THE GUIDANCE DOCUMENT DILEMMA: REFORMING THE FDA'S USE OF GUIDANCE DOCUMENTS FOR THE 21ST CENTURY

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INTRODUCTION

Concern with regulatory agency (mis)use of guidance documents has ebbed and flowed over time.[1] As of late, sustained criticism from each branch of the federal government has been the order of the day. With respect to the executive branch, at the 2017

1. *See generally* K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507 (2011).

Federalist Society's National Lawyers Convention in Washington, D.C., former Attorney General Jeff Sessions expressed concern that regulatory agencies were using guidance documents impermissibly. Sessions explained, "Too often, rather than going through the long, slow regulatory process provided in statute, agencies make new rules through guidance documents . . . . Guidance documents should be used to reasonably explain existing law – not to change it."[2] He continued, stating that he had "prohibited all Department of Justice (DOJ) components from issuing any guidance that purports to impose new obligations on any party outside the executive branch [and that the DOJ] will review and repeal existing guidance documents that violate this common sense principle."[3]

In Congress, a handful of senators have also taken up the guidance issue. In May of 2015, Senators Lamar Alexander and James Lankford sent a letter to the Department of Labor that laid out their concerns about the Agency's use of guidance documents. The Senators first noted that guidance documents are exempt from notice-and-comment procedures "because they do not have the force of law," and then stated their worry that "federal agencies are increasingly using guidance that appears to create new requirements without the benefit of notice-and-comment but with the expectation that the public comply."[4] In addition to the letter, the Senators held hearings in 2016 entitled "Examining the Use of Agency Regulatory Guidance" that looked into agencies' use and abuse of guidance documents.

Although, as will be discussed below, the judiciary infrequently reviews use of guidance documents, it too has registered its disapproval of the ways in which agencies employ them. For example, in *Appalachian Power Co. v. Environmental Protection Agency*,[5] the D.C. Circuit lamented:

> The phenomenon we see in this case is familiar . . . . One guidance document may yield another and then another and

2. Jefferson B. Sessions, Att'y Gen., Dep't of Just., Remarks at the Federalist Society 2017 National Lawyers Convention (Nov. 17, 2017), https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-federalist-society-2017-national-lawyers [https://perma.cc/P6NE-YJLP].

3. *Id.*

4. Letter from Lamar Alexander, Chairman, S. Comm. on Health Educ. and Pensions, & James Lankford, Chairman, S. Subcomm. on Regulatory Affairs and Fed. Mgmt., to Thomas E. Perez, Sec'y, U.S. Dep't of Labor (May 7, 2015), https://www.help.senate.gov/chair/newsroom/press/alexander-lankford-begin-investigation-into-federal-agencies-use-of-regulatory-guidance [https://perma.cc/P98V-EZBG].

5. 208 F.3d 1015, 1020 (D.C. Cir. 2000).

> so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.

As will be discussed in Part II, administrative law scholars have largely reached conclusions similar to those above. Namely, that there are serious problems with agencies'—and the Food and Drugs Administration's (FDA) in particular—uses of guidance documents.

This Note, then, seeks to address the guidance problem. However, taking the approach advocated by Jill Family—that the "best approach to reforming agency use of guidance documents is an agency-by-agency approach"[6]—this Note focuses exclusively on the FDA's use of guidance documents in the medical drug, device, and technology context.

In brief, this Note argues that while there are real problems with guidance documents as currently employed,[7] seriously curtailing or ossifying guidance document issuance would be a grave mistake in light of the virtual revolution in science and technology confronting the FDA.[8] Instead, the right formulation would acknowledge the critical role guidance documents play and will continue to play in the future, and balance the needs of regulated entities (e.g., clarity, speed, and agency accountability) with the needs of the FDA (e.g., speed, flexibility, and resource conservation).[9]

To that end, this Note offers a novel framework for the issuance and judicial review of FDA guidance documents consisting of two stages. At stage one, the FDA would issue a draft guidance document, including an explanation of its legal basis and a sunset provision. Upon issuance, concerned parties could then challenge the legal basis of the draft guidance in court, with the FDA's analysis receiving *Skidmore* deference in judicial proceedings.[10] After the propriety of the draft guidance is either unchallenged or affirmed, the FDA would then have until the end of the sunset provision to issue a final guidance or repeal the draft.

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6. Jill E. Family, *Easing the Guidance Document Dilemma Agency by Agency: Immigration Law and Not Really Binding Rules*, 47 U. MICH. J.L. REFORM 1, 1 (2013).

7. *See infra* Part I.

8. *See infra* Part III.

9. *Id.*

10. *See infra* Section IV.A.

At stage two, the FDA would issue a final guidance document. It would contain the guidance's factual bases. Once promulgated, regulated entities could then challenge the final guidance in court under a modified *State Farm*[11] arbitrary and capricious standard.[12] Draft challenges would be filed in federal circuit courts and final guidance challenges would be lodged in federal district courts.[13]

Altogether, this Note comprises five parts. Part I discusses the codification of the FDA's guidance practices as well as the current state of play. Part II addresses scholarly approaches to the guidance problem as well as the shortcomings of those proposals. Part III seeks to reframe the debate concerning guidance documents and explain why guidance documents should be seen as valuable—perhaps necessary—tools of regulation at the FDA, and why, despite their prominence, guidance documents should not be subject to rule-like formality in issuance and review. Part IV lays out the two-stage process of guidance issuance and judicial review and explains the advantages of this proposed framework. Part V concludes.

I.
THE FDA'S RELATIONSHIP WITH GUIDANCE DOCUMENTS

The FDA has long used guidance documents or something similar to inform both regulated entities and Agency personnel.[14] The nature of those informal guidance documents has changed over time depending on a variety of factors, including the needs of industry, the needs of the Agency, and the shifting views of various interested parties as to the propriety of the documents.[15] In the last two decades, however, guidance documents have begun to play an unprecedented role in the Agency's regulatory apparatus,[16] effectively supplanting legislative rules and leading to considerable consternation. This Part discusses the codification of the FDA's guidance practices, the current state of affairs, and the vocal concerns attendant to them.

11. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42–43 (1983).

12. *See infra* Section IV.B.

13. *See infra* Section IV.D.

14. *See* Lewis, *supra* note 1. R

15. *Id.*

16. *Id.* at 509 (describing a recent "explosion of guidance at the FDA"); *see also infra* notes 31–32, 41. R

A. The FDA and Guidance Documents: Codification

After playing a somewhat moderate role in the FDA's regulatory scheme for many years,[17] "informal guidance [had become] FDA's primary method of policymaking" by the mid-1990s.[18] Numerically, that meant that the number of guidance documents issued by the FDA from the 1970s to the 1990s grew by leaps and bounds while the number of notice-and-comment rules decreased.[19] Due to this pronounced shift, "cries that the [then-]required procedure was being subverted"[20] and pressure from industry and the courts, the FDA began investigating how it could formalize the nature of and issuing process for guidance documents.[21] After a series of public hearings, the FDA's efforts culminated in the Agency adopting "Good Guidance Practices"[22] ("GGP") in 1997.[23] GGP, which ultimately became law[24] in the 2000 FDA Modernization Act ("FDAMA"),[25] remains in force today.

Among other changes,[26] GGP divided FDA guidance documents into two tiers and injected significant guidance documents

17. *See* Lewis, *supra* note 1, at 509–23 (discussing the FDA's use of and rationale for employing a variety of informal guidance documents including "FIDs," "TCs," and "Formal Statements"). R

18. *Id.* at 520.

19. Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000) (noting that as compared to "the late 1970s or early 1980s . . . . the number of FDA regulations adopted each year [in the early to mid-90s through notice-and-comment procedures] declined by about fifty percent while . . . . the rate per year [of guidance documents issued was] about four hundred percent greater than the rate for the 1980s").

20. *See id.*; *see also* NICHOLAS R. PARRILLO, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE 169 (2017).

21. *See* Lewis, *supra* note 1, at 520–23; *see also* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 98 (2014) ("This policy [Good Guidance Practices] represented a response to complaints that the FDA inappropriately used guidance documents as if they constituted binding rules that regulated entities had to follow."). R

22. 21 C.F.R. § 10.115.

23. For more detailed histories of the development of GGP, *see, e.g.*, Family, *supra* note 6, at 31–34; Lewis, *supra* note 1, at 509–23; Noah, *supra* note 21, at 90–110. R

24. 21 U.S.C. § 371(h) *et seq.*

25. Noah, *supra* note 21, at 99 n.41. R

26. Good Guidance Practices also includes the requirement that the FDA not include mandatory language in guidance documents, the mechanism by which interested parties can petition the FDA for review of guidance documents, and the reaffirmance that guidance is neither binding on the FDA nor on regulated parties. *See generally* 21 C.F.R. § 10.115.

with watered down notice-and-comment procedures.[27] Level 1 guidance documents "[s]et forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; include complex scientific issues; or cover highly controversial issues."[28] Level 2 guidance documents are "guidance documents that set forth existing practices or minor changes in interpretation or policy" and "include all guidance documents that are not classified as Level 1."[29]

Commensurate with that division, Level 1 and Level 2 guidance documents demand different levels of procedural formality. Most notably, whereas Level 2 guidance documents can be acted on immediately after publication in the Federal Register, Level 1 guidance documents cannot be adopted until the public has had an opportunity to comment on them,[30] though the FDA need not actually respond to those comments.

B. Current State of Play

Even after the formalization of guidance procedures, guidance documents remain the FDA's primary means of policymaking.[31] According to Lars Noah, the FDA continues to issue guidance documents much faster than it issues rules, and there may be nearly two thousand FDA guidance documents currently circulating.[32] In fact, there is some indication that, notwithstanding whatever the implementation of GGP was intended to accomplish,[33] it actually has

27. Professor Rakoff remarked around the time of Good Guidance codification that, in fact, the "new" guidance processes looked a lot like the original understanding of notice-and-comment rulemaking. Rakoff, *supra* note 19, at 169 ("It would not be far-fetched to rephrase these matters by saying the FDA now proposes to issue its important regulations mostly in accordance with the notice-and-comment rulemaking procedures set forth in the APA, as it was understood before 1970."). R

28. 21 C.F.R. § 10.115(c)(1)(i–iv).

29. *Id.* at (c)(2).

30. *Id.* at (g)(1)(ii)(C).

31. *See, e.g.*, Noah, *supra* note 21, at 90 (noting the FDA's "shift from the promulgation of binding rules to the issuance of nonbinding guidance documents"). R

32. *Id.* at 103 ("The latest version of [a sporadically published guidance document compendium] reveals almost two thousand guidance documents, in both draft and final form, and in recent years the FDA has produced more than a hundred new ones annually, easily outpacing the frequency of notice-and-comment rulemaking."); *see also id.* at 103 n.68; Clyde Wayne Crews Jr., *Mapping Washington's Lawlessness: An Inventory of Regulatory Dark Matter*, COMPETITIVE ENTERPRISE INSTITUTE, Mar. 2017, at 28 ("The Food and Drug Administration (FDA) acknowledges 1,819 pieces of final guidance as of this writing.").

33. *See* Lewis, *supra* note 1, at 523 ("FDA's aim in these reforms was to render all forms of informal guidance, including formal advisory opinions and guidelines, R

stamped guidance documents with a level of "legitimacy" such that FDA personnel view them and notice-and-comment rules on relatively equal footing.[34]

Regardless of how widespread this belief is within the Agency, the reality in practice is that the guidance documents often do function like legislative rules[35] even though they are neither the result of adjudication nor the byproduct of formal or informal rulemaking.[36] Numerous commentators have sought to explain why this is. The crux of these various expositions is that the FDA, as the gatekeeper to the food and drug market, has extraordinary leverage over regulated entities.[37] In other words, the FDA's pre-market ap-

non-binding upon the agency, while allowing for greater public participation and clarity in the policymaking process.") (internal quotations omitted).

34. *See* PARRILLO, *supra* note 20, at 183 (discussing the perception that Good Guidance Practices "have heightened the FDA personnel's sense of guidance's legitimacy"). *See also* Noah, *supra* note 21, at 97 ("Congress largely has endorsed and even encouraged [guidance documents'] development."). R R

35. *See, e.g.*, Rakoff, *supra* note 19, at 168 ("In short, guidance documents are meant to be statements of no legal consequence but immense practical consequence about virtually everything the agency regulates."); Noah, *supra* note 21, at 104–05 ("[I]n spite of their explicitly 'nonbinding' character, draft or final guidance still often operate as de facto requirements."); PARRILLO, *supra* note 20, at 4 ("The concern is that agencies in reality are not tentative or flexible when it comes to guidance but instead follow it as if it were a binding legislative rule, and regulated parties are under coercive pressure to do the same."); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 343 (2011) ("Essentially, the policy [i.e., guidance] becomes practically binding in that it induces compliance even though it does not command independent force of law."). R R R

36. Although GGP uses "guidance document," guidance documents encompass two different sorts of documents: statements of policy and interpretive rules. *See, e.g.*, Seidenfeld, *supra* note 35, at 332. Even though guidance documents would tend to fall within the APA's definition of a "rule," they are exempt from the APA's notice-and-comment procedures because they are theoretically non-binding. *See, e.g.*, Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1204 (2015) ("The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. But that convenience comes at a price: Interpretive rules 'do not have the force and effect of law and are not accorded that weight in the adjudicatory process.'") (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)). R

37. *See, e.g.*, Richard A. Epstein, *The Role of Guidance in Modern Administrative Procedure: The Case for* De Novo *Review*, 8 J. LEGAL ANALYSIS 47, 70–71 (2016); PARRILLO, *supra* note 20, at 39 ("Given the nature of premarket approval, explained one food and drug industry attorney when discussing conformity to guidance, an applicant must anticipate how the FDA thinks; and it would be 'foolish' to proceed with an application without following the agency's guidance."); Noah, *supra* note 21, at 90 ("The FDA enjoys significant leverage over regulated entities, by virtue of its powers of enforcement and product licensing, and in both settings it can com- R R

proval process imposes enormous costs—both monetarily and temporally—on regulated firms, and the cost-benefit analyses of those entities often lead them to comply.[38]

These coercive effects are not, however, the only problems with the FDA's current use of guidance documents. Additionally, guidance documents are largely unreviewable by courts, and the FDA not infrequently circumvents what limited procedural requirements GGP imposes. As to the former, commentators have noted that the judicial doctrines surrounding guidance documents—namely, inquiries into finality and ripeness—are deeply problematic and make "it difficult if not impossible to challenge agency action at any point prior to an enforcement action."[39] Thus, guidance documents not only bind parties, but also leave firms with limited opportunities to challenge them. As Todd Rakoff commented, so far as the FDA is concerned, guidance documents are "beyond the purview of the courts."[40]

As to the circumvention of GGP procedural requirements, the FDA has a tendency to leave guidance documents in draft form for

municate threats and offers that (more often than not) secure 'voluntary' compliance with whatever the agency demands.").

