FINAL AGENCY ACTION IN THE ADMINISTRATIVE PROCEDURE ACT

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Under section 704 of the Administrative Procedure Act, courts can only review agency actions when they are "final." In Bennett v. Spear*, the Supreme Court put forth a seemingly simple two-part test for assessing final agency action. However, the second prong of that test—which requires agency actions to "create rights or obligations from which legal consequences flow" to be final—poses several problems. Most importantly, because it overlaps with the legal tests for whether a rule is a legislative rule or a nonbinding guidance document, it seems to effectively bar courts from reviewing nonlegislative rules before agencies have taken enforcement action. Because of this overlap, the* Bennett *test conflicts with—and thus undercuts—other principles of administrative law that seem to promote a pragmatic, flexible approach for courts to use in determining whether, when, and how to review agency rules. The result is a confusing standard of review that can prevent plaintiffs from challenging agency rules in court, especially when those plaintiffs are beneficiaries of regulation who will never be subject to enforcement action down the road. At the same time, however, courts should not be able to review every single agency rule before it is enforced. Agencies should be able to experiment, but should not be permitted to indefinitely shield potentially dangerous deregulatory programs from judicial review, as* Bennett *seems to allow. Accordingly, this Note argues that to be faithful to the Court's commitment to "pragmatic" interpretation of the finality requirement, lower courts should follow a two-pronged approach to analyzing questions of final agency action. When courts can compel an agency to finalize its allegedly temporary action because of "unreasonable delay," they should interpret* Bennett*'s second prong formally, holding that only truly legally binding action can be final. If this bars some plaintiffs from suing now, they will be able to challenge the rule later when the agency's process is finished. But when courts cannot force agencies to finalize their rules, they should construe* Bennett *functionally, conceptualizing the agency's allegedly temporary action under a "practically binding" standard. Under this framework, if the agency's "temporary" action in practice consistently follows certain criteria, it should be viewed as binding and final under* Bennett*, and thus subject to judicial review, regardless of what the agency or its employees are legally required to do. This two-pronged approach would help to strike the right balance between the private party and the agency in a practical manner that depends upon the context.*

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INTRODUCTION

Courts can review agency decisions under the Administrative Procedure Act (APA) only when they are "final."[1] The policy behind the finality requirement is a simple one: Temporary day-to-day management decisions are best left to the government agency, while final definitive determinations that cause hardship to private parties should be subject to judicial review.[2] But what happens when an agency indefinitely operates under a "temporary" policy?

In 1997, fearing that its process for exempting substances "generally recognized as safe" (commonly known as "GRAS substances") from the requirements of the Food, Drug, and Cosmetic Act (FDCA)[3] was too cumbersome on business, the Food and Drug Administration (FDA) issued a proposed rule replacing the old process with a new one.[4] Like the old process, the new process would be voluntary for food manufacturers, but unlike the old process, it would involve fewer steps and less agency scrutiny of a substance's safety, and would

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[1] *See* 5 U.S.C. § 704 (2012) ("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."); Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt., 460 F.3d 13, 18 (D.C. Cir. 2006) ("Whether there has been 'agency action' or 'final agency action' within the meaning of the APA are threshold questions; if these requirements are not met, the action is not reviewable.").

[2] *See* Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 376 (2011) ("The foundation for the [first prong of the final agency action test] is avoidance of judicial interference with agency decision making until the agency has completed its own resolution."); *infra* note 85 and accompanying text (explaining the policy behind the ripeness doctrine); *infra* note 94 and accompanying text (explaining that section 704 of the APA can be understood to have codified the ripeness doctrine).

[3] *See* 21 U.S.C. § 321(s) (2012) (excluding substances "generally recognized . . . to be safe under the conditions of [their] intended use" from the definition of "food additive" in the FDCA). Because of this exclusion, the FDA is not legally obligated to enact any program to determine whether or not a manufacturer's substance is GRAS. *See* Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114, 117 (D.D.C. 2015).

[4] *See Ctr. for Food Safety*, 126 F. Supp. 3d at 118.

accordingly take much less time.[5] After outlining the less stringent new process in the proposed rule, the FDA requested comments, as is customary.[6] But it then noted in a brief paragraph titled "Interim Policy" that "[b]etween the time of publication of this proposal and any final rule," the FDA would follow the newly announced process rather than the old one.[7] The FDA indicated that this was to be a trial-run to help the agency determine whether it needed to modify its proposals when it issued the final rule, and it made clear that while the FDA would "[i]n general" follow the new procedures outlined in the proposed rule, the agency "would not be bound" by them.[8]

This "trial-run," however, lasted nearly twenty years. When a food safety organization filed suit in 2014, the FDA had never finalized its proposed rule, and it had never responded to comments from over thirty organizations.[9] Instead, the agency had operated under this experimental "interim" approach for "seventeen years with no end in sight" without taking any further action.[10] But the FDA had a very simple defense for its behavior: that the nearly twenty-year-old proposed rule was merely tentative, and thus was not "final agency action" that a court could review under the APA.[11]

The FDA may have had a point—the GRAS Interim Policy might in fact not be final agency action. Under a two-pronged test that the Supreme Court set forth in *Bennett v. Spear*, agency actions are only final if they 1) constitute the "consummation of the agency's decisionmaking process"; and 2) impose "'rights or obligations' from which 'legal consequences will flow.'"[12] The GRAS Interim Policy may not be final agency action under this test because the FDA expressly stated that its decisionmaking process was still ongoing and because the policy as a formal matter was not binding on either the agency or

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[5] *See id.* (describing the types of nonbinding notifications the FDA could provide to a company after reviewing its GRAS notice).

