SHOULD THE PUBLIC GET TO PARTICIPATE BEFORE FEDERAL AGENCIES ISSUE GUIDANCE? AN EMPIRICAL STUDY

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1. Professor of Law, Yale Law School. This Article draws heavily upon a study I conducted as a consultant to the Administrative Conference of the United States (ACUS) in 2016–2017. NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE, FINAL REPORT TO THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES (Oct. 12, 2017), https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf [hereinafter PARRILLO REPORT]. The study provided the empirical basis for Admin. Conf. of the U.S., Recommendation 2017-5, *Agency Guidance Through Policy Statements*, 82 Fed. Reg. 61,728, 61,734 (Dec. 29, 2017). I am grateful to the Conference for its financial and logistical support and advice, particularly to Gisselle Bourns, staff counsel; Alissa Ardito, former staff counsel; Lee Liberman Otis, committee chair; Reeve Bull, research chief; Matthew Wiener, vice chair; and Paul Verkuil, former chair. ACUS agency contacts performed the service of identifying, and often setting up interviews with, agency officials. Public members of ACUS did the same in identifying other knowledgeable interviewees. Notwithstanding ACUS's support, I formulated my analysis and drew my conclusions independently, on my own responsibility. As noted on the cover page of my report: "This report was prepared for the consideration of the Administrative Conference of the United States. The opinions, views and recommendation expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees, except where formal recommendations of the Conference are cited." For advice about the project, I am also grateful to Cary Coglianese, Cynthia Farina, Ron Levin, Jerry Mashaw, Ricky Revesz, Sarah Ryan, Jason Schwartz, Kevin Stack, Wendy Wagner, Chris Walker, Susan Yackee, and participants in ACUS's committee meetings and plenary session and in conferences and talks hosted by the American Bar Association (ABA) Administrative Law Section, the District of Columbia Bar, Loyola University Chicago, and Vanderbilt. For work on the quantitative research for the project, as well as some of the legal research and citation checking, I owe many thanks to Yale Law School student research assistants Juliana Brint, Katie Choi, José Argueta Funes, Samir Doshi, Julia Hu, Arjun Ramamurti, Christine Smith, Isra Syed, and Garrett West. For additional financial support I thank the Oscar M. Ruebhausen Fund and Yale Law School. All errors are my own.

When issuing binding regulations, agencies must follow procedural safeguards (including notice-and-comment) that allow the regulated industry and other stakeholders to participate in formulating agency policy. But regulations always leave gaps and ambiguities. Because of this, agencies also issue huge amounts of "guidance," that is, statements to advise the public on how the agency is tentatively planning to exercise all the discretion that its regulations have left to it. Because guidance is not binding, agencies issuing it need not follow any procedural safeguards. This is what allows them to issue so much of it so quickly.

While ubiquitous and essential, guidance also entails a certain danger. To the extent that officials follow guidance rigidly—and they sometimes do—guidance documents become de facto binding regulations, but ones that the agency issues at will, with the public having no say. One might think the solution is to get agencies to use guidance less rigidly, but that is easier said than done, since it is inherently difficult for large cross-pressured organizations like the federal government to be flexible.

An alternative solution is to beef up the procedure by which agencies issue guidance in the first place to make it more participatory. This solution has recently been proposed by academics, members of Congress, and presidential administrations. But the literature on the proposal is mainly theoretical, without much empirical understanding of how these participatory arrangements work when they are tried, or what their consequences are. To fill the gap, this Article draws upon interviews with 135 individuals who had firsthand experience with guidance as employees of agencies, industry, or non-governmental organizations (NGOs). While the interviews indicate that public participation in the issuance of guidance is sometimes worthwhile, they also provide a body of new evidence that the benefits of such participation are uncertain, and the pitfalls complex and potentially severe, in ways that are unknown or underexplored in the literature. In analyzing the interviews, this Article aims to provide a realistic and concrete assessment of participation's value and a guide for what factors an agency needs to evaluate (and what pitfalls it must anticipate) in deciding when and how to invite participation—factors and pitfalls that vary substantially across agencies and even across documents. In light of this variation, I conclude that decisions about whether and how to invite participation should normally be made on a relatively local basis: document by document, or, at most, agency by agency. I caution against hard government-wide mandates of the kind proposed by some lawmakers and scholars.

INTRODUCTION

As voluminous and complicated as federal agency regulations are, they leave a great many important matters to the agency's discretion or interpretation. Individuals and firms naturally want to know how the agency regulating them will exercise this discretion and how it will read the regulations' ambiguous words. Agencies respond by issuing huge amounts of "guidance," that is, statements to advise the public on how the agency proposes to exercise discretion or interpret law.[2] Guidance documents—advisories, circulars, bulletins, memos, interpretive letters, manuals, FAQs, and the like—occupy a large portion of the typical agency's website and of the typical regulatory lawyer's day-to-day reading. The total page count of guidance issued by any given agency is estimated to dwarf that of actual regulations by a factor of twenty, forty, or even two-hundred.[3]

Omnipresent and essential though it is, guidance sparks fiery controversy. When agencies impose actual regulations that officially bind the agency and the public (known as "legislative rules"), there are safeguards in place for how they do it: the costly, time-consuming process mandated by the Administrative Procedure Act (APA), including notice-and-comment, in which the parties who will be bound by a policy have input into its formulation.[4] By contrast, agencies can issue guidance without any such process

2. On the exact legal definition of "guidance," see *infra* note 6.

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

4. *See generally* 5 U.S.C. § 553 (2012) (governing the rulemaking process of agencies).

because the APA's exemptions for "general statements of policy" and "interpretative rules" combine to cover guidance in all its forms.[5] This means that guidance can be produced and altered at greater speed, in higher volume, and with less accountability than legislative rules can. The justification for this procedural looseness is that guidance, unlike a legislative rule, is not supposed to be binding on the agency or the public.[6] It is merely a tentative suggestion of the agency's current thinking about how to proceed in individual proceedings for adjudication or enforcement, unlike a legislative rule that the agency would follow automatically. Guidance is supposed to leave latitude, in each individual case, for the regulated party to argue for flexible treatment, and for officials to be open to that argument. If officials use guidance flexibly, it does not seem terribly worrisome for the agency to

5. *See* 5 U.S.C. § 553(b)(A).

6. Let me say a word about exactly which guidance documents have nonbinding status—and, relatedly, about the scope of this Article. In general parlance, an agency statement is guidance if it is either a "general statement of policy" (a.k.a., policy statement) or an "interpretative rule" (a.k.a., interpretive rule) under the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(A). While neither term is defined in the APA, the much-cited *Attorney General's Manual on the Administrative Procedure Act* defines policy statements as "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power," while defining interpretive 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." ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (1947). There is general agreement that policy statements are supposed to be nonbinding. *See* Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 287–317 (2018). The question of whether interpretive rules are supposed to be nonbinding is subject to much confusion and not fully settled. *See* PARRILLO REPORT, *supra* note 1, at 23 & n.35; *see also* Levin, *supra*, at 317–53. In conducting my study (e.g., in telling interviewees what kinds of guidance documents I was interested in), I focused on all agency guidance that was legally supposed to be nonbinding. This includes (a) all policy statements and (b) interpretive rules insofar as the interviewee thought interpretive rules were supposed to be nonbinding. Usually the categories of "policy statement" and "interpretive rule" played little to no role in the interviews. Rather the interviewee would instantly recognize a category of "guidance" that was supposed to be nonbinding and discuss it, not pausing to think about whether this category consisted solely of policy statements or also encompassed interpretive rules. In fact, the question of whether to label a guidance document "policy statement" or "interpretive rule" may never occur to many agency officials or stakeholders unless and until there is a lawsuit about the document under the APA. For more on the study's scope, see PARRILLO REPORT, *supra* note 1, at 22–26. Because it is uncertain whether interpretive rules are supposed to be nonbinding, ACUS, in formulating its best practices on the basis of my study, confined those best practices to policy statements, while noting they might be "helpful" in administering interpretive rules, as well. *See* Recommendation 2017-5, *supra* note 1, at 61,734.

be unconstrained in issuing guidance from the beginning.[7]

Yet many observers worry that guidance's official promise of flexibility may not be borne out in reality. One hears complaints that agency officials are not tentative or flexible when it comes to guidance, but instead follow it as they would a binding legislative rule, and regulated parties are under coercive pressure to do the same. The more these complaints are true, the more the APA approaches the status of a dead letter, with agencies free to issue de facto regulations at will, just by couching them as "guidance," without the participation of individuals and firms who will be effectively bound. Invoking this fear, recent exposés on guidance documents have condemned them as "underground regulations" whose escape from APA safeguards reflects "Washington's lawlessness."[8] In 2017, former Attorney General Sessions initiated a campaign to root out "improper guidance documents" and to stop the government from "circumventing the rulemaking process."[9]

At first glance, you might think the way to address the danger of coercive guidance is to make sure that officials act flexibly and not rigidly when they conduct the numerous individual proceedings to which a guidance document pertains. But that is easier said than done. In recent empirical work, I have found that agencies' rigid adherence to guidance is, in some circumstances, a real and at times intractable phenomenon. Even when officials operate in good faith and want to use guidance in a legally proper manner (as is usually the case), their wish to be flexible can run up against a set of obstacles that are inherent to large, cross-pressured organizations like federal agencies. Overcoming those obstacles requires resources and managerial initiative that are usually in short supply.[10] Thus, we cannot practically

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

8. CLYDE WAYNE CREWS JR., MAPPING WASHINGTON'S LAWLESSNESS: AN INVENTORY OF REGULATORY DARK MATTER (2017); NAT'L FED'N OF INDEP. BUSINESSES, THE FOURTH BRANCH & UNDERGROUND REGULATIONS (2015).

9. OFFICE OF THE ATT'Y GEN., PROHIBITION OF IMPROPER GUIDANCE DOCUMENTS 1–2 (2017), https://www.justice.gov/opa/press-release/file/1012271/download; *see also* OFFICE OF THE ASSOC. ATT'Y GEN., LIMITING USE OF AGENCY GUIDANCE DOCUMENTS IN AFFIRMATIVE CIVIL ENFORCEMENT CASES (2018), https://www.justice.gov/file/1028756/download. The campaign has resulted in rescission of several dozen Department of Justice guidance documents. *See, e.g.*, *Attorney General Jeff Sessions Rescinds 24 Guidance Documents*, OFF. OF PUB. AFF. (July 3, 2018), https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-24-guidance-documents (discussing rescission of twenty-four documents and previous rescission of another twenty-five).

10. Perhaps most importantly, officials face pressures from outside stakeholders to act consistently across cases, both because competing industry players want a level playing field

expect all agencies to be flexible about all guidance all the time. Furthermore, even if case-by-case flexibility is achieved, that only benefits some of the stakeholders who can be hurt by guidance's circumvention of the rulemaking process—mainly regulated businesses who are in a position to ask for flexibility when an unfavorable policy is applied to them in an individual proceeding. Case-by-case flexibility does not much help stakeholders like regulatory beneficiaries (say, people harmed by pollution, or the NGOs who represent them) because those people and organizations do not have the resources to get involved in more than a tiny fraction of the countless individual proceedings to which guidance documents pertain.[11]

Given the limits on how much flexibility agencies can achieve in applying guidance, plus the limited advantages of whatever flexibility they do achieve, it is natural to seek out additional remedies for the threat that guidance may pose to the APA's safeguards on regulatory power. One possible remedy, invoked frequently by practitioners and academics, is to change the process by which guidance gets issued in the first place to make it more participatory. To be sure, the very definition of a guidance document is that the agency's issuance of it is *exempt* from the APA's requirement for public input on legislative rules, and many people would say the whole point of guidance is that it does not require much process—it is a means to keep the public informed quickly and easily without the APA's delays and costs. Nonetheless, an agency can invite stakeholders to participate by methods that are faster and less elaborate than for legislative rules yet still have some (if not all) the participatory virtues of full-blown legislative rulemaking. These methods can involve a little participation or a lot, up to and including "voluntary notice-and-comment," in which the agency does something similar to what it does for a legislative rule—publish the guidance document in a draft and invite the public to send its reactions—though more streamlined (e.g., offering little or no response to the comments, or building less of a record).

While public participation in the issuance of guidance has been considered off and on since the 1940s,[12] the last couple of decades have seen the

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and because non-governmental organizations (NGOs) and the media are vigilant against the appearance of favoritism. Officials are loath to depart from a policy, even if officially nonbinding, absent some explanation that will shield them against stakeholder criticism. But formulating explanations is costly in time and resources, so officials often default to sticking with the policy. *See* PARRILLO REPORT, *supra* note 1, at 90–116.