38. *See, e.g.*, PARRILLO, *supra* note 20, at 64–65 ("The regulated party will compare the upside it sees in guidance-noncompliant behavior with the downside, which varies with four factors: (1) the probability of the agency detecting the regulated party's guidance-noncompliant conduct and initiating enforcement to begin with, (2) the potential cost of the resulting enforcement proceeding irrespective of its outcome, (3) the probability that the proceeding will result in a finding that the party violated the relevant legislative rule or statute, and (4) the potential cost of sanctions attached to that finding."); Michael S. Greve & Ashley C. Parrish, *Administrative Law Without Congress*, 22 GEO. MASON L. REV. 501, 532–33 (2015) ("[Draft guidance] documents do not bind the agency, but as a practical matter, they *are* binding on regulated firms . . . . The legal uncertainty created by the lack of regulations, combined with agency threats to seek massive penalties, produces an *in terrorem* effect sufficient to generate large settlements."); David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 311 & n.180 (2010). R

39. Gwendolyn McKee, *Judicial Review of Agency Guidance Documents: Rethinking the Finality Doctrine*, 60 ADMIN. L. REV. 371, 374 (2008); *see also, e.g.*, Stephen Hylas, *Final Agency Action in the Administrative Procedure Act*, 92 N.Y.U. L. REV. 1644, 1644 (2017) ("[T]he second prong of [*Bennet v. Spear*] . . . . seems to effectively bar courts from reviewing nonlegislative rules before agencies have taken enforcement action."); Stephen M. Johnson, *Good Guidance, Good Grief*, 72 MO. L. REV. 695, 712 (2007) ("[Due to uncertainty surrounding judicial challenges to guidances], businesses will be reluctant to make major changes to their activities that might conflict with the position taken by the agency in the rule, even though they may want to do so, and even though they believe that the rule is inconsistent with the law.").

40. Rakoff, *supra* note 19, at 169. R

years.[41] This has several consequences. First, by leaving Level 1 draft guidance documents in draft form, the FDA effectively turns them into Level 2 documents, thereby violating the spirit, if not the letter, of GGP.[42] Second, given finality and ripeness concerns, leaving the guidance documents in draft form renders judicial review even more unlikely to occur than when the guidance is finalized. Third, draft guidance documents lead to increased confusion for regulated entities and decreases their confidence and trust in the Agency.[43] Fourth, despite all of the above, the FDA still manages to obtain compliance. As Professor Parrillo relayed in his Administrative Conference of the United States ("ACUS") report, a trade agency official noted that it would be "folly" not to follow the FDA's draft guidance in the context of the pre-market approval process.[44]

While the FDA has taken notice of complaints about its use of draft guidances, there is little to no evidence that the Agency plans to adjust their use any time soon.[45] In fact, there appears to be a sense within certain parts of the Agency that draft guidances are sufficient. Professor Parrillo documented this tension in his ACUS report. He relays, for example, the thoughts of one former FDA official who said, "FDA personnel think draft guidance is 'good enough' . . . . [T]he draft gives regulated parties what they need to know about agency thinking and stops them from asking questions about what the agency wants, thus taking away the perceived need for more explanation from the agency."[46]

Taken together, there are very good reasons to be concerned with the FDA's use of guidance documents as it currently stands. This is true whether viewed from a separation of powers standpoint, from a rule of law standpoint, or from a regulated entity or beneficiary standpoint. Simply put, a federal agency that can bind parties

41. Noah, *supra* note 21, at 104; PARRILLO, *supra* note 20, at 179 ("FDA is not the only agency that has left guidance in ambiguous draft status for long periods."); Greve & Parrish, *supra* note 38, at 532 ("In recent years, FDA has largely forsworn regulation through notice-and-comment rulemaking procedures. Instead, it regulates through never-finalized 'draft' guidance documents."). R R

42. Noah, *supra* note 21, at 104 ("Level 1 guidance often remain in draft form, which makes the procedures for their issuance (as drafts) essentially the same as those used for Level 2 guidance."). R

43. PARRILLO, *supra* note 20, at 171–81 (discussing the confusion that arises out of indefinite draft guidance). *See also* Johnson, *supra* note 39, at 712 (describing the uncertainty that arises out of inconsistency in judicial review). R R

44. PARRILLO, *supra* note 20, at 40. *See also* Noah, *supra* note 21, at 104–05. *But see* PARRILLO, *supra* note 20, at 178–79 (relaying that some of his interviewees said whether to comply with draft guidance was context-specific). R R

45. *See* PARRILLO, *supra* note 20, at 174–75. R

46. *Id.* at 174.

without a single traditional safeguard—public input, agency response, judicial review—is a lawless one. It should thus come as little surprise that the FDA has been subject to substantial criticism from diverse actors.

II.
ACADEMIC SOLUTIONS TO THE GUIDANCE DOCUMENT PROBLEM

Although public umbrage with guidance documents has grown increasingly pronounced in the last few years, scholars have been sounding the alarm for the better part of three decades. In 1992, Robert Anthony questioned whether "*Interpretive Rules, Policy Statements, Guidance Manuals, and the Like*"[47] should bind the public. Since then, scholars have taken several different approaches to addressing the guidance problem. Those approaches can be grouped into three categories: (A) procedural changes, (B) non-governmental changes, and (C) doctrinal changes. This section elaborates on those approaches and explains why each is unsatisfactory.

A. Procedural Changes

The "procedural changes" category encompasses proposed changes to the procedures attendant to guidance document issuance. For example, a handful of scholars have suggested that guidance documents, or at least certain guidance documents, should be subject to procedures akin to those required of notice-and-comment rulemaking.[48] In the same vein, but more modestly, another scholar has suggested that, among other alterations, agencies should provide some limited opportunity for public comment on guidance documents.[49]

With respect to the former suggestion, turning guidance documents into legislative rules would deny the FDA the benefits of guidance documents—*e.g.*, speed, flexibility, and resource conservation.[50] Generally, even scholars who believe that coercive

47. Robert A. Anthony, *Interpretive Rules Policy Statements, Guidance Manuals, and the Like – Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311 (1992).

48. *See, e.g.*, Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 444–45 (2007) (discussing this possibility); *see generally* Anthony, *supra* note 47 (advocating for such a change expressly). R

49. *See* Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 ADMIN. L. REV. 343, 398–405 (2009).

50. *See, e.g.*, PARRILLO, *supra* note 20, at 7 (Guidance documents make R "frontline agency decisionmakers more decisive and fast . . . . saving time and re-

guidance documents should be addressed still hold that guidance documents can serve important functions as they currently exist.[51] As to the latter suggestion, while it addresses some of the problems with guidance documents—*i.e.*, that the public is often shut out—it fails to confront the unreviewable nature of guidance documents. Moreover, as exemplified by the FDA's use of Level 1 guidance documents, simply adding a comment period alone is insufficient to protect regulated entities and quickly runs into the problems associated with the first proposed solution.

Another scholar has suggested that agencies should explain why they have chosen to proceed through, for example, guidance document rather than legislative rule.[52] As with the above, one major shortcoming of this proposal is that it does not address the reality that most guidance documents do not receive judicial review by virtue of going unchallenged. Furthermore, as Elizabeth Magill acknowledges (even though she rejects the justifications for it being so), discretionary agency choices surrounding which policymaking form an agency will deploy are ordinarily unreviewable.[53] Accordingly, even if courts were to review an agency's choice, it is not clear that such a review would present a meaningful check.

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sources"; make agency decisions "more predictable, comprehensible, and uniform"; are "better for dealing with conditions of uncertainty" than legislative rules; and often take "less time and resources than legislative rulemaking."); Epstein, *supra* note 37, at 48, 66; Franklin, *supra* note 38, at 303–04 (describing the various benefits of guidance documents); Lewis, *supra* note 1, at 538; Seidenfeld, *supra* note 35, at 341–42, 374. R R R

51. *See, e.g.*, Anthony, *supra* note 47, at 1317 ("The use of nonlegislative policy documents generally serves the important function of informing staff and the public about agency positions, and in the great majority of instances is proper and indeed very valuable."). *Cf.* Franklin, *supra* note 38, at 306 ("By the same token, however, there is good reason not to insist that all agency policymaking take place via notice and comment . . . . To put matters simply, one of the benefits of nonlegislative rulemaking, at least in contexts where notice and clarity are especially important, is that it is not pure adjudication."). R R

52. *See generally* Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383 (2004). As Mark Seidenfeld notes, Magill's argument is "implicit." Seidenfeld, *supra* note 35, at 364 n.174. R

53. *See* Magill, *supra* note 52, at 1385 ("An agency can choose among its available policymaking tools and a court *will not* require it to provide an explanation for its choice."); *see also* Stephen M. Johnson, *In Defense of the Short Cut*, 60 U. KAN. L. REV. 495, 504–06 (2012) (noting the same). *Cf.* Heckler v. Chaney, 470 U.S. 821, 826 (1985) (discussing that, although a narrow exception, certain agency decisions are unreviewable because they are "committed to agency discretion by law"). R

B. Non-Governmental Changes

The "non-governmental changes" category includes an amalgam of scholarly responses that look outside the procedural requirements for issuing guidance documents. For example, focusing on the downside of guidance documents to regulatory beneficiaries, Nina Mendelson has suggested that a more aggressive and formalized citizen petition process would rein in guidance document abuse.[54] But, as Mark Seidenfeld notes, Professor Mendelson's proposal has several issues: an agency's obligation to respond would slow down guidance document issuance to the point of approximating notice-and-comment rulemaking;[55] Professor Mendelson's solution does not address courts' disinclination to review the documents;[56] and such a procedure appears already to exist but is virtually never used.[57]

Another approach under this header, offered by William Baude, suggests that regulated entities should be able to invoke a kind of qualified immunity. Thus, "[i]f presented with executive guidance that takes an aggressive or questionable interpretation of the [underlying] statute, the regulated entity would now be able to more confidently go on about its business, ignoring the agency's position."[58]

This approach is attractive, but regulated entities may nevertheless be concerned about the collateral consequences that come with being subject to an enforcement proceeding, even if they prevail.[59] Similarly, given the cost-benefit analyses of regulated entities in the premarket approval process, even a good chance that their actions will be deemed "reasonable" may not be enough of an in-

54. Mendelson, *supra* note 48, at 438–44. R

55. Seidenfeld, *supra* note 35, at 366–68. R

56. *Id.*

57. *Id.* at 370–72 ("In light of the clear language and the nondefinitive judicial treatment of the applicability of the right to petition for modification to guidance documents, the dearth of cases in which stakeholders attempted to petition for modification of such a document seems to reflect an assessment that such a strategy is unlikely to succeed in getting courts to hold the agency accountable for the guidance document, rather than a belief that the strategy was precluded by the APA.").

58. William Baude, *Congressional Control over Agencies: The Problem of Coercive Guidance* 15, HOOVER INSTITUTION (May 30, 2016), https://www.hoover.org/sites/default/files/baude2c_congress_and_guidance_2b.pdf [https://perma.cc/2B7Y-P3XR].

59. PARRILLO, *supra* note 20, at 65 (relaying a drug manufacturer executive's account of his company's cost-benefit analysis, including "are we prepared to take a warning letter and defend ourselves" and "the 'probability' of enforcement 'times' the 'damage' to the business in the event of enforcement"). R

centive for them to disregard the FDA's pronouncements in light of the costs of being wrong. Lastly, while certain actors have robust qualified immunity, there are good reasons to believe that regulated entities would not have such substantial coverage. For example, both police officers and regulated entities of course should follow the law, but a doctrine protecting police officers may have clearer policy underpinnings than one protecting pharmaceutical companies.

C. Doctrinal Changes

Far and away, however, the third and largest category of proposed changes encompasses modifications to judicial review of guidance documents. As Mark Seidenfeld explained, "[s]cholarship on guidance documents has developed into a debate between those who bemoan judicial doctrines that enable agencies to issue them too easily and those who complain that courts have imposed arbitrary barriers to their use."[60] In particular, the debate has centered around how and whether courts should go about determining if an agency pronouncement is "legislative."

