

**Written Testimony of  
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**Before  
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Committee on Oversight and Government Reform**

**“Shining Light on the Federal Regulatory Process”  
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Chairman Gowdy, Ranking Member Cummings, and members of the Committee, thank you for the opportunity to testify on the federal regulatory process and the role of guidance in that process.

The term “guidance” covers all general statements that an agency makes, short of issuing full-blown binding regulations, that advise the public on how the agency plans to exercise its discretion or interpret law.<sup>1</sup> Part I of my testimony explains that guidance is a very important means for increasing the transparency of federal agencies, though the use of guidance can detract from transparency if it substituted for notice-and-comment rulemaking. If one’s goal is to increase transparency, one must confront a difficult tradeoff: if you attempt to increase transparency by requiring an agency to make policy only through highly participatory processes like notice and comment (which eat up lots of agency resources), the agency may give up articulating any policy at all, which is actually the worst outcome for transparency. Part II examines the principal justification for why guidance can be issued without notice and comment:

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<sup>1</sup> “Guidance” is an umbrella term that covers what the Administrative Procedure Act (APA) calls “general statements of policy” and “interpretative rules.” 5 U.S.C. § 553(b)(A). Neither of these two terms is defined in the APA, but the widely cited ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947) defines general statements of policy as “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power” and defines interpretative rules 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.” *Id.* at 30 n.3. “Guidance” is conventionally understood to include not only statements addressed directly to the public but also public statements addressed to agency staff with the understanding that the statements will affect the staff’s treatment of members of the public (e.g., a published enforcement manual or permit-writing manual). See Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520, 556 (1977) (noting that guidance “might be addressed either to the staff or to the public without any real difference in impact”). Also, “guidance” is conventionally understood to include not only statements formally addressing a generic class of persons but also statements that are technically addressed to just one or a few named parties yet are understood to advise the public more generally on similar situations going forward (e.g., letters in response to individual requests for interpretations insofar as these are published and understood as precedential). See Office of Management and Budget, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3435 (2007).

that guidance, unlike a full-blown regulation, is not binding. In particular, I consider a common critique of this justification, i.e., that guidance is practically coercive in real life. Guidance can have powerful coercive effects in certain identifiable circumstances, but these effects are far from universal, and even when they happen, they typically are not consciously intended by agency officials. Coercive effects can be mitigated by certain institutional reforms, though many of these reforms would require resources and managerial initiative that may be in short supply. Part III considers the distinct questions that arise when guidance is deregulatory in nature, such that its use may shut out the people protected by regulatory statutes from participating in agency initiatives that may harm them. Part IV examines the ways in which agencies, when using guidance instead of notice-and-comment rulemaking, can foster transparency and public participation in ways that approach what is done in full-blown rulemaking. I consider the costs and benefits of these practices, which vary widely between different agencies and policies, and I note how they may sometimes lead to unintended and perverse consequences that require our vigilance.

Overall, this is a subject fraught with tradeoffs between competing goods, variation between different regulatory areas, the risk of unintended consequences, and solutions that will work only with a commitment of scarce resources. Because of all this, improvements are most likely to be effective if pitched at a workable level of specificity. This counsels caution regarding any sweeping trans-agency legislation. It counsels in favor of seeking improvement at the level of an individual agency or program, either through oversight or possibly through legislation if there is sufficient groundwork laid through dialogue with the agency and experimentation at the agency. In dealing with any particular agency or program, my hope is that this testimony is helpful in setting forth questions that must be asked, pitfalls that must be watched for, and a toolkit of potential reform practices to be considered for their suitability.

The principal basis for my testimony is a study that I conducted on federal agency guidance as a consultant for the Administrative Conference of the United States (ACUS).<sup>2</sup> The

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<sup>2</sup> NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE, FINAL REPORT TO THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES (Oct. 12, 2017), available at <https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf> [hereinafter Parrillo Report]. The focus of the study was guidance documents that are supposed to be nonbinding on the agency and the public. This focus definitely includes all general statements of policy (a.k.a. policy statements), as there is a consensus that policy statements are defined—and distinguished from full-blown regulations—by their nonbinding status. This focus would also include interpretative rules insofar as interviewees thought such rules were supposed to be nonbinding. However, there is inconsistency and confusion in the case law and among officials and

study rested mainly on interviews that I conducted with people from a range of agencies, industries, and NGOs. In all, I interviewed 135 individuals, with the vast majority of interviews lasting for between 60 and 90 minutes each, all between September 2016 and July 2017. The interviews were unstructured. Of the 135 interviewees, 26% were in 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.”<sup>3</sup>