11. *Id.* at 132–37.

12. Members of Congress who enacted the APA in 1946 contemplated that agencies might voluntarily take public comment on guidance "where useful to them or helpful to the public." Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy State-*

idea gain a formalized foothold in parts of the government and become the focus of intense advocacy and debate—a reaction to the long-run rise in guidance's importance. The most influential real-world experiment with such participation has been at the Food and Drug Administration (FDA). As the FDA ramped up its reliance on guidance in the 1990s,[13] it was moved, by internal rethinking and external political pressure, to regularize its use of this newly prominent policymaking mode. The result was the FDA Good Guidance Practices (GGPs), a set of procedural rules initially adopted by the agency in early 1997,[14] specifically authorized and required by Congress later that year,[15] and then repromulgated, without fundamental changes, in 2000.[16] Under the GGPs, the FDA conducts notice-and-comment prior to the adoption of all "Level 1" guidance documents, defined by an elaborate provision that encompasses basically any guidance of consequence.[17]

Using the FDA "as a model,"[18] the Office of Management and Budget

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ments, 75 MICH. L. REV. 520, 559 (1977) (quoting the Senate Judiciary Committee report). As of the mid-1970s, at least a few agencies were doing this for "many or even most" of their "generally applicable" guidance documents. *See id.* at 529 & n.45; *see also id.* at 524–28. ACUS recommended in 1976 that agencies "normally should" do voluntary notice-and-comment for guidance that was "likely to have a substantial impact on the public." *See* Admin. Conf. of the U.S., Recommendation 76-5, *Interpretive Rules of General Applicability and Statements of General Policy*, 41 Fed. Reg. 56,769, 56,770 (Dec. 30, 1976). The ABA in 1993 urged the same, when "practical to do so," for guidance "likely to have significant impact." *See Recommendation*, 1993 A.B.A. SEC. ADMIN. L. & REG. POL'Y REP. 120C.

13. K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507, 549–50 fig. 5 (2011); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000).

14. The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Jan. 2, 1997); *see id.* at 8968 (providing the notice-and-comment provision).

15. FDA Modernization Act, 111 Stat. 2296, 2368 (1997) (codified as amended at 21 U.S.C. § 371(h) (2012)). The provision on participation is § 371(h)(1)(C)(i).

16. Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56,468 (Jan. 3, 2000) (codified mainly in 21 C.F.R. § 10.115). On the Food and Drug Administration's (FDA's) Good Guidance Practices' (GGPs') adoption, see *infra* text and accompanying notes 256–263. *See also* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 97–105 (2014).

17. 21 C.F.R. § 10.115(c)(1) (2001) (defining Level 1 to cover any guidance documents 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").

18. Paul R. Noe & John D. Graham, *Due Process and Management for Guidance Documents: Good Government Long Overdue*, 25 YALE J. ON REG. 103, 107 (2008). Noe drafted the Office of

(OMB) during the George W. Bush Administration adopted its own version of Good Guidance Practices to be followed by all executive agencies.[19] In particular, OMB told executive agencies to conduct notice-and-comment before adopting any "economically significant" guidance document.[20] This did not go as far as the FDA because OMB's mandate for "economically significant" guidance covered a category of documents that (while loosely defined) was obviously narrower than that for which the FDA took public comment.[21] Along another dimension, however, OMB went further than the FDA: it told the agencies to write a "robust" response to comments received (whereas FDA requires no response).[22] Though originated under Bush, the OMB GGPs have been kept on the books by Obama and Trump.[23]

Despite the formal continuity of OMB's policy, the proper level of public participation for guidance remains quite unsettled, with a variety of players pushing for more. For one thing, the scope of the OMB mandate is vaguely defined and much contested. Under Obama, agencies generally construed the category of guidance documents subject to notice-and-comment under the OMB GGPs to include very little, prompting the former Bush Administration official who drafted the OMB practices to condemn the

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Management and Budget (OMB) GGPs, and Graham was head of the office within OMB that produced them. *Id.* at 103 n.†.

19. Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007) [hereinafter OMB Bulletin].

20. OMB Bulletin, *supra* note 19, § IV.

21. *Compare* 21 C.F.R. § 10.115(c)(1) (2001) (providing FDA's definition of "Level 1" guidance, quoted in *supra* note 17), *with* OMB Bulletin, *supra* note 19, § I(5) (defining "economically significant guidance document" as one 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"), *and* OMB Bulletin, *supra* note 19, at 3435 (stating that economically significant guidance documents are "only a relatively narrow category"). *See also* Noe & Graham, *supra* note 18, at 108 (confirming narrowness as compared to FDA GGPs). The OMB GGPs also call for public comment on a broader category of "significant" guidance documents, but this can be post-adoption, and no response is required. *See* OMB Bulletin, *supra* note 19, § I(4). But the preamble says pre-adoption comment on such documents "is often beneficial" when "practical." *Id.* at 3438.

22. OMB Bulletin, *supra* note 19, § IV(1)(d) (requiring a "response-to-comments document"); *id.* at 3438 (stating the agency "must prepare a robust response-to-comments document").

23. The continuity of the OMB GGPs is striking because the Obama Administration did rescind a separate Bush initiative regarding guidance. *See* Executive Order 13,497, 74 Fed. Reg. 6113 (Feb. 4, 2009) (revoking Bush's Executive Order 13,422 regarding OMB review of guidance documents).

agencies for "gross noncompliance" with the mandate.[24] Under Obama and now Trump, congressional Republicans have introduced several bills to redress this alleged recalcitrance by forcing agencies to take public comment on categories of guidance that match or expand upon the OMB mandate.[25] But notably, the push for greater participation is not confined to Republicans. Cass Sunstein, formerly the regulatory chief at Obama's OMB, wrote in 2016 that it "would probably be a good idea" to make a "statutory change, generally requiring significant policy statements to be preceded by a period for public comment"[26]—*significant* being a term of art at OMB that encompasses a bigger universe of documents than is currently covered by the OMB mandate, further down the spectrum toward FDA's position.[27] Further, it was under Obama that one of the federal government's most up-and-coming regulatory offices—the National Organic Program (NOP)—made a promise to do notice-and-comment on a category of documents that, similar to the FDA, covered most of the agency's guidance.[28] Also under Obama, the immigration-services wing of the Department of Homeland Security began seeking public comment on a large

24. *Examining the Use of Agency Regulatory Guidance, Part II: Hearing Before the Subcomm. on Regulatory Affairs & Fed. Mgmt. of the S. Comm. on Homeland Sec. & Gov't Affairs*, 114th Cong. 15–16 (2016) (statement of Paul Noe) [hereinafter *Senate Hearing*]. Noe said agencies since 2007 had recognized "about three" economically significant guidance documents. *Id.* at 16. This figure is roughly consistent with my finding on the period 2011–2018, *infra* note 252 and accompanying text. Noe also drew upon a Government Accountability Office study, *see Senate Hearing*, *supra*, at 16, which is U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-368, REGULATORY GUIDANCE PROCESSES: SELECTED DEPARTMENTS COULD STRENGTHEN INTERNAL CONTROL AND DISSEMINATION PRACTICES (2015). The statistics cited by Noe appear in *id.* at 17–18. On Noe's role as drafter of the OMB GGPs, see Noe & Graham, *supra* note 18, at 103 n.†.

25. *E.g.*, Truth in Regulations Act of 2017, S. 580, 115th Cong. § 2(e) (making notice-and-comment the default for any guidance with exceptions to be made by the agency in consultation with OMB); Truth in Regulations Act of 2016, H.R. 6283, 114th Cong. § 2(d) (legislating the existing OMB mandate); Article I Regulatory Budget Act, H.R. 5319, 114th Cong. § 4(b) (2016) (requiring notice-and-comment for any "significant" guidance by the OMB definition); Article I Regulatory Budget Act of 2016, S. 2982, 114th Cong. (same as H.R. 5319).

26. Cass R. Sunstein, *"Practically Binding": General Policy Statements and Notice-and-Comment Rulemaking*, 68 ADMIN. L. REV. 491, 504 (2016).

27. *Compare* 21 C.F.R. § 10.115(c)(1) (2001) (providing FDA's definition of "Level 1" guidance, quoted in *supra* note 17), *with* OMB Bulletin, *supra* note 19, at § I(4) (defining "significant guidance document" to include documents that, inter alia, "may reasonably be anticipated to . . . [r]aise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12,866, as further amended").

28. *See infra* notes 264–265 and accompanying text.

number of guidance documents, posting scores of drafts within about two years.[29]

Several scholars have expressed support for public comment on guidance across government. In addition to Sunstein's endorsement, his Harvard colleague Todd Rakoff is on record praising the FDA GGPs as a model of the kind of "half-formal processes" that he thinks are generally best for agencies, in contrast to the procedural excess of legislative rulemaking.[30] Stephen Johnson endorses the OMB GGPs as the best means "to balance" the "competing objectives" of encouraging agencies to provide guidance while allowing the public to participate.[31] Jessica Mantel likewise argues for a government-wide mandate, though with a different balancing, urging public comment for *all* guidance documents but with only a limited and general obligation to respond, not comment-by-comment.[32] To Nina Mendelson, public participation on guidance is good in itself but likely not enough: she questions whether the FDA or OMB approach is sufficient to prevent agencies from circumventing APA safeguards in ways that harm regulatory beneficiaries.[33] Taking a different tack from all these scholars, who speak in terms of what approach is best across the whole government, immigration expert Jill Family argues that United States Citizenship and Immigration Services (USCIS) could benefit greatly from following several aspects of the FDA GGPs, though she advises USCIS to depart from the FDA on certain points (e.g., to be transparent about revisions made in response to comments).[34] In Family's view, the fact that the FDA's approach is partly but not fully usable for USCIS indicates that agencies should generally have latitude to choose guidance-issuance procedures tailored to their respective situations, in contrast to the search for a pan-government solu-

29. Jill E. Family, *Easing the Guidance Document Dilemma Agency by Agency: Immigration Law and* Not Really *Binding Rules*, 47 MICH. J.L. REFORM 1, 15–16 (2013). Though it was unclear how the agency decided which documents merited this treatment. *Id.*

30. Rakoff, *supra* note 13, at 172.

31. Stephen M. Johnson, *In Defense of the Short Cut*, 60 KANSAS L. REV. 495, 538–45 (2012). Johnson notes that the OMB mandate for public comment applies only "in very limited circumstances." *Id.* at 544.

32. Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 ADMIN. L. REV. 343, 398 (2009).

33. Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 447–50 (2007).

34. Family, *supra* note 29, at 44–47. Family discusses certain unusual features of United States Citizenship and Immigration Services (USCIS) (like fee funding and the prevalence of unrepresented parties), *id.* at 28–30, but does not explicitly connect these features to the points on which she advises USCIS to depart from the FDA approach.

tion that we see at OMB and in the other scholarship.[35]

While the literature just reviewed is illuminating, it has the limitation of being more theoretical than empirical in orientation. In particular, its source material is confined overwhelmingly to case law and official government publications. With few exceptions, it does not give us the firsthand perspectives of private industry or NGOs—the very parties most likely to engage in participation—nor even the perspectives of officials that do not find their way into institutional pronouncements. Nor does it give us much evidence of the numerous agency practices that are not enshrined in such pronouncements, to say nothing of agencies' operational pathologies.[36]

In this Article, I seek to deepen our empirical understanding of public participation in guidance's issuance, drawing upon interviews that I conducted with 135 individuals who had firsthand experience with guidance.[37] Of the 135 interviewees, 26% were employed in agencies (all career officials), 48% in industry, 19% in NGOs and unions, and 7% elsewhere. Of the people outside the agencies (that is, in industry, NGOs and unions, or elsewhere), 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,[38] beginning with a nucleus of well-networked individuals with diverse sectoral affiliations: agency contacts and non-government members at the Administrative Conference of the

35. *Id.* at 23–31.

36. Of the works cited in the preceding paragraph, the only one to draw upon interviews is Mendelson, who has seven citations to interviews with current and former officials at various agencies. *See* Mendelson, *supra* note 33, at 397 n.†, 425, 427, 432. Broader interview research was conducted in Asimow, *supra* note 12, at 524–29, but that is now more than forty years ago; and also in Michael Asimow, *California Underground Regulations*, 44 ADMIN. L. REV. 43, 55–62 (1992), but that is not about the federal government. Seiguer and Smith use interviews with eight FDA officials and twelve FDA stakeholders to analyze the agency's processes for legislative rules and guidance, but they do not go beyond the food and drug field to engage the broader discourse on guidance and participation. *See* Erica Seiguer & John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD & DRUG L.J. 17 (2005).