As Seidenfeld noted, the two sides of the debate can largely be divided into two categories: the "ex ante legal effects" school and the "ex post monitoring" school.[61] The ex ante school, spearheaded by Robert Anthony[62] and endorsed by scholars such as David Franklin,[63] believes that courts should look at whether "the [guidance] document was issued with the intent to bind or otherwise had binding legal effect."[64] Put another way, this inquiry seeks to determine whether an agency pronouncement is, in fact, a legislative rule as opposed to the nonlegislative rule it purports to be. If a court determines that the agency pronouncement is binding but was promulgated through means other than notice-and-comment or formal rulemaking, it will invalidate the pronouncement. This legislative/

60. Seidenfeld, *supra* note 35, at 332. R

61. *Id.* at 346, 352.

62. *Id.* at 345. *See also* Anthony, *supra* note 47, at 1355 (containing a section titled, "The Key Tests: Intend to Bind or Binding Effect"); Robert A. Anthony, *"Well, You Want the Permit, Don't You?" Agency Efforts to Make Nonlegislative Documents Bind the Public*, 44 ADMIN. L. REV. 31, 34 (1992); PARRILLO, *supra* note 20, at 7–9 (commenting on Anthony's position). R R

63. *See generally* Franklin, *supra* note 38, at 276 (arguing that judges have been "wise" in not adopting the ex ante school's "shortcut" and should stick with the current doctrine); *see also* David L. Franklin, *Two Cheers for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 111 (2011) (defending his position). R

64. Seidenfeld, *supra* note 35, at 346. R

nonlegislative line of inquiry is, by and large, the doctrine as it exists today in federal courts.[65]

Despite, or perhaps because of its widespread adoption, the "ex ante legal effects" school has come under sustained criticism from scholars who claim it is deeply confused. In fact, one scholar broadly supportive of the current state of affairs even noted the doctrine suffers from "smog and muddle."[66] The criticism tracks several different lines but is succinctly captured by Professor Seidenfeld:

> Because the binding-effect approach provides no demarcation of the kind of binding force required, the extent of binding force required, or how likely the agency must be to apply the statement with binding force for a court to conclude that the statement is a legislative rule, the resulting judicial decisions are inconsistent and seemingly ad hoc.[67]

In addition, at least in the context of the FDA, it seems that arbitrariness is practically inevitable. Per Professor Parrillo, underlying FDA machinations are not what lead regulated entities to comply with guidance documents.[68] Instead, guidance documents act as binding due to structural issues arising out of the FDA's gatekeeping role and the immense cost of premarket approval.[69] Thus, there is a sense in which *all* guidance documents will have coercive effects. This means, barring a structural overhaul of the FDA and its approval process, a judicial doctrine that examines the "bindingness" of a guidance document will necessarily be ad hoc unless it strikes down virtually all guidance documents. Altogether, there are substantial reasons to leave behind inquiries into a guidance docu-

65. *See, e.g.*, Franklin, *supra* note 38, at 294 ("[C]ourts continue to take the long road, attempting to draw distinctions between legislative and nonlegislative rules based on substantive criteria such as substantial impact, legal effect, and the agency's intent to bind itself and others."). R

66. *Id.* at 324. *See also id.* at 278–79 ("[I]t is no wonder that courts have labeled the distinction between legislative and nonlegislative rules 'tenuous,' 'baffling,' and 'enshrouded in considerable smog.'").

67. Seidenfeld, *supra* note 35, at 349. R

68. PARRILLO, *supra* note 20, at 9 ("That regulated parties often (though not always) feel strong pressure to follow guidance is absolutely true, but the origins of this fact usually lie not in some plot hatched by the agency but instead in a series of structural features of modern regulation and of the legislation that establishes it, nearly all of which are vastly beyond the control of the agency officials who are issuing a guidance document."); *see also id.* at 9–10 (laying out structural reasons for guidance compliance: (1) pre-approval; (2) "continuous monitoring and frequent evaluations by the agency"; (3) compliance officers and relationships, and; (4) cost-benefit analyses). R

69. *Id.*

ment's degree of "bindingness." This, then, is the movement championed by the ex post school.

The ex post school, which includes scholars such as William Funk[70] and Jacob Gersen,[71] believes that courts should stop seeking to determine whether or not an agency pronouncement is legislative. Instead, the ex post school "advocates that a rule adopted without notice-and-comment procedures should be deemed a policy statement or interpretive rule, and that courts should monitor the agency's reliance on these rules to ensure that it does not use them as if they have independent legal force."[72] While this approach certainly streamlines review—it has been informally titled the "shortcut"[73]—it leaves a great deal to be desired. As scholars have repeatedly emphasized, the coercive nature of guidance documents often operates *sub silentio*. Therefore, potentially problematic guidance documents—whether because they are beyond the bounds of an agency's statutory jurisdiction or because they are lacking in a factual basis—will not be reviewed despite the likely effects on regulated entities. In response to these shortcomings, Mark Seidenfeld[74] and Richard Epstein[75] have argued that direct substantive review of the guidance documents is the best way to deal with the problem posed by guidance documents, although the two disagree, at a minimum, about the appropriate standard of review. Seidenfeld advocates for an arbitrary and capricious standard, while Epstein claims that the review should be done de novo. Both arguments deserve a closer look.

Seidenfeld begins by suggesting that guidance documents should be able to receive substantive review upon issuance.[76] He provides two persuasive reasons for direct review: first, "any official issuing a guidance document that takes effect without further agency action should first seriously consider its consequences"; and second, because "a stakeholder adversely affected by such a guidance document is entitled to an explanation for the official's decision."[77] Because direct review may currently be hindered by finality

70. *See, e.g.*, William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1324–25 (2001).

71. *See, e.g.*, Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1718–19 (2007).

72. Seidenfeld, *supra* note 35, at 352–53. R

73. Franklin, *supra* note 38, at 289 n.65. R

74. Seidenfeld, *supra* note 35. R

75. Epstein, *supra* note 37. R

76. Seidenfeld, *supra* note 35, at 373. R

77. *Id.*

and ripeness doctrines, Seidenfeld suggests modifying these doctrines to reduce doctrinal barriers preventing review.[78]

Seidenfeld then argues that this direct review should be governed by a modified arbitrary and capricious standard: "Reasoned decisionmaking of guidance documents could mandate that agencies explain actions in terms of factors that are relevant and alternatives that are plausible given the state of knowledge available to the agency when it acted."[79] Further, the explanation provided by the agency should not be limited simply to general knowledge. Rather, "the general state of knowledge should be that of one who is familiar with the underlying predicates for the policy or interpretation."[80]

Seidenfeld argues that this model provides multiple benefits: it commands agencies to build reasonable factual records,[81] permits members of the public as well as regulated entities to challenge guidance documents without first having to comply,[82] and is relatively quick.[83] On the last point, Seidenfeld notes first that, as opposed to a formal production procedure, the agency retains "flexibility to develop the information it believes it needs to meet the standard of review by the means it chooses"; and second that, rather than respond to each public submission, the agency need only consider common, meritorious arguments on the issue.[84] As such, the model balances accountability with speed and flexibility.

Epstein tracks Seidenfeld's stance insofar as both argue for direct substantive review. Epstein, however, believes that an arbitrary and capricious standard is too "timid."[85] Instead, Epstein argues that courts should employ de novo review of agency interpretive rules and statements of policy (e.g., guidance documents), where they present pure questions of law.[86] In so doing, Epstein points to a concurrence by Justice Scalia in *Perez v. Mortgage Bankers Association* in which the late Justice expressed deep reservations as to judicial deference to agency interpretive statements (i.e., one form of

78. Seidenfeld, *supra* note 35, at 375–85. Seidenfeld is not the first to suggest this kind of change. *See generally* Epstein, *supra* note 37; Hylas, *supra* note 39; McKee, *supra* note 39. R R R

79. Seidenfeld, *supra* note 35, at 388. R

80. *Id.*

81. *Id.* at 390.

82. *Id.* at 374.

83. *Id.* at 393–94.

84. *Id.* at 393.

85. Epstein, *supra* note 37, at 65. R

86. *Id.* at 68, 72.

guidance document): "Interpretive rules that command deference do have the force of law."[87]

Both Epstein's and Seidenfeld's views have much merit. First, they address head-on the current state of guidance "unreviewability," and ensure that most, if not all, guidance documents can be reviewed pre-enforcement. Second, they are fairly attuned to the time and resource constraints that agencies face as well as the benefits of guidance documents with respect to speed and flexibility. As noted above, Seidenfeld explains expressly how that is so, and Epstein notes the likelihood of a self-selection process: "A powerful selection process will be at work in this idealized system. Those guidances that pose no threat will not be challenged. Those that do will be challenged."[88]

Both, however, do have some shortcomings. For example, Stephen Johnson criticizes Seidenfeld's version of guidance document reform on several bases. First, he criticizes Seidenfeld for treating nonlegislative rules too much like legislative rules.[89] It may be, in the context of other agencies, that this criticism is stronger where there is a larger functional gap between legislative and nonlegislative rules. In the context of the FDA, however, and certainly under the proposal here, that is somewhat beside the point. Regulated entities and the FDA are, themselves, already treating nonlegislative rules like legislative rules. It makes sense, therefore, to treat them alike.

Second, Johnson criticizes direct substantive review because it will slow down the issuance process. This is so, Johnson says, because it will increase the amount of litigation[90] and increase the costs of nonlegislative rules by demanding the FDA compile a factual record.[91] As to the potential flood of litigation, while it is true that the FDA could be faced with more litigation, it is far from clear that it would be a "flood." First, as Epstein notes, it is likely that regulated entities would only challenge a small subset of drug and device regulations given cost-benefit analyses attendant to the drug and device approval processes. It stands to reason, and is at least intimated by the trade agency official comment highlighted in Section I.B, that if a company believes the lawfulness of new requirement is a toss-up, it would err on the side of letting it be. This is so

87. *Id.* at 67 (quoting Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1212 (2015) (Scalia, J., concurring)).

88. *Id.* at 49.

89. Johnson, *In Defense*, *supra* note 53, at 534. R

90. *Id.*

91. *Id.* at 535.

particularly if the consequence of being wrong is the denial or delay of FDA approval. Similarly, as noted in Section III.B, if, as indicated in interviews with Professor Parrillo, companies really want clarity, it would seem incongruous for them to then upset the apple cart through legal challenges unless the FDA's change is particularly onerous. Second, the Agency would likely adapt its guidance documents—whether by incorporating input from regulated parties or by narrowing the scope of its guidances—in an effort to stave off precisely this potential problem. Third, the method of issuance and judicial review outlined below should limit the length of litigation by determining the propriety of the guidance from a legal standpoint in short order. Fourth, litigation is not necessarily bad even if it slows down the FDA to some degree. Given the current dynamic of binding guidance, regulated parties should have the opportunity to challenge the FDA when it goes too far.

As to the second criticism that substantive review will slow down the process too much, while it may be the case that the Agency will need a greater factual record than it has now, that record is not so great and the procedural hurdles are not so high that its development will unduly delay the FDA. More particularly, by eliminating any specific method by which the FDA compiles its factual record, allowing the proposed draft guidance to be issued without factual or procedural hurdles on the front end, and limiting the nature of the factual record to relevant debates and other more general questions, the framework proposed here should limit the resources and time required for the FDA to compile its record.

More, however, could be said by Seidenfeld and Epstein in defense of guidance documents, and more attention could be paid to agencies' rationales for employing them. Additionally, neither addresses the problems attendant to draft guidance documents. Even if the judicial doctrines were augmented such that final draft guidance documents were "final" and "ripe," the question of what to do with draft guidance documents still would remain. In view of these shortcomings, this Note develops a framework in Part IV for issuance and judicial review of guidance documents, building on Seidenfeld's and Epstein's works. This framework addresses draft guidance issuance, ensures reviewability, and yet is sensitive to the benefits that flow from guidance documents to both the FDA and regulated entities.

Before turning to the framework in Part IV, however, Part III reframes the debate around guidance documents at the FDA. It argues that guidance documents not only serve a useful role as is, but

also that the challenges facing the FDA mean that guidance documents' role will continue to grow in importance going forward.

III.
REFRAMING THE DEBATE AROUND GUIDANCE DOCUMENTS AT THE FDA

Despite the issues bound up in the FDA's current use of guidance documents, any effort seriously to curtail their issuance would be a mistake. The FDA's traditional regulatory regime is now being foundationally challenged by technological and scientific advances. Depriving the FDA of the ability to act quickly and flexibly in response to those challenges would do much more harm than good to both regulated entities and regulatory beneficiaries (*i.e.*, patients and doctors). While I am not alone in believing that guidance documents are useful,[92] the following section is a more full-throated defense of the potential benefits of guidance documents given challenges now facing the FDA.

To that end, this section discusses the fact that the FDA now confronts a virtual technological and scientific revolution and that, absent a complete overhaul of the FDA, guidance documents may be the only way for the FDA to regulate successfully in face of these profound shifts in science and medicine.

A. Technological Innovation

The FDA is, admittedly, facing a number of challenges to its traditional regulatory regime.[93] Several of these challenges come in

92. *See* sources cited *supra* note 50. R

93. *See, e.g.*, Press Release, Scott Gottlieb, Comm'r, Food & Drug Admin. (Jan. 9, 2018), https://www.fda.gov/news-events/fda-voices-perspectives-fda-experts/reflections-landmark-year-medical-product-innovation-and-public-health-advances-and-looking-ahead [https://perma.cc/V8BG-5J9R] ("These new advances also present new challenges. At FDA, we're being confronted with the need to regulate highly novel areas of science like gene therapy, targeted medicine, cell-based regenerative medicine, and digital health; where our traditional approaches to product regulation may not be as well suited. To meet these new challenges, we're taking a fresh look at how we can adapt our customary approaches to regulation. We need to make sure that we're allowing beneficial new technologies to advance, while continuing to protect consumers as part of our product review processes."); Press Release, Scott Gottlieb, Comm'r, Food & Drug Admin. (Dec. 7, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587890.htm [https://perma.cc/JE4V-BH3P] ("We're finding that in some parts of our regulatory portfolio, our traditional approach to overseeing certain health care products does not easily fit the types of innovations that are being developed. In these cases, we must adapt and evolve our policies to make sure we continue to provide a gold standard for oversight, while enabling advancement of beneficial

the form of new medical technologies and targeted, "individualized" medicines. Although it is beyond the scope of this Note to explore fully the nature of the current "disruption" in the medical field, three examples serve to demonstrate this larger trend. These examples also serve to demonstrate the utility of guidance documents: guidance documents can address pressing needs in relatively short order, permitting products to get to market significantly faster and with a more tailored regulatory regime than would be possible under a rulemaking-only strategy.