Although ACUS commissioned the study, my analysis and conclusions were my own; the study was published with me listed as sole author, including a disclaimer noting that the opinions

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stakeholders about whether interpretative rules are to be nonbinding or if they are to be defined instead (or perhaps additionally) by the fact that they are confined to providing merely incremental clarifications of the underlying statutes or regulations that they interpret. For an excellent critical review of how the case law has sought to define policy statements and interpretative rules, see Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. (forthcoming 2018), manuscript available at

[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2958267](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2958267) (Jan. 31, 2018). For more detail on the scope of my study with respect to policy statements and interpretative rules, see Parrillo Report, *supra* note 2, at 22-26. In adopting a Recommendation on the use of guidance after receiving my study on how agencies should handle documents meant to be nonbinding, ACUS directed its Recommendation at policy statements (the category of guidance that is clearly of nonbinding status) while noting that “many” parts of the Recommendation “may also be helpful with respect to agencies’ use of interpretive rules.” ACUS Recommendation 2017-5: Agency Guidance Through Policy Statements, 82 Fed. Reg. 61728, 61734 (Dec. 29, 2017).

<sup>3</sup> 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, because of its heavy reliance on guidance documents and its use of an unusually formalized process for issuing guidance). I also sought additional referrals on a supplemental basis to fill certain gaps in my understanding, yielding a small number of additional interviewees. 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 methodology, see Parrillo Report, *supra* note 2, at 196-205.

and views therein were my own and not necessarily those of ACUS's members.<sup>4</sup> In addition to conducting the study, I extensively participated in ACUS's internal process for devising and adopting a Recommendation on agency use of guidance. I broadly support the Recommendation that the Conference (drawing partly upon my suggestions but also making many changes to them) ultimately adopted.<sup>5</sup> I shall discuss certain aspects of that Recommendation in my testimony. However, I am not giving any of this testimony as a representative of ACUS.

## **I. Guidance as a Plus and Minus for Transparency**

### **A. Guidance as a Plus for Transparency**

Guidance is a very important means for boosting the transparency of government. This is clearest when, in the absence of issuing guidance, the agency would fall back on case-by-case individual decisionmaking.

To appreciate this point, we must start by recognizing that acts of Congress often give a lot of discretionary power to agencies. Congress may prohibit an activity in vague terms, and an agency may then be empowered to interpret the prohibition and, given limited resources, decide which violators will be pursued and which not. Or Congress may provide for the grant of a license or benefit on certain conditions, which may be vaguely stated, and a federal agency may then be empowered to fill in the gaps and decide which regulated parties seeking the license or benefit will get it.

In circumstances like these, where agencies have wide latitude to interpret law and exercise discretion in any individual proceeding, it is possible the agency will make its decisions case-by-case—an approach that is usually not transparent.<sup>6</sup> To be sure, certain legal doctrines

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<sup>4</sup> As noted on the cover page of my report, cited in *supra* note 2: "This report was prepared for the consideration of the Administrative Conference of the United States. The opinions, views and recommendation expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees, except where formal recommendations of the Conference are cited."

<sup>5</sup> ACUS Recommendation 2017-5, *supra* note 2. Besides serving as a consultant to ACUS on this project, I am also a member of the approximately 100-person assembly that is the plenary decisionmaking body for ACUS, having served in that capacity since July 2016. However, because I served simultaneously as consultant for the project on guidance, I was recused from voting on the Recommendation arising from that project.