[6] *See* 5 U.S.C. § 553(b)–(c) (2012) (requiring agencies to notify the public of proposed rules and give "interested persons" an opportunity to comment); Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,938 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pt. 170) (providing the requisite notice of the proposed rule and requesting comments).

[7] Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,954.

[8] *Id.*

[9] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-246, FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) (2010) [hereinafter GAO REPORT], http://www.gao.gov/assets/310/300743.pdf.

[10] *Ctr. for Food Safety*, 126 F. Supp. 3d at 122.

[11] *Id.* at 119.

[12] 520 U.S. 154, 175, 178 (1997).

private parties.[13] Yet for all intents and purposes, the 1997 proposed rule discarded the old process that required the FDA to comprehensively review the safety of food substances and replaced it with a new one that substantially weakened FDA review of foods "generally recognized as safe."[14] This is especially worrisome because some of these substances may not actually be so safe. For example, volatile oil of mustard, Olestra, and mycoprotein, three substances that "achieved GRAS status" through the new process, can allegedly pose serious health hazards like nausea, anaphylactic shock, anal leakage, cancer, and heart disease.[15] Indeed, trans fats, which were marketed as GRAS for decades, were finally denied GRAS status in 2013 after expert studies showed their tendency to contribute to heart disease and Type 2 diabetes.[16] Notwithstanding these very real concerns, however, the APA's final agency action requirement may bar the plaintiff food safety organization from challenging the FDA process in court.

As such, this case, *Center for Food Safety v. Burwell*, reveals the problems inherent in the finality doctrine. First, the *Bennett* test can create incentives for agencies to strategically abuse the final agency action requirement, thus potentially operating to preclude judicial review where it might otherwise be available.[17] Further, *Bennett*'s second prong—the command that agency actions must create "'rights or obligations' from which 'legal consequences will flow'" to be final—intermingles the determination of whether a rule is legislative or nonlegislative with the finality inquiry.[18] This seems to effectively eliminate challenges to nonlegislative rules, at least in situations where the agency has not yet taken enforcement action (which would

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[13] To be sure, the policy may also constitute final agency action. See *infra* Section II.A for a detailed discussion applying the *Bennett* test to the facts in *Center for Food Safety*.

[14] *See infra* notes 106–29 and accompanying text (discussing the old and new GRAS processes).

[15] Complaint ¶¶ 3–8, *Ctr. for Food Safety*, 126 F. Supp. 3d 114 (No. 1:14-cv-267) (alleging health hazards posed by these substances); *see also* Martha Rosenberg, *FDA Loophole Allows Possibly Dangerous Chemicals in Food*, HUFFINGTON POST (Feb. 28, 2016, 2:33 PM), http://www.huffingtonpost.com/martha-rosenberg/fda-loophole-allows-possi_b_9182800.html (calling the GRAS process a "dangerous 'honor system'").

[16] *See* Erin Quinn & Chris Young, *Why the FDA Has Never Looked at Some of the Additives in Our Food*, NPR (Apr. 14, 2015, 3:28 PM), http://www.npr.org/sections/thesalt/2015/04/14/399591292/why-the-fda-is-clueless-about-some-of-the-additives-in-our-food (discussing problems with the GRAS process and mentioning trans fats, a previously GRAS food now banned by the FDA).

[17] *See infra* note 132 and accompanying text (explaining that the final agency action test creates incentives for strategic abuse). To be sure, other doctrines, like standing, might also bar the plaintiff from obtaining judicial review, but the discussion in this Note is limited to the APA's finality doctrine.

[18] *See infra* notes 133–38 and accompanying text (explaining that the legislative rule tests and *Bennett*'s second prong conflict).

impose legal consequences and thus be final).[19] But under another less-frequently cited line of final agency action doctrine, courts have held that agency actions which have "day-to-day effects" on private parties should be considered final.[20] Nonlegislative rules, while not "legally binding" in a formal sense, can certainly have real effects on private parties—as *Center for Food Safety* shows. Consequently, the final agency action doctrine contradicts itself: The functional "day-to-day effects" inquiry may render a nonlegislative rule final while the formal *Bennett* test leads to the opposite result. Moreover, *Bennett*'s second prong conflicts with other background principles of administrative law—namely, the presumption that courts can review rules before they have been enforced, and the ripeness test, under which courts are generally more likely to review a rule when it currently poses hardships on the party that is challenging it.[21] The *Bennett* test is thus a puzzling standard of review that can make it exceptionally difficult for beneficiaries of regulation—plaintiffs who will never be subject to "final" enforcement action down the road—to challenge potentially dangerous deregulatory agency programs like the GRAS Interim Policy in court.[22]

Further, *Bennett*'s linking of the final agency action test with the inquiry into whether a rule is legally binding has another consequence. As this Note will explain, agency decisions like the GRAS program must be binding in order to receive deference from the courts; if rules are nonbinding, courts will subject them to closer judicial scrutiny.[23] But if agency rules are to be binding, they must go through the notice-and-comment process.[24] This process can be a time-consuming headache that allows the public to both inundate the agency with comments and file potentially endless lawsuits arguing that the procedures

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[19] *See infra* notes 133–38 and accompanying text.