First, an example from the medical device realm: Next Generation Sequencing ("NGS"), a kind of cutting-edge genetic test, poses unique challenges to the FDA's regulatory model. Barbara Evans, among others, has sought to bring attention to precisely this problem for several years. In a 2015 New England Journal of Medicine article, Evans argued that the FDA's present regulatory model is ill-equipped to regulate NGS because the current device regulations "simply do not add up to a comprehensive, modern framework to support continuous learning and nimble response."[94]

Second, an example from the pharmaceutical realm: targeted cancer therapies. Ordinarily, getting a drug to market takes years[95] and costs millions of dollars.[96] For all-purpose (*i.e.*, non-targeted)

innovations and greater consumer access to technologies that can improve their health."); Margaret A. Hamburg, *FDA's Program Alignment Addresses New Regulatory Challenges,* ORTHO SPINE NEWS (Oct. 9, 2014), http://www.orthospinenews.com/2014/10/09/fdas-program-alignment-addresses-new-regulatory-challenges/ [https://perma.cc/32XR-UFJ8] ("Over the last year, a group of senior FDA leaders, under my direction, were tasked to develop plans to modify FDA's functions and processes in order to address new regulatory challenges. Among these challenges are . . . . the ongoing trend of rapid scientific innovation and increased biomedical discovery."); Bob Roehr, *FDA Faces Regulatory Challenges with New Approaches to Medicine*, 348 BRITISH MED. J. at 1 (2014), http://www.bmj.com/content/bmj/348/bmj.g1530.full.pdf [https://perma.cc/6HFQ-N4VQ] ("The [FDA] faces unprecedented regulatory challenges not just with new products but with entirely new fields of activity that are likely to transform medicine in the decades to come.").

94. Barbara J. Evans et al., *The FDA and Genomic Tests – Getting the Regulation Right*, 372 NEW ENG. J. MED. 2258, 2260 (2015).

95. Rebecca S. Eisenberg, *Patents and Regulatory Exclusivity*, *in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 167, 169 (Patricia M. Danzon & Sean Nicholson eds., 2012) ("The FDA estimates that it takes on average 8 1/2 years to study and test a new drug before the FDA can approve it for sale to the public; industry estimates are even higher, ranging from 10 to 15 years.") (citations omitted).

96. Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 481 (2003) ("Recent estimates, which may err on the generous side, put

drugs, even if not the perfect solution, the FDA's traditional regulatory framework has worked reasonably well. Targeted cancer therapies, however, pose a serious challenge to that route. In short, targeted cancer therapies are designed around an individual's specific tumor and may be rendered useless if compelled to undergo a years-long approval process.[97]

Third, an example from the medical technology realm: Artificial Intelligence. As Jane Bambauer notes, "[p]redicting the future is a surefire way to embarrass oneself. But it is a relatively safe bet that Artificial Intelligence ("AI") will transform the practice of healthcare . . . . [because] healthcare is already being transformed by AI."[98] However, as Professor Bambauer continues, it is far from clear that the FDA is prepared for this transformation.[99] Increasingly, medical devices are looking like "knowledge devices."[100] That is, unlike traditional medical devices that mostly take measurements, medical devices are increasingly "analyz[ing] data (either preexisting or newly measured) and interpret[ing] the data to form opinions."[101] Despite this shift, the FDA is using the regulatory requirements associated with measurement devices and applying them to devices that do not fit that model—"the FDA is using the wrong baseline."[102]

B. Consequences of Changing Technology

These promising developments portend a healthier future. However, the degree of their success (*e.g.*, their safety, the speed

the average costs of developing a new drug to the point of new drug approval ('NDA') at approximately $800 million, after adjusting historical costs to present value to account for the time value of money.").

97. Press Release, Scott Gottlieb, Comm'r, Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on new FDA efforts to support more efficient development of targeted therapies (Dec. 15, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589248.htm [https://perma.cc/628S-YRL7] ("In recent years, the medical community has experienced a shift in the way health care is practiced. Rather than focusing solely on how to treat an overall disease type, medical innovators are now exploring how to tailor treatments that target unique characteristics of an individual's disease, such as the genetic profile of a person's tumor . . . . By providing clear guidance on the regulatory and scientific frameworks for product developers, safe and effective targeted treatments can be identified with scientifically valid tests and ultimately, made available to patients faster.").

98. Jane R. Bambauer, *Dr. Robot*, 51 U.C. Davis L. Rev. 383, 383 (2017).

99. *Id.* at 384.

100. *Id.* at 386.

101. *Id.*

102. *Id.* at 389.

with which they get on the market, their cost) depends, in no small measure, on the FDA's ability to regulate them well. As noted in the opening paragraph of Section III.A, commentators and FDA officials alike have suggested that the FDA's regulatory regime is not well suited to address these developments as currently constituted.[103]

The FDA should be commended for admitting the insufficiency of its regulatory regime and encouraged to alter its regulations accordingly. Unfortunately, forcing the FDA to proceed exclusively through traditional regulatory tools might well stifle the FDA's initiative. If the FDA were to proceed using only traditional tools of regulation—notice-and-comment procedures, for example—the likelihood that the FDA could adapt to these new challenges in any sort of quick timeframe is minimal.[104] Many commentators have noted rule creation "ossification," elaborating that promulgating a notice-and-comment rule can take years to accomplish if it is accomplished at all.[105] Rather than force the FDA to double down on its current regulations or work through notice-and-comment procedures (thereby potentially leaving the new drugs and devices unregulated, poorly regulated, or off-market) or adjudication (leaving open the possibility of considerable inconsistency) the FDA should have tools at its disposal to quickly get a regulatory handle on these drugs and devices.

Additionally, Professor Eisenberg and others have written about the important role that the FDA plays in medical innova-

103. *See* sources cited *supra* note 50; *see also* FOOD & DRUG ADMIN. SUBCOMM. ON SCI. & TECH., FDA SCI. & MISSION AT RISK 24 (2007) ("The FDA must develop a program to manage 'new science' that will provide a standardized approach to enable the FDA to address all emerging sciences and technologies."). R

104. According to a 2009 Government Accountability Office Report, it may take 3.5 to 4 years for the FDA to complete a "straightforward rulemaking." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-205, FED. RULEMAKING: IMPROVEMENTS NEEDED TO MONITORING AND EVALUATION OF RULES DEVELOPMENT AS WELL AS TO THE TRANSPARENCY OF OMB REGULATORY REVIEWS 17 (2009), https://www.gao.gov/assets/290/288538.pdf [https://perma.cc/S4Y4-5A8Q]. Further, FDA personnel noted that speed and resource conversation played a major role in their choice to proceed by guidance. *See* PARRILLO, *supra* note 20, at 7, 31 n.58 (discussing the value of guidances in conserving resources relative to rules and the fact that guidance could be produced quickly). R

105. *See, e.g.*, PARRILLO, *supra* note 20, at 147 ("[A]n FDA Office of Chief Counsel official [said], whereas legislative rulemaking was criticized for being 'ossified,' it was possible to issue guidance 'pretty quickly.'"); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1385 (1992) ("During the last fifteen years the rulemaking process has become increasingly rigid and burdensome."). R

tion.[106] Eisenberg, for example, has written that the FDA can foster innovation through mandating the production of high-quality information.[107] It may well be the case, however, that the FDA cannot perform such a function successfully unless it adapts to rapidly changing technologies and scientific discoveries.[108] Shoehorning novel devices and drugs into old regulatory frameworks is an ominous recipe incongruent with fostering innovation.

Guidance documents can fill this regulatory void. In fact, the FDA's continued and extensive use of guidance documents should be viewed as sensible and welcome from a practical perspective.[109] And indeed, at least some regulated entities (and Congress)[110] appear to desire guidance documents. A congressional staffer, in interviews conducted by Professor Parrillo, stated that "even those who argued that FDA improperly over-used guidance on some subjects simultaneously wanted the agency to issue *more* guidance *faster* on other subjects."[111] And again, an FDA Office of Policy official

106. *See, e.g.*, Rebecca S. Eisenberg & W. Nicholson Price II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCIENCES 3 (2017); Rebecca S. Eisenberg, *The Role of the FDA In Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007); Rebecca S. Eisenberg, *Shifting Institutional Roles in Biomedical Innovation in a Learning Healthcare System* (U. Mich. Law & Econ. Research Paper Series, Paper No. 17-011, 2017).

107. Eisenberg, *The Role of the FDA In Innovation Policy*, *supra* note 106, at 347 ("[D]rug regulation has come to play [an important role] in *promoting* a valuable form of pharmaceutical innovation—the development of credible information about the effects of drugs.").

108. *See* Eisenberg, *Shifting Institutional Roles in Biomedical Innovation in a Learning Healthcare System*, *supra* note 106 *passim* (discussing how the healthcare system and the FDA are beginning to shift in response technological changes.); *see, e.g.*, *id.* at 26 ("The transformation [caused by a learning healthcare system] is apparent at FDA, which has been gradually shifting the evidentiary basis for its regulatory decisions about an expanding list of technologies from reliance on premarket RCTs to earlier approval coupled with ongoing postapproval studies.").

109. Indeed, the FDA has already begun to address the regulatory challenges posed by NGS devices Evans' targeted therapies through guidance documents. Although it did not precisely adopt Evans' suggestions, the FDA issued a series of draft guidance documents during the year after Evans' article to begin informing industry how it was thinking about NGSs. Press Release, Food & Drug Admin., FDA Advances Precision Medicine Initiative by issuing draft guidance on next generation sequencing-based tests (July 6, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm509814.htm [https://perma.cc/E4WM-33DG]. And, in mid-2017, the FDA began to outline its thoughts on how targeted cancer therapies might be regulated. *See generally* Gottlieb, *supra* note 97.

110. *See* Noah, *supra* note 21, at 109 ("In short, statutory amendments enacted during the last couple of decades include more than thirty separate provisions that invite or require guidance-making by the FDA."). R

111. PARRILLO, *supra* note 20, at 36. R

"acknowledge[d] that FDA does not provide as much guidance as industry would like."[112]

One reason for this desire is that the FDA, despite having a substantial compass, is a relatively resource-constrained agency.[113] Thus, given the disparities in resources required to make one as compared to the other, guidance documents permit the FDA to accomplish its mandate in a way that rulemaking alone would not.[114] A second and related reason is the speed with which guidance documents can be issued and the increased likelihood that they will be tailored to current science. "[A]n executive at a drug manufacturer said he could see the argument 'in the abstract' for why legislative rulemaking was better, but . . . said . . . that he preferred to know what FDA was thinking 'rather than wait twenty years' for a legislative rulemaking to finish."[115] Officials from the FDA acknowledged as much as well. For example, Janet Woodcock, the current Director of the Center for Drug Evaluation and Research, noted that "guidance can be provided closer to 'real time' than can rulemaking, which takes a long time; by the time you complete a rulemaking, 'the science may have changed.'"[116]

Another reason is the industry's overarching desire for consistency and a clear path forward. After conducting an interview with Coleen Klasmeier, the current head of Sidley Austin's FDA practice and a former FDA Office of Chief Counsel attorney, Professor Parrillo relayed Klasmeier's sense of industry's view, noting: "[I]t was

112. *Id.* at 36 & n.78.

113. *See, e.g.*, Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 924 (2008) (commenting that the FDA has, historically, struggled "to protect the public health with its limited statutory powers and often inadequate resources"); Lewis, *supra* note 1, at 538 ("[The] FDA operates under severe resource constraints."); PARRILLO, *supra* note 20, at 12 & n.19 (quoting an interviewee who describes the agency as "resource-constrained"). R R

114. *See, e.g.*, PARRILLO, *supra* note 20, at 31 & n.59 (congressional staffer noting "FDA personnel say that legislative rulemaking is cumbersome and they will do guidance if they can"); Lewis, *supra* note 1, at 538 & n.268 ("Many FDA officials have therefore agreed that using guidance instead confers massive cost advantages to the agency."); Franklin, *supra* note 38, at 304 & n.150 ("[N]onlegislative rules avoid opportunity costs by freeing up agencies to redirect resources—resources that would otherwise be expended in the cumbersome process of notice-and-comment rulemaking—toward potentially more important priorities."); Seidenfeld, *supra* note 35, at 368 ("Given the limited resources available to agencies, I suspect that many would instruct their staff members to avoid issuing guidance documents unless the agency deemed the guidance to be absolutely necessary."). R R R R

115. PARRILLO, *supra* note 20, at 33. R

116. *Id.* at 31 & n.58; *see also id.* at 95 (discussing the need to keep up with scientific change).

