate for notice-and-comment on a large category of its guidance. I then point out the danger that, if an agency adopts such a policy for a large enough category of guidance as to strain the

⁶⁴⁹ Interview with Marc Freedman, Executive Director of Labor Law policy, U.S. Chamber of Commerce. For the Chamber's preliminary comment, see document ID OSHA-2010-0032-0079 on [regulations.gov](http://www.regulations.gov). For announcement of the withdrawal, see OSHA National News Release No. 11-74-NAT (Jan. 19, 2011).

agency’s resources, the result may be that guidance remains in draft indefinitely, defeating the purpose of notice and comment and—if the regulatory program entails strong incentives to follow guidance—causing confusion and risk for stakeholders. I also consider the possibility that strong policies in favor of public comment for guidance (especially if ratified by Congress or the White House) could have the effect of legitimating the replacement of legislative rulemaking by guidance. Given the variability of public comment’s benefits and costs (discussed in Section C) and the risks discussed in this Section, I conclude that it is best to proceed document-by-document, or at most agency-by-agency, and that a government-wide mandate for public comment on a large category of guidance would be imprudent given our present knowledge.

1. Models for Requiring or Encouraging Notice and Comment

Let us begin by considering existing models for requiring or encouraging notice and comment on guidance. We shall first consider OMB’s mandate for notice and comment on certain guidance documents across all executive agencies, then agency-specific approaches.

OMB’s mandate is broad in terms of the agencies covered but narrow in terms of the documents covered. Its Good Guidance Practices of 2007 generally require that all executive agencies engage in pre-adoption notice and comment (with a response) on any guidance document that is “economically significant,”⁶⁵⁰ i.e., that “may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy.”⁶⁵¹ To appreciate the narrowness of coverage, consider the annual number of OMB reviews of “economically significant” regulatory actions (for which the criteria nearly track those for economically significant guidance documents,⁶⁵² though of course the regulatory actions category also includes legislative rules, proposed legislative rules,

⁶⁵⁰ OMB Good Guidance Practices § IV.

⁶⁵¹ OMB Good Guidance Practices § I(5).

⁶⁵² OMB’s criteria for what makes a regulatory action “economically significant” consist of the first of the four items in the definition of “Significant regulatory action” in Executive Order 12866 § 3(f), which reads: “Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, *productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities*” (emphasis added). Maeve P. Carey, Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register, CRS Report R43056, at 10-12 (Oct. 4, 2016). See also Leland E. Beck, Economically Significant: A Threshold Snapshot of OMB’s Regulatory Docket, Federal Regulations Advisor (Aug. 9, 2013), available at www.fedregsadvisor.com/2013/08/09/economically-significant-a-threshold-shapshot-of-ombs-regulatory-docket. As you can see by comparing the quoted text with the OMB Good Guidance Practices’ criteria for economically significant guidance documents, the criteria for economically significant regulatory actions add disjunctively a few triggers to the \$100 million trigger and the “adversely affect” trigger that we find in the Good Guidance Practices.

and other rulemaking-related vehicles besides guidance). Annual OMB reviews of economically significant regulatory actions averaged 109.8 in the calendar years 2011-2015.⁶⁵³ Technically, this category of OMB reviews is supposed to include each year's economically significant guidance documents,⁶⁵⁴ but in fact, an examination of lists of all the OMB reviews reveals only two in the entire period 2011-2015 that were designated as reviews of guidance documents (the vast majority being designated proposed rules or final rules).⁶⁵⁵ This does not necessarily mean that economically significant guidance documents across all executive agencies in 2011-2015 “really” numbered only two. Maybe there were more, but they did not get formally designated as such by OMB, or the agencies did not report them as such.⁶⁵⁶ Still, it does seem fair to assume—given the interstitial nature of guidance—that the number of economically significant guidance documents would be substantially less than the number of economically significant legislative rules. That suggests their average annual number across the whole range of executive agencies would be well under 109.8. To appreciate how tiny this number is compared with the total number of executive agency guidance documents, consider that at FDA alone, the number of final guidance documents presently operative that were issued in the past 20 years is about 1,600, that is, roughly 80 per year (and that excludes documents that were issued but later withdrawn).⁶⁵⁷ Thus, at least if we guesstimate the amount of covered guidance by extrapolating from how OMB designates and counts economically significant rules,⁶⁵⁸ the OMB notice-and-comment requirement applies only to the tip of the guidance iceberg.

⁶⁵³ Calculations based on the years 2011-2015 in Table 4 in Carey, *supra* note 652, at 11-12.

⁶⁵⁴ On the inclusion of guidance documents and legislative rules in the “economically significant” reviews, see Carey, *supra* note 652, at 12.

⁶⁵⁵ Lists of OMB reviews of economically significant regulatory actions for all five years from 2011 to 2015 were obtained through year-specific queries to the Historical Reports database available at www.reginfo.gov/public/do/eoHistoricReport. The numbers of actions listed for each year are identical or nearly identical to the figures in Table 4 in Carey, *supra* note 652, at 11-12. The two actions listed as guidance are both EPA actions regarding the scope of Clean Water Act jurisdiction; their respective “Completed” dates are 04/27/2011 and 09/17/2013. EPA did take public comment on this guidance. Draft Guidance on Identifying Waters Protected by the Clean Water Act, Docket EPA-HQ-OW-2011-0409, available at regulations.gov.

⁶⁵⁶ See Statement of Paul R. Noe, Vice President, Public Policy, American Forest & Paper Association, Before Senate Committee on Homeland Security and Governmental Affairs Subcommittee on Regulatory Affairs and Federal Management, “Examining the Use of Agency Regulatory Guidance, Part II,” June 30, 2016, at 8 (arguing that “clearly [agencies] have not” complied with the OMB Good Guidance Practices).

⁶⁵⁷ That count is drawn from a search, conducted February 5, 2017, of FDA’s online database of guidance, searching for final guidance documents still operative (excluding bioequivalence recommendations) for which dates were assigned in the database itself or could be assigned through simple online research.

⁶⁵⁸ There is some bureaucratic political gaming that goes into what legislative rules are actually reviewed by OMB. Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 Harv. L. Rev. 1755 (2013).

When OMB’s narrow requirement is not in play, agencies have discretion in deciding when to take public comment on guidance. Given this latitude, there are three patterns of agency behavior: (1) adopt a policy of taking public comment on one or more large categories of guidance documents; (2) take public comment on a large number of guidance documents but let them be chosen on a more ad hoc, decentralized basis; or (3) reserve notice and comment only for exceptional guidance documents.

The first model—to have a policy of notice and comment on one or more large categories of guidance documents—is exemplified by FDA’s Good Guidance Practices (GGPs), a set of procedural rules adopted by the agency in February 1997.⁶⁵⁹ Subsequently Congress in November 1997 passed a specific statutory mandate for such procedural rules (including to “ensure public participation [in guidance’s formulation] prior to implementation”),⁶⁶⁰ and the procedural rules were repromulgated, without fundamental changes from the original, in 2000.⁶⁶¹ Under its GGPs, FDA generally must conduct pre-adoption notice and comment for all “Level 1” guidance documents, which are defined broadly as those that “(i) Set forth initial interpretations of statutory or regulatory requirements; (ii) Set forth changes in interpretation or policy that are of more than a minor nature; (iii) Include complex scientific issues; or (iv) Cover highly controversial issues.”⁶⁶² FDA’s initial adoption of the GGPs in February 1997 had several causes. The agency’s use of guidance documents had been increasing rapidly in the 1990s because of the increasing complexity of the relevant science, and there was a felt need to regularize the documents’ use.⁶⁶³ There had been internal reform initiatives in parts of FDA prior to the advent of the agency-wide GGPs.⁶⁶⁴ What immediately precipitated their formulation and adoption was a petition from the Indiana Medical Devices Manufacturers Council,⁶⁶⁵ combined with pressure from congressional overseers.⁶⁶⁶

⁶⁵⁹ 62 Fed. Reg. 8961 (1997). The notice and comment provision appears in *id.* at 8968.

⁶⁶⁰ 111 Stat. 2296, 2368 (1997), codified in 21 U.S.C. § 371(h). The quotation is from § 371(h)(1)(C)(i).

⁶⁶¹ 65 Fed. Reg. 56468 (2000), codified mainly in 21 C.F.R. § 10.115.

⁶⁶² 21 C.F.R. § 10.115(c)(1). For guidance other than “Level 1,” FDA also invites public comment, post-adoption. 21 C.F.R. § 10.115(g)(4)(C). More generally, FDA is willing to receive comments on any guidance document at any time. 21 C.F.R. § 10.115(g)(5).

⁶⁶³ Interview with Source 110, former senior FDA official.

⁶⁶⁴ Interview with Source 27, FDA Office of Chief Counsel official; Interview with Source 112, former senior FDA career official.

⁶⁶⁵ Cited in 62 Fed. Reg. 8961 (1997).

⁶⁶⁶ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

Another agency following this pattern is the USDA National Organic Program. In the Introduction to its Handbook (effective March 2011), NOP promised it would generally take pre-adoption public comment on all “Level 1” guidance documents, which it defined as those that “set forth interpretations of NOP statutory or regulatory requirements, changes in interpretation or policy, or address unusually complex or highly controversial issues.”⁶⁶⁷ Most NOP guidance documents are Level 1.⁶⁶⁸

The second model is to take public comment on a large number of guidance documents but select them on an ad hoc, decentralized basis, not according to a broad pre-defined category. EPA follows this approach. According to an EPA official, the final decision whether to take public comment on a guidance document is normally made by the Assistant Administrator who runs whichever program office is developing the guidance (e.g., the Air Program office, the Water office, etc.), although most commonly the guidance is actually signed by an official one level down, who runs the relevant component of the program office. The program office is more likely to opt for public comment (a) the more it thinks it will learn from comments, (b) the less time pressure there is to issue the guidance, and (c) the less the guidance could easily be changed if problems with it are encountered later.⁶⁶⁹ The decision whether to take public comment, said an EPA Office of General Counsel official, is really a policy decision, not a legal decision. The Office General Counsel plays an advisory role, but it is really up to the program people.⁶⁷⁰ While EPA has gone through a general shift toward notice and comment, each program office has gone at its own pace.⁶⁷¹ But the overall result of these many program-office decisions is that notice and comment for guidance is now a familiar thing at EPA. It may be impossible to put a percentage on it, since the forms of EPA guidance are so numerous and variable that the denominator is hard to define. Interviewees gave impressionistic takes on how common it was. One former EPA official said the breakdown between guidance with and without public comment was something like “fifty-fifty.”⁶⁷² An attorney at an environmental NGO said notice and comment for guidance is “not the norm” at EPA but “not unusual.”⁶⁷³ (Another agency

⁶⁶⁷ USDA National Organic Program, Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations, Introduction (effective March 9, 2011) at 1.