[20] *See infra* notes 97–100 and accompanying text (discussing the two strands of finality doctrine). Compounding the confusion, some cases seem to insist upon both at the same time. *See* U.S. Army Corps of Eng'rs v. Hawkes Co., 136 S. Ct. 1807, 1813–15 (2016) (applying both the formal and the functional tests).

[21] *See infra* notes 77–82 and accompanying text (discussing the presumption of reviewability); *infra* notes 84–93 (discussing the ripeness test). Indeed, as Section I.B explains, the finality inquiry is part of the ripeness inquiry, and the final agency action requirement in section 704 of the APA can in fact even be described as merely codifying the ripeness test. *See infra* note 94 and accompanying text. Accordingly, it makes little sense for the two doctrines to contradict each other.

[22] *See infra* note 149 and accompanying text (discussing the problems the finality requirement poses for regulatory beneficiaries seeking to challenge deregulatory agency programs).

[23] Some scholars refer to this as the "trade-off." *See* David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 280 (2010) (discussing the trade-off).

[24] See *infra* Section I.A for an in-depth discussion.

are arbitrary and capricious.[25] Because of *Bennett*'s second prong, however, the FDA may be able to avoid both the cumbersome notice-and-comment process at the front-end and more exacting scrutiny at the back-end by escaping judicial review altogether, thus undermining the "trade-off" between deference and process that lies at the heart of administrative law.[26]

This Note will proceed in three parts. Part I will explore the different types of agency action, examine legislative and nonlegislative rules, and explain when and how these rules are judicially reviewable, discussing the prerequisite of final agency action. Part II will discuss the problems with the current finality requirement, using the *Center for Food Safety* case as a focal point. Part III will then suggest as a limited solution that lower courts should take a two-pronged approach to the finality inquiry. If a court can force an agency to finalize its action in the event of "unreasonable delay," the court should apply a more formal version of *Bennett*'s second prong, holding that only actions with true legally binding effect count as final. But if the reviewing court cannot force an agency to finish its process, the court should follow a more functional approach to *Bennett*'s "legal consequences" inquiry. Under this functional framework, the court would look to see whether the agency in practice consistently follows certain criteria, or whether by contrast agency officials remain completely "free to exercise discretion."[27] If an agency consistently follows the same criteria, regardless of what the agency or its employees are legally required to do, its action should be viewed as final agency action under the *Bennett* test.[28]

While this approach to finality might not allow a plaintiff like the Center for Food Safety to challenge every single deregulatory agency action in court, it would help to unify an inconsistent doctrine. It would tell courts when to apply a formal test and when to apply a functional test in a consistent and predictable manner, and it would harmonize the finality doctrine with other background principles of

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[25] *See* 5 U.S.C. § 706(2)(A) (2012) (authorizing courts to set aside agency action that is "arbitrary, capricious, . . . or otherwise not in accordance with law"). *See generally* Alexandra Bursak, Note, *Preclusions*, 91 N.Y.U. L. REV. 1651, 1652 (2016) (explaining that preclusion doctrine does not prevent duplicative litigation in the public rights context).

[26] *See* Franklin, *supra* note 23, at 280 (discussing the trade-off).

[27] Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting Am. Bus. Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980)).

[28] Alternatively, as a doctrinal matter, the Supreme Court should consider conceptualizing *Bennett*'s second prong as part of the APA's reviewability exception for action "committed to agency discretion by law" rather than as part of the final agency action inquiry. To the extent that the Court wants to limit pre-enforcement judicial review of certain types of agency action, limiting it in this way is more straightforward. See *infra* Part III for a more detailed discussion of this suggestion.

administrative law. This Note's approach to final agency action would also allow plaintiffs to possibly challenge agency actions like the GRAS Interim Policy that have real effects on them while at the same time granting agencies sufficient time and flexibility to refine new policies. As such, the framework proposed in Part III would promote the interests of both agencies and affected parties in a balanced way.

I
Types of Agency Action and Judicial Review

Before a plaintiff can challenge an agency decision in court, the agency must have "acted," and that action must be such that a court can review it on the merits.[29] "Agency action," defined broadly in the APA,[30] can take many different forms. Agencies can grant licenses to governmental bodies and private parties;[31] they can take enforcement action against regulated entities that are not complying with statutory requirements; and they can formally adjudicate disputes after notice and a hearing.[32] Whether the above actions are "final" is perhaps an elementary exercise: A license has been issued, or it has not; a hearing has been held, or it has not. But when an agency puts forth a general rule, policy, or program under which it has not yet taken enforcement action, plaintiffs have a harder time establishing final agency action and thus more difficulty challenging the rule in court. Because the fine distinction between legislative and nonlegislative rules proves important in elucidating problems plaintiffs have in meeting the second prong of the *Bennett* final agency action test, Section I.A will examine the two types of rules. Section I.B will then explore first the standards courts employ when reviewing legislative and nonlegislative rules on the merits, and second the issue of whether and when plaintiffs can challenge them at all.