'far more common' for the complaint of industry to be that an FDA reviewer was *not* following guidance than that the reviewer was following it too closely. Industry . . . just wants 'certainty' and a 'level playing field.'"[117] Additionally, Parrillo relayed that a former senior FDA official "observed that, although some guidance had to be flexible because science is changing, 'flexibility' is not a 'primary interest' for pharmaceutical companies; instead they 'want certainty'—'tell me what to do, and I'll do it.'"[118]

Altogether, guidance documents could be viewed as occupying a sweet spot where the needs of the FDA and the interests of firms and regulatory beneficiaries (*i.e.*, patients and doctors) converge. At a minimum, if not a sweet spot, guidance documents could, in the absence of an expedited rulemaking process, be viewed as the best among least-best options. They permit the FDA to act quickly and creatively while allowing the Agency to tailor its regulations to promote safety and innovation.[119] Furthermore, guidance documents work prospectively, and so they should not interfere with the settled interests of parties whose devices do not fit clearly within current regulatory guidelines. Rather, guidance documents will promote stability by offering the FDA's thoughts on how to proceed with novel drugs and devices, encourage speed by allowing the FDA to address new issues quickly, and ensure safety both by permitting tailored regulations and by ensuring worthwhile devices reach the market expeditiously.

Accepting guidance documents will mean accepting that regulated firms might treat these documents as binding, regardless of whether the FDA intends them to be so. Given Professor Parrillo's extensive research, however, that reality may not be as bad as it sounds. To an extent, his investigation suggests that regulated entities care less about the method by which they are told to act and more that they can be sure they will, in short order, be given a clear, reliable path that is more or less equally applied.[120] In a sense then, severely curtailing guidance documents without some com-

117. *Id.* at 95.

118. *Id*. *See also* 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, 29 (2005) ("In the majority of cases, guidances are treated the same way as rules (that is, industry follows them as if they were legally binding) because industry desires consistency.").

119. *See* sources cited *supra* note 50 (describing the value of guidance). R

120. *See supra* pp. 27–28; *see also* Seiguer & Smith, *supra* note 118, at 29–30 (quoting an "industry representative" who said the industry does not care whether the FDA's pronouncements come as a guidance or as a regulation, so long as it can rely on them).

mensurate change in the FDA's regulatory structure is tantamount to cutting off the nose to spite the face.[121] At a time when the FDA is facing daunting technological and scientific changes and demands to get products to market cheaper and faster persist, forcing the FDA to go through years-long notice-and-comment rulemaking would render its role largely impossible while, it seems, simultaneously doing exactly the opposite of what regulated entities desire.

This is not to say the entire current state of affairs is acceptable. It is not, and there are many instances in which regulated entities object to regulations both in substance and in form. But it is to say that any reform to guidance documents must be sensitive to the important role they currently play, and must continue to play if the FDA is to accomplish its broad mandate with a level of reasonable success.

As will be explained below, however, reforming the issuance and judicial review of guidance documents should alleviate some concerns with respect to "bindingness" and uncertainty. Not by making them less coercive *per se*, but by ensuring that regulated entities can judicially challenge documents that impose greater costs than benefits, are beyond the permissible scope of the authorizing statute or rule, and/or lack a sufficient factual basis.

121. To put a finer point on it, in the 21st Century Cures Act, Pub. L. No. 114-225 (2016), Congress tasked the FDA with reassessing its regulatory model with respect to technologies and innovation. *See*, Press Release, Scott Gottlieb, Comm'r, Food & Drug Admin, How FDA Plans to Help Consumers Capitalize on Advances in Science (July 7, 2017), https://www.fda.gov/news-events/fda-voices-perspectives-fda-experts/how-fda-plans-help-consumers-capitalize-advances-science [https://perma.cc/26GT-FE69] ("'Cures' provides FDA with tools aimed at modernizing our regulatory programs."). Part of that reassessment led the FDA to believe it needs to take more tailored approaches to regulating drugs and devices. In a conference on the FDA's PreCert Program, discussed briefly in Section IV.A *infra*, the director of Center for Devices and Radiological Health, Jeffrey Shuren, explained, pursuant to the Cures Act, the idea of "flexible regulatory paradigms." Jeffrey Shuren, Director, Ctr. for Devices and Radiological Health, Remarks at the Fostering Digital Health Innovation: Developing the Software Precertification Program Public Workshop 18 (Jan. 30, 2018), https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM600093.pdf [https://perma.cc/FP2R-9EUD]. He elaborated, "The idea is rather than take technologies and put them down in cookie cutter pathways, design the regulatory paradigm around the technology. What are its unique evidence generation needs, patient access needs, innovation cycles?" *Id.* Without guidance documents leading the way, it is hard to see how the FDA will accomplish this task. Thus, a Congress that seeks seriously to curtail the use of guidance documents both giveth (the mandate) and taketh (the tools to effectuate it). While such a situation may make for good political optics, it does nothing to advance the interests of the FDA, regulated entities, or regulatory beneficiaries.

IV.
FRAMEWORK FOR ISSUANCE AND JUDICIAL REVIEW

Under my proposal, guidance document issuance and review would occur in two stages. First, draft guidance documents would lay out the FDA's guidance and the legal basis for it. That legal basis would be subject to immediate judicial review, with the Agency's interpretation accorded *Skidmore*[122] deference. Second, after a set period of time, the draft would either be repealed or replaced by a final guidance. The final guidance would also be subject to judicial review but only as to its factual basis, since its legal review would have been either foregone or completed at stage one. At this second stage, a modified *State Farm*[123] arbitrary and capricious standard of review would apply. Consequently, the final guidance would need to contain a factual basis, the breadth and depth of which would allow it to withstand this modified arbitrary and capricious standard of review.

The bifurcated process can be viewed analogically through a *Chevron* lens. Without wading too deeply into how many steps are involved in a *Chevron* analysis, I will borrow loosely from Professor Catherine Sharkey's recent proposal that infuses the currently murky *Chevron* Two-Step framework with a *State Farm* arbitrary and capricious review at Step Two.[124] As a general matter, this means that courts should scrutinize the legal basis for the Agency's action at Step One,[125] and scrutinize the factual foundation for the administrative action at Step Two under a *State Farm* standard of review.[126]

122. Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (stating that agency interpretations should be afforded the weight they deserve given "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade").

123. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42–43 (1983).

124. Catherine M. Sharkey, *Cutting in on the* Chevron *Two-Step*, 86 FORDHAM L. REV. 2359 (2018).

125. While the focus of her paper is not on Step One, Professor Sharkey does appear to suggest that an agency's legal interpretation should be accorded *Skidmore* deference at Step One. *See id.* at 2375 n.72 ("[A] purely legal statutory analysis should not suffice where such an analysis inevitably hinges on policy choices dependent upon facts which the agency should have to justify. Alternatively, an agency's legal interpretations should be subject to *Skidmore* deference (at *Chevron* Step One), not mandatory deference at Step Two."). In any event, that is the standard I adopt here.

126. *Id.* at 2384 ("[C]ourts at Step Two should demand the relevant agencies' *policy*-relevant analyses and not instead be lulled into accepting agencies' *legal* in-

The process of review suggested here is a bit unusual procedurally. Specifically, the first stage of judicial review would be tantamount to a motion to dismiss, and the second stage of judicial review would deal with the "facts" underpinning the guidance. Despite the unusual format, I believe bifurcating court procedures and guidance documents as described is a sensible means of increasing guidance document legitimacy without unduly hampering the FDA's incentives to issue them. The overall structure and the benefits that flow from it are explained in the following sections.

A. Draft Issuance and Review

1. Draft Content and Standard of Review

As noted above, draft guidance documents often remain in draft form for years.[127] Indeed, some are never converted into final guidances at all but nevertheless lead regulated entities to comply. This state of affairs leads to uncertainty among regulated entities and even more limited opportunities for review by courts. My proposal seeks to give draft guidance documents a different role from that which they currently occupy, one that would make them meaningfully distinct from final guidance documents and ensure that draft guidances are either finalized or repealed.

In practice, this would mean that, rather than act as an early run of final guidance documents, draft guidances would pronounce only the meaning of certain text, new factors the Agency will consider, or other novel policy positions and the legal bases for those pronouncements. Thus, at *Chevron* Step One, *i.e.*, the draft guidance stage, the reviewing court will decide "whether the [A]gency's construction is permissible as a matter of statutory interpretation,"[128] in light of the "[A]gencies' legal interpretations on the basis of statutory text, legislative history, and canons of statutory interpretation."[129]

Even though draft guidances would only address the legal bases for the new pronouncements, I am not convinced, unlike Professor Epstein, that they should be reviewed de novo. While it is true that guidance documents can present pure questions of law, "[a]s *Chevron* itself illustrates, the resolution of ambiguity in a statu-

terpretations on the basis of statutory text, legislative history, and canons of statutory interpretation (which might guide courts at Step One).").

127. *See supra* notes 41–46 and accompanying text. R

128. Matthew C. Stephenson & Adrian Vermeule, Chevron *Has Only One Step*, 95 VA. L. REV. 597, 599 (2009).

129. Sharkey, *supra* note 124, at 2384.

tory text is often more a question of policy than of law."[130] Agencies should, therefore, have some policy space within which to operate when they are interpreting ambiguous statutes or their own rules and regulations. Peter Strauss has made an argument along these lines. He explains that, in his view, *Chevron* gives rise to "space" in which "an administrative agency has been statutorily empowered to act in a manner that creates legal obligations or constraints;" and *Skidmore* gives rise to "weight" which "addresses the possibility that an agency's view on a given statutory question may in itself warrant respect by judges who themselves have ultimate interpretive authority."[131]

With respect to draft guidance review, under my framework this means that "Step One defines boundaries for the realm of 'reasonable' agency interpretations,"[132] where the court should accord the FDA's legal interpretation *Skidmore* deference and defer to it if the court finds the statute, rule, or regulation can bear the Agency's interpretation under the *Skidmore* standard.[133] Further, as intimated, the analysis would cover the Agency's own rules and regulations in addition to statutes, thereby eliminating the extreme deference that otherwise might be accorded to the Agency's interpretations under *Auer* or *Seminole Rock* deference.[134] Once the court has determined that the FDA's legal analysis supports its draft guidance document as a legal matter, the FDA could proceed to the final guidance stage.

Because the review of draft guidance documents would turn only on questions of statutory interpretation, the first step of judicial review should be relatively straightforward. For the same reason, regulated entities should not need much time to challenge them. Therefore, after the issuance of a draft guidance document,

130. Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 696 (1991).

131. Peter L. Strauss, *"Deference" is Too Confusing - Let's Call Them "*Chevron *Space" and "*Skidmore *Weight,"* 112 COLUM. L. REV. 1143, 1145 (2012).

132. Sharkey, *supra* note 124, at 2387 (summarizing in part Kenneth A. Bamberger & Peter L. Strauss, Chevron*'s Two Steps*, 95 VA. L. REV. 611 (2009)).

133. Skidmore, *supra* note 122, at 140.

134. Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 413–14 (1945) ("Since this involves an interpretation of an administrative regulation a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt . . . . [T]he ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation."); Auer v. Robbins, 519 U.S. 452, 461 (1997) ("Because the salary-basis test is a creature of the Secretary's own regulations, his interpretation of it is, under our jurisprudence, controlling unless 'plainly erroneous or inconsistent with the regulation.'") (internal quotations omitted). *See also* Chase Bank USA, N.A. v. McCoy, 562 U.S. 195 (2011).

all parties objecting to its legal basis would have two months[135] from the date of issuance to challenge the document. Such a limitation is not unheard of. The EPA often limits the timeframe for challenging its legislative rules, with some cutoffs running as short as forty-five days.[136] So too does the FDA, on occasion.[137] Given the commonality of potential objections, reviewing courts would also have the ability to consolidate legal challenges at their discretion.[138]

2. Standing

In order for this direct substantive review of draft guidance to occur, however, guidance documents would need to be "final" and "ripe." I address each issue in turn.

The judiciary's concern with finality of agency action is eminently sensible and—not to mention—statutorily mandated.[139] This sensibility holds true whether viewed from a conservation of resources, separation of powers, or Article III justiciability standpoint.[140] In the FDA context, however, there are good reasons to believe that the reality on the ground does not align with the usual concerns. There are three reasons for this: guidance documents are already treated as final, guidance issuance is centralized to the FDA, and guidance challenges should not be too numerous.

First, as previously noted,[141] both the FDA and regulated entities are already treating guidance documents as final regardless of whether they technically are – with good reason, too. They often

135. As with the six-month limit below, the timing could be changed. Perhaps more significant guidance documents would have longer timeframes and less consequential ones would have shorter ones. Nevertheless, two months to file what is effectively a motion to dismiss seems sufficient.

136. *See* Johnson, *supra* note 39, at 712 n.84 (citing environmental laws imposing time restrictions on challenges to rules issued under them). R

137. *See, e.g.*, The United States Federal Food, Drug, and Cosmetic Act § 912(a)(1)(A–B), 21 U.S.C. § 387l (limiting the filing date for petitions for judicial review of regulations "establishing, amending, or revoking a tobacco product standard; or . . . . a denial of an application under section [910(c)]" to thirty days after regulation issuance or application denial).

138. *Cf.* FED. R. APP. P. 3(b)(2) ("When the parties have filed separate timely notices of appeal, the appeals may be joined or consolidated by the court of appeals.").

139. Administrative Procedure Act of 1946 § 704, 5 U.S.C. § 704 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.").