⁶⁶⁸ Interview with Miles McEvoy, Deputy Administrator (for NOP), Agricultural Marketing Service, USDA.

⁶⁶⁹ Interview with Source 99, EPA official.

⁶⁷⁰ Interview with Source 61, EPA Office of General Counsel official.

⁶⁷¹ Interview with Source 71, former EPA program office director.

⁶⁷² Interview with Source 54, former EPA official.

⁶⁷³ Interview with Source 97, attorney at environmental NGO.

commonly taking public comment on guidance without a highly objective agency-wide policy is DOT, according to a former general counsel who said the agency had “evolved” toward doing it “often.”⁶⁷⁴)

A third approach is to undertake notice and comment for guidance only for exceptional matters, with no set policy on when to do it. This appears to be the pattern at OSHA⁶⁷⁵ and CMS.⁶⁷⁶

2. The Danger that Agencies May Leave Guidance in Draft Indefinitely

If an agency seeks to take and process comments on guidance documents—especially under a mandate covering a large enough number of documents as to strain the agency’s resources—there is a danger that the agency will not process the comments for a substantial number of documents and refrain from finalizing them, leaving them in published “draft” status indefinitely. Such an outcome can partly or wholly defeat the purpose of notice and comment. And it can potentially create further problems by channeling agency policy into a “draft” format whose status is ambiguous and confusing to regulated parties.

Something approaching this pattern has occurred, at some times and in some contexts, at FDA. While the FDA GGP’s are an important innovation that have done much good—and may well be the optimal arrangement for FDA itself—we must carefully consider the difficulties FDA

⁶⁷⁴ Kathryn Thomson, Partner, Morrison and Foerster; former general counsel, DOT; former chief counsel, FAA. See also Interview with Sources 64, 65, and 66, officials at Airlines for America (stating that FAA usually provides for notice and comment on common forms of guidance called advisory circulars). The DOT website states: “Although the OMB Bulletin does not require us to seek comment on other guidance documents, we may voluntarily do so. The DOT has sought comment on many draft guidance documents in the past, and we will continue to do so in the future when we deem it appropriate. We will place a copy of the guidance document on which we are seeking comments in [the Federal Document Management System] and use it for the filing of any comments when we do so.” Public Feedback on DOT Guidance Documents, available at <https://www.transportation.gov/regulations/public-feedback-dot-guidance-documents>.

⁶⁷⁵ Interview with Frank White, former Deputy Assistant Secretary (for OSHA), DOL (“virtually” never; no set process for seeking input); Interview with Celeste Monforton, Lecturer, Department of Health and Human Performance, Texas State University; Professorial Lecturer, Milken Institute School of Public Health and Health Services, George Washington University; former legislative analyst, OSHA; former policy advisor, MSHA (historically not, though it happened a couple of times under Obama); Interview with Marc Freedman, Executive Director of Labor Law Policy, U.S. Chamber of Commerce (“rare,” with noise exposure guidance in 2010 being exception).

⁶⁷⁶ Interview with Source 67, former HHS Office of General Counsel official (“rarity,” no formal process for it); Interview with Source 93, former CMS division director (by and large no stakeholder input on manual changes); but see Interview with Source 58, healthcare industry attorney (noting a few matters on which statutes require notice and comment on guidance).

has encountered regarding long-term draft status before we contemplate broader adoption of something like the FDA model.

FDA guidance documents not infrequently remain in published draft form for years before they are finalized or withdrawn.⁶⁷⁷ In a submission to a Senate committee on March 9, 2015, FDA reported that, for guidance documents finalized between June 1, 2009, and June 30, 2014, the median time between draft publication and finalization was 743 days at the Center for Biologics Evaluation and Research (CBER), 710 days at the Center for Drug Evaluation and Research (CDER), and 797 days at the Center for Devices and Radiological Health (CDRH).⁶⁷⁸ In addition, FDA reported a list of guidance documents that were still pending in draft since before Dec. 31, 2013 (i.e., for more than 14 months at the time of the report), and these numbered 10 at CBER, 77 at CDER, and 52 at CDRH.⁶⁷⁹ As FDA has not compiled comparable data since 2015,⁶⁸⁰ my research assistants and I used the agency's comprehensive online database to locate all guidance documents that were finalized between July 1, 2014, and February 5, 2017, and for which we could find a date of prior draft publication. We found 208 documents fitting this description and calculated the time to finalization for each of them. We found that, compared with the Senate submission, median days to finalization had risen at CDER, by 116, to 826; had fallen at CBER, by 181, to 562; and had fallen at CDRH, by 269, to 528. (The median for joint CDRH/CBER guidances, which were almost as numerous as CBER guidances and for which there was no comparable number in the Senate submission, was 710 days.)⁶⁸¹ In addition, we counted guidance documents that were still pending in draft since before November 5, 2015 (i.e., for 15 months or more at the time we gathered data on February 5, 2017). These numbered 4 at CBER, 93 at CDER, and 22 at CDRH. While these figures indicate some speedup at CDRH since 2015,⁶⁸² it seems that finalization of FDA guidance still often takes substantial periods of time.

⁶⁷⁷ This has been previously noted in secondary literature. Noah, *Governance*, *supra* note 86, at 103-05; 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, 31 (2005).

⁶⁷⁸ Letter from Thomas A. Kraus, Associate Commissioner for Legislation, FDA, to Sen. Lamar Alexander (March 9, 2015), at 12.

⁶⁷⁹ Calculated from *id.*, Appendix I.

⁶⁸⁰ Interview with Source 25, FDA Office of Policy official. FDA has not confirmed the figures that I report in the remainder of this paragraph.

⁶⁸¹ All these calculations exclude bioequivalence recommendations.

⁶⁸² On measures that CDRH has taken to speed the development of guidance, see Letter from Thomas A. Kraus, Associate Commissioner for Legislation, FDA, to Sen. Lamar Alexander (March 9, 2015), at 6.

Interviewees on FDA frequently expressed concern about the amount of time guidance remains in draft. An FDA Office of Policy official readily acknowledged that this was an industry concern.⁶⁸³ A former senior FDA career official said the agency did “not do a good job” on finalizing draft guidance, which could remain in draft “many years.”⁶⁸⁴ A former FDA official said it was a “prevalent” phenomenon at FDA that guidance remained in draft a long time.⁶⁸⁵ A partner in a large law firm healthcare practice observed there were “many” FDA guidances that had been pending “several years.”⁶⁸⁶ A trade association official said FDA could go for “years” without finalizing draft guidance and might “never” finalize it.⁶⁸⁷ A partner in a large law firm and former senior federal official observed that FDA has a tendency to leave guidance in draft “indefinitely.”⁶⁸⁸ The delay was cited not only by current and former officials and industry people but also by advocates at Public Citizen, who said there was “often a huge lag time” between draft and finalization, and “often” the document was “never” finalized but just stayed in draft.⁶⁸⁹ Long-term draft status had “always been a problem,” said a former senior FDA official.⁶⁹⁰ It was “confounding” for stakeholders according to another former senior FDA official,⁶⁹¹ and a “significant frustration,” according to a congressional staffer.⁶⁹² Stopping at the draft stage, which FDA “often” did, was “problematic” and “troubling,” said a former FDA chief counsel.⁶⁹³

FDA’s tendency to leave guidance in draft arises mainly from the interaction of two factors: (a) the agency has very limited resources to process comments and make revisions and finalization decisions for the large category of documents covered by the notice-and-comment mandate of the GGPs and (b) the strong incentives that FDA-regulated parties have to comply with final guidance are largely applicable to draft guidance as well, meaning the agency has relatively little incentive to finalize, since the draft by itself already sends a pretty clear signal of the agency’s wishes and will often be followed by regulated parties. From the agency’s

⁶⁸³ Interview with Source 25, FDA Office of Policy official.

⁶⁸⁴ Interview with Source 112, former senior FDA career official.

⁶⁸⁵ Interview with Source 20, former FDA official.

⁶⁸⁶ Interview with Source 101, partner in large law firm healthcare practice.

⁶⁸⁷ Interview with Source 24, trade association official.

⁶⁸⁸ Interview with Source 78, partner in large law firm and former senior federal official.

⁶⁸⁹ Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group.

⁶⁹⁰ Interview with Source 107, former senior FDA official.

⁶⁹¹ Interview with Source 80, former senior FDA official.

⁶⁹² Interview with Source 82, congressional staffer.

⁶⁹³ Interview with Daniel Troy, General Counsel, GlaxoSmithKline.

perspective, finalizing guidance expends resources with relatively little upside. Given all the demands on FDA staff, it is no surprise they do not give it a high priority.

Let us examine these two factors in turn, starting with FDA's limited resources to finalize guidance. Reading comments and coming to a rational decision about whether and how to incorporate them (even without writing a response to the comments) takes time. The parts of FDA charged with these tasks are "way under-resourced and under-staffed," said a partner in a large law firm healthcare practice,⁶⁹⁴ and they simply do not have enough resources to finalize all drafts, according to a former senior FDA official.⁶⁹⁵ FDA personnel responsible for finalization face competing demands, not the least of which is (often) the writing of guidance on matters for which there is not yet even a draft document—matters on which industry may be demanding new draft guidance more loudly than it is demanding finalization of existing drafts. As FDA itself stated in a 2011 report, it was a serious question "how the Agency should balance the need to publish new draft guidance against the desire to complete final guidances that are already out in draft, given limited Agency resources for guidance development."⁶⁹⁶ Janet Woodcock, the director of CDER, said that while her center made an effort either to finalize draft guidance or withdraw it, the staff sometimes said, "we have other things to do."⁶⁹⁷ A former senior FDA career official recalled that CDER's internal policy shop tried to get the reviewers to finalize draft guidance, but the reviewers did not see it as a high priority, given everything else they had to do. Once guidance was published in draft, that addressed the need to provide guidance on FDA's expectations on that particular issue, and finalizing the draft guidance that was already out was less important than other projects, such as conducting reviews or preparing new draft guidance on other topics.⁶⁹⁸ Bradley Merrill Thompson, the device maker association counsel, recounted how personnel from CDRH told him that they had no intention of moving to finalize some draft guidance, because Congress had not given them the resources to do so. They felt they had the means to finalize existing drafts or write new drafts on other matters, but not both.⁶⁹⁹ In

⁶⁹⁴ Interview with Source 101, partner in large law firm healthcare practice.

⁶⁹⁵ Interview with Source 80, former senior FDA official.

⁶⁹⁶ Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency (December 2011) at 16. Indeed, Congress in recent years has increasingly enacted statutory requirements for the issuance of guidance. Communication from Source 25, FDA Office of Policy official.