37. For a full description and explanation of the study's methodology, see the Appendix in PARRILLO REPORT, *supra* note 1, at 196–205. All interviews took place from September 2016 through July 2017. *Id.* at 202.

38. The chain-referral 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 use and issuance of guidance, which is empirically unexplored and rife with "unknown unknowns."

United States (ACUS).[39] I asked the agency contacts and non-government members for names of people who knew about guidance from experience, interviewed those people, asked those interviewees for yet more names, and so forth iteratively. I sought 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 selected regulatory areas, and then for the third "link" only for two agencies: the FDA because of its famous GGPs; and the Environmental Protection Agency (EPA), because it is by various metrics the government's biggest regulator and its most controversial user of guidance.[40] In total, 24% of the interviewees were experts on the EPA, 23% on the FDA, and between 4% and 11% each on the Occupational Safety and Health Administration (OSHA), the Department of Energy (DOE), the Department of Agriculture (USDA), the Federal Aviation Administration (FAA), the Department of Health and Human Services (HHS) besides the FDA, and the banking regulatory agencies.[41] In general, the interviews were unstructured and free-ranging; of the 135 interviewees, about 80 ended up speaking to the subject of participation in guidance's issuance and are cited in this Article.[42]

While the interviews indicate that public participation in the issuance of guidance is sometimes worthwhile, they also provide a body of new evidence that the benefits of such participation are uncertain, and the pitfalls complex and potentially severe, in ways that are unknown or underexplored in the literature. In analyzing and synthesizing the interviews, this Article aims to provide a realistic and concrete assessment of participation's value and a guide for what factors an agency needs to evaluate (and what pitfalls it must anticipate) in deciding when and how to invite participation—factors and pitfalls that vary substantially across agencies and even across documents. In light of this variation, I conclude that decisions about

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39. The interviews were conducted for a study that I carried out under contract for ACUS, *see* PARRILLO REPORT, *supra* note 1, on which this Article draws extensively.

40. I also sought additional referrals on a supplemental basis to fill certain gaps in my understanding, yielding a small number of interviewees, as fully described in PARRILLO REPORT, *supra* note 1, at 198–202.

41. For interviewees who wished their identities to remain confidential, I have arbitrarily assigned male and female pronouns in different parts of the Article—female for Parts I and III and male for Parts II and IV—to avoid giving information on the identities of these sources.

42. The interviews also covered other subjects related to guidance, which I address elsewhere. Nicholas R. Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 YALE J. ON REG. (forthcoming 2019) (presenting findings on official flexibility and rigidity in guidance's application and on regulated parties' incentives to follow guidance).

whether and how to invite participation should normally be made on a relatively local basis: document by document, or, at most, agency by agency. This is not to leave agencies to their own devices—congressional overseers and the White House have at times pressured agencies to seek participation on guidance and should continue to do so—but that pressure is most rationally exerted when it occurs at a workable level of specificity. Compared with prior academic works, my conclusion is broadly consistent with Family's view that each agency should devise its own guidance practices, though the dimensions along which I find participation's value can vary are quite different from the ones identified by Family in her discussion, which is focused mainly on one agency (USCIS).[43]

In getting a better empirical understanding of this subject, the first thing to note is that, as documented in Part I, voluntary notice-and-comment is only one of several options for public participation in guidance's issuance. Agencies have honed a variety of alternatives: they reach out individually to selected stakeholders whom they already know; they hold public discussions at stakeholder meetings, workshops, forums, roundtables, sessions at conferences, webinars, or other such events (for which invitations will often be distributed through agency listservs); and they use advisory committees as a channel for input on guidance. So, while voluntary notice-and-comment is the maximal option in terms of broad, open, and impersonal participation, we should not evaluate it in isolation, against an implicit baseline of zero participation that would exaggerate public comment's value, but instead against a baseline of alternative, lesser forms of participation.

Part II explains why voluntary notice-and-comment on guidance, though typically more costly than other forms of public participation in guidance's issuance, is still usually far less costly than actual legislative rulemaking (even though the term "notice-and-comment" is often casually used as a synonym for legislative rulemaking). There are several reasons for this difference, but the main ones are that (a) statutory and presidential requirements for economic analysis are nonexistent or far lighter for issuance of guidance than of legislative rules, regardless of processes for public input; and (b) the availability of preenforcement judicial review of legislative rules makes response-writing and record-building far more onerous for legislative rules than for guidance, which is usually not subject to preenforcement litigation and accordingly does not entail the need to write much of a response, or build much of a record, in reaction to any critical comments that

43. Compare my summary of these dimensions at the opening of Section IV.D, *infra*, with Family, *supra* note 29, at 28–31 (identifying the factors that differentiate USCIS as the prevalence of unrepresented parties, the fee-based funding of the agency, and the lack of fit between immigration policy and economic analysis).

arrive. Thus, the actual burden of voluntary notice-and-comment on guidance, while substantial and not always justified, should be kept in perspective: a call for public comment on guidance documents is not per se a threat to convert guidance-making into legislative rulemaking.

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, analyzed in Part III. At a high level of generality, these costs and benefits are already familiar in the discourse on guidance and participation: on the plus side, improved technical and political information and heightened legitimacy;[44] and on the minus side, delay and expenditure of agency resources that could be invested in other things.[45] But the interviews reveal the benefits to be less predictable and more qualified, and the drawbacks sometimes more perverse, than that discourse acknowledges.

The first 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 from 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,[46] in the

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44. *E.g.*, OMB Bulletin, *supra* note 19, at 3438 (stating that public comment can "increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments"). For a review of the conventionally understood benefits of public participation in legislative rulemaking, see Michael Livermore et al., *Computationally Assisted Regulatory Participation*, 93 NOTRE DAME L. REV. 977, 982–86 (2018).

45. *E.g.*, Asimow, *supra* note 7, at 403–08.

46. For an in-depth political theory treatment of legitimacy as it relates to agency rule-

sense of giving stakeholders an idea 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. I identify 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 counterproductive 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 the kind of deliberative and analytic decisionmaking process that the APA contemplates.

Against the potentially great yet uncertain benefits of notice-and-comment on guidance (technical and political information and legitimacy), one must measure the costs, both 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.[47] 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

making and guidance processes, see Mantel, *supra* note 32.

47. *Infra* notes 220–226 and accompanying text.

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, especially if those beneficiaries view the excessive buildup of procedure as the result of deliberate gaming by other stakeholders whom they oppose. This is an unintended and extremely perverse consequence of efforts to legitimize agency power through participation.[48]

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

After Part III's discussion of the benefits and costs of notice-and-comment for any given guidance document, Part IV shifts focus to discuss more general approaches to requiring or encouraging notice-and-comment across large numbers of documents. I identify two principal models for doing this. The first, exemplified by EPA, is to have a general inclination in favor of notice-and-comment but make actual decisions about whether to do it on a document-by-document basis. The second model, exemplified by the FDA GGPs, is to adopt an agency-wide procedural rule requiring notice-and-comment for an objectively-defined broad category of the agency's guidance. Either of these models is potentially workable. But in light of the complexity and variability revealed in Part III, going broader—adopting a government-wide requirement for notice-and-comment on anything but the very most extraordinary guidance documents—would be rash.[49] 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.

Even an agency-wide mandate (though less unwieldy than a government-wide mandate) can have problematic unintended consequences. I identify two. First, if there is an agency-wide procedural rule requiring notice-and-comment for a large category of guidance, and the agency lacks

48. Mantel argues that while process increases legitimacy, that legitimacy must be traded off against the competing good of administrative effectiveness. *See* Mantel, *supra* note 32, at 389. My finding here is different: that diminishment in agency effectiveness due to perceivedly excessive process actually reduces legitimacy in the eyes of part of the stakeholder community. For some audiences, legitimacy is premised not just on process but also efficacy, especially if the audience thinks their opponents within the stakeholder community are deliberately manipulating process to reduce efficacy.

49. The OMB GGPs, calling for pre-adoption public comment on "economically significant" guidance documents, would—even if construed more broadly than in recent years—plausibly cover only a relatively tiny number of very extraordinary documents. *See infra* notes 249–255 and accompanying text.

the resources to process all of the comments it receives on all of the documents, the agency may end up leaving many guidance documents in published "draft" form indefinitely, without officially adopting them. This has been a recurring problem at the FDA, among other agencies. When regulated parties face strong incentives (as they often do) to comply with whatever they perceive to be the agency's wishes, those parties may take a draft guidance document to reflect those wishes, and they may therefore follow its content, regardless of its draft status. This industry reaction diminishes agency staff's incentive to invest scarce resources to incorporate comments and officially adopt the guidance, since adoption is not necessary to get industry to change its ways. In this manner, the whole purpose of notice-and-comment is defeated. 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. In addition, indefinite draft status invites agency opportunism: whenever the agency wants to depart from guidance in an individual proceeding, it will be tempting for officials 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 an agency-wide mandate for notice-and-comment on guidance is that guidance may thereby become *so legitimate*—in the eyes of agency officials and stakeholders or political overseers—that it may come close to replacing legislative rulemaking altogether.[50] This would not necessarily be a bad outcome. Some critics think legislative rulemaking's process burdens have risen too high, and a shift to guidance 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

50. Family raises this as a speculative future possibility at USCIS. *See* Family, *supra* 29, at 50–51. My interviews provide evidence that it has actually happened at the FDA.

for some substantial fraction of the agency's policies.

The idea of fostering public participation (especially notice-and-comment) on guidance has received a lot of support in government and the academy, and justifiably so. But the findings in this Article indicate that any hard mandate for such participation needs to operate at a workable level of specificity. A government-wide mandate is likely too unwieldy to be workable, and even agency-wide mandates should be carefully structured to anticipate risks that have so far received too little attention.

I. DIVERSE MEANS OF STAKEHOLDER PARTICIPATION

Although a guidance document can remain an intra-agency secret until the day it becomes official,[51] 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.[52]

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 stakeholders[53]—a point for which the interviews offer some support, though the picture is mixed. At the 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.[54] Officials at Public Citizen (a leading FDA watchdog), said they had never given, nor tried to give, this kind of pre-draft input, but they guessed the FDA had such interchanges

51. According to an official at a public interest organization working on immigrants' rights, her group had no forewarning of the Department of Homeland Security's (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. *See* Interview with Source 45, official at a pub. interest org. working on immigrants' rights (notes on file with author).

52. *See generally* Interview with Source 61, official, EPA Office of Gen. Counsel (notes on file with author) (stating that the development of each guidance document involves "some level" of outreach).

53. Mendelson, *supra* note 33, at 427–28.

54. Interview with Source 24, official at a trade ass'n (notes on file with author). This is, of course, in addition to the FDA's routinized taking of public comment on guidance once it is published in draft.

with industry.[55] At the EPA, as stated by 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.[56] In administering the Safe Drinking Water Act (SDWA), for which the states are co-regulators, the EPA may send the draft document to all the state governments,[57] or to (say) a half-dozen states that know the issue.[58] According to Lynn Thorp of Clean Water Action, the office administering the 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.[59] OSHA sends drafts of guidance documents to "key players,"[60] and has made alliances with industry associations on certain guidances, such as the National Staffing Association (for temps).[61] An interviewee who held senior posts at the Consumer Financial Protection Bureau (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 were 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.[62] To balance the industry perspective, the banking agencies reach out to the main consumer protection groups in the same way.[63] A former senior Federal Reserve official said that, before issuing a guidance document, she 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 she was

55. Interview with Michael Carome and Sammy Almashat, Pub. Citizen Health Research Grp. (notes on file with author).

56. Interview with Source 61, *supra* note 52.

57. Interview with Carrie Wehling, EPA Office of Gen. Counsel (notes on file with author).

58. Interview with Source 84, former official, EPA Office of Water (notes on file with author).

59. Interview with Lynn Thorp, Campaigns Dir., Clean Water Action (notes on file with author).

60. Interview with Adam Finkel, Senior Fellow & Exec. Dir., Program on Regulation, Univ. of Pa. (notes on file with author) (also former Regional Administrator at Occupational Safety and Health Administration (OSHA)).

61. Interview with Source 36, official, AFL-CIO (notes on file with author).

62. Interview with Source 90, person who held senior posts at the Consumer Fin. Prot. Bureau (CFPB) and other federal agencies (notes on file with author).