A. Agency Action—Legislative and Nonlegislative Rules

The APA defines a rule broadly as "the whole or a part of an agency statement of general or particular applicability and future

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[29] This Note does not discuss the Article III "case or controversy" requirement, nor does it address the Supreme Court's standing doctrine pursuant to that requirement, but this issue of course looms heavily in the background of any discussion into whether agency decisions are judicially reviewable.

[30] 5 U.S.C. § 551(13) (2012) (defining an "agency action" as the "whole or a part of an agency rule, order, license, sanction relief, or the equivalent of denial thereof, or failure to act").

[31] *See, e.g.*, Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 406 (1971) (reviewing the Department of Transportation's grant of approval to a state agency to construct a highway).

[32] *See* § 554 (outlining formal adjudication procedures).

effect designed to implement, interpret, or prescribe law or policy."[33] The most common way for an agency to promulgate a rule is through a process known as informal rulemaking, or "notice-and-comment" rulemaking, which follows the procedures outlined in section 553 of the APA.[34] Under this process, an agency must simply 1) publish a notice in the Federal Register with a brief description of the agency's proposal; 2) give "interested persons" an opportunity to comment by providing alternative data and viewpoints; and 3) after considering the comments, adopt a final rule with a "concise general statement of [its] basis and purpose."[35] Though this process seems "barebones,"[36] in fact "[o]ver the last several decades, [it] has changed significantly in ways that have created so many disadvantages to use of the process that many agencies avoid it whenever possible."[37] Notice-and-comment rulemaking has become "expensive, burdensome, and time-consuming" as a result of several factors, not least of which are court decisions that demand, as a practical matter, an onerous explanation of why the agency is enacting the rule it is enacting.[38]

Because of this burden, and because of other benefits that will be discussed below, agencies often instead try to opt-out of the section 553 process by merely posting a notice on their websites or sending a letter to affected parties stating the agency's opinion.[39] They can proceed in this manner because of two carveouts in section 553: Neither "interpretive rules" nor "general statements of policy" are subject to the APA's notice-and-comment requirements.[40] Interpretive rules and policy statements, often referred to together as "guidance documents"

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[33] § 551(4).

[34] *See* § 553 (outlining notice-and-comment procedures); *see also* Franklin, *supra* note 23, at 282 (examining the different ways in which agencies promulgate rules).

[35] § 553(b)–(c); *see also* Franklin, *supra* note 23, at 282.

[36] Franklin, *supra* note 23, at 282.

[37] RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW 64 (2d ed. 2012).

[38] *Id.*; *see, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) (heightening the standard an agency must satisfy for its decisionmaking not to be arbitrary and capricious under the APA).

[39] *See* Jeff Bowen & Susan Rose-Ackerman, *Partisan Politics and Executive Accountability: Argentina in Comparative Perspective*, 10 SUP. CT. ECON. REV. 157, 196 (2003) ("Guidance documents or policy statements are increasingly used by agencies to articulate general policies without needing to follow APA procedures."). Note that while these documents are often informal in nature, they do not have to be; sometimes, in fact, nonlegislative rules are even formally published in the Federal Register or Code of Federal Regulations. *See* Thomas J. Fraser, Note, *Interpretive Rules: Can the Amount of Deference Accorded Them Offer Insight into the Procedural Inquiry?*, 90 B.U. L. REV. 1304, 1308 (2010).

[40] § 553(b)(A) (2012); *see also* Franklin, *supra* note 23, at 286 (noting that the APA does not define these terms).

or "nonlegislative rules,"[41] are intended to be nonbinding and merely advisory.[42] They do not carry the "force of law."[43] Not every rule, however, can be promulgated in this manner. If a rule is legislative—that is, if it is a legally binding regulation that carries the force of law—it must be promulgated through notice-and-comment procedures. Agencies cannot enact binding rules via guidance document.[44]

Clear though this distinction may seem, however, courts often struggle to determine whether a document in question is a legislative rule or instead nonbinding guidance.[45] The distinction between the two is in fact "fuzzy"[46] and "enshrouded in considerable smog."[47] Distinguishing one type of rule from the other is not made easier by the fact that private parties often act as if they are bound by agency pronouncements of any stripe. Securities and Exchange Commission (SEC) no-action letters, for instance, are considered nonbinding guidance documents,[48] but private entities regard them as illuminating how the SEC will act upon its enforcement authority, and they respond accordingly.

To help resolve the confusion, courts have adopted several tests to distinguish legislative from nonlegislative rules, with mixed results. An older test—the "substantial impact" test—looked to the practical effects of agency action to determine whether the act had a "substan-

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41 For the sake of variety and simplicity, this Note will refer to "interpretive rules," "policy statements," "nonlegislative rules," and "guidance documents" interchangeably.

42 *See* Franklin, *supra* note 23, at 286. While interpretive rules and policy statements are difficult to define with precision, and the APA itself provides no definition, the 1947 Attorney General's manual provides a helpful framework. *See* Fraser, *supra* note 39, at 1307 (discussing the Attorney General's manual). An interpretive rule is a "rule[ ] or statement[ ] issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." A policy statement, by contrast, is a "statement[ ] issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." U.S. DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (1947).

43 CHARLES A. BREER & SCOT W. ANDERSON, DAVIS GRAHAM & STUBBS LLP, REGULATION WITHOUT RULEMAKING: THE FORCE AND AUTHORITY OF INFORMAL AGENCY ACTION 13 (2012), https://www.dgslaw.com/images/materials/379427.PDF.