⁶⁹⁷ Interview with Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA.

⁶⁹⁸ Interview with Source 112, former senior FDA career official

⁶⁹⁹ Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green. While reporting officials' views, Thompson added he believed they were mistaken to see the problem in such zero-sum terms: the finalization process could be streamlined if FDA took the initiative to do it, he said.

general, said a former FDA official, FDA personnel think draft guidance is “good enough”: they work hard to formulate the draft, and the draft gives regulated parties what they need to know about agency thinking and stops them from asking questions about what the agency wants, thus taking away the perceived need for more explanation from the agency.⁷⁰⁰ An FDA Office of Policy official said that people at FDA were “sensitive to the issue” and did “the best we can,” but they had to balance a “complex set of considerations” about “resources and priorities.”⁷⁰¹

Now consider the second factor: regulated parties’ incentives to comply with guidance regardless of whether its status is draft or final.⁷⁰² As discussed in Part II, FDA-regulated companies are often seeking pre-market approval for their products, and in that context, they have reason to follow any indication of the agency’s wishes, whatever its format. Facing draft guidance, said a former senior FDA official, regulated firms would say, “I’ll do this [i.e., what the draft suggests] because it will get me through the process”—will “get me what I need from FDA.”⁷⁰³ A trade association official singled out pre-market approval as a context in which firms would follow draft guidance; it would be “folly” not to follow it, even in draft.⁷⁰⁴ Even outside the pre-approval context, some firms are sufficiently invested in their continuing relationship to FDA (also discussed in Part II) that they will follow agency wishes, including draft guidance, to preserve that. According to a partner in a large law firm healthcare practice, “a lot” of his clients follow draft guidance, which “often” has the same effect on them as a legislative rule; the clients are worried about “antagonizing FDA” and their “good relations” to the agency.⁷⁰⁵ A partner in a large law firm and former senior federal official said companies were “hungry” for any and all indications of what FDA wants, so they “often” did not distinguish in practice between draft and final guidance.⁷⁰⁶ Richard Naples, the chief regulatory officer of Becton Dickinson, said FDA reviewers could be expected to behave consistently with draft

⁷⁰⁰ Interview with Source 20, former FDA official. See also Interview with Source 78, partner in large law firm and former senior federal official (stating that FDA officials have a lot to do, must balance many priorities, and are buffeted by events, so finalizing draft guidance is often not the highest priority).

⁷⁰¹ Interview with Source 25, FDA Office of Policy official.

⁷⁰² See Noah, *Governance*, *supra* note 86, at 104-05 (briefly noting that “draft or final guidance still often operate as de facto requirements”).

⁷⁰³ Interview with Source 107, former senior FDA official.

⁷⁰⁴ Interview with Source 24, trade association official.

⁷⁰⁵ Interview with Source 101, partner in large law firm healthcare practice. See also Interview with Source 104, law firm partner who deals frequently with FDA and CMS (recalling an instance in which FDA took enforcement action based on draft guidance regarding products labeled “for research use only”).

⁷⁰⁶ Interview with Source 78, partner in large law firm and former senior federal official.

guidance and that his company followed it, departing only by the same procedures they would follow for departing from final guidance (i.e., seeking a meeting with officials beforehand to convince them to sign off on the departure).⁷⁰⁷ Asked whether he would advise a client to follow FDA draft guidance, a food and drug industry attorney said, “you know it’s where FDA is” and reflects what the staff are “thinking,” regardless of whether it is draft or final.⁷⁰⁸ Only two interviewees made more qualified statements about the tendency to follow draft guidance: an executive at a drug manufacturer said a draft would have “less authoritative” status than a final guidance and could be subject to “pushback,” adding that for an approval, draft status would “somewhat” alter the compliance calculus—it was “not black and white”;⁷⁰⁹ and the trade association official (cited above for the view that firms would surely follow draft guidance for approvals) said that outside the approval context a firm would only be “likely” to follow a draft, and compliance would depend more on the firm’s risk tolerance.⁷¹⁰

FDA’s resource limitations and regulated firms’ incentives combine to disincline FDA personnel to finalize guidance. As former FDA Deputy Commissioner for Policy William Schultz explained it, the structure of the regulatory scheme gives the agency leverage to get the firms to comply with a draft, and once industry is complying, the staff see relatively less reason to make the effort to finalize the document, as competing demands are vying for their time.⁷¹¹

If that were the entire story, one might say that the consequence of indefinite draft status is to defeat, at least partly, the purpose of notice and comment. But in fact, the consequences go beyond that. Indefinite draft status can have the further effect of undermining the transparency of what the agency’s policy is, leading to inconsistency and inequality in the counseling and decisionmaking of regulated parties. The reason for this effect is that, while the cause of the agency’s failure to finalize draft guidance is *usually* limited resources, it *can* be something else, such as uncertainty or disagreement within the agency about what policy to pursue. As a former FDA official said, a document could get stuck in draft *either* because it is a low priority resource-wise *or* because FDA has found it to be more controversial than anticipated.⁷¹² Naples, of

⁷⁰⁷ Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson, and Company.

⁷⁰⁸ Interview with Source 92, food and drug industry attorney. See also Interview with Source 20, former FDA official (stating that industry conforms to draft guidance).

⁷⁰⁹ Interview with Source 108, executive at a drug manufacturer.

⁷¹⁰ Interview with Source 24, trade association official.

⁷¹¹ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁷¹² Interview with Source 107, former senior FDA official.

Becton Dickinson, said he thought limited resources could be the cause of delay, but it could also be because there was “no broad agreement” on what the guidance should say.⁷¹³ Another former senior FDA official said guidance could be stuck in draft because the agency realized problems with the document and was leaving it in draft while trying to “reset”; relatedly, it could be due to a change of heart resulting from a new presidential administration.⁷¹⁴

Here lies the problem. Whereas regulated parties are well-advised to follow draft guidance if it captures the agency’s view and remains non-final merely because of resource limitations, those parties are *not* well-advised to follow draft guidance if it remains non-final because the agency is uncommitted to its content by reason of uncertainty or disagreement.

The trouble is how to tell which is which—a matter of uncertainty and guesswork for regulated parties and other stakeholders. A regulatory policy executive at a drug manufacturer explained that his firm would treat draft guidance as FDA policy if the draft had not received many public comments or attracted complaints, for under those circumstances, one could infer that the document was just a low priority resource-wise. Alternatively, a guidance might be so controversial that it could not be finalized, and his firm would not follow that kind of draft document. Overall, he said, he would rely on a draft guidance document if it had been “out there a while” and was not controversial and if there were individual FDA adjudicatory decisions consistent with it. As between the two kinds of draft guidance, “you have a sense of which it is,” though “not always.”⁷¹⁵ Similarly, an executive at a (different) drug manufacturer said that his company, in deciding whether to follow draft guidance, would consider, among other things, whether it seemed to be a mere “trial balloon” floated by the agency, or was instead consistent with FDA practice.⁷¹⁶ Coleen Klasmeier, the head of Sidley Austin’s FDA regulatory practice, said that, in counseling clients, she had to judge whether a draft guidance document represented current FDA thinking that the agency would follow, or was instead a “trial balloon.” Clients should rely upon the former but not the latter. The latter tended to be on more controversial subjects (e.g., implicating the First Amendment), while the former tended to be on regulatory

⁷¹³ Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson, and Company.

⁷¹⁴ Interview with Source 80, former senior FDA official. Some interviewees added that FDA might keep guidance in draft in order to avoid judicial review, as one reason among others for not finalizing. Interview with Source 78, partner in large law firm and former senior federal official; Interview with Source 92, food and drug industry attorney; Interview with Source 101, partner in large law firm healthcare practice.

⁷¹⁵ Interview with Source 109, regulatory policy executive at a drug manufacturer.

⁷¹⁶ Interview with Source 108, executive at a drug manufacturer.

science. But it was not always easy to tell. For example, if FDA floated draft guidance as a trial balloon, received pushback in comments, and then simply left the draft sitting there, that could mean FDA intended to follow the draft itself, or that it intended to follow a course that was modified according to the sentiments expressed by those who pushed back. Ambiguities like these, said Klasmeier, made it difficult to counsel clients.⁷¹⁷

On the NGO side, advocates at Public Citizen were similarly perplexed. They recalled how FDA had issued a draft guidance on off-label communication in February 2014, against which Public Citizen orchestrated a campaign of opposition, with an overwhelming majority of comments going against the draft. In response, the FDA simply left the document in draft, in which status it was still pending at the time of our interview (October 2016), after two years and eight months. FDA, observed the Public Citizen advocates, has a tendency to engage in this kind of ambiguous delay. They said they “can’t explain” the behavior and think it strange. “Maybe,” they said, FDA did “not want to come down” and take a position “amid competing comments.” They added that they did not know how this draft guidance was affecting regulated-party behavior, thought they would’ve liked to find out.⁷¹⁸

As one would expect, the level of confusion and anxiety that regulated parties feel about draft guidance’s status appears to diminish the more they have access to other sources of information about what the agency really thinks. According to an FDA Office of Policy official, device makers were more disturbed by long-term draft status and more inclined to pressure FDA to finalize than were drug makers. The reason, posited the official, was that the different structure of the approval processes for devices and drugs (at CDRH and CDER respectively) meant that drug makers had more opportunity for “constant dialogue” with agency personnel and were engaged in a more “hands-on” process with them.⁷¹⁹ Device makers, it seems, had to rely more on published communications, so the ambiguities of draft guidance mattered more to them.

Whatever these subtleties, it seems that in general regulated parties not uncommonly find FDA’s thinking hard to discern by reason of guidance remaining in draft. This uncertainty has costs. As a former senior FDA official said, it opens the door for agency officials and regulated firms to see things differently and misunderstand each other.⁷²⁰ Further, noted a partner in a

⁷¹⁷ Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice.

⁷¹⁸ Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group.

⁷¹⁹ Interview with Source 25, FDA Office of Policy official.