63. *Id.*

missing any implications the guidance would have.[64] An official at a nonprofit public policy research organization said that, relative to the CFPB, prudential banking regulatory agencies like the Federal Reserve were, in her experience, not proactive in seeking non-industry input (though they were always receptive to meetings when she sought them).[65]

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), the EPA "often" does stakeholder meetings related to guidance when administering its toxic chemicals program, its pesticides program, and parts of its Air Program, which are valuable, though they are usually in D.C. (unless it is a huge initiative with meetings around the country) and thus limited to attracting "beltway people" and trade associations, although the EPA tries hard to "grow" the group of stakeholders, e.g., through webinars.[66] 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 she had observed some controversy (e.g., with a major trade association) over whether full-blown notice-and-comment was needed for certain guidance.[67] The FDA, for its part, sometimes obtains early input on guidance through a public meeting, noted a trade association official.[68] According to an FDA Office of Policy official, the agency has held workshops on guidance, pre-draft and post-draft.[69] HHS's Centers for Medicare and Medicaid Services (CMS), said a partner in a large law firm healthcare practice, take input on guidance at policy forums, though they could do more.[70] The CFPB, observed

64. Interview with Source 72, former senior Fed. Reserve official who has counseled financial institutions (notes on file with author).

65. Interview with Source 131, official at a nonprofit pub. policy research org. (formerly a consultant and product manager in consumer finance industry) (notes on file with author).

66. Interview with Lynn Bergeson, Managing Partner, Bergeson & Campbell P.C. (notes on file with author); *see also* Interview with Source 61, *supra* note 52 (noting public meetings and webinars).

67. Interview with Source 84, *supra* note 58.

68. Interview with Source 24, *supra* note 54. This is, of course, in addition to the FDA's routinized taking of public comment on all Level 1 guidance once it has been published in draft.

69. Interview with Source 25, official, FDA Office of Policy (notes on file with author); *see also* Interview with Source 31, official, FDA Ctr. for Devices & Radiological Health (notes on file with author) (noting stakeholder meetings on guidance).

70. Interview with Source 101, Partner at a large law firm healthcare practice (notes on

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.[71]

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 certifying organizations. 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, the NOP asked the NOSB to address this question, and the NOSB took public comment on it.[72] The NOSB then recommended that evaluations be conducted every three to five years, but the 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; they and other stakeholders used the NOSB proceedings to express themselves, and the NOSB ultimately engaged in dialogue with the NOP to seek a modification of the guidance.[73] The NOP ultimately granted this, backing off its every-year stance.[74] In general, although the 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), which see a higher volume of comments than do the solicitations by NOP on guidance directly.[75] This can make the 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.[76] Jake Lewin, president of a large

file with author).

71. Interview with Source 131, *supra* note 65.

72. *See* Interview with Jean Richardson, former Chair, Nat'l Organic Standards Bd., USDA (notes on file with author).

73. *Id.*

74. NAT'L ORGANIC PROGRAM, USDA, NOP 2027, INSTRUCTION: PERSONNEL PERFORMANCE EVALUATIONS (2017), https://www.ams.usda.gov/sites/default/files/media/2027.pdf.

75. Interview with Miles McEvoy, Deputy Adm'r for Nat'l Organic Program, Agric. Mktg. Serv., USDA (notes on file with author).

76. Interview with Jean Richardson, *supra* note 72.

certifier, said NOP was good at listening to public comment through the NOSB channel.[77]

The USDA's NOP is not the only program in which an advisory committee serves as a conduit for stakeholder participation on guidance. Several committees at the EPA play this role, including in the offices administering the SDWA,[78] and the pesticides program.[79] OSHA's National Advisory Committee is asked to review some guidance,[80] as are some FDA advisory committees.[81]

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.[82] Or it can be done through the *Federal Register* and the regulations.gov website, as with the FDA.[83] Other agencies alternate between these venues depending on the document. The 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 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*.[84]

Thus, in evaluating the pros and cons of soliciting public comment on guidance, we must remember that the baseline is not necessarily zero public participation. It is, rather, the less-elaborate but sometimes effective forms

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77. Interview with Jake Lewin, President, Cal. Certified Organic Farmers Certification Servs. (notes on file with author).

78. Interview with Lynn Thorp, *supra* note 59 (noting the role of the National Drinking Water Advisory Council in issuing guidance, as well as ad hoc working groups and advisory committees).

79. Interview with Source 41, official, EPA (notes on file with author) (noting the role of the pesticide program's Scientific Advisory Panel, whose reports effectively serve as a kind of guidance for agency and industry on emergent scientific questions).

80. Interview with Source 36, *supra* note 61.

81. *E.g.*, Interview with Source 30, official, FDA Ctr. for Biologics Evaluation & Research (notes on file with author) (noting that guidance may go through an advisory committee).

82. Interview with Kathryn Thomson, Partner, Morrison & Foerster LLP (notes on file with author) (former General Counsel, DOT; former Chief Counsel, FAA); Interview with Sources 64, 65, and 66, officials at Airlines for Am. (notes on file with author).

83. Interview with Bradley Merrill Thompson, Member, Epstein, Becker, and Green P.C. (notes on file with author).

84. Email from Carrie Wehling, EPA Office of Gen. Counsel (Feb. 17, 2017) (notes on file with author).

of participation just discussed.

II. 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, which unlike guidance is genuine binding law? 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. I discuss these in roughly descending order of prominence.

A. 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' "significant" guidance documents.[85] The relevant Executive Order's definition of "significant" is, in many ways, open-ended.[86] According to an official at the

85. PETER R. ORSZAG, DIR., OFFICE OF MGMT. & BUDGET, M-09-13, MEMORANDUM FOR THE HEADS AND ACTING HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES: GUIDANCE FOR REGULATORY REVIEW (2009) (stating that from 1993–2007, "[Office of Information and Regulatory Affairs (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 12,866"). *But see Senate Hearing*, *supra* note 24, at 36 (prepared testimony of Mr. Noe) ("My understanding is that, under that approach [i.e., the 2009 Orszag memo], OIRA reviewed little guidance, and when it did, the practice was ad hoc and disorganized.").

86. Exec. Order No. 12,866, § 3(f), 58 Fed Reg. 51,735, 51,738 (Oct. 4, 1993) ("'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

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.[87]

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 the EPA's Air Program office said he thought OMB review of guidance took less time than that of legislative rules.[88] Lynn Thorp of Clean Water Action observed that OMB scrutiny of the EPA guidance was less than that for legislative rules.[89] A former senior FDA official noted that OMB was not much engaged with the agency's day-to-day scientific guidance,[90] while a former senior FDA career official said many FDA guidance documents did not go through OMB at all.[91] 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 delays, which he said can be severe.[92] Daniel Troy, general counsel of GlaxoSmithKline and former chief counsel of the FDA, said one reason for FDA personnel's preference for guidance over legislative rulemaking was that it avoided OMB review.[93] At

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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.").

87. Interview with Carrie Wehling, *supra* note 57.

88. Interview with Source 103, former senior official, EPA Air Program Office (notes on file with author).

89. Interview with Lynn Thorp, *supra* note 59. A somewhat more qualified view appeared in Interview with Source 96, former senior EPA official with cross-office responsibilities (notes on file with author) (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 the interviewee was not sure that was true anymore, though historically people perceived it to be true).

90. Interview with Source 107, former senior official, FDA (notes on file with author).

91. Interview with Source 112, former senior career official, FDA (notes on file with author); *see also* Interview with Source 24, *supra* note 54 (stating that FDA legislative rules would go through OMB "always," but guidance "not necessarily").

92. Interview with William Schultz, Partner, Zuckerman Spaeder LLP (former FDA Deputy Comm'r for Policy 1994–1998; former HHS Gen. Counsel 2011–2016) (notes on file with author).

93. Interview with Daniel Troy, Gen. Counsel, GlaxoSmithKline (notes on file with author).

USDA NOP, which does notice-and-comment on "most" of its guidance,[94] the head of the program cited OMB review as one of a few factors that makes legislative rulemaking generally slower than guidance.[95] Richardson, the former chair of the NOSB, 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.[96] At the Department of Transportation (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.[97] At the DOE 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.[98]

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.[99] 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 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.[100] A former senior Federal Reserve official noted that, while the Federal Reserve's legislative-rulemaking-specific cost–benefit analysis was "sometimes a bit skip-

94. Interview with Miles McEvoy, *supra* note 75 (noting that "most" guidance is "Level 1" under the NOP's guidance practices, for which NOP does notice-and-comment).

95. *Id.*

96. Interview with Jean Richardson, *supra* note 72; *see also* Interview with Miles McEvoy, *supra* note 75 (noting that internal USDA economic analysis, though valuable, takes time and is a reason why legislative rulemaking takes longer than guidance).

97. Interview with Kathryn Thomson, *supra* note 82.

98. Interview with Michael McCabe, former Div. Dir., Dep't of Energy (notes on file with author).

99. On statutory requirements, see DAVID W. PERKINS & MAEVE P. CAREY, CONG. RESEARCH SERV., R44813, COST-BENEFIT ANALYSIS AND FINANCIAL REGULATOR RULEMAKING 7–8 (2017).

100. Interview with Source 90, *supra* note 62.

py," 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.[101]

B. 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 *Motor Vehicles Manufactures Ass'n v. State Farm*,[102] 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.[103] 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."[104] Likewise, lawyers were vigilant in making sure the agency accounted for all comments.[105] By contrast, "very little" of this was required for EPA guidance.[106] 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.[107] And even if the 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.[108] 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 rulemakings, and public comments did not need to be ad-

101. Interview with Source 72, *supra* note 64.
102. 463 U.S. 29 (1983).
103. Interview with Source 99, official, EPA (notes on file with author).
104. *Id.*
105. *Id.*
106. *Id.*
107. *Id.*
108. *Id.*

dressed at the same level of detail as for legislative rulemaking.[109]

There is a similar dynamic at the FDA, which, per the GGPs, takes public comment on a very large proportion of its guidance documents. 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."[110] Whereas legislative rules were "law" and had to be supported, the agency in issuing guidance felt freer not to develop a voluminous record, and the comments on guidance did not require the kind of response that was required on legislative rules.[111] The fact that the FDA was sued much more on legislative rules than on guidance, he said, was surely part of this.[112] Similarly, a congressional staffer observed that, although the 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.[113] A former senior FDA official thought the lack of a requirement to respond to comments was a crucial and salutary feature of the FDA's process for guidance: if you required a preamble, you might as well do legislative rulemaking, and the whole thing would become "unworkable."[114] 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.[115] 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."[116]

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109. Interview with Source 103, *supra* note 88. *But see* Interview with Source 96, *supra* note 89 (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).

110. Interview with Source 107, *supra* note 90.

111. *Id.*

112. *Id.*

113. Interview with Source 82, cong. staffer (notes on file with author).

114. Interview with Source 110, former senior official, FDA (notes on file with author).

115. Interview with Source 112, *supra* note 91; *see also* Interview with William Schultz, *supra* note 92 (citing response to comments as one reason legislative rulemaking is slower than guidance at the FDA).

116. Interview with Source 27, official, FDA Office of Chief Counsel (notes on file with author).

Elsewhere, too, the research and analytic demands are less for guidance than for legislative rulemaking. At OSHA, said the former deputy solicitor of the Department of Labor (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.[117] 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).[118]

C. Taking Comments 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 the CFPB and other federal agencies, the comment period tends to be shorter for guidance, and the comments fewer.[119] The comment period was also said to be shorter for guidance at the USDA NOP,[120] and in EPA clean water regulation.[121] Comments were said to be less voluminous on guidance compared to legislative rules at the FDA.[122]

D. 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."[123] Guidance, he said, does not involve the same sweating of details.[124] As to the FDA, a former senior career offi-

117. Interview with Jonathan Snare, Partner, Morgan, Lewis & Bockius LLP (former Deputy Solicitor, DOL) (notes on file with author).

118. Interview with John Newquist, Partner, Newquist Safety (former Assistant Reg'l Adm'r, OSHA) (notes on file with author).

119. Interview with Source 90, *supra* note 62.

120. Interview with Jake Lewin, *supra* note 77.

121. Interview with Lynn Thorp, *supra* note 59.

122. Interview with Source 107, *supra* note 90.

123. Interview with Source 99, *supra* note 103.

124. *Id.*

cial 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 more free to put in details, use narrative form, Q&A form, and plain language, since the document is not "set in stone."[125] 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.[126] In banking regulation, an interviewee who held senior posts at the 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.[127]

E. 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.[128] 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' rights 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.[129] 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.[130] A former DOE 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,

125. Interview with Source 112, *supra* note 91.

126. *Id.*

127. Interview with Source 90, *supra* note 62.

128. Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 799–800 (2010); William F. West, *Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis*, 64 PUB. ADMIN. REV. 66, 72–73 (2004).