<sup>6</sup> Case-by-case decisionmaking, despite its disadvantages for transparency, is generally permitted as a matter of administrative law. *SEC v. Chenery Corp.*, 332 U.S. 194 (1947).

require the agency to treat like cases alike, but those doctrines do not apply to enforcement,<sup>7</sup> and even in areas where they do apply, they may do little practical good where individual cases are so fact-bound, or so few, or (conversely) so numerous that it is hard to identify relevant precedent when new cases arise. Case-by-case decisionmaking can therefore subject regulated parties to great uncertainty about what they are supposed to do and what to expect of the agency. A regulated party may invest a lot of resources in seeking a license or benefit according to a certain understanding of what the agency expects, only to find out, after the investment is sunk, that the agency wanted something different. Or a regulated party may take a certain course of action, believing it will not lead to any trouble, only to be hit with an enforcement proceeding, at which point the party finds out what the agency expected *after* suffering the reputational damage and process costs of enforcement. In either of these cases, the regulated party could have avoided serious losses if only it had known in advance what the agency was thinking. When regulated parties do not know what the agency is thinking, it becomes harder for them to plan for the future and invest in productive activity. Moreover, when individual proceedings are decided case-by-case, there is higher risk that similarly situated parties will be treated differently; this is always problematic, and especially if the parties are market competitors.

Guidance is the readiest means for an agency to tell the public what it is thinking—to announce how it plans to make individual decisions on enforcement, licenses, benefits, etc., and to do so in a more general, comprehensive, and understandable way than is possible through particularized explanations of fact-bound individual determinations.<sup>8</sup>

Given that regulated parties want to know what the agency is thinking, it is no surprise that a huge number of them—I would guess most firms in most industries most of the time—consider guidance a positive good that they affirmatively want. For example, when I interviewed the counsel to the home appliance manufacturers’ association, he said that, without guidance, we would be “cast adrift” in terms of what the agency regulating us thinks.<sup>9</sup> Even interviewees who mounted very substantial critiques of what they considered the abuse of guidance recognized that

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<sup>7</sup> Heckler v. Chaney, 470 U.S. 821 (1985) (holding that individual nonenforcement decisions are committed to agency discretion and not subject to judicial scrutiny).

<sup>8</sup> For full discussion of the advantages of guidance over case-by-case decisionmaking, see Parrillo Report, *supra* note 2, at 28-30.

<sup>9</sup> Cited in *id.* at 35.

much guidance was nonetheless essential and that businesses sometimes wanted agencies to issue *more* guidance.<sup>10</sup>

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.<sup>11</sup> When regulated firms come to EPA saying they are confused and need something explained, "EPA's instinct is to answer the question," as a former program office director at the agency told me.<sup>12</sup> This is no surprise: regulated parties seek guidance so they can get in line with agency expectations and head off confrontation, and that is in the agency's interest, too. And once the agency starts answering questions, it would be hard for the agency to keep those answers secret even if it wanted to. The same interviewee gave an example of how EPA clarificatory letters could be obtained by a regulated party through the Freedom of Information Act.<sup>13</sup> 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.<sup>14</sup> 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 playing field among regulated parties, some of whom phoned while others did not.<sup>15</sup> 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.

The upshot of all this is that numerous agencies issue large amounts of guidance. Guidance's page count for various agencies has been estimated to dwarf that of actual

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<sup>10</sup> On regulated parties' demand for guidance, see *id.* at 35-37.

<sup>11</sup> This paragraph draws upon Parrillo Report, *supra* note 2, at 36-37.

<sup>12</sup> Cited in *id.* at 36.

<sup>13</sup> Cited in *id.* at 36.

<sup>14</sup> Cited in *id.* at 36.

<sup>15</sup> Cited in *id.* at 36-37.

regulations by a factor of twenty, forty, or even two-hundred.<sup>16</sup> As suggested in the preceding paragraph, guidance can proliferate in so many diverse, decentralized, and program-specific ways—often in bottom-up fashion when regulated parties ask questions of frontline officials—that there is no comprehensive catalogue of all of it.

## **B. Guidance as a Minus for Transparency**

Despite guidance’s potential to promote transparency, it can sometimes be a minus for transparency if an agency issues guidance when it would otherwise issue full-blown binding regulations (known as “legislative rules”). The reason is that legislative rules are required to be issued through the legislative rulemaking process of the Administrative Procedure Act (APA), including notice and comment, in which the agency publishes a proposed rule, takes comments from the public, and then, upon issuing a final rule, gives an extensive response to the comments—an extraordinary degree of agency engagement with stakeholders. Guidance, by contrast, is exempt from this highly participatory and open process.<sup>17</sup> What officially justifies this lessened process for guidance is that guidance is not binding on the agency or the public in the way a legislative rule is. (On whether this nonbinding status is a reality or a fiction—and thus whether it can really justify the less-open process for issuing guidance—see Part II below.)