⁷²⁰ Interview with Source 80, former senior FDA official.

large law firm healthcare practice, the ambiguity of draft guidance created a situation where some companies followed it and others did not, depending on their risk tolerances. This, he said, was unfair. There was not a “level playing field.”⁷²¹

FDA is not the only agency that has left guidance in ambiguous draft status for long periods of time. DHS’s Citizenship and Immigration Services, for example, took up notice and comment for some of its guidance documents but, as of 2013, more than a quarter had been pending in draft for more than a year.⁷²²

The same phenomenon happens at least somewhat at EPA. That agency, like FDA, is strapped for resources on guidance matters. A partner in a large law firm and former senior EPA official noted that EPA had become more stretched in terms of staffing and budget in the last 25 years. Under these constraints, he said, if a draft guidance document is out there “and it works,” and the process to finalize it is costly, then the agency must move on and “shoot the next wolf at the door.”⁷²³ Perhaps most strikingly, a very important EPA guidance document for administration of the Clean Air Act has been in “draft” *for 27 years*. This is the New Source Review Workshop Manual, Prevention of Significant Deterioration and Nonattainment Area Permitting, also known as “The Puzzle Book,” which to this day has each of its 322 pages stamped “Draft October 1990.”⁷²⁴ The document governs EPA-supervised state agency permitting decisions on new power plants. An environmental NGO employee observed that state agencies and EPA generally followed the Puzzle Book “very closely.” This is no surprise given the pre-approval requirement. Normally the utility company and the state agency just wanted the permit to go through and not be halted by EPA review. Yet, in some instances, a well-connected utility would, for some business reason, want a departure from the Puzzle Book. In that case, the guidance’s draft status (despite its age) would always make an appearance for one paragraph of the utility’s brief. And if the state agency and EPA agreed to the departure, they would invoke the draft status to help justify it. But really, said the NGO employee, it was hard to pin down what difference the draft status made. What actually made a departure more likely, in his

⁷²¹ Interview with Source 101, partner in large law firm healthcare practice.

⁷²² Jill E. Family, *Easing the Guidance Document Dilemma Agency by Agency: Immigration Law and Not Really Binding Rules*, 47 U. Mich. J. Law Reform 1, 50 (2013).

⁷²³ Interview with Source 52, partner in large law firm and former senior EPA official.

⁷²⁴ The document is available at <https://www.epa.gov/sites/production/files/2015-07/documents/1990wman.pdf>. For background, see Richard G. Stoll, *Effective EPA Advocacy* 64 (2d ed. 2014). I learned of the “Puzzle Book” nickname from Interview with Adam Kushner, Partner, Hogan Lovells; former EPA director of civil enforcement.

experience, was whether a well-connected utility really wanted a guidance-noncompliant permit for a new plant, especially a coal-fired one. Asked why EPA had never finalized the draft, he said it was because EPA feared that, if finalized, the document would be challenged as a legislative rule. Considering that the document was already enjoying a high degree of compliance from state agencies and utilities, finalization did not seem worth the risk to EPA.⁷²⁵

The story of the Puzzle Book points up another problem with longstanding draft guidance. Insofar as such a document effectively becomes real guidance for an adjudicatory process (as will often happen if there is a pre-approval requirement), its draft status is always available to be opportunistically invoked whenever the agency wants to make a departure for some other reason. Draft status interferes with truly principled flexibility in the use of guidance, that is, flexibility where the reasons for departures are stated in an upfront, rational manner.

Importantly, it is possible for an agency to prevent regulated parties from developing any expectation that they ought to comply with draft guidance, even if the draft is public for a long period, and even if the regulated parties are subject to something approaching pre-approval. At the USDA National Organic Program, noted former NOSB chair Jean Richardson, draft guidance might take two years to finalize, and yet certifiers generally would not begin following it before its effective date. Richardson, who was aware of FDA's draft guidance problems and the tendency of FDA-regulated firms to follow FDA drafts, drew an express contrast with NOP draft guidance, adding that she did not have a perfect answer as to why the two regulatory schemes differed in this way. She suggested it was because NOP would not "ding" a certifier for engaging in behavior that was inconsistent with draft guidance, and the certifiers were aware of this.⁷²⁶ Likewise, an official at a certifier said that historically a draft guidance and final guidance were just viewed differently, without an expectation that the former be followed.⁷²⁷ This contrasts with the approach at FDA, where the understanding is that reviewers *may*, through their discretion in case-by-case adjudication, treat a particular issue *in the same way* that a draft guidance document does, though of course they may not *rely upon* the draft guidance document in doing so.⁷²⁸ It seems the USDA National Organic Program engaged in a kind of self-denying

⁷²⁵ Interview with Source 128, employee at environmental NGO.

⁷²⁶ Interview with Jean Richardson, former chair, National Organic Standards Board.

⁷²⁷ Interview with Source 114, official at a certifier. However, the interviewee added that, at a 2016 training session for certifiers, NOP made a statement that draft guidance should be viewed as guidance. This "caused some heartburn" among the certifiers, he said. *Id.*

⁷²⁸ Interview with Source 25, FDA Office of Policy official.

behavior, refusing to send a noncompliance letter on the basis of an understanding of an issue that was the same as the understanding set forth in draft guidance, unless and until the draft was finalized. But perhaps FDA, being a public-health guardian on life-and-death issues, feels that such self-denial would be irresponsible. Some issues are too important not to treat in the most up-to-date manner, even if not all the participatory formalities have been carried out.

3. The Possibility of Marginalizing Legislative Rulemaking

There has been innovation at FDA not only in the participatory procedures established for guidance, but also in the elevation of guidance as a means of general policymaking. FDA does operate under statutory requirements to use legislative rulemaking on certain specified matters, and there are examples of the agency voluntarily carrying out legislative rulemakings even outside such statutory mandates.⁷²⁹ But for the mine run of policymaking, it is a widespread view among FDA specialists outside the agency that guidance has now eclipsed legislative rulemaking as the dominant approach (though this view is contested from within FDA itself).⁷³⁰ “Nowadays,” wrote food and drug scholar Lars Noah in 2014, “it seems, legislative rulemaking [at FDA] only happens when Congress insists on that course of action.”⁷³¹ A former senior FDA official stated outright that FDA only does legislative rulemaking when there is a specific statutory requirement to do so or when the agency is amending a preexisting legislative rule.⁷³² Advocates at Public Citizen Health Research Group said they now assumed that guidance, not legislative rulemaking, was how FDA would address any “major” issue.⁷³³ A congressional staffer said FDA, as between guidance and legislative rulemaking, now generally did everything by guidance unless a statute forced it to proceed by legislative rulemaking.⁷³⁴

Consistent with this, the agency is said to use guidance more expansively than other agencies. This point was made by several practitioners who each deal intensively with both FDA and CMS. A law firm partner who works frequently with the two agencies explained how they

⁷²⁹ Interview with Source 112, former senior FDA career official (giving examples of legislative rulemaking not mandated by statute in the areas of physician labeling, pregnancy labeling, and combination drugs).

⁷³⁰ Communication from Source 25, FDA Office of Policy official (stating that FDA does not intend guidance documents to be replacements for binding legislative rules, noting for example that many such documents serve to clarify existing legislative rules).

⁷³¹ Noah, *Governance*, *supra* note 86, at 114.

⁷³² Interview with Source 110, former senior FDA official.

⁷³³ Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group.

⁷³⁴ Interview with Source 82, congressional staffer.

differed. According to him, FDA had well-established procedures for notice and comment on guidance, which was praiseworthy, but FDA was also more likely to use guidance when it should have used a legislative rule, which was frustrating. CMS, he said, was “almost the opposite”: much of its guidance had no notice and comment or inadequate notice and comment, but it was much more inclined to do legislative rulemaking, instead of defaulting to guidance like FDA.⁷³⁵ A partner in a large law firm healthcare practice stated, similarly, that CMS used guidance appropriately to fill gaps in preexisting legislative rules, whereas FDA used guidance more aggressively, as a substitute for legislative rulemaking, not just interpreting preexisting law but going beyond it.⁷³⁶ A partner in another law firm healthcare practice observed that CMS did a good job of doing legislative rulemaking and keeping guidance confined to its appropriate role of illuminating the legislative rules while remaining consistent with those rules, whereas FDA would use guidance more aggressively to regulate in the absence of a rule and even to act inconsistently with a statute.⁷³⁷ According to a trade association official, CMS sought to ensure that the most important matters were addressed by legislative rulemaking and was constantly making legislative rules, whereas FDA “almost never” issued legislative rules and did guidance instead.⁷³⁸ A former senior FDA official said that CMS “never” faced the industry complaints about its use of guidance that FDA had.⁷³⁹ Advocates at Public Citizen, while not comparing FDA to CMS, did find FDA aggressive in its use of guidance, stating that FDA could issue a guidance document that would “eviscerate” a legislative rule already in place.⁷⁴⁰

Is there a connection between FDA’s expansive use of guidance, on the one hand, and its well-established (indeed congressionally blessed) procedures for public participation in the formulation of guidance, on the other? This is a complicated question about FDA’s institutional development, and many interpretations are possible. One former senior FDA official believed that the agency’s dramatic shift toward guidance was inevitable, given the explosion in scientific complexity that occurred in the 1990s, and the GGP’s were simply a means of regularizing and

⁷³⁵ Interview with Source 104, law firm partner who deals frequently with FDA and CMS.

⁷³⁶ Interview with Source 101, partner in large law firm healthcare practice.

⁷³⁷ Interview with Source 91, partner in law firm healthcare practice.

⁷³⁸ Interview with Source 24, trade association official.

⁷³⁹ Interview with Source 107, former senior FDA official.

⁷⁴⁰ Interview with Michael Carome and Sammy Almashat, Public Citizen Health Research Group.

improving a form of administrative communication that had already become central to the agency's work before 1997.⁷⁴¹

Other interviewees, however, suggested that FDA's degree of reliance on guidance has been taken farther, or at least has been sustained, partly because the GGPs and the congressional mandate behind them have heightened FDA personnel's sense of guidance's legitimacy. An FDA Office of Policy official said the agency did not have to "worry" about the distinction between legislative rulemaking and guidance in the way other agencies did: FDA's liability exposure was lessened by the notice-and-comment process for guidance and by its specific statutory authorization, and the transparency of the process meant stakeholders had less reason to sue.⁷⁴² Indeed, Congress has continued to give extraordinary treatment to FDA guidance since 1997. In 2011, for example, new legislation ordered FDA to make certain policies by *rule or guidance*—a move that one scholar called a "peculiar concession about their interchangeability."⁷⁴³

Other interviewees similarly thought the GGPs had conferred special legitimacy on guidance in FDA's eyes, but they had a different normative take, contending that this was a bad thing and an overreading of the relevant legislation. Klasmeier, the head of Sidley's FDA regulatory practice, argued that the GGPs and the legislation had made FDA "overly confident" in the success of its guidance program, with the result that the agency was now handling "everything under the sun" by guidance. The existence of the GGPs, she believed, did not make it lawful for the agency to dispense with legislative rulemaking to the degree it had.⁷⁴⁴ A congressional staffer said the GGPs had made guidance seem so robust to FDA staff that they no longer saw a reason to use legislative rulemaking, despite the absence of OMB or judicial review. Applying the FDA model to other agencies, he posited, could encourage those agencies to rely on guidance more than they otherwise would. He added that blessing guidance through authorizations and processes contained in legislation or executive orders tended to make guidance seem more legitimate, not least in the eyes of Congress and the White House, thereby diminishing agencies' tendency to use legislative rulemaking.⁷⁴⁵ William Schultz, who served as

⁷⁴¹ Interview with Source 110, former senior FDA official.