44 *See* RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.3, at 317 (4th ed. 2002) (explaining that the "beauty of the 'binding effect' test" is that the "agency cannot have it both ways" because, if a document is binding, the court will require onerous procedures, but if it is not, then the agency cannot use the document to bind the public).

45 *See* STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES 544 (6th ed. 2006); PIERCE, *supra* note 37, at 70–71 (surveying various judicial tests to distinguish these two categories); Franklin, *supra* note 23, at 285–86 (noting that "[t]he most difficult cases . . . arise when a party asserts that a document promulgated without notice and comment is really a legislative rule and is therefore procedurally invalid").

46 Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1046 (D.C. Cir. 1987).

47 Noel v. Chapman, 508 F.2d 1023, 1030 (2d Cir. 1975).

48 *See, e.g.*, N.Y.C. Emps.' Ret. Sys. v. SEC, 45 F.3d 7, 13–14 (2d Cir. 1995).

tial impact" on affected parties.[49] If it had such an impact, the action was a legislative rule that needed to undergo notice-and-comment; if it did not, it was a nonbinding guidance document only.[50] This test, however, has fallen into disfavor in recent years.[51] Other tests include the "legal effects" test, which asks whether the documents "create[ ] new legal rights or duties" or instead merely "clarify[ ] existing ones";[52] the "impact on agencies" test, which asks whether the agency treats the allegedly nonlegislative rule "as binding when conducting adjudications";[53] and the deceptively simple "legally binding" test, which holds that if an agency action is legally binding, it is a legislative rule that must undergo notice-and-comment procedures.[54] This last test is notable for its circularity—it "really just restates the conclusion that only legislative rules can be 'legally binding.'"[55] Moreover, it is especially difficult to apply because "challenged rules often contain disclaimers renouncing any binding effect."[56] To get around this problem, some commentators advocate the "agency's label" or "short cut" test, which effectively allows the agency "to characterize its rule however it wishes."[57] Under this simple proposal, if a document undergoes notice-and-comment rulemaking, courts would consider it

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[49] William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1324 (2001).

[50] *See* Fraser, *supra* note 39, at 1312.

[51] *See id.*; *see also* Cabais v. Egger, 690 F.2d 234, 237 (D.C. Cir. 1982) (rejecting the substantial impact test and explaining that "[s]imply because agency action has substantial impact does not mean it is subject to notice-and-comment"). Scholars have argued that the substantial impact test faded from prominence after the Supreme Court's decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978). *See* Kathleen Taylor, Note, *The Substantial Impact Test: Victim of the Fallout from* Vermont Yankee*?*, 53 GEO. WASH. L. REV. 118–19 (1984) (arguing that *Vermont Yankee*'s prohibition of judicially created agency procedure in addition to the requirements of the APA effectively ended the substantial impact test).

[52] Franklin, *supra* note 23, at 287–88. Fraser also cites a 1974 D.C. Circuit case for this proposition. *See* Fraser, *supra* note 39, at 1311. In that case, the D.C. Circuit held that a Federal Power Commission policy was a nonlegislative policy statement because the agency stated that in specific cases it would reexamine the underlying policy rather than applying the policy to the facts of every case. *See id.* (citing Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 50 (D.C. Cir. 1974)).

[53] *See* Fraser, *supra* note 39, at 1313 (citing U.S. Tel. Ass'n v. FCC, 28 F.3d 1232, 1235 (D.C. Cir. 1994) (noting that the FCC only deviated from its allegedly nonbinding policy once in over 300 adjudications)).

[54] *See* Funk, *supra* note 49, at 1326.

[55] *Id.*

[56] Franklin, *supra* note 23, at 288.

[57] *Id.* at 287–88; *see also* William Funk, *When Is a "Rule" a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN. L. REV. 659, 663 (2002) (advocating for the "short-cut"); John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 929 (2004) (same); Fraser, *supra* note 39, at 1325–29 (same). Franklin has criticized the short-cut on the grounds that it inadequately protects the interests of regulatory beneficiaries. *See* Franklin, *supra* note 23, at 309 (explaining that for regulatory

a binding legislative rule; if it does not, courts would consider it a nonbinding guidance document.

Additionally, a D.C. Circuit case, *Appalachian Power Co. v. EPA*,[58] created what Richard Pierce refers to as the "practically binding" test for distinguishing policy statements from legislative rules.[59] In that case, the D.C. Circuit held that an Environmental Protection Agency (EPA) document was a binding legislative rule that needed to be promulgated through notice-and-comment because "[i]t commands, it requires, it orders, it dictates."[60] The court then elucidated the "practically binding" standard:

> If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."[61]

Thus, because the EPA in practice treated this "guidance" document as binding, it was a legislative rule requiring notice-and-comment. It did not matter that the EPA disclaimed all binding effect at the bottom of its document because the disclaimer, the court held, was mere "boilerplate."[62] In fact, the court even suggested that the agency proceeded the way that it had with the express purpose of immunizing its lawmaking from judicial review.[63]

The *Appalachian Power* court suggested this because obtaining judicial review of a legislative rule can be significantly easier than obtaining review of a nonlegislative rule.[64] This is the case in large part because of the final agency action doctrine as well as its close cousin, the ripeness doctrine. Accordingly, the distinction between the

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beneficiaries, the short-cut guarantees "neither public input at the promulgation stage nor judicial review at some later stage").