129. Interview with Source 45, *supra* note 51.

130. *Id.*

that group would marshal evidence and political support to stop the process, enlisting friendly members of Congress or the White House.[131] With respect to the USDA NOP, the 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.[132]

III. BENEFITS AND COSTS OF NOTICE-AND-COMMENT FOR GUIDANCE

The question of whether to take such public comment on guidance—instead of opting for no participation or one of the lesser forms of participation noted in Part I—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, are more qualified and uncertain than we might think.

A. 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. A former senior Federal Reserve official said it was wrong to issue guidance without prior public comment because "nobody is that smart."[133] That is, no agency knows enough to design guidance without first getting outside perspectives on how the policy will actually work. Public comment, she said, really helps make "better policy."[134] A former senior FDA official emphasized that the FDA often had a lack of understanding of how things worked internally at regulated companies, and for those instances, the agency's practice of taking comment could fill knowledge gaps and have a real impact.[135] Jonathan Snare, former deputy solicitor of

131. Interview with Michael McCabe, *supra* note 98.

132. Interview with Jake Lewin, *supra* note 77.

133. Interview with Source 72, *supra* note 64.

134. *Id.*

135. Interview with Source 80, former senior official, FDA (notes on file with author); *see also* Interview with Source 109, regulatory policy exec. at a drug mfr. (notes on file with

DOL, said notice-and-comment could help with the problem that OSHA sometimes did not understand how a guidance document would practically impact employers.[136] 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."[137] According to Charles Samuels, who represents the appliance manufacturers' trade association before the DOE, notice-and-comment improves the quality of guidance.[138]

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.[139] As a counter-example, she recalled how she represented a trade association for an industry consisting of a small number of large companies with concentrated expertise.[140] The association met with agency officials to provide input on a guidance document. In that meeting room, she 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."[141] 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.[142] 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!"[143]

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author) (making similar point).

136. Interview with Jonathan Snare, *supra* note 117.

137. Interview with Kathryn Thomson, *supra* note 82.

138. Interview with Charles Samuels, Partner, Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C. (counsel to the Association of Home Appliance Manufacturers) (notes on file with author).

139. Interview with Source 69, former agency gen. counsel (notes on file with author).

140. *Id.*

141. *Id.*

142. Interview with Source 118, senior envtl. counsel at a Fortune 100 company (notes on file with author).

143. Interview with Source 73, gen. counsel to a Fortune 500 company (notes on file with author).

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 toxics and pesticides, observed that, whereas a stakeholder meeting would normally be located in D.C. and attract trade associations, national NGOs, and associations of state agencies, it would usually not include parties outside D.C.: regional stakeholder groups, state agencies without D.C. associations (or not aligned with their D.C. associations), mid-sized businesses, or start-ups.[144] These same kinds of stakeholders were also less likely to be on the 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.[145]

The agency must 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.[146] 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.[147] They 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.[148]

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

144. Interview with Lynn Bergeson, *supra* note 66.

145. *Id.*

146. 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).

147. *See generally* Cynthia R. Farina et al., *Rulemaking vs. Democracy: Judging and Nudging Public Participation That Counts*, 2 MICH. J. ENVTL. & ADMIN. L. 123 (2012).

148. *Id.* at 147.

lived experience in the complex reality into which the proposed regulation would be introduced."[149] Farina et al. give the example of small-business truck 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.[150]

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, 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."[151]

B. 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. According to Thomson, the former

149. *Id.* at 148.

150. *Id.* at 147–48.

151. West, *supra* note 128, at 70–74. For more on this dynamic, see RICHARD STOLL, EFFECTIVE EPA ADVOCACY 73 (2d ed. 2014); E. Donald Elliott, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490, 1492–93 (1992); Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L.J. 1321, 1366–69, 1380–83 (2010); *cf.* Keith Naughton et al., *Understanding Commenter Influence During Agency Rule Development*, 28 J. POL'Y ANALYSIS & MGMT. 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. *See* West, *supra* note 128, at 73. So perhaps the unavailability of preenforcement 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.

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."[152] 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 necessary. In taking comment on guidance, she said, DOT wanted to find out where the "landmines" were.[153] According to James Conrad, a regulatory consultant and former attorney at the American Chemistry Council, the 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.[154]

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 stakeholders without public comment, one possibility is stakeholders 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, better-prepared itself for combat, or reached a compromise before the atmosphere was poisoned.[155] 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.[156] Charles Samuels, a partner at Mintz Levin who deals with guidance at the DOE, 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.[157] But if the agency makes the guidance final immediately upon revealing it, industry may let it go.[158] Getting operative guidance rolled back can be harder than fighting a proposal that is tentative by its own terms. Being tentative can invite resistance.

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152. Interview with Kathryn Thomson, *supra* note 82.

153. *Id.*

154. Interview with James Conrad, Conrad Law & Policy Counsel (formerly Assistant Gen. Counsel at the Am. Chemistry Council) (notes on file with author).

155. For an example of this kind of dynamic playing out in a context besides guidance, see Nina A. Mendelson, *Should Mass Comments Count?*, 2 MICH. J. ENVTL. & ADMIN. L. 173, 181 (2012).

156. *See* Raso, *supra* note 128, at 799 (positing that guidance without advance publicity can "set a new status quo before opponents mobilize").

157. Interview with Charles Samuels, *supra* note 138.

158. *Id.*

C. 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 more cooperative with and supportive of the agency. A former senior Federal Reserve official said that taking comments on guidance, even if the agency does not follow the comments, "adds legitimacy."[159] According to a former senior EPA official with cross-office responsibilities, "we gained more legitimacy" by doing notice-and-comment on significant guidance.[160] In this Section, 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.[161] Richard Naples, the chief regulatory officer of the Fortune 500 medical device maker Becton Dickinson, observed that the FDA's policy of taking public comments on a large category of its guidance documents allowed for a "meaningful dialogue" with regulated firms.[162] An official at a national public interest organization said that FDA accepted her organization's comments "not infrequently," and she found the agency "responsive."[163] Regarding the USDA NOP, 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.[164] 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."[165]

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159. Interview with Source 72, *supra* note 64.

160. Interview with Source 96, *supra* note 89.

161. Interview with Charles Samuels, *supra* note 138.

162. Interview with Richard Naples, Chief Regulatory Officer, Becton, Dickinson, & Co. (notes on file with author).

163. Interview with Source 133, official at nat'l pub. interest org. (notes on file with author).

164. Interview with Jake Lewin, *supra* note 77.

165. Interview with Source 114, official at an organic certifier (notes on file with author). Other interviewees' assessments were more middling or mixed. Officials at Public Citizen thought the FDA's level of responsiveness to their comments was variable, and that it was hard to explain why it varied. *See, e.g.*, Interview with Michael Carome & Sammy

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 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 Section). The former EPA Civil Enforcement Director and current head of an environmental NGO, Eric Shaeffer, said that officials at EPA sometimes undertook notice-and-comment on guidance "just to cover themselves," which left stakeholders "frustrated."[166] 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."[167] An executive at an environmental services firm said that one EPA office with which she frequently dealt took public comment on guidance but did not actually pay attention to the input, which was frustrating to regulated firms.[168] A former EPA official said "nobody has faith" that the EPA is actually looking at the comments submitted on guidance.[169] She generally had not seen more than minor changes to a guidance document as a result of notice-and-comment.[170] The exercise felt like the agency was doing notice-and-comment just to say it had done it—to "check the box."[171] That said, the interviewee later cited one document, the 2011 guidance on Best Available Control Technology to reduce CO_2 from bioenergy production, that she thought well-received because there had been "a lot" of public par-

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Almashat, *supra* note 55. Daniel Troy, general counsel of GlaxoSmithKline, found the FDA's responsiveness to comment "quite variable." Interview with Daniel Troy, *supra* note 93. Richard Stoll thought that, regarding public comment on guidance, the 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 & Lardner LLP (notes on file with author).

166. Interview with Eric Schaeffer, Exec. Dir., Envtl. Integrity Project (also former Dir. of Civil Enforcement, EPA) (notes on file with author).

167. *Id. But see supra* note 108 and accompanying text; *infra* note 231 and accompanying text (other interviewees stating that EPA usually does give some response to public comment on guidance).

168. Interview with Source 106, exec. at an envtl. services co. (notes on file with author).

169. Interview with Source 54, former official, EPA (notes on file with author).

170. *Id.*

171. *Id.*

ticipation in its formulation and the EPA had "listened to both sides."[172]

Meanwhile, at the FDA, a former official there said a major disadvantage of guidance, compared to legislative rulemaking, was that the FDA generally gives no written response to comments, thereby cutting out a "huge" part of the process of agency-industry dialogue.[173] In cases where industry comments do not get incorporated into the guidance document, "nobody knows" why.[174] More generally, said the interviewee, the FDA's preference for guidance over legislative rulemaking "reduces industry acceptance" of FDA policy.[175] As for OSHA, said U.S. Chamber of Commerce executive director of labor law policy, Marc Freedman, public comment on guidance 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."[176]

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 D.C.), 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 her organization because her organization did not have the same "intimate" lobbying relationship with the FDA that industry players had, nor the resources to "always be there all the time" the way industry could be.[177] Notably, the openness of notice-and-

172. *Id.*

173. Interview with Source 20, former official, FDA (notes on file with author).

174. *Id.*

175. *Id.*

176. Interview with Marc Freedman, Exec. Dir. of Labor Law Policy, U.S. Chamber of Commerce (notes on file with author). Baruch Fellner, founding partner of Gibson Dunn's occupational safety and health (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 & Crutcher LLP (notes on file with author).

177. Interview with Source 133, *supra* note 163.

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 DOE's appliance standards as a major area of focus, stated that his group had never actually commented on a Department guidance document.[178] 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.[179] 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.[180] In the event that such concerns arose, the Department's transparent process meant that ASAP could object.[181] This, said DeLaski, was an improvement over the less transparent, more ad hoc approach to guidance that the Department had followed before it adopted notice-and-comment circa 2009.[182] 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.[183]

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.[184] That anxiety can be quite real.[185] 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."[186]

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178. Interview with Andrew DeLaski, Exec. Dir., Appliance Standards Awareness Project (notes on file with author).

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.* 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.*

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

185. *Cf.* West, *supra* note 128, at 70 (discussing agency officials' concerns about ex parte contacts in the legislative rulemaking process).

186. Interview with Source 73, *supra* note 143.

Frank White, the former deputy head of OSHA and former president of a health and safety 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.[187] 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."[188] Notice-and-comment rulemaking, he noted, provided this comforting balance "automatically."[189] 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 the FDA. While the 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.[190] In fact, the procedures say that anyone outside the FDA "can submit drafts of proposed guidance documents for FDA to consider."[191] Yet it proves difficult, as a political matter, for the FDA to sustain—alongside notice-and-comment—the kind of fluid, intimate, and 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.[192] This was 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."[193] The 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."[194] For

187. Interview with Frank White, former Deputy Assistant Sec'y for OSHA, DOL (notes on file with author).

188. *Id.*

189. *Id.*

190. 21 C.F.R. § 10.115(g)(1)(i) (2018).

191. 21 C.F.R. § 10.115(f)(3).

192. Interview with Richard Naples, *supra* note 162.

193. *Id.*

194. *Id.*

officials to formulate draft guidance in ignorance of industry knowledge was inefficient and ended up creating more work later in the process.[195] Other interviewees agreed that, despite the 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 the 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 former Commissioner Robert Califf, having been subjected to "absurd" accusations about coziness with industry during his confirmation hearings, was "sensitive" about the matter.[196] 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.[197] It "looks like capture."[198] An FDA Office of Policy official confirmed that the agency "rarely" sees industry submit draft guidance.[199] Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, likewise said outside submissions of draft guidance were "very uncommon," partly because parties might fear an "appearance of impropriety," though she thought industry had many ways to participate besides this.[200]

A similar dynamic may occur at parts of the EPA. An executive at an environmental services firm said that, while the 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.[201] She 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

195. *Id.*

196. Interview with Bradley Merrill Thompson, *supra* note 83.

197. Interview with Daniel Troy, *supra* note 93.

198. *Id.*

199. Interview with Source 25, *supra* note 69.

200. *See* Interview with Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, FDA; *see also* Interview with Source 80, *supra* note 135 (noting that the FDA sometimes encourages submission of draft guidance and that it has happened); Interview with Source 20, *supra* note 173 (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).