⁷⁴² Interview with Source 25, FDA Office of Policy official.

⁷⁴³ Noah, *Governance*, *supra* note 86, at 108.

⁷⁴⁴ Interview with Coleen Klasmeier, head of Sidley Austin's FDA regulatory practice; former FDA OCC attorney.

⁷⁴⁵ Interview with Source 82, congressional staffer. The interviewee acknowledged that, for the scientific and technical matters that made up much of FDA's work, the shift toward guidance made more sense, but he believed

FDA Deputy Commissioner for Policy (1994-98) and HHS General Counsel (2011-16) said that, although FDA personnel had initially resisted the GGPs in 1997, they now “totally endorsed” them—“probably to a fault,” he added, for he had recently seen instances in which he felt FDA had “gone too far” in using guidance.⁷⁴⁶

I am not saying that, if legislative rulemaking across the government were largely or entirely abandoned in favor of guidance issued through FDA-like processes, that would necessarily be a bad thing. I take no position on that question. There are serious arguments on both sides. In favor of shifting away from legislative rulemaking, one may cite the long line of scholarship indicating that, at least at some agencies, the intensely participatory and analytic regulatory process that originated around the 1970s undermined agencies’ capacity to carry out their statutory mandates.⁷⁴⁷ Against this background, one might argue that a shift from legislative rulemaking toward relatively-participatory guidance would constitute a salutary return to a more relaxed and workable pre-1970 regulatory process and, perhaps, to what Congress really intended when it enacted the APA in 1946. Soon after FDA adopted its GGPs, Todd Rakoff wrote of the new framework: “It would not be far-fetched to rephrase [the GGPs] by saying that the FDA now proposes to issue its important regulations mostly in accordance with the notice-and-comment rulemaking procedure set forth in the APA, as it was understood before 1970.”⁷⁴⁸

But whether you think a shift away from legislative rulemaking would be good or bad, there is no doubt it presents a profound and portentous choice, even as applied to one agency, to say nothing of the whole government. FDA’s simultaneous proceduralization and elevation of guidance suggests (though it hardly proves) that a strong mandate for notice and comment on an agency’s guidance may embolden the agency to use guidance more expansively. That possibility should give pause to anyone advocating for such a mandate. Adopting it obligates us to think through just how far-reaching the consequences might be, and whether we think them good.

FDA’s inclination to use guidance had gone too far in areas where it was not justified by scientific and technical considerations. Interview with Source 82, congressional staffer. See also Interview with Coleen Klasmeier, head of Sidley Austin’s FDA regulatory practice; former FDA OCC attorney (making a similar point).

⁷⁴⁶ Interview with William Schultz, Partner, Zuckerman Spaeder; former FDA Deputy Commissioner for Policy (1994-98); former HHS General Counsel (2011-16).

⁷⁴⁷ E.g., Jerry L. Mashaw & David L. Harfst, *The Struggle for Auto Safety* (1990); McGarity, *supra* note 643; Wagner, *supra* note 581.

⁷⁴⁸ Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 Admin. L. Rev. 159, 169 (2000).

4. Against “One Size Fits All”

As this Part shows, a series of questions ought be addressed in determining whether public comment is appropriate for a given guidance document and, even more importantly, for a large category of guidance documents. What is the distribution of information within the stakeholder community? and how broadly is useful information diffused beyond stakeholders already reachable through low-cost targeted invitations? Does targeting disproportionately exclude the views of non-industry parties (who are least likely to have a chance to challenge the guidance at the implementation phase)? Is the perception of bias or favoritism a problem for the program, and will targeting invitations for input aggravate it? Would the contemplated guidance benefit more from focused stakeholder response to a set proposal, or from more free-ranging discussion that allows for iterative learning—and would providing for the former crowd out the possibility of the latter? What resources are available to agency personnel tasked with processing comments and finalizing guidance? If resources are few, and incentives to follow guidance strong, is the agency prepared to provide clarity to stakeholders on whether they should understand draft guidance to reflect *current* agency expectations? Are stakeholders willing to accept lessened provision of guidance as the price for more participation in the formulation of guidance that is provided? Finally, how comfortable are agency personnel and stakeholders with using formalized public participation on guidance as a substitute for legislative rulemaking?

Answers to these questions are likely to vary document by document and will certainly vary agency by agency. Given this variation—and the consequences of getting things wrong—it would be rash to adopt a government-wide requirement of notice and comment for a large category of guidance documents (i.e., for something substantially beyond the OMB GGPs’ focus on the most extraordinary guidance). Experimenting agency by agency allows for more learning and cabins the consequences of failure. As Neil Eisner argued, a “one-size-fits-all” approach to participation in the issuance of guidance does not take sufficient account of how much agencies vary in their tasks, resources, and capacities.⁷⁴⁹

This is not to say that agency-by-agency decisions will be left to the agencies. Congress and the White House have already demonstrated their capacity to shape public participation on

⁷⁴⁹ Interview with Neil Eisner, consultant; former Assistant General Counsel for Regulation and Enforcement, DOT. For a similar argument that participation on guidance should be decided on an agency-specific basis, see Family, *supra* note 722, at 27-31.

guidance in a tailored, agency-specific manner. As noted above, FDA’s initial adoption of the GGPs in February 1997 was driven in part by pressure from congressional overseers.⁷⁵⁰ As to EPA, a former senior official with cross-office responsibilities recalled how OMB pressured the agency to take public comment on certain key guidance documents when OMB felt it was appropriate. He remembered that some EPA career officials strongly opposed public comment on certain documents, but the OMB people insisted, and “we knuckled under.”⁷⁵¹ Congress and the White House have been wise to apply this pressure in areas confined enough that one can make an informed judgment about the consequences and control the damage if things go wrong.

VI. PROPOSED RECOMMENDATION

Preamble

Guidance consists of agency statements of general applicability, not binding on members of the public, that advise the public of the manner in which the agency proposes to exercise a discretionary power or of the agency’s construction of the statutes and legislative rules it administers. *[NOTE FROM CONSULTANT TO THE JUDICIAL REVIEW COMMITTEE: As drafted, this opening sentence would make the Recommendation applicable to both policy statements and interpretive rules as those terms are used in APA § 553(b). It is possible that, instead, the Recommendation should apply only to policy statements (as Recommendation 92-2 did), and not to interpretive rules.⁷⁵² The law is clear that policy statements are to be nonbinding, meaning that this Recommendation’s focus on how agencies should handle nonbinding documents is clearly applicable to policy statements. But the law is unclear as to whether interpretive rules are to be nonbinding. On this confusion, see the Report, Introduction, Subsection B.1. Notwithstanding the unclarity of the law regarding the nonbinding status of interpretive rules, the Conference might decide that agencies should, as a matter of good government, treat interpretive rules as having the same nonbinding status—that is, entailing the same aspiration for the agency to keep an “open mind”—as policy statements have. I do not think the findings in the Report compel this view, but neither do they preclude it. (For*

⁷⁵⁰ See *supra* text at note 666.

⁷⁵¹ Interview with Source 96, former senior EPA official with cross-office responsibilities.

⁷⁵² In that case, the word “guidance” throughout the Recommendation could be replaced with “policy statements.”

elaboration, see the Report, Introduction, Subsection B.I.) Alternatively, the Conference could remain agnostic as to whether interpretive rules should be treated as nonbinding but suggest that each agency apply the approach set forth in this Recommendation to interpretive rules insofar as the agency itself thinks interpretive rules should be treated as nonbinding.]

Guidance is an essential instrument of administration across numerous agencies. Compared with adjudication or enforcement in which there is nothing to go by except statutes and legislative rules, guidance can make agency decisionmaking faster and less costly, saving time and resources for the agency and the regulated public. It can also make agency decisionmaking more predictable and uniform, shielding regulated parties against unequal treatment, unnecessary costs, and unnecessary risk and promoting compliance with law.⁷⁵³ Compared with legislative rulemaking, guidance is generally better for dealing with conditions of uncertainty and for making agency policy comprehensible to regulated parties who lack counsel. Further, the provision of guidance often takes less time and resources than legislative rulemaking, freeing up the agency to address more issues within its statutory mission.⁷⁵⁴

Despite its usefulness, guidance is sometimes criticized for coercing members of the public, as if it were a legislative rule, notwithstanding its officially nonbinding status. Although an agency issuing guidance may act with no coercive purpose, structural features of certain regulatory schemes may deprive regulated parties of any practical choice but to follow the guidance. These features include the following:

--The law may require regulated parties to obtain the affirmative assent of the agency (pre-approval) 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

⁷⁵³ See Report, Section I.A. See also ACUS Recommendation 71-3 (“Agency policies which affect the public should be articulated and made known to the public to the greatest extent feasible. To this end, each agency which takes actions affecting substantial public or private interests, whether after hearing or through informal action, should, as far as is feasible in the circumstances, state the standards that will guide its determination in various types of agency action, either through published decisions, general rules or policy statements other than rules.”). Additional prior ACUS Recommendations regarding guidance, apart from the one just cited and others to be referenced specifically in this preamble, include Recommendation 2015-3, Declaratory Orders, 80 Fed. Reg. 78163 (Dec. 4, 2015); and Recommendation 2014-3, Guidance in the Rulemaking Process, 79 Fed. Reg. 35992 (June 25, 2014).

⁷⁵⁴ See Report, Section I.B.

discretionary and subject to delay, the incentive to follow whatever the agency's wishes appear to be (including guidance) can be overwhelming.⁷⁵⁵

--The regulatory scheme may subject the regulated party to frequent monitoring and evaluation by the agency. If the law is complex, regulated parties may inevitably fail to comply with at least a few of its requirements. To insure against this contingency, a regulated party may 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.⁷⁵⁶

--A regulated party subject to ex post enforcement will have an incentive to follow guidance that increases with the probability of detection of guidance-noncompliant behavior, the cost of an enforcement proceeding irrespective of outcome, the probability of an unfavorable outcome, and the probable sanction in that event. In some (though far from all) contexts, it may be that the regulated party cannot expect, without prohibitive risk, to get the accusation meaningfully examined and adjudicated by an official distinct from the enforcement personnel. This creates a strong incentive to avoid being accused in the first place, as by following guidance.⁷⁵⁷

In addition, guidance may operate on the beneficiaries of a regulatory statute or legislative rule as if the guidance were itself a legislative rule. The guidance can operate this way if it promises to treat regulated parties less stringently than the statute or legislative rule would. Such guidance may cause regulated parties to take advantage of the new latitude by shifting their behavior in a direction that does harm to the beneficiaries. The guidance may thus effectively deprive the beneficiaries of the protection of the governing statute or legislative rule.⁷⁵⁸

While these legislative-rule-like effects on regulated parties and regulatory beneficiaries may obtain whenever the guidance is operative, we must remember that the agency itself

⁷⁵⁵ Report, Section II.A.