140. *See, e.g.*, Seidenfeld, *supra* note 35, at 376 ("The foundation for [one prong of the finality test] is avoidance of judicial interference with agency decision making until the agency has completed its own resolution."). R

141. *See supra* Section I.B.

remain on the "books" for years[142] and affect party behavior notwithstanding any tentative and noncommittal language.[143] As a practical matter, then, if the relevant parties are treating them as final, the judiciary ought to as well. The FDA should not be able to skirt judicial review by portraying an air of uncertainty incommensurate with reality.[144]

Furthermore, as explained in Section IV.E, guidance documents would be further legitimized and stabilized under my proposal. For the same reasons, then, courts should treat them as final under my proposal as well. That is not to say that guidances will not change. They will. But so will rules, and courts ought not to elide

142. My review of withdrawn guidances listed on the FDA's website reveals the following. Since 1977, listed guidance documents pertaining to drugs have been withdrawn, on average, 11.34 years after issuance (standard deviation of 6.5, N=105) with the longest guidance lasting just shy of twenty-seven years and the shortest guidance lasting just shy of six months. Since 2000, i.e., year of GGP's codification, the listed guidance documents were withdrawn, on average, just shy of 7.5 years after issuance (standard deviation of 4.36, N=55), with the longest lasting just shy of fifteen years and the shortest lasting just shy of six months (the same guidance as above). Since 1977 listed guidances pertaining to devices are with withdrawn, on average, 15.9 years after issuance (standard deviation of 8.88, N=117) with the longest lasting just shy of forty years and the shortest lasting a little more than four months. Since 2000, the listed guidance documents were withdrawn, on average, just shy of eight years after issuance (standard deviation of 4.40, N=52), with the longest lasting about 17.5 years, and the shortest lasting a little more than four months (the same guidance as above). I note that there is something of a discernable trend towards guidances being withdrawn more quickly in the last three years than in years prior. It remains to be seen whether that will continue. Underlying drug data available at: FOOD & DRUG ADMIN., WITHDRAWN GUIDANCES (DRUGS), https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm528107.htm [https://perma.cc/M7RT-3AYB]. Underlying device data available at: FOOD & DRUG ADMIN., WITHDRAWN GUIDANCE, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm [https://perma.cc/3Q45-D7NR].

143. *Cf.* McKee, *supra* note 39, at 384 ("Even if a court found the document to [meet the first prong of the finality test], it would not likely qualify . . . . [under the] second prong of the overly complex finality requirements of *Bennett*. This is at least partially because the FDA inserted two disclaimers stating the document is not legally binding, and used nonmandatory terms like 'should' instead of 'must' when describing suggestions for producers. This seemingly tentative language does not disguise reality; the FDA produced the guidance because it expects that producers will follow its suggestions."). R

144. *See, e.g.*, Noah, *supra* note 113, at 907 n.34 (listing two cases in which the FDA argued its guidances were not final). *See also, e.g.*, BBK Tobacco & Foods, LLP v. U.S. Food & Drug Admin., 672 F. Supp. 2d 969 (D. Ariz. 2009) (finding the FDA's guidance was not final); Mallinckrodt Inc. v. United States Food & Drug Admin., No. CV DKC 14-3607, 2015 WL 13091366, at *10 (D. Md. July 29, 2015) (same).

deliberate change and incompleteness. The fact that the agency may change a document does not mean that one currently "in force," as it were, is not final agency action with respect to that document.

Second, guidances are centralized at the FDA.[145] Thus, unlike another agency where field officers and the like might issue them or where they are more readily subject to change, an FDA guidance document is far from a perfunctory piece of work. This would be truer still under my proposal where they function as quasi-rules. Third, as elaborated in Section IV.E.i, guidance document challenges should not be too numerous. Thus, concerns stemming from conservation of judicial resources should be mitigated as well.

Because, however, this proposal speaks only to the FDA and courts must deal with guidances from all agencies, I believe the FDA should make explicit that guidances issued pursuant to the proposed framework at both the draft and the final guidance stage are "final" for the purposes of judicial review. Such a statement would streamline review of FDA guidance documents without affecting those of other agencies, and it would have the added benefit of saving all parties from having to brief the issue continuously.[146]

145. FDA guidances contain language noting that the document represents the "*Agency's* thinking on a particular subject" (emphasis added); *see also* 21 U.S.C. § 371(h) *et seq*.

146. Concerns related to finality—indeed many concerns related to the reviewability of guidance documents—might well be addressed if regulated entities could bring constitutional separation of powers challenges. *Cf.* Kent H. Barnett, *Standing for (and up to) Separation of Powers*, 91 INDIANA L.J., 665, 670 (2016) (arguing that regulated entities should be able to bring separation of powers challenges and that "[structural] challenges rest comfortably with existing standing and cause-of-action doctrine," as they are analogous to "ubiquitous procedural challenges," "fall comfortably within structural safeguards' 'zone of interests,'" and "neither founding history nor historical practice is to the contrary"); *see also id.* at 694–710. In the guidance context, such a challenge would have the advantage of removing certain statutory standing barriers that currently limit (or eliminate) guidance challenges—"finality" under the APA in particular—by transforming standing issues into merits questions. For example, constitutional standing ordinarily requires an injury-in-fact, a showing that the government's wrong caused the injury, and a demonstration that the harm can be remedied by a court. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992). For guidance documents, these elements could be shown through allegations that, by promulgating a rule *ultra vires* which is de facto binding, the FDA violated separation of powers principles and that violation, coupled with the plaintiff's cost of compliance and inability otherwise to seek redress, makes out a constitutional violation, causation, and injury-in-fact. Alternatively, this could possibly be accomplished by curtailing judicial review [*cf.* Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1213–25 (2015) (Thomas, J., concurring) (arguing that giving deference to agency interpretations of regulations usurps the judiciary's constitutional role and violates separation of powers principles)]. Thus,

As it stands now, however, an FDA pronouncement stating that a guidance document is final would likely be insufficient to render it so. Under *Bennett v. Spear*, agency action is "final" if it is the " 'consummation' of the agency's decisionmaking process"[147] *and* "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.' "[148] Thus, while the Agency's statement of finality might well satisfy prong one, such a statement might not suffice at prong two, and both conditions must be met. Without wading too deeply into which of the two is preferable, several scholars have argued that the second *Bennett* prong should be altered[149] or eliminated.[150] I agree. With the doctrine altered such that prong one is the primary (or only) inquiry, a statement by the FDA that its draft and final guidances are final for the purposes of judicial review should suffice to make most if not all FDA guidances reviewable, while leaving other agencies sufficient play in the joints.

With respect to ripeness, Seidenfeld adopts the current distinction between rules that "directly address regulated entities' conduct, which almost always are ripe," and those that "have only secondary effects on conduct, which are not."[151] This seems like a reasonable limiting principle. Additionally, as a general matter, Seidenfeld states that "challenges to nonlegislative rules that specify how the agency views a matter of policy or interpretation generally should be ripe."[152] Further, Seidenfeld suggests that hardship sufficient to challenge a guidance document can stem from guidances that are pragmatically binding, and that courts should not block guidances from arbitrary and capricious review due to uncertainty in how they will be applied.[153] These appear to be sensible altera-

rather than have APA "finality" be a question of justiciability, it becomes part-and-parcel of causation. Put another way, the injured party and the FDA would likely argue about whether, *inter alia*, the regulated entity actually had to comply. Whether the guidance was binding and final would seem to be central to that argument as a matter of proof, but it would have limited bearing at the pleading stage – certainly as compared to the current state of affairs. It is beyond the scope of this paper to explore this avenue further, but it appears to be an alternative worthy of further investigation.

147. Bennett v. Spear, 520 U.S. 154, 178 (1997) (quoting Chi & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948)).

148. *Id.* (citing Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

149. *See, e.g.*, Hylas, *supra* note 39 *passim*. R

150. *See, e.g.*, McKee, *supra* note 39 *passim*; Seidenfeld, *supra* note 35, at 380. R

151. Seidenfeld, *supra* note 35, at 381. R

152. *Id.*

153. *Id.* at 383.

tions in the doctrine, geared towards increasing review, a goal this paper shares.

3. Sunset Provision and Response Obligation

To keep draft documents from remaining in force, so to speak, without being finalized or reviewed, all draft guidance documents also would have to be issued with sunset provisions. To wit, the Agency would have something like six months from the end of litigation challenging the draft guidance, or six months after the two-month window for challenges closes, within which it must either repeal the draft guidance or replace it with a final guidance. While six months is not the only possible timeline, some impetus to usher the process along must exist.[154]

Finally, during the draft period, the FDA may solicit feedback on the new regulation, but it is under no obligation to do so and need not respond to the feedback it receives. The primary reason for this is speed. A comment period with an obligation to respond would unduly hamper the speed at which the FDA can regulate and would effectively transform guidance documents into notice-and-comment rules. Additionally, because regulated parties can challenge the guidance document immediately, presumably any legal concern that might otherwise have been submitted as a comment could instead be brought as a legal challenge at stage one. Also, if, for example, a comment suggests that the FDA ought to consider a particular important factual issue and the Agency fails to do so, the concerned party, as will be explained below, can bring a suit at the final guidance stage arguing the FDA's action was arbitrary and capricious.

I understand that the lack of a mandated comment period or obligation to respond could be fertile ground for objecting to these proposed draft guidance changes. In light of that, I offer the following four responses. First, as Seidenfeld explained, one issue with a lack of input is that it blocks regulated entities who are not party to informal channels of communication from participating and instead favors "repeat players."[155] The drug and device industry, however, is largely comprised of "repeat players,"[156] for whom a

154. Professor Mendelson also suggested six months to respond to petitions related to guidance documents. *See* Mendelson, *supra* note 48, at 439. R

155. Seidenfeld, *supra* note 35, at 342. R

156. *See* Rakoff, *supra* note 19, at 169–70 ("In this highly regulated industry, in which all the players—including the agency, the drug companies, and even the representatives of consumers—are repeat players, it may well be that 'the force of law,' in the strict sense of enforceability in court, is of little value compared to the R

strong relationship with the FDA is nearly paramount.[157] Additionally, the comment process already is "dominated by insiders."[158] Further still, some commentators have noted that agencies have more or less already set the policy in stone by the time the comment period is open.[159] Taken together, removing a comment period may not be as problematic in reality as it seems at first blush. Smaller entities often do not comment to begin with, and as an industry composed largely of familiar faces and prone to "revolving doors," informal communications may occur in both directions in any event.

Second, as elaborated by Seidenfeld himself, immediate review of guidance documents under a modified form of arbitrary and capricious review "holds the potential for encouraging agencies to consult with stakeholders who are not repeat players or politically powerful groups when developing guidance, as well as to seriously consider the impacts of such guidance on these stakeholders."[160] Indeed, the FDA has reasons to want to avoid litigation: limited resources, legitimacy concerns, and so forth. Likewise, by working with regulated entities, the FDA can, in a sense, outsource its labor by having the firms provide some of the factual resources on which the FDA can build its guidance.

Third, in *Fixing Innovation Policy: A Structural Perspective*, Professors Rai and Benjamin closely examined the value of the comment process in the context of innovation. After reviewing three FCC rulemakings that focused on innovation and garnered significant public attention, Rai and Benjamin concluded that "the results of the available theoretical and empirical work, including [their] own, strongly suggest that an APA-style comment process is not essential,

'force of law' in the practical sense as dictated by existing relationships."); PARRILLO, *supra* note 20, at 54 ("As to why the firms followed the guidance, [an official at a national public interest organization] said it was partly because . . . . the firms were 'repeat players' at the FDA, dealing with the agency on multiple issues including pre-approvals and needing to maintain relationships at a reasonable level."); *id.* at 118 (The "general counsel of GlaxoSmithKline said you have to be really careful with appeals within FDA, because all the companies are 'repeat players.'"). R

157. *See* PARRILLO, *supra* note 20, at 117–19, 126, 175 (discussing the perceived importance of relationships with the FDA). R

158. Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 72 & n.279 (2008) ("Many commentators over the years have noted that the vast majority of rulemakings attract few or no individual comments, and that the comment process is thus dominated by insiders.").

159. *See, e.g.*, Franklin, *supra* note 38, at 317 (discussing observers, such as Donald Elliott, who "note that nowadays most rules have in effect been finalized long before the agency issues its notice of proposed rulemaking"). R

160. Seidenfeld, *supra* note 35, at 385. R

or even particularly helpful, for purposes of improving innovation regulation."[161] To the extent Professors Rai and Benjamin's findings can be extrapolated to comments on other agencies' pronouncements, or at least to those of the FDA, the loss of commenting might not be quite so problematic, at least not as it pertains to the FDA's role in fostering innovation through regulation.

Fourth, although it does not appear that the FDA is currently using the procedure widely, the FDA has sought on a few recent occasions to employ pilot programs when testing new methods of regulation. A more expansive use of pilot programs may be a way for the FDA to obtain meaningful input from regulated entities in the absence of a comment period. Take, for example, the PreCert program for medical software developers. The FDA explained:

> Digital health technology has become a new health care revolution . . . . At the FDA, we recognize this revolution and are reimagining our oversight of digital health technology to help provide patients with timely access to high-quality, safe, and effective digital health products . . . . FDA's traditional approach to moderate and higher-risk, hardware-based medical devices is not well suited for the faster and iterative design, development, and validation used for software products.[162]

To that end, the FDA developed a program that ultimately allowed nine creators of medical digital health technology to participate in a program to help, *inter alia*, "[e]nable a modern and tailored approach that allows software iterations and changes to occur in a timely fashion."[163] This sort of cooperative framework, then, could be a promising method to develop quick and relevant regulation without the cost and time burdens associated with comment periods and response obligations.

Finally, it should be noted that these challenges might look different for the two categories of pronouncements that comprise guidance documents.[164] Interpretive statements, as Professor Epstein

161. Benjamin & Rai, *supra* note 158, at 75.

162. FOOD & DRUG ADMIN., DIGITAL HEALTH SOFTWARE PRECERTIFICATION (PRE-CERT) PROGRAM, https://web.archive.org/web/20180227214203/https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265 [https://perma.cc/24VH-ADBP].