## **C. The Transparency Tradeoff**

When it comes to transparency, guidance involves a difficult tradeoff. On the one hand, guidance provides more transparency about what the agency’s thinking is than does case-by-case decisionmaking. On the other hand, guidance provides less transparency about how the agency formulates what it thinks than does legislative rulemaking. It would be a mistake to think we can maximize transparency by telling agencies always to formulate their general thinking through legislative rulemaking. That is because such rulemaking takes a long time and expends a lot of

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<sup>16</sup> See Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468-69 (1992) [hereinafter Strauss, *Rulemaking Continuum*]; Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 805 (2001). For more on the ubiquity of guidance, see Parrillo Report, *supra* note 2, at 34-35.

<sup>17</sup> 5 U.S.C. § 553(b)(A). I must add a qualification to the point that guidance, when substituted for legislative rulemaking, diminishes transparency. Because legislative rules are officially binding while guidance is not (see *infra*, Part II), it is possible to write guidance in more colloquial language than can be used in legislative rules. This makes it easier to use guidance as a means to explain regulatory schemes to less-sophisticated regulated parties who lack counsel—a plus for transparency. Parrillo Report, *supra* note 2, at 30-31.

agency resources.<sup>18</sup> There is only so much policy that can be formulated through that process in the near term. If we tell an agency that, on a certain matter, it must formulate its general thinking (if at all) only through legislative rulemaking, then maybe the agency will opt for such rulemaking instead of guidance, and there will be an increase in transparency. But maybe the agency will instead give up developing *any* general thinking on the matter, or greatly delay doing so, because it has already expended all the resources it has currently available for legislative rulemaking on other matters that are crying out for such treatment. In that case the agency ends up leaving the matter to case-by-case decisionmaking, which is the worst outcome for transparency.<sup>19</sup> 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.”<sup>20</sup> More generally, we should be cautious about imposing additional process requirements on the issuance of guidance in the name of transparency, because such requirements can potentially discourage issuance of guidance to begin with, perversely diminishing transparency on net.

## **II. Is the Nonbinding Status of Guidance Reality or Fiction?**

How should an agency strike a balance between the transparency benefits of issuing guidance and the transparency disadvantages of not going through legislative rulemaking? The conventional answer is that legislative rules are legally defined by the fact that they are binding on the agency and the public, whereas guidance documents are not.<sup>21</sup> Thus, if the agency wants to articulate its thinking in a way that is cut-and-dried, to be followed automatically in later individual proceedings, then it must formulate that thinking through legislative rulemaking. But if the agency wants to articulate its thinking on a more tentative basis, with the understanding that it reserves discretion to be flexible and open-minded about doing things differently in later individual proceedings, then it can articulate its thinking through guidance. It is okay for the

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<sup>18</sup> See Parrillo Report, *supra* note 2, at 31-34.

<sup>19</sup> See *American Mining Congress v. MSHA*, 995 F.2d 1106, 1111-12 (D.C. Cir. 1993).

<sup>20</sup> Cited in Parrillo Report, *supra* note 2, at 33.

<sup>21</sup> At least, general statements of policy are universally thought to be nonbinding; the question of whether interpretative rules are nonbinding is more uncertain. See *supra* note 2.



agency to forego public engagement when it originally formulates a norm wholesale *so long as* the agency is going to engage with regulated parties' arguments for doing things differently later, at the retail level, when the norm is individually applied.<sup>22</sup>

This mandate that guidance be nonbinding and flexible has made guidance a subject of controversy. The fear is that agencies in real life 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. If agencies do use guidance as a binding norm, as feared, they undermine the mandate of the APA that general binding policies should be made only through the open and participatory procedures of legislative rulemaking.

Is this fear based on reality? To answer this question, we must break it into two parts. First, we must ask what pressure a regulated party feels to follow guidance when the guidance is operative, that is, when the agency has not granted a party's individual request for a dispensation from the guidance. Second, we must ask whether agencies are practically open to granting such dispensations—in other words, are agencies flexible?