[58] 208 F.3d 1015 (D.C. Cir. 2000).

[59] PIERCE, *supra* note 37, at 78. See *infra* note 201 and accompanying text for Pierce's criticism of the "practically binding" test.

[60] *Appalachian Power*, 208 F.3d at 1023.

[61] *Id.* at 1021.

[62] *Id.*

[63] *Id.* at 1020 ("The phenomenon we see in this case is familiar. . . . Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. . . . The agency may also think there is another advantage—immunizing its lawmaking from judicial review.").

[64] *See* Funk, *supra* note 49, at 1333 ("[M]any courts are reluctant to review general statements of policy until after they have been applied, whereas generally the same courts would be willing to review the rule if it was legislative."); *infra* Section II.B (explaining how the final agency action requirement plays into this reluctance).

two types of rules is crucial in the court's analysis. The next Section first discusses the standards of review courts employ when examining both legislative and nonlegislative rules. It then considers the question of whether these rules can be challenged in the first place, focusing on the ripeness and finality prerequisites to judicial review.

B. Reviewability of Legislative and Nonlegislative Rules in Administrative Law

First, plaintiffs subject to enforcement action under validly promulgated legislative rules may make both substantive and statutory claims under the APA.[65] In a substantive claim, the plaintiff alleges that the rule is "arbitrary and capricious" and should thus be invalidated.[66] Under this standard of review, the court will closely examine the agency's stated basis for its rule in both the proposed and final versions, and may hold the rule to be arbitrary and capricious if the agency, for example, relied on undisclosed scientific evidence,[67] failed to consider other possible rules, or otherwise did not support its rule through facts in evidence.[68] In a statutory claim, by contrast, the plaintiff argues that the rule violates the statutory text that the agency is relying on to support its action.[69] When reviewing such claims, courts apply the two-step test from the seminal *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[70] Under this test, if statutory provisions are ambiguous, courts will generally accept any agency interpretation that is "reasonable."[71] The *Chevron* framework is widely considered quite deferential, granting agencies broad discretion to construe ambiguous statutory provisions in the manner of their choosing.[72]

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[65] This Note only discusses the general cause of action in the APA; other statutory causes of action, such as the cause of action within the Clean Air Act, fall outside the scope of this Note.

[66] 5 U.S.C. § 706(2)(A) (2012) (authorizing courts to "hold unlawful and set aside agency action" if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

[67] *See* United States v. N.S. Food Prods. Corp., 568 F.2d 240, 243 (2d Cir. 1977) (holding that the FDA's failure to make available the scientific studies on which it relied to promulgate a rule caused that rule to be arbitrary and capricious).

[68] *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 45–49 (1983) (holding that an agency rulemaking is arbitrary and capricious if the agency provides no reasons for its decisions); *see also* PIERCE, *supra* note 44, § 11.4, at 1018–34 (outlining the different cases that apply the arbitrary and capricious test).

[69] *See* § 706(2)(C) (authorizing reviewing courts to set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right").

[70] 467 U.S. 837, 842–44 (1984).

[71] *Id.* at 844.

[72] *See, e.g.*, Richard J. Pierce, Jr., Chevron *and Its Aftermath: Judicial Review of Agency Interpretations of Statutory Provisions*, 41 VAND. L. REV. 301, 302 (1988) (describing

Second, plaintiffs subject to enforcement action under ostensibly *nonlegislative* rules may also make procedural and statutory claims alleging that 1) the rule is actually a binding legislative rule that must be promulgated through the section 553 process (as described above); or 2) the rule is inconsistent with the statutory text. When reviewing these latter statutory claims for genuinely nonlegislative rules, however, courts do not generally apply the same level of deference as they do for legislative rules. Instead, under *United States v. Mead*[73] and its progeny, because nonlegislative rules do not "carry the force of law,"[74] courts generally review them with less deference and apply more exacting scrutiny.[75]

However, in the pre-enforcement context—*before* the agency has applied the rule in question in an enforcement action—the question is often not what level of deference the court will apply to the agency's action, but rather whether the court can review it at all. On the one hand the Supreme Court established, in 1967's *Abbott Laboratories v. Gardner*,[76] a broad presumption of pre-enforcement judicial review.[77] In *Abbott*, after the FDA published, following notice-and-comment procedures, a final regulation mandating that drug labels include generic names in addition to trade names, the Pharmaceutical Manu-

Chevron as having dramatically changed how courts review agency interpretations of statutory provisions); Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 189 (2006) (describing *Chevron* as a "kind of counter-*Marbury*" that seemed to declare that "in the face of ambiguity, it is emphatically the province and duty of the administrative department to say what the law is").

73 United States v. Mead Corp., 533 U.S. 218, 227 (2001) (applying the less deferential *Skidmore* standard to a tariff classification ruling).

74 *Id.* at 221. But, as Fraser notes, rules promulgated without following notice-and-comment procedures may in some cases "still be eligible for *Chevron* deference." Fraser, *supra* note 39, at 1323; *see also* Franklin, *supra* note 23, at 321 ("[N]onlegislative rules are not automatically disqualified from receiving *Chevron* deference."). For the purposes of this Note, however, it is enough to say that because genuinely nonlegislative rules do not "carry the force of law," *see Mead*, 533 U.S. at 221, they are generally subject to more exacting scrutiny.