163. FOOD & DRUG ADMIN., DIGITAL HEALTH SOFTWARE PRECERTIFICATION (PRE-CERT) PROGRAM, https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/Default.htm [https://perma.cc/R5VQ-6QFS] (listing the nine companies).

164. *See* sources cited *supra* note 36. R

noted, are often primed for legal analysis as they tend to be traditional questions of statutory construction.[165] Policy statements may present less clear-cut questions of statutory interpretation; however, "in most cases, their precatory language does not hide how the agency intends for the rule [flowing from the policy statement] to operate."[166] Nevertheless, to the extent policy statements do not present clean statutory interpretation questions, they will be swept up and challengeable at the final guidance stage.

B. Final Guidance Issuance and Review

After the draft guidance time period has elapsed, the FDA will then have to replace it with a final guidance document. The final guidance, unlike the draft, must present the factual and/or policy bases for the new regulation.

To continue the *Chevron* analogy as relayed by Professor Sharkey, this stage of review would be akin to *Chevron* Step Two. At *Chevron* Step Two, *i.e.*, the final guidance stage, the court will employ arbitrary and capricious review.[167] Here, however, the arbitrary and capricious review will follow Seidenfeld's model. Put succinctly, "[r]easoned decisionmaking of guidance documents [would] mandate that agencies explain actions in terms of factors that are relevant and alternatives that are plausible given the state of knowledge available to the agency when it acted,"[168] in view of the knowledge of an individual or company well-versed in the field.

As Professor Seidenfeld noted, perhaps the major difficulty presented by direct substantive review is how to define the record. On the one hand, if the FDA is permitted to present a severely limited factual record, then the door is open to arbitrary and capricious acts. Similarly, the FDA would be permitted to issue regulations untethered from the actual dangers presented by the drug or device and potentially bog down the approval process. If, on the other hand, the FDA is required to present a fully-fledged factual record akin to what it would have to produce when issuing a rule, two of the major advantages of proceeding through guidance—speed and resource conservation—would be sacrificed.

165. Epstein, *supra* note 37, at 65 ("We are not dealing with how to make general standards more concrete on questions as, for example, how to measure the presence and severity of black lung disease, which cannot be regarded as pure questions of law."). R

166. Seidenfeld, *supra* note 35, at 384. R

167. Sharkey, *supra* note 124, at 2374.

168. Seidenfeld, *supra* note 35, at 388. R

Seidenfeld's response, and the review standard I adopt here, is that a modified *State Farm*[169] arbitrary and capricious review can, nevertheless, address a less-than-full record adequately. Essentially, knowing that the final guidance review standard would require the FDA "to acknowledge well-recognized debates in the relevant field about issues of fact and prediction, and explain the substance of interpretations or polices announced in guidance documents in light of its resolution of those issues," the FDA would have a reasonable sense of the parameters of the factual record it would have to build before issuing final guidance[170]—a record considerably more than none at all, but far less than that required of a rule.

Regulated entities that believe the factual record does not support the Agency's guidance can raise claims of arbitrary and capricious rulemaking and would be able to appeal as is usual. They would, however, be precluded from bringing legal challenges based on statutory interpretation concerns. That window closes after the disposition of the draft guidance.

Finally, the Agency can either repeal or augment a final guidance by restarting this process from the draft stage. As the Supreme Court explained in *Perez*, notice-and-comment rulemaking is not required under the APA to repeal an interpretive statement.[171] However, under this framework, in the interest of party reliance, if the Agency decides to augment a final guidance, it would have to leave the old one in place until the new guidance becomes final. Thus, while the FDA would not need to justify the repeal *per se*, it would open itself to claims of arbitrariness and capriciousness if the subsequent guidance's factual record insufficiently accounts for the Agency's change in position.

169. *State Farm* review was first developed in the case Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Under *State Farm*, "[n]ormally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Although there are debates around what, precisely, *State Farm* requires of courts, the general crux of the doctrine is that courts must dig into the factual record offered by the agency, as well as Congress's instructions, and determine whether the agency has acted reasonably.

170. Seidenfeld, *supra* note 35, at 388. **R**

171. *See* Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1206 (2015).

C. Summary of the Proposed Process

To summarize, the process of issuance and review offered here occurs in two stages. At stage one, the FDA issues a draft guidance that contains the legal bases for the guidance and a sunset provision. Prior to the draft issuance, the Agency may solicit comments, but is under no obligation to do so or to respond to submitted comments. After the draft is promulgated, challenging parties will have a set, short period of time during which they can bring legal challenges to the draft guidance. As explained in the following subsection, these proceedings will be filed in courts of appeals. In those proceedings, the FDA's legal analysis will be accorded *Skidmore* deference. If the draft guidance is ultimately struck down, the Agency must start anew. If the draft guidance is upheld, then the FDA has the sunset provision's duration to either finalize or repeal the draft.

At the final guidance stage, the FDA would issue the same guidance, but with the factual basis for it included. Having already dealt with the legal basis of the guidance, parties can now challenge its factual basis under a modified version of *State Farm* arbitrary and capricious review. As will be explained below, these challenges will be filed in district courts. If the guidance is upheld, it remains in force. If it is struck down, the final guidance will be returned to draft form, and the Agency will have one more opportunity to finalize or otherwise repeal the document.

D. Reviewing Courts

A few notes with respect to reviewing courts are in order. To that end, this subsection addresses two questions: in what judicial fora should draft and final guidance challenges be filed, and why should they be filed in those fora?

Stage one challenges should be filed in circuit courts. Although direct-to-circuit review ordinarily follows a full course of administrative proceedings, immediate circuit review is appropriate here as well because expeditious resolution is essential, stage one challenges present pure question of law, and direct review by circuit courts would eliminate completely the delay inherent in proceedings at the district court level. Therefore, I propose that the Food, Drug, and Cosmetic Act ("FDCA") be amended to require that petitions for review of draft guidances be filed in the U.S. Court of Appeals for the District of Columbia or in the circuit in which the petitioner resides or has its principal place of business. Currently, section 912 of the FDCA provides for petitions to circuit courts con-

cerning FDA tobacco-related rulings and regulations, so this would not be an entirely unusual development.[172]

Because final guidance suits would occur without prior agency proceedings (*e.g.*, no exhaustion), it makes sense for an inquiry heavily reliant on facts to be developed in district courts before proceeding to courts of appeals. This would permit full factual development and a closed record for subsequent review. Therefore, I also propose, for purposes of clarity, that the FDCA be amended to provide that petitions for review of final guidances be filed in the U.S. District Courts for the District of Columbia or in the federal district court that encompasses petitioner's residence or principal place of business.

As to the location of review, there are good reasons for all FDA guidance challenges to be lodged in the D.C. Circuit and District Courts. At stage one, it would help to ensure uniformity in FDA regulations—one circuit, no splits. At stage two, coordinating all proceedings in one district court would avoid the delay resultant from transfer motions under 28 U.S.C. §1404(a) or multidistrict proceedings under 28 U.S.C. §1407. Further, many, if not most, challenges to federal agency actions are currently brought in the Washington, D.C. federal courts, and regulated entities challenging federal agency action presumably have legal or other advisers who are either based in Washington or regularly appear in administrative matters there. Additionally, for the process to work well at stage two, reviewing courts would need to move swiftly while still meeting their obligation to dig deeply into the factual record. Because of their semi-specialized nature in administrative matters, the D.C. courts may best promote the twin goals of speed and meaningful factual review.[173]

172. 21 U.S.C. § 387l ("[A]ny person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.").

173. With respect to speed, Judge Ginsburg noted in 2011 that, "[l]ooking back over these last twenty-five years, from a statistical point of view . . . . [t]he D.C. Circuit has fewer administrative law cases and yet a larger share than ever of all the administrative law cases in the federal courts of appeals." Douglas H. Ginsburg, *Remarks Upon Receiving the Lifetime Service Award of the Georgetown Federalist Society Chapter*, 10 GEO. J.L. & PUB. POL'Y 1, 12 (2012); *see also id.* at 2 ("The number of cases filed in the D.C. Circuit has declined more or less continuously over the last twenty-five years. More surprising, the number of administrative law cases filed in our court also has declined over that period, again consistently, and the percentage of administrative law cases on our docket is lower now than it has been in all but two of the last twenty-five years."). In view of this change, there is some reason to believe the Circuit can handle the increased workload that would come with

Nevertheless, lodging all challenges in one circuit—as opposed to several—would give up more than would be gained. First, stage one challenges would present questions of statutory interpretation only. Notwithstanding the advantages the D.C. Circuit may have with respect to administrative matters generally, it has no such advantage when it comes to statutory interpretation. Second, with respect to stage two, while it is true that the D.C. courts see more administrative challenges than other jurisdictions, there is little reason to believe that the D.C. courts are uniquely well-versed in drug- and device-related matters as compared to other circuits. Third, as with other legal matters, advantages adhere to having multiple courts weigh in on legally complex and economically weighty questions. Under this model, presumably, it would only—or at least largely—be difficult questions that entities find cost-effective to challenge.

This is not to say there are no issues attendant to having challenges spread out. Most notably, the diversity may well lead to splits among circuits on certain guidance documents. This likelihood is further heightened by the fact that *Skidmore* rather than *Chevron* would be applied at stage one and that *State Farm* would be applied at stage two.[174] If, however, the scheme were to work as it is outlined here, such splits may be welcome developments. In other words, if regulated entities primarily challenge particularly cost- and/or time-burdensome regulations and/or ones involving difficult questions of statutory interpretation, circuit splits may encourage further scrutiny either by the Agency, other circuit courts, Congress, or the Supreme Court.

direct substantive review of FDA guidance documents. As to expertise, see *id.* at 3 ("In consequence, the D.C. Circuit has become a relatively specialized court in the area of administrative law."); John M. Golden, *The Federal Circuit and the D.C. Circuit: Comparative Trials of Two Semi-Specialized Courts*, 78 GEO. WASH. L. REV. 553, 554–55 (2010); Eric M. Fraser et al, *The Jurisdiction of the D.C. Circuit*, 23 CORNELL J.L. & PUB. POL'Y 131, 146 ("It is reasonable to believe that the [D.C.] Circuit has a particular expertise in administrative law simply because of the nature of its docket over the last few decades.").

174. One advantage of *Chevron* is that it fosters national uniformity in administrative law. *See, e.g.*, Peter L. Strauss, *One Hundred Fifty Cases per Year: Some Implications of the Supreme Court's Limited Resources for Judicial Review of Agency Action*, 87 COLUM. L. REV. 1093, 1121 (1987) ("By removing the responsibility for precision from the courts of appeals, the Chevron rule subdues this diversity, and thus enhances the probability of uniform national administration of the laws."). Lack of uniformity is not unprecedented, however. *See, e.g.*, Samuel Estreicher & Richard L. Revesz, *Nonacquiesence by Federal Administrative Agencies*, 98 YALE L.J. 679 (1989) (discussing how agencies ought to handle circuit splits).

E. Advantages

The method of issuance and review advocated here has several advantages that this section will address. Before turning to them, however, Stephen Johnson's critique of direct substantive review merits brief response.

1. Advantages of the Proposed Framework

The proposed framework offered here has at least five advantages, each of which this section discusses. First, it preserves FDA resources. If the ultimate determination will turn on the fact that the regulation is without legal basis, it seems unwise to compel the Agency to expend resources to formalize the record beforehand. Although it could be argued that the FDA should not produce guidances prior to solidifying a formal factual record, the current state of guidance documents suggests otherwise. As is, the FDA puts forth detailed pronouncements without compiling a formal record in at least some instances. Further, as Mark Seidenfeld notes, resource and time savings adhere in the FDA's having no formal method by which it must compile a record as well as the FDA's having no formal obligation to respond to input by regulated firms.[175]

The preservation of resources is a critically important aspect of this proposal. As noted above, one of the main reasons the FDA employs guidances is that it simply lacks the resources both to proceed by more formal means and to address the many issues within its ambit.[176] To the extent having the FDA act quickly and cover the wide range of drugs, devices, and food within its charge is important, resource preservation is essential.

Second, this proposed change to guidance documents would increase the legitimacy of these pronouncements. Regulated entities would know that they can challenge guidance documents they believe to be beyond the FDA's purview and would be assured that the FDA is not proceeding through guidance solely to evade judicial review. Additionally, as Justice Scalia noted in *Perez*, agency interpretations of nonlegislative rules that are afforded deference function as de facto rules.[177] While it may not be possible to completely rid guidance documents of their coercive effects given the structure of the FDA, its approval process, and the desires of regulated entities, judicial scrutiny commensurate with the force of

175. Seidenfeld, *supra* note 35, at 393. R

176. PARRILLO, *supra* note 20. R

177. Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1212 (2015) (Scalia, J., concurring).

guidances would provide regulated entities with a valuable counterweight. Further, by previewing the proposed guidance, the FDA would give interested parties the opportunity to submit additional facts to the Agency. Thus, although the Agency would not have an obligation to respond, if an interested party submits something that speaks to an issue that would be arbitrary and capricious to ignore, the FDA would have to incorporate it and adapt its guidance to it.

Relatedly, as Professor Sharkey noted, judicial review for "reasoned decision making" at Step Two (the final stage here) has certain benefits that touch on the legitimacy of agency action.[178] In particular, meaningful factual review ensures the agency's expertise is properly brought to bear.[179] It mandates that, after the agency's guidance is deemed plausible from a legal standpoint, the agency put forth a factual basis for the policy-laden judgment demonstrating the reasonableness of its choice.[180] In this way, then, regulated entities would be assured that the Agency's policy choice is grounded in the facts before it.