### **A. When and Why Regulated Parties Are Under Pressure To Follow Guidance Absent a Dispensation**

Regulated parties often (though not always) feel strong pressure to follow guidance. But the origins of this pressure usually lie not in some plot hatched by the agency but instead in a series of structural factors hard-wired into modern regulation and the legislation that establishes it, nearly all of which are vastly beyond the control of the agency officials who are issuing or using a guidance document. In other words, this is not the kind of pressure that can be mitigated by using legislation or oversight to tell officials not to act with coercive intent, for official intent is not usually what is at play here.

There are four major structural factors that incentivize regulated parties to follow guidance. 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

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<sup>22</sup> 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.

is uncertain and subject to delay, the incentive to follow whatever the agency's wishes appear to be (including guidance) can be overwhelming.<sup>23</sup> 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.<sup>24</sup> 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.<sup>25</sup> 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.<sup>26</sup>

Conversely, in areas where these four structural factors are mostly weak or absent, interviews indicate that regulated parties are relatively less likely to follow guidance. Examples are FTC consumer protection, CFPB regulation of most nonbanks, EPA enforcement against permitless discharges into protected waters, and OSHA regulation of most employers.<sup>27</sup> Thus, the pressure to follow guidance, though real, is far from universal.

If an agency official works within a statutory and regulatory structure where most or all of the four factors are robust, then whatever that official issues in the form of guidance will quite

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<sup>23</sup> Parrillo Report, *supra* note 2, at 37-44.

<sup>24</sup> *Id.* at 45-56.

<sup>25</sup> *Id.* at 56-64. 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 Justice Department prosecutorial practice, *id.* at 58, rather than from any regulatory agency.

<sup>26</sup> *Id.* at 64-76.

<sup>27</sup> *Id.* at 76-90.

likely be followed by regulated parties. But that is not because any agency official sets out with conscious purpose to coerce anybody. 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, 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 high-stakes 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, despite its importance to government transparency and the fact that numerous regulated parties demand it. That cannot be right.

If we really want to protect regulated parties from feeling strongly pressured to follow guidance in the absence of an agency dispensation, 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,<sup>28</sup> but abolishing them would entail radical rollbacks of health, safety, and environmental regulation and could worsen uncertainty for regulated industry; more incremental reforms are also possible, but these, too, implicate wide-ranging questions.<sup>29</sup> 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,<sup>30</sup> and might incline it to become

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<sup>28</sup> Richard A. Epstein, *The Permit Power Meets the Constitution*, 81 IOWA L. REV. 407 (1995)

<sup>29</sup> 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).

<sup>30</sup> 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").

more impersonal, exacting, and punitive.<sup>31</sup> The rise of the compliance profession has been attacked as a stealth reform imposed on corporate America by unelected and ill-informed Justice Department prosecutors,<sup>32</sup> 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 personnel<sup>33</sup>—these, too, have high costs and wide-ranging implications.

## **B. When and Why Agencies are Inflexible When Asked for Dispensations**

Although structural factors create a strong incentive to follow certain guidance absent a dispensation, the agency can mitigate this coercive effect by being open-minded and flexible when a regulated party seeks a dispensation.<sup>34</sup> But in real life, agencies are sometimes inflexible. 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.

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

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<sup>31</sup> 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).

<sup>32</sup> Sean J. Griffith, *Corporate Governance in an Era of Compliance*, 57 WM. & MARY L. REV. 2075, 2117-30 (2016).

<sup>33</sup> Rachel E. Barkow, *Overseeing Agency Enforcement*, 84 GEO. WASH. L. REV. 1129, 1143-50 (2016).

<sup>34</sup> See Parrillo Report, *supra* note 2, at 13 (collecting authorities on the need for flexibility and open-mindedness on guidance).

cause them to withdraw from cooperation with the agency, thereby diminishing compliance and making the whole regulatory program less effective.<sup>35</sup> 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.<sup>36</sup> 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.<sup>37</sup>

Significantly, there is a way for an agency to maintain flexibility while addressing these legitimate pressures for consistency: it can take an approach that emphasizes transparency about departures from guidance, which I call *principled flexibility*.<sup>38</sup> 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. 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. 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

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<sup>35</sup> Parrillo Report, *supra* note 2, at 93-98.