⁷⁵⁶ Report, Section II.B.

⁷⁵⁷ Report, Section II.D.

⁷⁵⁸ Report, Part IV.

controls whether the guidance is operative in any given instance. If the guidance remains truly tentative, in that the agency affords members of the public a fair opportunity to seek modification of or departure from the guidance in any given instance, then the guidance does not operate like a legislative rule. Paragraph 1 articulates this principle; in so doing, it follows ACUS Recommendation 92-2,⁷⁵⁹ but it expands the applicability of the principle from regulated parties to members of the public more generally, so as to include regulatory beneficiaries who may be harmed if denied a fair opportunity to seek relief from deregulatory guidance.⁷⁶⁰ Paragraph 2 clarifies that, although guidance can permissibly bind some agency employees,⁷⁶¹ guidance cannot bind those employees in a manner that forecloses the fair opportunity called for Paragraph 1.⁷⁶² (For example, the guidance could bind officials at one level of the agency hierarchy, with the proviso that officials at a higher but still accessible level can authorize departure from the guidance.) Paragraphs 3, 4, and 5, set forth minimum practical measures to ensure the fair opportunity is provided.⁷⁶³

Despite the aspiration to be flexible, agencies are sometimes inflexible in their use of guidance, and the guidance can therefore have a coercive, legislative-rule-like effect on members of the public. One might think flexibility is the path of least of resistance for an agency, so inflexibility must reflect some bad-faith intent on the part of the agency. But that is not so. The very real fact of agency inflexibility can be explained to a large degree (though not entirely) 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.⁷⁶⁴ Paragraph 6 sets forth additional measures (beyond the minimum in Paragraphs 3-5) that agencies may take in order to maintain flexibility despite these factors that tend toward inflexibility.

On this point, we must recognize that agencies are often under active stakeholder pressure to be inflexible (i.e., to be consistent) and that these stakeholder pressures spring from

⁷⁵⁹ ACUS Recommendation 92-2, paragraph II.B.

⁷⁶⁰ Note also that Paragraph 1's phrase "to particular conduct" indicates that agencies should be open to requests for departures from regulated parties not only during an enforcement proceeding, but also before one has begun (and before the regulated party has engaged in the conduct that would be subject to such a proceeding).

⁷⁶¹ ACUS Recommendation 92-2, paragraph III.

⁷⁶² Report, Introduction Section B.2. The approach taken is similar to that in OMB Good Guidance Practices § II(2)(h).

⁷⁶³ Notices of nonbinding status and avoidance of mandatory language are already common practice at some agencies. See Report, Part III, preface.

⁷⁶⁴ See generally Report, Part III.

legitimate concerns that agencies would be remiss to ignore entirely. For one thing, if a regulated party obtains a favorable departure from guidance, this may put the party's competitors at a disadvantage, and they may 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, may seem like favoritism and thereby attract the negative scrutiny of the media, NGOs, and members of Congress. On top of all this, some competitors of the party that received a favorable departure from guidance may view it as unfair and ask why they themselves cannot get the same exception. One departure may therefore invite other requests for departure, and these requests can 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 to begin with.⁷⁶⁵

However, as set forth in Sub-paragraph 6(a), 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*. That is, for each departure the agency makes, it can give 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 can then 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.⁷⁶⁶ All that said, as Paragraph 6 recognizes, principled flexibility can be challenging to implement. The need for reason-giving means that every request for departure requires time and money to evaluate, and the giving of reasons must be reconciled with legitimate needs for confidentiality.⁷⁶⁷

⁷⁶⁵ Report, Section III.A.

⁷⁶⁶ Report, Section III.B.

⁷⁶⁷ Report, Section III.C.

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: the antagonism of some officials toward being challenged; the institutional motives of higher-level officials to back their subordinates; the counter-intuitive nature of the rule/guidance distinction for many people; and the fact that some agency offices, by reason of their principal day-to-day business, may be socialized to be less receptive to stakeholder requests than others.⁷⁶⁸ Sub-paragraphs 6(b) through 6(f) set forth additional measures that agencies may take in order to maintain flexibility in the face of these obstacles, recognizing again that such measures take agency resources and managerial initiative.

All that said, there are some instances in which agencies refuse to entertain requests for departures from 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's substantive content is right, that is the archetypal scenario for legislative rulemaking.⁷⁶⁹

Because being flexible often requires agency resources and managerial initiative, agencies cannot, as a practical matter, be flexible on everything all the time. Priorities must be set, as recognized in Paragraph 7. In deciding which guidance documents warrant the most active exertions in favor of flexibility, agencies should assign a higher priority to a document (a) the more it is likely to alter regulated-party behavior when operative;⁷⁷⁰ (b) the more the value of the document to the agency lies in its choice of substantive content;⁷⁷¹ and (c) the less it is subject to legitimate stakeholder pressures for consistency.⁷⁷²

⁷⁶⁸ Report, Section III.D.

⁷⁶⁹ Report, Section III.E.

⁷⁷⁰ On structural features of certain regulatory schemes that tend to cause guidance to alter regulated-party behavior, see Report, Part II. On how deregulatory guidance can alter regulated-party behavior in a way that affects regulatory beneficiaries, see Report, Part IV.

⁷⁷¹ Report, Section III.E. Although one might think an agency's commitment to a guidance document's substantive content would make it a fool's errand to encourage the agency to be flexible on that guidance, one must remember that the agency is a "they" not an "it." Some intra-agency offices or categories of personnel may be less committed to the guidance's substantive content than others, and therefore they may check each other, if a strong norm in favor of flexibility can be articulated. This point is elaborated in Report, Section III.E.

⁷⁷² On these legitimate stakeholder pressures for consistency, see Report, Section III.A.

Whereas the Paragraphs discussed so far focus mainly on agencies' administration of guidance in individual proceedings, Paragraphs 8 and 9 address agencies' processes for adopting guidance to begin with—wholesale rather than retail—and especially the role of public participation in those processes. It is often appropriate for agencies to invite public participation when considering whether to adopt guidance, through means such as outreach to selected stakeholders, stakeholder meetings and webinars, advisory committee proceedings, or voluntary use of notice-and-comment procedures.⁷⁷³ ACUS Recommendation 76-5 says that agencies should undertake pre-adoption notice and comment on a guidance document when the document is “likely to have substantial impact on the public” and when it would not be “impracticable, unnecessary, or contrary to the public interest to use such procedures.”⁷⁷⁴ Broad participatory measures at the time of a guidance document's adoption may be of value to the agency, to regulated parties, and especially to regulatory beneficiaries and organizations representing them, for beneficiaries often (if not always) lack the opportunity and resources to participate in the individual adjudicatory or enforcement proceedings in which a guidance document will be applied.⁷⁷⁵

In choosing a level of public participation that is appropriate to a guidance document's likely impact and is practicable, an agency should weigh several factors, as set forth in Paragraph 8. Broader participation is more appropriate the greater the guidance's likely impact, which can be gauged according to the factors discussed earlier in this preamble.⁷⁷⁶ Broader participation may increase the agency's access to useful technical or political information, though it may reach the point of diminishing returns.⁷⁷⁷ It may increase stakeholders' willingness to accept the policy of the guidance and their sense of “buy-in,” although relatively more formalized means of participation (such as notice and comment) may cause the agency to become invested in a formal proposal, which may sometimes diminish opportunities for agency

⁷⁷³ On the variety of forms of participation, see Report, Section V.A. Note that voluntary notice and comment on a guidance document generally does not involve nearly the same costs as notice and comment on legislative rulemaking. See Report, Section V.B.

⁷⁷⁴ ACUS Recommendation 76-5, paragraph 1. Recommendation 76-5 also states, in Paragraph 2, that agencies not undertaking notice and comment for adoption of a guidance document prior to adoption should undertake it soon after adoption, though an agency “may omit these post-adoption comment procedures when it incorporates in the interpretive rule or policy statement a declaration, with a brief statement of reasons, that such procedures would serve no public interest or would be so burdensome as to outweigh any foreseeable gain.”

⁷⁷⁵ See Report, Part IV and also text at notes 601-602.

⁷⁷⁶ See *supra* within this preamble text at notes 755-758.

⁷⁷⁷ Report, Subsections V.C.1 and V.C.2.

learning.⁷⁷⁸ Broader forms of participation also have costs that may reduce agencies' resources for other tasks, including provision of guidance on other subjects, and may even slow agency policymaking processes to the point of alienating part of the stakeholder community.⁷⁷⁹

Given the complexity of these potential costs and benefits and their tendency to vary with context, Paragraph 9 suggests that decisions about whether and how to seek public participation on guidance should be made on a document-by-document or agency-by-agency basis.⁷⁸⁰ Paragraph 9 does not suggest any government-wide requirement for notice and comment on guidance documents, which, unless confined to the very most extraordinary guidance documents,⁷⁸¹ would be rash. This is due not only to the complex cost-benefit considerations discussed above but also because broad mandates for notice and comment on guidance risk two additional unintended consequences. First, a broad mandate applied to a resource-strapped agency may cause the agency to fail to process and incorporate comments and instead leave many guidance documents in published "draft" form indefinitely, which may at least partly defeat the purpose of notice and comment and cause stakeholder confusion.⁷⁸² (Paragraph 9 suggests measures to head off this possible result.) Second, a broad mandate may so legitimize guidance in the eyes of agency personnel and political overseers that guidance will end up largely supplanting legislative rulemaking.⁷⁸³

Recommendation

Guidance Documents Not to Bind the Public

1. An agency should not treat a guidance document as if it were a legislative rule binding on the public. Instead the agency should afford the public a fair opportunity to seek

(a) modification of the guidance document in general, including rescission;

⁷⁷⁸ Report, Subsection V.C.3.

⁷⁷⁹ Report, Subsection V.C.4.

⁷⁸⁰ Some agencies have adopted procedural rules requiring notice and comment for large and well-defined categories of their guidance documents, while others have undertaken notice and comment for a large number of guidance documents but selected those documents on a decentralized, ad hoc basis. Report, Subsection V.D.1.

⁷⁸¹ The Office of Management and Budget's Good Guidance Practices calls for pre-adoption public comment on "economically significant" guidance documents, but this appears to cover only a very small number of quite extraordinary documents. See Report, text and accompanying notes 650-658.

⁷⁸² Report, Subsection V.D.2.

⁷⁸³ Report, Subsection V.D.3.

(b) departure from the guidance document as applied in a particular proceeding or to particular conduct in the case of a request from (i) a regulated party subject to the proceeding or contemplating the particular conduct or (ii) any other interested person participating in the proceeding.