75 The deference courts apply here actually is a "sliding scale" that gives the agency's interpretation of the statute as much weight as it has "power to persuade," but in practice it is less deferential and more exacting than *Chevron*. Fraser, *supra* note 39, at 1322–23 (citing Christensen v. Harris Cty., 529 U.S. 576, 587 (2000)); *see also Christensen*, 529 U.S. at 597 (Breyer, J., dissenting) (explaining that courts should give less deference to an agency's interpretation when it is doubtful that Congress intended to "delegate interpretive authority to the agency").

76 387 U.S. 136 (1967).

77 PIERCE, *supra* note 44, § 17.6, at 1258; *see also* BREYER ET AL., *supra* note 45, at 775; Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 HARV. L. REV. 1285, 1286 (2014) (explaining that the presumption is "[r]outinely described as 'strong,' 'basic,' 'fundamental,' 'far-reaching,' and even a 'truism'"); Franklin, *supra* note 23, at 301 ("Moreover, the prevailing view is that pre-enforcement APA notice-and-comment challenges are indeed ripe for review.").

facturers Association brought suit alleging that the regulation exceeded the FDA's statutory authority.[78] Even though the FDA had yet to enforce the rule against the Pharmaceutical Manufacturers Association or its members, the Court held the rule reviewable, stating that under the APA, judicial review should be generally available and restricted "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent."[79]

But on the other hand, this presumption of reviewability[80] is subject to two important exceptions—it does not apply when "(1) statutes otherwise preclude judicial review; or (2) [when actions are] committed to agency discretion by law."[81] In fact, the latter exception for actions "committed to agency discretion by law" has been found to establish the opposite presumption—a presumption of *non*reviewability—when agencies fail or refuse to act.[82]

More importantly, despite *Abbott*'s broad presumption of reviewability, two timing doctrines—ripeness and finality—can also create doubt as to whether judicial review is available in the pre-enforcement context.[83] First, agency actions must be "ripe" before courts can review them. Whether an agency's action is "ripe for review" is analyzed under *Abbott*'s two-part test. Under this test, courts consider first, the "fitness of the issues for judicial decision," and second, the "hardship to the parties of withholding court consideration."[84] Despite the seeming vagueness of the test, however, the *Abbott* Court elucidated the ripeness standard as, in essence, a policy concern:

> Without undertaking to survey the intricacies of the ripeness doctrine it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling

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[78] *See Abbott*, 387 U.S. at 138–39.

[79] *Id.* at 141 (quoting Rusk v. Cort, 369 U.S. 367, 379–80 (1962)).

[80] The presumption has also eroded over the years. For instance, *Block v. Community Nutrition Institute* seems to suggest that all that is required to meet the "clear and convincing" test is for an intent to preclude review to be "fairly discernible" in the statute. 467 U.S. 340, 351 (1984) (citation omitted).

[81] 5 U.S.C. § 701(a)(2) (2012).

[82] Heckler v. Chaney, 470 U.S. 821, 831–35 (1985). In *Heckler*, death row inmates sued the FDA alleging that the agency's failure to approve lethal injection drugs as "safe and effective" for human execution violated the agency's statutory mandate to enforce prohibitions against misbranded and adulterated drugs. *Id.* at 823–24. The Court held the agency's failure to act to be presumptively unreviewable and "committed to agency discretion by law" because there was "no law to apply." *Id.* at 826 (citation omitted). In the Court's words, "[I]f no judicially manageable standards are available for judging how and when an agency should exercise its discretion then it is impossible to evaluate agency action for 'abuse of discretion.'" *Id.* at 830–31.

[83] Parties seeking judicial review must also have exhausted their administrative remedies. PIERCE, *supra* note 37, at 80.

[84] *Abbott*, 387 U.S. at 149.

> themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effect felt in a concrete way by the challenging parties.[85]

With this in mind, the Court found the Pharmaceutical Manufacturers Association's lawsuit ripe for review. The issues were "fit for decision" because they were "purely legal"—the only arguments pertained to whether the FDA had exceeded its statutory power.[86] The regulation also had a "sufficiently direct and immediate" effect on the "day-to-day business" of all prescription drug companies because the companies either had to comply with the labeling requirement, or else risk enforcement action.[87] Further, there was hardship to the manufacturers by withholding court consideration. To comply with the rule, the companies had to change all their labels and invest in new costly printing type immediately, well before the FDA initiated any enforcement action.[88] In short, the Court could review the regulation before the FDA actually enforced it because to do so did justice to the challenging parties without greatly infringing on the agency's discretion.

Although *Abbott* took a generous view of ripeness, however, not all pre-enforcement challenges are ripe for review. For instance, in *Toilet Goods Ass'n v. Gardner*, the Court held the case to be unripe because the legal issues depended on contextual facts.[89] There, the Court held that it made more sense to wait for a specific search of a manufacturer's facility than it did to permit a facial challenge to the broader FDA rule promoting the searches before the FDA actually acted upon it.[90] Moreover, the Court in recent years has "cut back"[91] on the *Abbott* presumption. In a 2003 case, for example, the Court stated that regulations are not ordinarily ripe for review "until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation."[92] The Court, however, distinguished *Abbott* by stating that a "major exception" to this principle occurs when a plaintiff challenges "a substantive

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[85] *Id.* at 148–49.