201. Interview with Source 106, *supra* note 168.

to the agency.[202] By the time a draft was formulated and published, she noted, the EPA would already be "defensive" about the draft.[203] 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.[204]

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 website yield approximately fifty draft guidance documents that EPA chose to publish for public comment through the *Federal Register* in the period 2011–2014,[205] and of these, eight were subject to mass-comment campaigns yielding at least 5,000 comments each, with five that exceeded 40,000 comments.[206] These avalanches of comments might serve as prima

202. *Id.*

203. *Id.*

204. West, *supra* note 128, at 72; *cf.* Naughton et al., *supra* note 151 (finding more influence at the *advance* notice of proposed rulemaking stage).

205. Note these searches would not pick up guidance documents that the EPA published for public comment on its own website.

206. 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-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 147, at 141. The eight documents, with counts, are:

- ENVTL. PROT. AGENCY, EPA-HQ-OW-2011-0409, DRAFT GUIDANCE ON IDENTIFYING WATERS PROTECTED BY THE CLEAN WATER ACT (230,625 minus 3,878 equals 226,747).
- ENVTL. PROT. AGENCY, EPA-HQ-OW-2011-1013, UIC PERMITTING GUIDANCE FOR OIL AND GAS HYDRAULIC FRACTURING ACTIVITIES USING DIESEL FUELS—DRAFT (97,147 minus 2,732 equals 94,415).
- ENVTL. PROT. AGENCY, EPA-HQ-OAR-2007-0268, UPDATES TO PROTECTIVE ACTION GUIDES MANUAL: PROTECTIVE ACTION GUIDES (PAGS) AND PLANNING GUIDANCE FOR RADIOLOGICAL INCIDENTS (68,350 minus 2,213 equals 66,137).
- ENVTL. PROT. AGENCY, EPA-HQ-OPP-2014-0737, BENEFITS OF NEONICOTINOID

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 public commenting almost always stems from action campaigns by one or more advocacy groups."[207] The "primary purpose of the [groups'] campaigns," say Farina et al., "is persuasive, rather than educational," based on appeals to emotion, hyperbolic language, and "selective deployment of facts."[208] 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.[209] In fact, as Nina Mendelson has said, comments from the mass public often state value choices rather than make evidence-based argu-

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SEED TREATMENTS TO SOYBEAN PRODUCTION DOCKET FOLD (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."

- ENVTL. PROT. AGENCY, EPA-HQ-OW-2010-0315, SOLICITATION OF PUBLIC COMMENTS RE: GUIDANCE ON IMPROVING EPA REVIEW OF APPALACHIAN SURFACE COAL MINING OPERATIONS UNDER CWA, NEPA AND EJ EXECUTIVE ORDER (63,601 minus 810 equals 62,791).
- ENVTL. PROT. AGENCY, EPA-HQ-OW-2011-0466, NOTICE OF AVAILABILITY OF THE 2012 RECREATIONAL WATER QUALITY CRITERIA (10,513 minus 218 equals 10,295).
- ENVTL. PROT. AGENCY, EPA-HQ-OPP-2013-0676, CONSIDERATION OF SPRAY DRIFT IN PESTICIDE RISK ASSESSMENT (5,596 minus 118 equals 5,478).
- ENVTL. PROT. AGENCY, EPA-HQ-OPP-2014-0219, PESTICIDES; CONSIDERATION OF VOLATILIZATION IN PESTICIDE RISK ASSESSMENT: NOTICE OF AVAILABILITY AND REQUEST FOR COMMENT (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. *See, e.g.*, Mendelson, *supra* note 33, at 432.

207. *See* Farina et al., *supra* note 147, at 141.

208. *Id.*

209. *Id.* at 137–45; *see also* Michael Herz, *"Data, Views, or Arguments": A Rumination*, 22 WM. & MARY BILL OF RTS. J. 351, 371 (2013) (noting consensus among scholars that legislative rulemaking is not plebiscitary).

ments, and "agencies generally appear to be impatient with and unresponsive to value-focused commenting."[210] 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.[211] 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."[212] 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.[213]

D. 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."[214] Samuels, counsel to the Association of Home Appliance Manufacturers, noted that it takes "manpower."[215] According to an EPA official, one of the 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.[216] A former senior EPA official with cross-office responsibilities said a drawback of notice-and-comment on guidance was the processing time.[217] 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 agen-

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210. Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-Mail*, 79 GEO. WASH. L. REV. 1343, 1367 (2011).

211. Herz, *supra* note 209, at 373.

212. *Id.* at 372. For an argument that the Federal Communications Commission 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).

213. Livermore et al., *supra* note 44, at 992. 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. *See* Mendelson, *supra* note 210, at 1371–79.

214. Interview with Source 69, *supra* note 139.

215. Interview with Charles Samuels, *supra* note 138.

216. Interview with Source 99, *supra* note 103.

217. Interview with Source 96, *supra* note 89.

cies 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).[218] A former senior Federal Reserve official who has counseled financial institutions said she thought CFPB ought to undertake notice-and-comment on guidance more often, estimating it would add three to five months to the process for a given document.[219]

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 described the "tradeoff" as thus: "industry wants input," but it also "wants guidance," and more input means less guidance.[220] 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.[221] John Newquist, the former assistant administrator of OSHA's Region V, 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.[222] Celeste Monforton, an 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."[223] 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 in-

218. Interview with Source 90, *supra* note 62.

219. Interview with Source 72, *supra* note 64.

220. Interview with Source 81, former official, CFPB (now represents CFPB-regulated entities) (notes on file with author).

221. Interview with Source 108, exec. at a drug mfr. (notes on file with author).

222. Interview with John Newquist, *supra* note 118.

223. Interview with Celeste Monforton, Lecturer, Dep't of Health & Human Performance, Texas State Univ.; Professorial Lecturer, Milken Inst. Sch. of Pub. Health & Health Servs., George Washington Univ. (former legislative analyst, OSHA; former policy advisor, MSHA) (notes on file with author).

put.[224] She further stated that adding process burdens to the issuance of guidance risked taking away the value of guidance, that is, the capacity to change industry behavior for the better through informal nudging based on agency judgment.[225] A former HHS Office of General Counsel official, while urging that CMS do notice-and-comment for more of its guidance, said she 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.[226]

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 she said kept down process costs more than any other factor, including the absence of OMB review.[227] Consider the FDA, which does not obligate itself to give any response to comments on guidance and generally gives none.[228] When the 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.[229] William Schultz, who served as FDA Deputy Commissioner for Policy in 1994–1998, 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.[230] Meanwhile, at the EPA, officials usually *do* give a response to comments on guidance,[231] though much less in-depth than for legislative rulemaking.[232] DOT and the USDA NOP also give responses when they do take notice-and-comment on guidance.[233]

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224. Interview with Source 131, *supra* note 65.

225. *Id.*

226. Interview with Source 67, former official, HHS Office of Gen. Counsel (notes on file with author).

227. Interview with Source 69, *supra* note 139.

228. Interview with Source 24, *supra* note 54; Interview with Michael Carome & Sammy Almashat, *supra* note 55; Interview with Bradley Merrill Thompson, *supra* note 83.

229. Interview with Source 107, *supra* note 90.

230. Interview with William Schultz, *supra* note 92.

231. Interview with Richard Stoll, *supra* note 165.

232. *See supra* note 108 and accompanying text.

233. Interview with Kathryn Thomson, *supra* note 82; Interview with Miles McEvoy,

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 American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) official, employers had succeeded over the years in "shutting down" legislative rulemaking, to the point where promulgating a major rule can take ten to twenty years.[234] 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.[235] 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."[236] The whole challenge to guidance, said a second AFL-CIO official, was an "industry-generated" effort to get OSHA to "stop doing its job."[237] 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.[238] "The objection" to guidance, she said, "is not really about process but substance."[239] It was an effort to weigh down guidance with the same "baggage" as legislative rulemaking out of a substantive objection "to all government regulation."[240] 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.[241] "If you create an event," said a third AFL-CIO official, "you create a target."[242]

Given the AFL-CIO officials' view of notice-and-comment on guidance

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supra note 75.

234. Interview with Source 36, *supra* note 61.

235. Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1387–88, 1392–93, 1400–03 (1991).

236. Interview with Source 36, *supra* note 61.

237. Interview with Source 35, official, AFL-CIO (notes on file with author).

238. Interview with Source 36, *supra* note 61.

239. *Id.*

240. *Id.*

241. Interview with Source 35, *supra* note 237.

242. Interview with Source 37, official, AFL-CIO (notes on file with author).

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.[243] The document favored expansive engineering controls that would be costly to employers compared with the alternative of personal protective equipment.[244] The Chamber thought the new policy required legislative rulemaking and was unsound as a matter of substance.[245] It commissioned an economic analysis for its comment, which it expected would have no impact on OSHA, and submitted a preliminary comment on January 18, 2011, pending full comments to come in March.[246] But suddenly, on January 19, 2011, OSHA withdrew the draft.[247] 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."[248] 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.

IV. BROAD MANDATES FOR NOTICE-AND-COMMENT AND WHY THEY ARE PROBLEMATIC

The preceding Part 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

243. Interview with Marc Freedman, *supra* note 176.

244. *Id.*

245. *Id.*

246. *Id.*

247. For announcement of the withdrawal, see Press Release, U.S. Dep't of Labor, OSHA National News Release, No. 11-74-NAT (Jan. 19, 2011), https://www.osha.gov/news/newsreleases/national/01192011.

248. Interview with Marc Freedman, *supra* note 176. For the Chamber's preliminary comment, see Chamber of Commerce, Comment Letter on Docket No. OSHA-2010-0032-0079 Interpretation of OSHA's Provisions for Feasible Administrative or Engineering Controls of Occupational Noise (Jan. 18, 2011), https://www.regulations.gov/document?D=OSHA-2010-0032-0079. For announcement of the withdrawal, see Press Release, U.S. Dep't of Labor, *supra* note 247.

some guidance, that raises the question of whether whole agencies, or even the entire government, should have policies requiring its use. This Part considers that question. I begin by describing some existing models for requiring notice-and-comment, with particular attention to the kind of model in place at the FDA, i.e., 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 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 for firms 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 Part III) and the risks discussed in this Part, 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.

A. 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 the OMB Good Guidance Practices' (GGPs') 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 GGPs generally require that all executive agencies engage in pre-adoption notice-and-comment (with a response) on any guidance document that is "economically significant,"[249] 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."[250] How many guidance documents meet those criteria? The most relevant data come from OMB's historical reports database of the number of regulatory actions (including guidance documents) that were reported to OMB and reviewed by it as "economically significant" each year.[251] The number of guidance documents so reported and

249. OMB Bulletin, *supra* note 19, § IV.

250. OMB Bulletin, *supra* note 19, § I(5).

251. On the inclusion of guidance documents in OMB's figures for reviews of "eco-

reviewed for the whole period from January 2011 through July 2018 is only two.[252] Admittedly, the agencies in 2016 were accused by one expert observer of grossly under-counting economically significant guidance documents.[253] But even if the agencies were counting more expansively, the numbers would almost certainly still be quite low. The database gives the annual number of *legislative rules* reported and reviewed as economically significant as between 51 and 66 for the years 2011–2015, as 96 for the year

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nomically significant" regulatory actions, see MAEVE P. CAREY, CONG. RESEARCH SERV., R43056, COUNTING REGULATIONS: AN OVERVIEW OF RULEMAKING, TYPES OF FEDERAL REGULATIONS, AND PAGES IN THE FEDERAL REGISTER 12 (2016). Actually the criteria that OMB uses to define a regulatory action (including a guidance document) as "economically significant" for purposes of doing its own reviews are formally somewhat broader than how OMB defines a guidance document as "economically significant" for purposes of the OMB GGPs' mandate for notice-and-comment. This means my use of the number of OMB reviews as a means of estimating the number of economically significant guidance documents under the OMB GGPs will cause, if anything, an over-estimate (making it a conservative means of estimation for my argument that such documents are few). For purposes of its own reviews, 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 12,866 § 3(f), which says the action is "likely" to: "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.*" *See id.* at 10–12 (emphasis added); *see also* Leland E. Beck, *Economically Significant: A Threshold Snapshot of OMB's Regulatory Docket*, FED. REGS. ADVISOR (Aug. 9, 2013), https://web.archive.org/web/20170731020512/www.fedregsadvisor.com/2013/08/09/economically-significant-a-threshold-shapshot-of-ombs-regulatory-docket.
The words that I have italicized in the quoted text (which add disjunctively to the criteria) do not appear in the OMB GGPs' criteria for economically significant guidance documents. *See supra* note 19, at § I(5), and accompanying text.