2. An agency may treat a guidance document as binding on some of its own employees (e.g., on officials at one level in the absence of higher-level officials' permission to depart) but should ensure that this does not interfere with the fair opportunity called for in Paragraph 1.

Minimum Measures to Avoid Binding the Public

3. A guidance document should prominently state that it is not binding on members of the public and explain how members of the public can seek modification of or departure from the guidance document, per Paragraph 1, including the identity and contact information of officials authorized to decide such requests.

4. A guidance document should not include mandatory language unless the agency is using that language to describe a statutory or regulatory requirement, or the language is addressed to agency employees and will not foreclose agency consideration of positions advanced by members of the public.

5. The agency should instruct all employees applying guidance documents or advising on the basis of them not to give any indications to members of the public inconsistent with Paragraphs 1-4.

Additional Measures to Avoid Binding the Public

6. In order to avoid binding the public and to provide a fair opportunity for modification or departure, an agency should, subject to considerations of practicability and resource limitations and the priorities described in Paragraph 7 below, consider additional measures, including the following.

(a) Agencies may promote flexibility in a principled fashion, taking due account of needs for consistency and predictability, by ensuring that each departure from a guidance document in a particular situation is accompanied by a written explanation, accessible to other agency personnel and to the public (consistent with needs for confidentiality), which shall become the default policy for all like situations under that guidance document in the future.

(b) Agencies may assign the authority to grant departures from a guidance document to a component of the agency that is likely to engage in open and productive dialogue with persons who may seek modifications or departures, such as a program office that is accustomed to dealing cooperatively with regulated parties and regulatory beneficiaries.

(c) Agencies, when authorizing frontline officials to make departures from a guidance document, may direct appeals of adverse decisions by such officials to a higher-level

official who is not the direct superior of those frontline officials, in order to diminish the role played by a superior's institutional motivation to back his/her subordinates.

(d) Agencies may invest in training and monitoring of frontline personnel to ensure that they (i) understand the difference between legislative rules and guidance; (ii) treat parties' requests for departures in an open and welcoming manner; (iii) understand that departures from guidance, if undertaken according to the proper procedures for approval and justification, are appropriate and will not have adverse employment consequences for them; and (iv) are not to take personally, or retaliate against, a party's decision to seek departure from guidance or to appeal to a higher level of the agency when denied such a departure.

(e) Agencies may set up channels for anonymous requests for approvals of departures from a guidance document based on stated facts.

(f) Agencies may set up channels for anonymous feedback from members of the public on whether they perceive that requests for departures from a guidance document are given reasonable consideration.

Priorities in Deciding When to Take Additional Measures

7. Because the additional measures in Paragraph 6 are likely to take up agency resources, it will be necessary to set priorities for which guidance documents are most in need of such additional measures. In deciding when to take additional measures, an agency should assign a higher priority to a guidance document—

(a) the more likely the guidance is to alter the behavior of regulated parties, either because they have strong incentives to comply with guidance or because the guidance practically reduces the stringency of the regulatory scheme compared to the status quo;

(b) the more the value of the guidance to the agency lies in its adoption of one substantive approach instead of other substantive approaches that have been recently tried or seriously urged upon the agency;

(c) the less the value of the guidance to the agency or to stakeholders lies in consistency or predictability per se, irrespective of its substantive content.

Public Participation in Adoption of Guidance Documents

8. When an agency is contemplating adopting a guidance document, it should solicit an appropriate level of public participation before adopting the document, which may include outreach to selected stakeholder representatives, stakeholder meetings or webinars, advisory committee proceedings, or notice and comment (with or without a response to comments). In deciding what level is appropriate, the agency should consider:

- (a) the likelihood that the document will alter the behavior of regulated parties, either because they have strong incentives to comply with guidance or because the guidance would practically reduce the stringency of the regulatory scheme compared to the status quo;
- (b) the likely increase in useful information available to the agency from broadening participation, keeping in mind that non-regulated parties may offer different information than regulated parties and that non-regulated parties will often have no opportunity to provide input regarding guidance other than at the time of adoption
- (c) the likely increase in policy acceptance from broadening participation, keeping in mind that non-regulated parties will often have no opportunity to provide input regarding guidance other than at the time of adoption, and that policy acceptance may be less likely if the agency is not responsive to stakeholder input
- (d) whether the agency is likely to learn more useful information by having a specific agency proposal as a focal point for discussion, or instead having a more free-ranging and less formal discussion
- (e) the practicability of broader forms of participation, including notice and comment, keeping in mind that broader participation may slow the adoption of guidance and may diminish resources for other agency tasks, including the provision of guidance on other matters

9. An agency may make decisions about the appropriate level of participation document-by-document or by rules assigning certain participatory procedures to general categories of documents. If an agency opts for the latter, it should consider whether resource limitations may cause some documents to remain in draft for substantial periods of time and, if so, should either (a) make clear to stakeholders which draft guidance documents, if any, should be understood to reflect current agency thinking or (b) provide in each draft guidance document that, at a certain time after publication, the document will automatically either be adopted or withdrawn.

APPENDIX: METHODOLOGY FOR INTERVIEWS

A. Overall Approach

I located interviewees through a chain-referral process, beginning with a nucleus of well-networked individuals with diverse sectoral affiliations (ACUS agency contacts and ACUS public members) who could point me to people, inside and outside of federal agencies, who were knowledgeable from experience about federal agency use of guidance. I believe the chain-referral method was preferable to an alternative method of drawing a random sample of interviewees from a defined population. The state of academic knowledge about guidance's role

in federal administration did not provide much basis even for guesswork about what the relevant populations would be, or what biases they might entail. It is only in the course of the study, for example, that I learned about the potentially different attitudes toward guidance within agencies between program offices and enforcement offices, or within regulated industry between compliance officers, in-house counsel, and outside counsel. The chain-referral method—essentially using the knowledge of people within the system to identify who has relevant knowledge—is better-suited to the early stage of development of scholarship on guidance’s practical role in administration. It is a method suited to identifying and beginning to trace “unknown unknowns.” My hope is that this chain-referral interview study provides a provisional yet broad “map” of the subject matter, which future scholars—sometimes using more structured methods involving defined populations and random sampling—can employ as a guide to test more specific hypotheses.

The interviews were unstructured. Each began with an open-ended invitation for the interviewee to discuss the subject of federal agency guidance based on his/her experience, and the conversation went from there. I believe the unstructured format, like the chain-referral process, was the approach best-suited to the early stage of our learning about this subject. A method more similar to a survey, with pre-written questions asked on a uniform basis, could not have accounted for the numerous aspects of the subject that I learned about only in the course of doing the interviews. Again, I hope that the aspects of the problem identified through this more exploratory approach will later serve as the basis for future studies that can test more concrete hypotheses with more defined questions. Given the nature of my method, I have relied very little in my analysis upon quantitative reasoning (e.g., comparing the number of interviewees who said X to the number who said Y), because the interviews themselves had no uniform structure. It should also be noted that, because of the constraints of the Paperwork Reduction Act, any use of standardized questions would have made it impossible to interview any persons outside the federal government. That would have been a great loss, as the non-federal interviewees provided invaluable insights into guidance’s role from a stakeholder perspective. It was also extremely helpful to hear from people outside government who had previously been in government and could reflect upon their service from a distance.

B. Locating Interviewees

The chain-referral process of finding interviewees proceeded in several “rounds.” As I went from round to round, I tried to strike a balance between breadth and depth. Early on, I interviewed anyone who was referred to me with knowledge of guidance at any federal agency. As the rounds went on, I narrowed my focus to fewer and fewer agencies. The aim was to obtain *some* knowledge of a wide range of agencies and more in-depth knowledge of a few agencies. The agencies on which I went into the most depth, as I shall discuss below, were FDA and EPA. The reason to focus on FDA was the extraordinary importance of guidance at that agency and its use since 1997 of an unusually formalized process for issuing guidance, the FDA Good Guidance Practices. The reason to focus on EPA was the unmatched scale of its regulatory operations (in terms of benefits and costs) and its unmatched prevalence in legal controversy over both guidance and legislative rulemaking.

I began the chain-referral process in August 2016 by seeking a group of “first-round” interviewees. I sought out these interviewees through five channels:

(1) ACUS staff and I approached ACUS contacts at 17 agencies and asked them to arrange interviews between me and agency officials who could speak to the subject of guidance from experience.⁷⁸⁴ Six of the contacts responded and arranged interviews. These were at FDA,

⁷⁸⁴ Regarding selection of the 17 agencies: In beginning to solicit interviewees in August 2016, I wanted to focus on agencies that made the most use of guidance and legislative rulemaking in their operations. There is no official government-wide accounting of agency guidance documents. I therefore consulted one official metric of agency rulemaking activity, plus a privately-compiled metric of agency guidance activity.

The official metric of agency rulemaking activity was the annual OMB Report to Congress on the Costs and Benefits of Federal Regulations for 2015 (published March 2016). It gave all the executive agency components that promulgated one or more “major rules” in FY 2004-2014 and how many. *Id.* at 8-12. It also listed all the independent agencies that promulgated major rules in the same period, and how many. *Id.* at 97. I made a list of entities in the two categories that had 5 or more major rules in the covered period (13 executive agency components or independent agencies in all).

The privately-compiled metric of agency guidance activity was a count of the number of “significant guidance documents” listed on executive agency websites (pursuant to the OMB Good Guidance Practices from 2007), compiled from those websites by the Competitive Enterprise Institute (CEI) in a report critiquing agency use of guidance. Clyde Wayne Crews Jr., *Mapping Washington’s Lawlessness: A Preliminary Inventory of “Regulatory Dark Matter”* at 23 (Dec. 2015). The numbers were as of August 2015. I checked a few of the report’s numbers against current agency websites as of August 2016, and the numbers were very close (discrepancies small enough that they could result from changes between August 2015 and August 2016). I also checked the totals against a similar compilation from individual agency websites that appeared in Raso, *supra* note 84, at 813. The ranking of agencies by use of guidance that I gleaned from Raso’s data was pretty similar to the CEI report, except that HHS seemed to have reduced its listed guidance documents by a lot. I made a list of all executive agency components in the CEI compilation that had 15 or more significant guidance documents in force (13 in all, 2 of which overlapped with the OMB list).

EPA, USDA, the Department of Energy, DOT (including officials at FAA, NHTSA, and FMCSA), and the Federal Reserve. The agency officials thus interviewed totaled 31. (For the remaining eleven agencies that we approached but that did not participate in the study, I excluded, in all rounds of interview solicitations, any referral to an individual who was at that time an official at any of those agencies. To seek to interview such people would have been to circumvent the ACUS agency contact. The numbers reported throughout this Appendix exclude all referrals to officials at those eleven agencies.)