<sup>36</sup> *Id.* at 98-101.

<sup>37</sup> *Id.* at 101-03.

<sup>38</sup> *Id.* at 103-07. 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 suggestion that guidance be treated like agency adjudicatory precedent, with an APA-style obligation to give reasons for any departure. Strauss, *Rulemaking Continuum*, *supra* note 16, at 1472-73, 1485-86.

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.<sup>39</sup> 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.<sup>40</sup>

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.<sup>41</sup> 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 and prompt them to retaliate. Such retaliation may be unconscious, but the prospect of it can nonetheless chill regulated parties from seeking flexibility. Even if officials never retaliate, a perception within the regulated community that they do so, if not actively dispelled by the agency, can have a similar effect. For their part, higher-level officials, when faced with appeals, have various institutional motives to back up their subordinates irrespective of the merits of the case. More subtly, the rule/guidance distinction is not intuitive to most people (except perhaps lawyers), and that lack of understanding can make flexibility harder to achieve. In addition, the day-to-day business of a government office can socialize its personnel to be less receptive to regulated-party requests, though sometimes more receptive. Offices that have day-to-day habits of cooperating with industry (like program offices engaged in rulemaking) tend to be more flexible on guidance-related matters than, say, enforcement offices. Finally, it is possible to get

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<sup>39</sup> For full discussion of obstacles to implementing principled flexibility, see Parrillo Report, *supra* note 2, at 107-116.

<sup>40</sup> Cited in *id.* at 16.

<sup>41</sup> On obstacles discussed in this paragraph, see *id.* at 116-27.

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 think the guidance is right.<sup>42</sup> That is, they are committed to the substantive content of the guidance, and this can keep the agency from being practically open to the possibility of departure. Of the many reasons why agencies are inflexible, this one is the most problematic. If an agency is not going to consider departing from a policy, by reason of thinking the policy is right, that is the archetypal scenario for legislative rulemaking. Notably, however, the interviews indicate that 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;<sup>43</sup> thus, if a strong norm in favor of flexibility and open-mindedness can be articulated, it may be possible for the political to effectively invoke the norm against the career officials and vice versa.

Any reform effort to address the coercive effects of guidance must recognize that agency flexibility is a good aspiration, but it is not the path of least resistance. Being flexible requires undertaking active managerial reform and may involve expending resources. Consistent with this understanding, ACUS Recommendation 2017-5 sets forth organizational measures that will promote flexibility, including (1) publishing reasons for individual departure decisions and making them applicable to all like cases going forward; (2) assigning departure decisions to components of the agency most likely to be socialized to have productive dialogue with stakeholders; (3) redirecting appeals from frontline denials of flexibility to higher-level officials who are *not* the direct superiors of the officials who issued the initial denial; (4) training and monitoring frontline officials to ensure they understand the rule/guidance distinction and treat parties' requests for departures in a welcoming manner; and (5) facilitating opportunities for ombudspersons, stakeholder associations, or other intermediaries to make departure requests and give feedback to the agency on guidance practices more broadly. But the Recommendation

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<sup>42</sup> Id. at 128-32.

<sup>43</sup> Id. at 129-31.

recognizes that, given the costs of these measures, agencies cannot, as a practical matter, make these efforts in favor flexibility on everything all the time. Priorities must be set. In deciding which guidance documents warrant the most active exertions in favor of flexibility, the Recommendation assigns a higher priority to guidance documents likely to have a greater impact on the public, e.g., because regulated parties are under strong pressure to follow them absent a dispensation (due to structural factors discussed above). It assigns a lower priority to guidance documents whose value lies more in providing consistency and predictability per se than in the document's choice of substantive content.<sup>44</sup>

### **III. Deregulatory Guidance and Regulatory Beneficiaries**

Distinct questions may arise when it comes to deregulatory guidance, that is, 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 license 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 factors 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 individual proceeding, remains “open-minded” to the possibility of treating the regulated party *more stringently* than the deregulatory guidance suggests).<sup>45</sup>

It is doubtful that flexibility in deregulatory guidance is typically a useful remedy for regulatory beneficiaries. 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.<sup>46</sup> It seems the best approach—except in the select areas where NGOs representing beneficiaries have the practical capacity to participate in individual adjudication and

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<sup>44</sup> ACUS Recommendation 2017-5, *supra* note 2, at 61736 (paragraphs 7-8).