252. Lists of OMB reviews of economically significant regulatory actions (including guidance) for all years from 2011 to 2018 were obtained on August 6, 2018, through year-specific queries on "All" agencies to the Historical Reports database available at www.reginfo.gov/public/do/eoHistoricReport. The total numbers of economically significant regulatory actions listed for each year are identical or nearly identical to the figures in Table 4 in CAREY, *supra* note 251, at 11–12. (But note Carey only has data through 2015, so no check was available for the years 2016–2018). 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. ENVTL. PROT. AGENCY, EPA-HQ-OW-2011-0409, DRAFT GUIDANCE ON IDENTIFYING WATERS PROTECTED BY THE CLEAN WATER ACT, https://www.regulations.gov/docket?D=EPA-HQ-OW-2011-0409.

253. *See supra* note 24 and accompanying text.

2016, and as 34 for the year 2017.[254] The average across all these years is sixty. The number of economically significant guidance documents, it seems fair to assume, would be less than the number of economically significant legislative rules, given the normally interstitial nature of guidance. In other words, it would be well under sixty per year, on average, if we add up all executive agencies. To appreciate how tiny this number is compared with the total number of executive agency guidance documents, consider that at just one agency—FDA—the number of final guidance documents presently operative that were issued in the period 1997–2017 is about 1,600—that is, roughly 80 per year (and that excludes documents that were issued but later withdrawn).[255] Thus, even with more aggressive counting, it seems the OMB notice-and-comment requirement applies only to the very tip of the guidance iceberg.

When OMB's practically 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 the FDA's GGPs. These were originally a set of procedural rules adopted by the agency in February 1997.[256] Subsequently, Congress in November 1997, passed a specific statutory mandate for such procedural rules (including to "ensure public participation [in the guidance's formulation] prior to im-

254. I obtained these counts on August 6, 2018, through year-specific queries on "All" agencies to the Historical Reports database available at www.reginfo.gov/public/do/eoHistoricReport. I counted as legislative rules all entries in which the "Stage" said "Final Rule" or "Interim Final Rule." Admittedly, there is some bureaucratic political gaming that goes into what legislative rules are actually reviewed by OMB and with what scrutiny. *See* Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 HARV. L. REV. 1755, 1786–98 (2013).

255. That count is drawn from a search, conducted February 5, 2017, of FDA's online database of guidance, available at https://www.fda.gov/RegulatoryInformation/Guidances. We searched 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.

256. The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997). The notice-and-comment provision appears in *id.* at 8968.

plementation"),[257] and the procedural rules were re-promulgated, without fundamental changes from the original, in 2000.[258] Under its GGPs, the 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."[259] The 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.[260] There had been internal reform initiatives in parts of the FDA prior to the advent of the agency-wide GGPs.[261] What immediately precipitated their formulation and adoption was a petition from the Indiana Medical Devices Manufacturers Council,[262] combined with pressure from congressional overseers.[263]

Another agency following this pattern is the USDA NOP. 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."[264] Most NOP guidance documents are Level 1.[265]

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257. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2296, 2368 (1997) (codified as amended at 21 U.S.C. § 371(h) (2012)). The quotation is from 21 U.S.C. § 371(h)(1)(C)(i).

258. Administrative Practices and Procedures Good Guidance Practices, 65 Fed. Reg. 56,468 (Sept. 19, 2000) (to be codified at 21 C.F.R. § 10.115).

259. 21 C.F.R. § 10.115(c)(1) (2018). For guidance other than "Level 1," the FDA also invites public comment, post-adoption. *See* 21 C.F.R. § 10.115(g)(4)(C). More generally, the FDA is willing to receive comments on any guidance document at any time. *See* 21 C.F.R. § 10.115(g)(5).

260. Interview with Source 110, *supra* note 114.

261. Interview with Source 27, *supra* note 116; Interview with Source 112, *supra* note 91.

262. *See* The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961, 8961 (Feb. 27, 1997).

263. Interview with William Schultz, *supra* note 92.

264. NAT'L ORGANIC PROGRAM, U.S. DEPT. AGRIC., PROGRAM HANDBOOK: GUIDANCE AND INSTRUCTIONS FOR ACCREDITED CERTIFYING AGENTS AND CERTIFIED OPERATIONS iv (2011).

265. Interview with Miles McEvoy, *supra* note 75.

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. The 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.[266] 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.[267] The decision whether to take public comment, said an EPA Office of General Counsel official, is really a policy decision, not a legal decision.[268] The Office of General Counsel plays an advisory role, but it is really up to the program people.[269] While the EPA has gone through a general shift toward notice-and-comment, each program office has gone at its own pace.[270] But the overall result of these many program-office decisions is that notice-and-comment for guidance is now a familiar thing at the 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."[271] An attorney at an environmental NGO said notice-and-comment for guidance is "not the norm" at the EPA but "not unusual."[272] (Another agency 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."[273])

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266. Interview with Source 99, *supra* note 103.

267. *Id.*

268. Interview with Source 61, *supra* note 52.

269. *Id.*

270. Interview with Source 71, former program office dir., EPA (notes on file with author).

271. Interview with Source 54, *supra* note 169.

272. Interview with Source 97, attorney at envtl. NGO (notes on file with author).

273. Interview with Kathryn Thomson, *supra* note 82; *see also* Interviews with Sources 64, 65, and 66, *supra* note 82 (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

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 OSHA[274] and CMS.[275]

B. 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 will 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 the FDA. While the FDA GGPs are an important innovation that have done much good—and may well be the optimal arrangement for the FDA itself—we must carefully consider the difficulties the FDA 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.[276] In a submission to a Senate committee on March 9, 2015, the FDA reported that, for guidance documents finalized between June 1, 2009 and June 30, 2014, the

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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*, U.S. DEPT. OF TRANSP., https://www.transportation.gov/regulations/public-feedback-dot-guidance-documents (last visited Oct. 19, 2018).

274. Interview with Frank White, *supra* note 187 ("virtually" never; no set process for seeking input); Interview with Celeste Monforton, *supra* note 223 (historically not, though it happened a couple of times under Obama); Interview with Marc Freedman, *supra* note 176 ("rare," with noise exposure guidance in 2010 being exception).

275. Interview with Source 67, *supra* note 226 ("rarity," no formal process for it); Interview with Source 93, former Div. Dir., CMS (notes on file with author) (by and large no stakeholder input on manual changes). *But see* Interview with Source 58, healthcare indus. attorney (notes on file with author) (noting a few matters on which statutes require notice-and-comment on guidance).

276. This has been previously noted in secondary literature on the FDA. *See* Noah, *supra* note 16, at 103–05; Seiguer & Smith, *supra* note 36, at 31.

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).[277] In addition, the FDA reported a list of guidance documents that were still pending in draft since before December 31, 2013 (i.e., for more than fourteen months at the time of the report), and these numbered ten at CBER, seventy-seven at CDER, and fifty-two at CDRH.[278] As the FDA has not compiled comparable data since 2015,[279] 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.[280] 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 days, to 826; had fallen at CBER by 181 days, to 562; and had fallen at CDRH by 269 days, 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.[281]) In addition, we counted guidance documents that were still pending in draft since before November 5, 2015 (i.e., for fifteen months or more at the time we gathered data on February 5, 2017). These numbered four at CBER, ninety-three at CDER, and twenty-two at CDRH. While these figures indicate some speedup at CDRH since 2015,[282] it seems that finalization of FDA guidance still often takes substantial periods of time.

Interviewees for the 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.[283] A former senior FDA career official said the agency did "not do a good job" on finalizing

277. Letter from Thomas A. Kraus, Assoc. Comm'r for Legislation, FDA, to Sen. Lamar Alexander 12 (Mar. 9, 2015), https://www.help.senate.gov/imo/media/doc/3-9-2015%20FDA%20Guidance%20Letter%20Response.pdf.

278. Calculated from *id.* at Appendix I.

279. Interview with Source 25, *supra* note 69. FDA has not confirmed the figures that I report in the remainder of this paragraph.

280. The database is available at https://www.fda.gov/RegulatoryInformation/Guidances.

281. All of these calculations exclude bioequivalence recommendations.

282. On measures that the Center for Devices and Radiological Health (CDRH) has taken to speed the development of guidance, see Kraus, *supra* note 277, at 6.

283. Interview with Source 25, *supra* note 69.

draft guidance, which could remain in draft "many years."[284] A former FDA official said it was a "prevalent" phenomenon at the FDA that guidance remained in draft a long time.[285] A partner in a large law firm healthcare practice observed there were "many" FDA guidances that had been pending "several years."[286] A trade association official said the FDA could go for "years" without finalizing draft guidance and might "never" finalize it.[287] A partner in a large law firm and former senior federal official observed that the FDA has a tendency to leave guidance in draft "indefinitely."[288] 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.[289] Long-term draft status had "always been a problem," said a former senior FDA official.[290] It was "confounding" for stakeholders according to another former senior FDA official,[291] and a "significant frustration," according to a congressional staffer.[292] Stopping at the draft stage, which FDA "often" did, was "problematic" and "troubling," said a former FDA chief counsel.[293]

The 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) FDA-regulated parties have strong incentives to comply with whatever the agency signals to be its wishes, regardless of how informally that signal is given, which means the FDA has relatively little incentive to finalize guidance, 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 perspective, finalizing guidance expends resources with relatively little upside. Given all the demands on the FDA staff, it is no surprise they do not give it a high priority.

Let us examine these two factors in turn, starting with the FDA's limited resources to finalize guidance. Reading comments and coming to a ration-

284. Interview with Source 112, *supra* note 91.

285. Interview with Source 20, *supra* note 173.

286. Interview with Source 101, *supra* note 70.

287. Interview with Source 24, *supra* note 54.

288. Interview with Source 78, partner in large law firm and former senior federal official (notes on file with author).

289. Interview with Michael Carome & Sammy Almashat, *supra* note 55.

290. Interview with Source 107, *supra* note 90.

291. Interview with Source 80, *supra* note 135.

292. Interview with Source 82, *supra* note 113.

293. Interview with Daniel Troy, *supra* note 93.

al decision about whether and how to incorporate them (even without writing a response to the comments) takes time. The parts of the FDA charged with these tasks are "way under-resourced and under-staffed," said a partner in a large law firm healthcare practice,[294] and they simply do not have enough resources to finalize all drafts, according to a former senior FDA official.[295] The 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 the 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."[296] 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."[297] 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 the 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.[298] 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.[299] They felt they had the means to finalize existing drafts or write new drafts on other matters, but not both.[300] In 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

294. Interview with Source 101, *supra* note 70.

295. Interview with Source 80, *supra* note 135.

296. U.S. FOOD & DRUG ADMIN., FOOD AND DRUG ADMINISTRATION REPORT ON GOOD GUIDANCE PRACTICES: IMPROVING EFFICIENCY AND TRANSPARENCY 16 (2011), https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf.

297. Interview with Janet Woodcock, *supra* note 200.

298. Interview with Source 112, *supra* note 91.

299. Interview with Bradley Merrill Thompson, *supra* note 83.

300. *Id.* 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. *Id.*

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.[301] An FDA Office of Policy official said that people at the 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."[302]

Now consider the second factor: regulated parties' incentives to comply with guidance regardless of whether its status is draft or final.[303] As I have documented in other empirical work, FDA-regulated companies are often seeking pre-market approval for their products, and in that context, where the stakes are high and the FDA holds all the cards, the companies have a very strong incentive to follow any indication of the agency's wishes, whatever its format.[304] 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"—and will "get me what I need from FDA."[305] 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.[306] Even outside the pre-approval context, some firms are sufficiently invested in their continuing relationship to the FDA (as I have also discussed in other empirical work)[307] 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, as the clients are worried about "antagonizing FDA" and their "good relations" with the agency.[308] 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

301. Interview with Source 20, *supra* note 173; *see also* Interview with Source 78, *supra* note 288 (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).

302. Interview with Source 25, *supra* note 69.

303. *See* Noah, *supra* note 16, at 104–05 (briefly noting that "draft or final guidance still often operate as de facto requirements").