(2) On top of directly arranging interviews between me and agency personnel, two of the six responding ACUS agency contacts referred me (without directly arranging interviews) to individuals, both inside and outside the federal government, who could speak to the subject of guidance from experience. These individuals totaled four. I contacted all four, and three agreed to be interviewed.

(3) I approached all public members of ACUS as of August 2016 who had not spent their careers primarily in academia. These totaled 18. I asked each of them to refer me to individuals outside the federal government who could speak to the subject of federal agency guidance from experience. Of the 18 members, 15 responded, and 11 gave names. These names totaled 50. I contacted all 50, and 31 agreed to be interviewed; a few of these 31 people took the initiative of bringing along colleagues to meet/talk with me who also wanted to be interviewed (totaling 3), so the total number of interviewees yielded by this channel was 34.

Although these sources rested on agency self-reporting that was quite possibly imperfect, I felt comfortable going ahead with the combined lists compiled from the two metrics, because the agencies listed matched my impressionistic sense of places in federal administration where guidance was important. I relied on the metrics to provide an objective check on my impressions.

The agencies and agency components from the two lists numbered 24, but because ACUS contacts generally operated at the agency level rather than the component level, we ended up approaching the contacts at all the agencies of which these components formed parts. Those agencies totaled 15 (which reflects the fact that we treated HHS and FDA as separate agencies, because they have separate ACUS contacts). The 15 agencies were: CFTC, CFPB, USDA, Department of Education, Department of Energy, DHS, DOL, DOT, EPA, FCC, Federal Reserve, FDA, HHS, NRC, and SEC.

Several weeks into the interviews, ACUS staff and I approached ACUS contacts at two additional agencies, resulting in a total of 17 agencies solicited. The two additional agencies were the FTC and OCC. I decided to approach FTC because, based on one early interview, it seemed to offer—in its consumer protection activities—an interesting contrast with many other agencies in terms of its very broad jurisdiction combined with focus on ex post enforcement. I decided to approach OCC because, in an early interview, someone discussing CFPB made interesting comparisons to the prudential bank regulators, including OCC, which I thought should be further pursued.

(4) I approached one person to whom I was referred by a consultant on a previous ACUS project, as being highly knowledgeable from experience about guidance. This person agreed to be interviewed.

(5) I approached one individual who I learned from the press had long been a leading advocate on guidance-related matters at one agency. This person agreed to be interviewed.

The five channels described above yielded a total of 70 interviewees (31 from channel 1; three from channel 2; 34 from channel 3; one from channel 4; and one from channel 5). Readers may want to know the response rate. For channel 1, I am not able to calculate a response rate, because solicitations for interviews were conducted by the ACUS agency contacts, and I do not know what response rates they experienced. For the remaining channels (2, 3, 4, and 5), the aggregate response rate was 64%, that is, 36 people agreed to be interviewed out of 56 solicited across those channels.⁷⁸⁵

These 70 interviewees were the first-round interviewees. In addition to interviewing them, I generally asked all of them to name other persons they thought could speak to the subject of guidance from experience. (I did not ask this of the FDA officials to whom I was introduced through channel 1, because FDA's ACUS contact was extraordinarily generous in arranging for me to meet with nine FDA officials; asking all of them for referrals would have multiplied the number of FDA-related interviewees to an unmanageable degree, given that I was aiming to cover several agencies in addition to FDA.)

Many of the first-round interviewees did provide me with names, which provided the basis for locating the second-round interviewees. I decided that I had to be selective in contacting people for this second round, both to economize on time and to avoid letting the study become too scattered across too many agencies—to give the study some depth as well as breadth. I therefore narrowed my solicitations according to the agencies with which the named persons seemed to be experienced, based on what the referrer said. In particular, I solicited all named persons experienced with the six agencies participating through their ACUS contacts (FDA, EPA, USDA, the Fed, the Department of Energy, and DOT, although, at DOT, I narrowed my search to FAA alone, for the sake of manageability); and I also solicited all named persons outside the federal government who were experienced with three of the agencies that did not

⁷⁸⁵ The number 56 is the sum of the denominators for channels 2, 3, 4, and 5, and the number 36 is the number of initial respondents, which excludes the 3 people who were brought along to the interview sessions as colleagues.

participate: HHS (besides FDA), OSHA, and CFPB. I chose HHS because I wanted at least some depth on a benefit-administering agency (the interviews mostly pertained to Medicare). I chose OSHA because its guidance had attracted much attention in congressional oversight and litigation, which I found interesting because the agency seemed to lack the same kind of leverage over regulated parties and thick relationships with them that characterize several other agencies. I chose CFPB because first-round interviews about that agency and the Fed suggested that financial-services regulation would be an interesting way to balance the predominant focus of most of the other agencies on science, medicine, and engineering. The named persons who met these criteria totaled 58. I contacted all 58, and 32 agreed to be interviewed, for a response rate of 55%. Of those 32 interviewees, a few took the initiative of bringing along colleagues to meet/talk with me who also wanted to be interviewed (totaling 4), so the total number of interviewees yielded was 36.

These 36 interviewees were the second-round interviewees. I generally asked all of them to name other persons they thought could speak to the subject of guidance from experience. Many of them did give names, which provided the basis for locating the third-round interviewees. In this third round, I was even more selective, contacting all persons experienced with EPA and FDA, plus all persons outside the federal government experienced with OSHA or CFPB. (I focused on EPA and FDA for the reasons noted earlier. I focused on OSHA and CFPB because, of all the agencies on which the second round focused, I was most puzzled about them.) The named persons who met these criteria totaled 40. I contacted all 40, and 23 agreed to be interviewed, for a response rate of 58%.

These 23 interviewees were the third-round interviewees. With this round completed, the total number of interviewees was well over one-hundred, and I ceased seeking referrals on a general basis.

However, I did seek to expand the interviewee pool further with two supplemental rounds, which were as follows:

First, I felt that I needed to get more of an industry perspective on OSHA. I had learned much about OSHA from the eleven interviewees who discussed the agency during the first three rounds, but only two of these people had employer-side experience, and I had various puzzlements about OSHA guidance's role that I thought might be partly resolved by hearing more employer perspectives. Therefore, of the four third-round interviewees experienced with

OSHA, I asked for more names. Some of the interviewees gave names on the employer side, which totaled 4. I contacted all 4, and all 4 agreed to be interviewed.

Second, I felt that I needed to learn more about NGOs' perspectives on guidance at agencies besides EPA (the chain-referral process had already produced several EPA-related NGO interviewees). Therefore, I specifically sought names of NGO personnel who could speak to the subject of guidance from (a) two public members of ACUS experienced with agencies besides EPA and (b) two ACUS contacts at agencies besides EPA. Of these four ACUS people, three gave names, which totaled 7. I contacted all 7, and two agreed to be interviewed.

The total number of interviewees for the entire project was 135. This is the total of the first round (70), second round (36), third round (23), supplemental round for employer perspectives on OSHA (4), and supplemental round for NGO perspectives on agencies besides EPA (2).

A few notes about rules I followed through all stages of the chain-referral process: First, at every stage, I excluded any referral that was duplicative of a prior referral; the various numbers reported above exclude all duplicates. Second, in the course of obtaining referrals, I was occasionally given the names of academics. Because I wanted to focus the study on people who could speak about guidance from direct experience, I contacted these academics only if (a) they had spent their careers not primarily in academia but in other sectors that gave them more direct experience with guidance or (b) they had been in a federal government post within the preceding five years. Otherwise I excluded academics from the people I contacted; those excluded academics do not appear at all in the various numbers reported above.

C. Logistics of the Interviews

All interviews were conducted between September 2016 and July 2017. The individuals interviewed totaled 135. Several of the interviews were conducted in groups: four in pairs, two with three people, three with four people, and one with nine people. Because of the group interviewing, the total number of initial interviews was less than 135; it was 110. However, I conducted 13 follow-up interviews (all one-on-one, with 11 individuals subject to one follow-up and one to two follow-ups). Therefore the total number of interviews (initial plus follow-up) was 123. Of these 123, 35 were in person (including all those with more than two interviewees), and 88 were by phone. I took detailed handwritten notes on all interviews but did not record them in

any other way. The vast majority of all the initial interviews ran between 60 and 90 minutes, with some running shorter (there were about three as short as 20 minutes), approximately offset by some that ran longer (a few to two hours). The follow-up interviews were mostly shorter, in the 20 to 30 minute range.

D. Characteristics of the Interviewees

The breakdown of the 135 interviewees by the agency most discussed in the interview (always on the basis of the interviewee's experience) is as follows:

EPA	32
FDA	31
OSHA	15
Dept of Energy	10
USDA	8
FAA	7
HHS (besides FDA)	7
bank regulation (CFPB or Federal Reserve)	6
no particular agency	5
FMCSA	4
SEC	3
DOT	2
NHTSA	2
Dept of Education	1
DHS	1
FTC	1
TOTAL	135

The breakdown of the 135 interviewees by sectoral affiliation is as follows:

industry ⁷⁸⁶	65
current agency officials	35
NGOs ⁷⁸⁷	20
labor organizations	6
state or local government ⁷⁸⁸	4
academia ⁷⁸⁹	2
congressional staff	1
retired ⁷⁹⁰	1
think tanks	1
TOTAL	135

The breakdown of the 135 interviews according to whether they worked or are working in a federal agency, and in a political or career position within that agency, is as follows:

current career officials	35
former career officials	35
former political appointees (Democrat)	10
former political appointees (Republican)	13
none of the above	42
TOTAL	135

⁷⁸⁶ This includes people working at regulated firms, trade associations, industry associations, law firms representing regulated firms, or consulting firms serving regulated firms.

⁷⁸⁷ Organizations in the NGO category were comprised mostly of progressive advocacy organizations and more rarely of public policy research organizations that seek to influence federal administration. No organization in the NGO category was industry-aligned.

⁷⁸⁸ This includes people working for associations of state or local government agencies.

⁷⁸⁹ For interviewees who are currently academics but spent most of their careers in another sector, I have listed them as being in that other sector.

⁷⁹⁰ This category includes only people who retired after a career in the federal civil service. Retired people who ended their careers in another sector are listed as being in that sector.

Note that I have counted an interviewee as having prior federal agency service only if that service was closely related to the agency the interviewee discussed during the interview (e.g., an interviewee would be counted as having prior service if he/she served at DOJ frequently representing the agency discussed, but not if he/she served in a non-medical position in the Navy and then embarked on a separate, post-military career in the pharmaceutical industry). In the vast majority of cases, an interviewee listed as having prior agency service did that service at the exact same agency discussed in the interview.

If an interviewee served in both a career and a political position, I counted him/her as political. The chart takes account only of service in federal agencies, not service on congressional staff.

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