<sup>45</sup> See Parrillo Report, *supra* note 2, at 132-33.

<sup>46</sup> *Id.* at 135-37.



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.

#### **IV. Public Participation in the Issuance of Guidance**

Though the APA does not require it, agencies can voluntarily provide for public participation in the formulation and issuance of guidance. This means transparency and participation occur at the wholesale level, as distinct from the retail level when a guidance document is applied in individual proceedings where a particular party may argue for a dispensation. This wholesale form of participation may be especially suited to regulatory beneficiaries, as noted in Part III, 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.<sup>47</sup> 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.<sup>48</sup>

In deciding what level of public participation an agency should seek on the issuance of guidance—and especially in deciding whether the agency should undertake notice and comment on it—we must weigh several potential benefits and costs. One potential benefit is the technical

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<sup>47</sup> Id. at 139-43.

<sup>48</sup> Id. at 143-50.

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.<sup>49</sup>

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 and confrontation.<sup>50</sup>

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: 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).<sup>51</sup> Second, because notice and comment is more general and impersonal than other forms of participation, it 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 anxiety that officials commonly have about the possibility of

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<sup>49</sup> Id. at 150-53.

<sup>50</sup> Id. at 153-54.

<sup>51</sup> Id. at 155-57.

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.<sup>52</sup> 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.<sup>53</sup>

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.<sup>54</sup>

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

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<sup>52</sup> Id. at 157-60.

<sup>53</sup> Id. at 160-62.

<sup>54</sup> Id. at 162-66.

very most extraordinary guidance documents would be rash.<sup>55</sup> 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. Consistent with this, ACUS Recommendation 2017-5 says an agency “may make decisions about the appropriate level of public participation document-by-document or by assigning certain procedures for public participation to general categories of documents.” It urges agencies to consider many of the various costs and benefits listed in the discussion above.<sup>56</sup>

Further, broad mandates for notice and comment on guidance (even if only agency-wide rather than government-wide) risk two major unintended consequences. 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. This has sometimes happened at FDA, for example, and elsewhere.<sup>57</sup> 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 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. To head off these problems, ACUS Recommendation 2017-5 urges that, if an agency adopts the FDA-like approach of providing for participation on a general category of documents, it “should consider

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<sup>55</sup> The Office of Management and Budget’s Good Guidance Practices (cited in *supra* note 1), calling for pre-adoption public comment on “economically significant” guidance documents, appear to cover only a relatively tiny number of very extraordinary documents. See Parrillo Report, *supra* note 2, at 167-68.

<sup>56</sup> ACUS Recommendation 2017-5, *supra* note 2, at 61736-37 (paragraphs 9, 11).

<sup>57</sup> For full discussion of this phenomenon, see Parrillo Report, *supra* note 2, at 171-81.

whether resource limitations may cause some documents . . . to remain in draft for substantial periods of time,” and if so, it should either “(a) make clear to stakeholders which draft policy statements, if any, should be understood to reflect current agency thinking; or (b) provide in each draft policy statement that, at a certain time after publication, the document will automatically either be adopted or withdrawn.”<sup>58</sup>

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.<sup>59</sup> 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. Congressional overseers and the White House can put pressure on particular agencies with respect to their participation policies for guidance, or even their participation decisions regarding individual documents, as when congressional scrutiny (among other factors) caused FDA in 1997 to adopt an unusually participatory procedural framework for issuing guidance (later ratified by legislation), or when OMB successfully pressed EPA to take public comment on certain key guidance documents even though some EPA officials thought the agency should not.<sup>60</sup> 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.

Thank you again for the opportunity to discuss this important subject. I look forward to the Committee’s questions.

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<sup>58</sup> ACUS Recommendation 2017-5, *supra* note 2, at 61737 (paragraph 11).

<sup>59</sup> On this possibility, see Parrillo Report, *supra* note 2, at 181-84.

<sup>60</sup> *Id.* at 169, 185-86.