304. PARRILLO REPORT, *supra* note 1, at 39–41.

305. Interview with Source 107, *supra* note 90.

306. Interview with Source 24, *supra* note 54.

307. PARRILLO REPORT, *supra* note 1, at 53–55.

308. Interview with Source 101, *supra* note 70; *see also* Interview with Source 104, law firm partner who deals frequently with FDA and CMS (notes on file with author) (recalling an instance in which the FDA took enforcement action based on draft guidance regarding products labeled "for research use only").

draft and final guidance.[309] Richard Naples, the chief regulatory officer of Becton Dickinson, said FDA reviewers could be expected to behave consistently with draft 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).[310] 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.[311] 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";[312] 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.[313]

The 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.[314]

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 disa-

309. Interview with Source 78, *supra* note 288.

310. Interview with Richard Naples, *supra* note 162.

311. Interview with Source 92, food and drug indus. Attorney (notes on file with author); *see also* Interview with Source 20, *supra* note 173 (stating that industry conforms to draft guidance).

312. Interview with Source 108, *supra* note 221.

313. Interview with Source 24, *supra* note 54.

314. Interview with William Schultz, *supra* note 92.

greement 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.[315] Naples, of 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.[316] 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.[317]

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.[318] Alternatively, a guidance might be so controversial that it could not be finalized, and his firm would not follow that kind of draft document.[319] Overall, he said, he would rely on a draft guidance document if it had been "out there a while," was not controversial, and if there were individual FDA adjudicatory decisions consistent with it.[320] As between the two kinds of draft guidance, "you have a sense of which it is," though "not always."[321] 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.[322] Coleen Klasmeier, the

315. Interview with Source 107, *supra* note 90.

316. Interview with Richard Naples, *supra* note 162.

317. Interview with Source 80, *supra* note 135. Some interviewees added that the FDA might keep guidance in draft form to avoid judicial review, as one reason among others for not finalizing. *See* Interview with Source 78, *supra* note 288; Interview with Source 92, *supra* note 311; Interview with Source 101, *supra* note 70.

318. Interview with Source 109, *supra* note 135.

319. *Id.*

320. *Id.*

321. *Id.*

322. Interview with Source 108, *supra* note 221.

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."[323] Clients should rely upon the former but not the latter.[324] The latter tended to be on more controversial subjects (e.g., implicating the First Amendment), while the former tended to be on regulatory science.[325] But it was not always easy to tell. For example, if the 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.[326] Ambiguities like these, said Klasmeier, made it difficult to counsel clients.[327]

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.[328] 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.[329] The FDA, observed the Public Citizen advocates, has a tendency to engage in this kind of ambiguous delay.[330] They said they "can't explain" the behavior and think it strange.[331] "Maybe," they said, the FDA did "not want to come down" and take a position "amid competing comments."[332] They added that they did not know how this draft guidance was affecting regulated-party behavior, though they would have liked to find out.[333]

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 the

323. Interview with Coleen Klasmeier, Head of FDA Regulatory Practice, Sidley Austin LLP (notes on file with author).

324. *Id.*

325. *Id.*

326. *Id.*

327. *Id.*

328. Interview with Michael Carome & Sammy Almashat, *supra* note 55.

329. *Id.*

330. *Id.*

331. *Id.*

332. *Id.*

333. *Id.*

FDA to finalize than were drug makers.[334] 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.[335] 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 the 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.[336] Further, noted a partner in a 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.[337] This, he said, was unfair.[338] There was not a "level playing field."[339]

The FDA is not the only agency that has left guidance in ambiguous draft status for long periods of time. DHS's USCIS, 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.[340]

The same phenomenon happens at least somewhat at the EPA. That agency, like the FDA, is strapped for resources on guidance matters. A partner in a large law firm and former senior EPA official noted that the EPA had become more stretched in terms of staffing and budget in the last twenty-five years.[341] 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."[342] Perhaps most strikingly, a very important EPA guidance document for administration of the Clean Air Act has been in "draft" *for twenty-eight years*. This is the *New Source Review Workshop Manual, Prevention of Significant Deterioration and Nonattainment Area Permitting*, also known as "The Puzzle Book,"

334. Interview with Source 25, *supra* note 69.

335. *Id.*

336. Interview with Source 80, *supra* note 135.

337. Interview with Source 101, *supra* note 70.

338. *Id.*

339. *Id.*

340. Family, *supra* note 29, at 50.

341. Interview with Source 52, partner in large law firm (former senior EPA official) (notes on file with author).

342. *Id.*

which to this day has each of its 322 pages stamped "Draft October 1990."[343] The document governs EPA-supervised state agency permitting decisions on new power plants. An environmental NGO employee observed that state agencies and the EPA generally followed the Puzzle Book "very closely."[344] This is no surprise given that permitting schemes like the one involved here impose strong incentives on permit-seekers to follow guidance.[345] 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 company 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 the 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.[346] What actually made a departure more likely, in his experience, was whether a well-connected utility company really wanted a guidance-noncompliant permit for a new plant, especially a coal-fired one.[347] Asked why the EPA had never finalized the draft, he said it was because the EPA feared that, if finalized, the document would be challenged as a legislative rule.[348] 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 the EPA.[349]

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 we are dealing with a high-stakes licensing scheme where firms' incentives to follow guidance are strong), its draft status is always available to be opportunistically invoked whenever the agency wants to make a departure for some other reason. This means departures from guidance become less principled and less transparent in their reasoning.

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343. ENVTL. PROT. AGENCY, DRAFT, NEW SOURCE REVIEW WORKSHOP MANUAL, PREVENTION OF SIGNIFICANT DETERIORATION AND NONATTAINMENT AREA PERMITTING (1990), 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 an Interview with Adam Kushner, Partner, Hogan Lovells (former EPA Director of Civil Enforcement) (notes on file with author).

344. Interview with Source 128, employee at an envtl. NGO (notes on file with author).

345. PARRILLO REPORT, *supra* note 1, at 37–45.

346. Interview with Source 128, *supra* note 344.

347. *Id.*

348. *Id.*

349. *Id.*

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 strong incentives to follow agency wishes. At the USDA NOP, 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.[350] Richardson, who was aware of the FDA's draft guidance problems and the tendency of the 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.[351] She suggested it was because the NOP would not "ding" a certifier for engaging in behavior that was inconsistent with draft guidance, and the certifiers were aware of this.[352] 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.[353] This contrasts with the approach at the 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.[354] It seems the USDA NOP engaged in a kind of self-denying 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 the 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.

C. The Possibility of Marginalizing Legislative Rulemaking

There has been innovation at the FDA not only in the participatory procedures established for guidance, but also in the elevation of guidance as a means of general policymaking. The 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 rule-

350. Interview with Jean Richardson, *supra* note 72.

351. *Id.*

352. *Id.*

353. Interview with Source 114, *supra* note 165. However, the interviewee added that, at a 2016 training session for certifiers, NOP made a statement that draft guidance should be viewed as guidance. *Id.* He said this "caused some heartburn" among the certifiers. *Id.*

354. Interview with Source 25, *supra* note 69.

makings even outside such statutory mandates.[355] 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).[356] "Nowadays," wrote food and drug scholar Lars Noah in 2014, "it seems, legislative rulemaking [at the FDA] only happens when Congress insists on that course of action."[357] 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.[358] Advocates at Public Citizen Health Research Group said they now assumed that guidance, not legislative rulemaking, was how the FDA would address any "major" issue.[359] A congressional staffer said the FDA, as between guidance and legislative rulemaking, now generally did everything by guidance unless a statute forced it to proceed by legislative rulemaking.[360]

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 the FDA and CMS. A law firm partner who works frequently with the two agencies explained how they differed.[361] According to him, the FDA had well-established procedures for notice-and-comment on guidance, which was praiseworthy, but the FDA was also more likely to use guidance when it should have used a legislative rule, which was frustrating.[362] 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.[363] A partner in a large law firm healthcare practice stated, similarly, that CMS used guidance appropriately to fill gaps in preexisting legislative rules, whereas the FDA used guidance more aggressively, as a substitute for legislative rulemaking, not just interpreting preexisting law but going beyond it.[364] A partner in another law firm healthcare practice observed that CMS did a good job of doing legisla-

355. Interview with Source 112, *supra* note 91 (giving examples of legislative rulemaking not mandated by statute in the areas of physician labeling, pregnancy labeling, and combination drugs).

356. On the view from within FDA, see PARRILLO REPORT, *supra* note 1, at 181.

357. Noah, *supra* note 16, at 114.

358. Interview with Source 110, *supra* note 114.

359. Interview with Michael Carome & Sammy Almashat, *supra* note 55.

360. Interview with Source 82, *supra* note 113.

361. Interview with Source 104, *supra* note 308.

362. *Id.*

363. *Id.*

364. Interview with Source 101, *supra* note 70.

tive rulemaking and keeping guidance confined to its appropriate role of illuminating the legislative rules while remaining consistent with those rules, whereas the FDA would use guidance more aggressively to regulate in the absence of a rule and even to act inconsistently with a statute.[365] 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 the FDA "almost never" issued legislative rules and did guidance instead.[366] A former senior FDA official said that CMS "never" faced the industry complaints about its use of guidance that the FDA had.[367] Advocates at Public Citizen, while not comparing the FDA to CMS, did find the FDA aggressive in its use of guidance, stating that the FDA could issue a guidance document that would "eviscerate" a legislative rule already in place.[368]

Is there a connection between the 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 the FDA's institutional development, and many interpretations are possible.[369] 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 GGPs were simply a means of regularizing and improving a form of administrative communication that had already become central to the agency's work before 1997.[370]

Other interviewees, however, suggested that the 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,

365. Interview with Source 91, partner in a law firm healthcare practice (notes on file with author).

366. Interview with Source 24, *supra* note 54.

367. Interview with Source 107, *supra* note 90.

368. Interview with Michael Carome & Sammy Almashat, *supra* note 55.

369. From a quantitative perspective, my calculations based on K.M. Lewis's admittedly rough count of guidance documents annually issued by the FDA indicates a jump leading up to the adoption of the GGPs (from annual average of 15.6 in 1987–1991 to 45.2 in 1992–1996) but also a jump afterward (to annual average of 102.6 in 1998–2002). Calculations based on Lewis, *supra* note 13, at 549–50 fig. 5.

370. Interview with Source 110, *supra* note 114.

and the transparency of the process meant stakeholders had less reason to sue.[371] Indeed, Congress has continued to give extraordinary treatment to FDA guidance since 1997; in 2011, for example, new legislation ordered the FDA to make certain policies by *rule or guidance*—a move that one scholar called a "peculiar concession about their interchangeability."[372]

Other interviewees similarly thought the GGPs had conferred special legitimacy on guidance in the 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 the 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.[373] 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.[374] 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.[375] Applying the FDA model to other agencies, he posited, could encourage those agencies to rely on guidance more than they otherwise would.[376] 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.[377] William Schultz, who served as FDA Deputy Commissioner for Policy (1994–1998) and HHS General Counsel (2011–2016) 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 the FDA had "gone too far" in using guidance.[378]

I am not saying that, if legislative rulemaking across the government were largely or entirely abandoned in favor of guidance issued through

371. Interview with Source 25, *supra* note 69.

372. Noah, *supra* note 16, at 108.

373. Interview with Coleen Klasmeier, *supra* note 323.

374. *Id.*

375. Interview with Source 82, *supra* note 113.

376. *Id.*

377. Interview with Source 82, *supra* note 113. 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 the FDA's inclination to use guidance had gone too far in areas where it was not justified by scientific and technical considerations. *Id.*; *see also* Interview with Coleen Klasmeier, *supra* note 323 (making a similar point).

378. Interview with William Schultz, *supra* note 92.

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.[379] 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 the 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."[380]

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. The 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.

D. Against "One Size Fits All"

As Parts III and IV show, a series of questions ought to 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 con-

379. *E.g.*, JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY (1990); McGarity, *supra* note 235; Wagner, *supra* note 151.

380. Rakoff, *supra* note 13, at 169.

templated 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.[381]

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 guidance in a tailored, agency-specific manner. As noted above, the FDA's initial adoption of the GGPs in February 1997 was driven in part by pressure from congressional overseers.[382] As to the 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.[383] He remembered that some EPA career officials strongly opposed public comment on certain documents, but OMB insisted, and "we knuckled under."[384] 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.

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381. Interview with Neil Eisner, former Assistant Gen. Counsel for Regulation & Enforcement, DOT (notes on file with author).

382. *See supra* note 263 and accompanying text.

383. Interview with Source 96, *supra* note 89.

384. *Id.*

EDITOR'S NOTE

This Article draws its primary research from, and overlaps with the text of, the report by Parrillo to ACUS titled "Federal Agency Guidance: An Institutional Perspective," acknowledged in the first footnote to the text. The Article reframes the report's findings to integrate them into the academic discourse on public participation in agency policymaking.