Third, proceeding this way would enhance guidance documents' stability. As stated above, draft guidances and *ad hoc* judicial review leave regulated entities with great uncertainty.[181] In the face of this uncertainty, regulated entities often believe their best option is to comply. Compliance does not, however, alleviate the uncertainty, given that the FDA can change the drafts on a whim and treat the pronouncements flexibly or inflexibly at their discretion. This sort of uncertainty helps neither regulatory beneficiaries nor regulated firms. Regulated firms have said as much, noting they would rather have clarity than flexibility.[182] The two-part issuance and review process advocated here would alleviate those concerns. The FDA would no longer be permitted to leave guidances in draft form, and regulated entities will know they can have their day in

178. Sharkey, *supra* note 124, at 2395–96 ("The implications of adopting the *Chevron-State Farm* model go beyond the outcomes of particular disputes . . . . It highlights a functional comparative expertise rationale for agency deference . . . . The incorporation model tips the balance further to make clear that 'we defer to an agency's statutory interpretations not only because Congress has delegated lawmaking authority to the agency, but also because that agency has the expertise to produce a reasoned decision.'") (internal citations omitted).

179. *Id.*

180. *Id.* at 2438 ("[T]he *Chevron-State Farm* model will ensure that agency expertise is at the center of the discussion and will produce more effective regulatory decisions.").

181. *See* sources cited *supra* notes 38–39, 43. R

182. *See supra* pp. 27–28.

court if they so choose. And, if they do not choose to do so, the regulated entities would know they have a clear path forward.

Fourth, the framework would ensure that the FDA could act with the speed required by technological and scientific change. As elaborated above, the FDA is confronting a tide of scientific and technological innovation that its traditional regulatory regime is ill-equipped to handle.[183] This is true both at the specific level (*i.e.*, the literal regulations) and at the structural level (*e.g.*, the incongruence between four-year-long rulemaking and rapidly changing science and technology). As is, the FDA is employing guidance documents to tackle these challenges. The FDA should continue to have a tool at its disposal to address these innovations in a timely and targeted manner. By eliminating a comment period and limiting the breadth of the factual record that the FDA must complete at the final guidance stage, the method of issuance and judicial review offered here would allow guidance documents to continue being that tool, but within sensible limits.

Fifth, the review advocated here may well preserve the FDA's ability to employ guidance documents as a general matter. As noted earlier, guidance documents have caught the attention of Congress and the current Administration.[184] Given the FDA's relationship with guidance documents, it is not hard to imagine the Agency's becoming a focal point of the two branches' ire. These reforms, however, could preserve some space within which the FDA could operate since it then could be held accountable.

2. Example – Laboratory Developed Tests

The FDA and industry's battle over laboratory developed tests ("LDTs") is instructive as to the value of this system. For years, the FDA exercised "enforcement discretion" with respect to LDTs, a subset of *in vitro* diagnostic tests.[185] In a series of guidance documents responding to major developments in the LDT arena (genetic tests being one likely recent catalyst),[186] however, the FDA

183. *See supra* Part II.

184. *See supra* Introduction.

185. For more detailed histories, see Jeffrey N. Gibbs, *LDTs: The Saga Continues*, FOOD & DRUG L. INST. (2017); Ronald L. Weiss, *The Long and Winding Regulatory Road for Laboratory-Developed Tests*, 138 AM. J. CLINICAL PATHOLOGY (2012); Gail Javitt, *FDA Regulation Of Laboratory Developed Tests: A Long Saga*, LAW 360 (2016), https://www.law360.com/articles/873238/fda-regulation-of-laboratory-developed-tests-a-long-saga [https://perma.cc/M2NL-J6UP].

186. *See, e.g.*, Weiss, *supra* note 185, at 21–22; *see also* Javitt, *supra* note 185 ("Since the late 1990s, the FDA has grappled with LDT regulation in fits and starts,

revealed that it intended largely to discontinue such discretion.[187] Instead, it would phase in LDT regulations over several years.[188] Industry was, and continues to be, displeased with this development as it threatens a major and potentially expensive overhaul.[189] The FDA, although apparently sensitive to these concerns (*e.g.*, it delayed finalizing the guidances),[190] has forged ahead with its efforts to regulate LDTs nevertheless.[191] Indeed, as noted, a lack of finalization does not necessarily mean a lack of impact. Consequently, regulated firms have expended substantial sums in protest[192] while the FDA has "expanded its reach over LDTs well beyond where it was 25 years ago."[193]

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often in response to a newly-emerging category of tests that the agency perceived as threatening the public's health.").

187. *See, e.g.*, FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, FOOD AND DRUG ADMINISTRATION STAFF, AND CLINICAL LABORATORIES: FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTs), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf [https://perma.cc/3AB7-LPU8], at 15–30.

188. *Id.* at 5 ("Specifically, this document describes FDA's priorities for enforcing premarket and postmarket requirements for LDTs as well as the process by which FDA intends to phase in enforcement of FDA regulatory requirements for LDTs over time.").

189. *See, e.g.*, PAUL D. CLEMENT & LAURENCE H. TRIBE, LABORATORY TESTING SERVICES, AS THE PRACTICE OF MEDICINE, CANNOT BE REGULATED AS MEDICAL DEVICES 1 (2015).

190. FOOD & DRUG ADMIN., DISCUSSION PAPER ON LABORATORY DEVELOPED TESTS (LDTs) (Jan. 13, 2017), https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf [https://perma.cc/9HZ2-8ME3], at 1 ("The Food and Drug Administration (FDA) recently announced that we would not issue a final guidance on the oversight of laboratory developed tests (LDTs) at the request of various stakeholders to allow for further public discussion on an appropriate oversight approach, and to give our congressional authorizing committees the opportunity to develop a legislative solution.").

191. *Id.* The Discussion Paper offers the FDA's current thoughts and solicits additional feedback, but does not state that the FDA intends to discontinue its quest to regulate LDTs.

192. Javitt, *supra* note 185 ("In short, the FDA has proposed much but implemented relatively little in terms of LDT regulation. At the same time, the specter of regulation, and the numerous public meetings, draft guidance documents and agency pronouncements have resulted in the expenditure of significant stakeholder resources to either stave off or encourage (depending on the stakeholder's point of view) definitive FDA action.").

193. Gibbs, *supra* note 185 ("While FDA maintains it has the power to regulate LDTs, it does not have a policy to exercise that authority, and so nothing has changed. And yet, viewed from a different perspective, FDA's role in regulating LDTs has shifted profoundly. Even in the absence of a formal, overarching policy, FDA has expanded its reach over LDTs well beyond where it was 25 years ago.").

The turf battle is far from over. Most recently, a diverse group of interested parties—including the American Clinical Laboratory Association ("ACLA")—expressed their support for the Diagnostic Accuracy and Improvement Act ("DAIA") and urged Congress to act on it.[194] Among other things, the DAIA would combine in vitro diagnostic devices ("IVDs") and LDTs into a single "in vitro clinical test ("IVCT") category."[195] In other words, LDTs and IVDs would be brought under the same general, relatively relaxed, regulatory structure. Notwithstanding the bipartisan sponsorship of the bill, industry support, and stakeholder input, the FDA's response has been anything but supportive. According to "some policy experts . . . . what the FDA had submitted to legislators was an entirely new bill."[196]

Writing in 2015 for the ACLA, Paul Clement and Laurence Tribe sought to lay out the case against the FDA's assertion of jurisdiction.[197] Among other arguments, Tribe and Clement posited that the FDA lacks jurisdiction over laboratory-developed testing services[198] and that, even if it does have jurisdiction, it cannot now claim it through guidance documents.[199] Tribe and Clement's arguments have not, however, been tested in court, and regulated entities continue to spend and adjust accordingly.[200] That would not be the case, however, under the framework advocated for here. Once the FDA produced a draft guidance announcing the legal basis for its decision to regulate LDTs, challenges would be able to be filed right away.

Beyond industry's ability to push back, several other benefits adhere to a direct challenge. Immediate review would allow regu-

194. Press Release, Am. Clinical Lab. Ass'n, Patient Advocates, Providers, Laboratories and Diagnostic Manufacturers Urge Congressional Leaders to Modernize Regulation of Clinical Diagnostics (May 10, 2018), http://www.acla.com/patient-advocates-providers-laboratories-and-diagnostic-manufacturers-urge-congressional-leaders-to-modernize-regulation-of-clinical-diagnostics/ [https://perma.cc/D9WD-SPYA].

195. *Diagnostic Industry Stakeholders Send Letter to Congress in Support of DAIA*, 360Dx (May 10, 2018), https://www.360dx.com/clinical-lab-management/diagnostic-industry-stakeholders-send-letter-congress-support-daia#.Wvw8NFMvzaY [https://perma.cc/KT2G-8TK5].

196. Turna Ray, *FDA Details Vision for Regulating In Vitro Clinical Tests to Legislators*, GenomeWeb (Aug. 8, 2018), https://www.genomeweb.com/molecular-diagnostics/fda-details-vision-regulating-vitro-clinical-tests-legislators#.W2syD9hKhPM [https://perma.cc/US6H-HUFE].

197. *See* Clement & Tribe, *supra* note 189, at 1.

198. *Id.* at 25; *see also id.* at 1–19.

199. *Id.* at 19–25.

200. *See* sources cited *supra* notes 193–94.

lated entities to save time and resources. Rather than spending time and effort adjusting to or preemptively combatting the pronouncements (with as of yet undetermined success) over several years, they could challenge them directly—both as to law and to fact—and arrive at a relatively expeditious conclusion. The same goes for the FDA. The Agency would get a quicker, more certain result with undoubtedly less time and fewer resources expended. Indeed, the Agency would not have to put forth the factual basis for its change until after the legal challenges to draft guidances conclude. Also, because Tribe and Clement's arguments do not lead to easy resolution, and LDT regulation is seriously consequential, parties could benefit from having several circuits weigh in. In addition to the usual benefits of multiple judicial decisions, potential circuit splits could spur congressional action or Supreme Court review. Finally, to the extent these battles frustrate industry and plausibly harm consumers, less ill will would be directed toward the FDA.

CONCLUSION

This Note recognizes that guidance documents, as currently employed, have deep flaws. Under any theory of the regulatory state, an agency that can act without any traditional safeguards—public input, an obligation to respond, judicial scrutiny—is antithetical to democracy. At the same time, this Note argues that guidance documents, though problematic as currently employed, are promising tools of regulation going forward if properly reformed.

Guidance documents, unlike notice-and-comment rules, can be issued quickly, narrowly tailored, and made reasonably flexible. As such, they can be responsive to technological and scientific change. Given the challenges the FDA admits it is currently facing and those it predicts it will face in the future, curtailing guidance document use at this moment would render the FDA's job virtually impossible. At a minimum, it would undermine the Agency's ability to get products to market quickly and to tailor its regulations to new drugs and devices. Although perhaps politically nice, guidance document curtailment and ossification would, on balance, do more harm than good. Patients want drugs and devices that can save their lives; regulated entities want clarity and a path to market their product quickly; and the FDA has an obligation both to protect individuals and to enhance their well-being by allowing novel drugs and devices to reach them.

Given the critiques of guidance document use as well as the benefits of guidance documents, this Note proposes reforms to the issuance and review of guidance documents that re-introduces cer-

tain checks without unduly sacrificing guidance documents' valuable functions. This Note does not ignore the fact that guidance documents will continue to have coercive effects even under the reforms it proposes. This paper suggests, however, that such coercive effects are partly inevitable, not altogether bad, and that regulated entities, realizing a complete overhaul of the FDA is not on the table, appear to be amenable to that reality. Additionally, the alternative of reviewing guidance documents for their degree of "bindingness" is fraught with uncertainty and has failed sufficiently to address the issues arising out of guidance documents as they currently stand.

From a realistic standpoint, then, by balancing the costs and benefits to interested parties, this Note provides a middle ground through which the most extreme guidance documents—those whose costs greatly outweigh their benefits to regulated entities and those whose stability from a legal and factual standpoint are most dubious—can be reviewed, while preserving those guidance documents that are useful to all parties. Altogether, this Note argues that such a balance of incentives best serves public and private interests without upsetting too much of the administrative state as it currently exists.

I close, then, approximately where I began. Though the framework and alterations for which I advocate could serve as a template for other agencies' reform, this Note focuses only the FDA's use of guidance documents in the drug and device context. As noted in the Introduction, however, the guidance issue extends to the entire administrative state. In her paper discussing reforms to agency use of guidance documents in the immigration context, Professor Family advocated for an agency-by-agency approach to guidance reform.[201] Family noted that guidances have several general advantages and disadvantages, but that each agency's employment of them is idiosyncratic such that lasting success depends on tailored reform.[202] I echo that sentiment.

Thus, as a final thought, I believe other agency-specific investigations would be valuable. There is a wealth of scholarship addressing the propriety of guidance documents in general, and Professor Parrillo's research for ACUS and his conclusions stemming from

201. Family, *supra* note 6, at 9, 27–31. R

202. *See, e.g.*, *id.* at 28 ("Agency initiative is also important because a ground-up process holds the promise of tailoring Good Guidance Practices to each agency. Not every agency uses guidance documents in the same way, and problems with agency use of guidance documents do not manifest uniformly. Additionally, the composition and characteristics of agency stakeholders differ across agencies.").

that research are exceedingly valuable resources to aid in more tailored approaches. Scholars, therefore, have a solid foundation on which to build, and build they should. The administrative state, regulated entities, and regulatory beneficiaries would all be the better for it.