[86] *Id.* at 149.

[87] *Id.* at 152.

[88] *See id.* at 152–53 (noting district court findings).

[89] 387 U.S. 158, 162–64 (1967).

[90] *See id.* at 163 ("At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order.").

[91] *See* PIERCE, *supra* note 37, at 108–09 (noting cases between 1990 and 2003).

[92] Nat'l Park Hosp. Ass'n v. Dep't of the Interior, 538 U.S. 803, 808 (2003) (quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 891 (1990)).

rule which as a practical matter requires the plaintiff to adjust his conduct immediately."[93]

Part and parcel of the ripeness doctrine is "final agency action," another prerequisite to judicial review; though ripeness and finality are technically treated separately because finality is codified in section 704 of the APA,[94] in practice they blend together.[95] In *Abbott* itself, the Court included finality in the first prong of the ripeness test, holding the regulation to be final and positing that the finality requirement should be interpreted in a "pragmatic" way.[96] Since *Abbott*, however, the caselaw has seemed to follow two strands. The first, exemplified by *FTC v. Standard Oil Co. of California*, posits that agency action is final when it is a "definitive" statement of the agency's position, and has a "'direct and immediate . . . effect on the day-to-day business' of complaining parties."[97] The second strand, which emerged in *Bennett v. Spear*, puts forth a two-part test for deciphering whether an agency's action is final. First, the agency action must mark "the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature."[98] Second, "the action must be one by which 'rights or obligations have

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[93] *Id.*

[94] 5 U.S.C. § 704 (2012) (restricting judicial review to "final agency action for which there is no other adequate remedy in [ ] court"); *see also* Eacata Desirée Gregory, Comment, *No Time Is the Right Time: The Supreme Court's Use of Ripeness to Block Judicial Review of Forest Plans for Environmental Plaintiffs in* Ohio Forestry Ass'n v. Sierra Club, 75 CHI.-KENT L. REV. 613, 615 n.16 (2000) ("Technically, the statutorily-based finality is a separate doctrine from judicially created ripeness.").

[95] BREYER ET AL., *supra* note 45, at 887, 915 (stating that the finality requirement can be understood to have codified the ripeness doctrine); *see also* Jason Fowler, Note, *Finality: What Constitutes Final Agency Action? The Practical Implications of the D.C. Circuit's Ruling in* Reliable Automatic Sprinkler Co. v. Consumer Product Safety Commission, 24 J. NAT'L ASS'N ADMIN. L. JUDGES 311, 316 (2004) (explaining that within the D.C. Circuit, the question of whether the agency's action is sufficiently final is evaluated as part of the first prong of the *Abbott* test).

[96] Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967) ("The cases dealing with judicial review of administrative actions have interpreted the 'finality' element in a pragmatic way.").

[97] 449 U.S. 232, 239 (1980) (quoting *Abbott*, 387 U.S. at 152); *see also* Dalton v. Specter, 511 U.S. 462, 469 (1994) (interpreting whether a Presidential directive on military bases was final agency action by examining whether it "directly affect[ed]" the bases at issue); Or. Nat. Desert Ass'n v. U.S. Forest Serv., 465 F.3d 977, 990 (9th Cir. 2006) (holding that Forest Service annual operation instructions were final agency action because they had a "'direct and immediate . . . effect on the day-to-day business' of the permit holder" (quoting *Standard Oil*, 449 U.S. at 239 (internal citation omitted))); Indep. Petroleum Ass'n of Am. v. Babbitt, 235 F.3d 588, 594 (D.C. Cir. 2001) (declaring definitiveness and effect on day-to-day business to be the test for final agency action); Ciba-Geigy Corp. v. EPA, 801 F.2d 430, 436 (D.C. Cir. 1986) (same).

[98] 520 U.S. 154, 177–78 (1997) (citation omitted).

been determined,' or from which 'legal consequences will flow.'"[99] Circuits have also put their own glosses on these tests—the Fourth Circuit, for instance, asks whether the action is "dependent upon future uncertainties or intervening agency rulings" to determine if it is final.[100]

The *Bennett* approach has become the main test for interpreting whether agency action is final,[101] although the *Standard Oil* strand has not entirely disappeared, even in Supreme Court jurisprudence.[102] The difference between these two strands may be subtle but is not merely semantic.[103] The *Standard Oil* formulation—discussing effects on day-to-day business—is linguistically and conceptually the same as the *Abbott* ripeness inquiry. The second prong of the *Bennett* test, by contrast, for all intents and purposes asks the same question as in Section I.A above: whether the rule in question is a binding legislative rule or a nonbinding guidance document.[104] Because agency action

[99] *Id.* at 178 (quoting Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62 (1970)).

[100] Fowler, *supra* note 95, at 346–47 (quoting Charter Fed. Sav. Bank v. Office of Thrift Supervision, 976 F.2d 203, 208 (4th Cir. 1992)).

[101] *See, e.g.*, U.S. Army Corps of Eng'rs. v. Hawkes Co., 136 S. Ct. 1807, 1813 (2016) ("[W]e distilled from our precedents two conditions that generally must be satisfied for agency action to be 'final' under the APA."). The Court then cited the *Bennett* factors. *Id.*; *see also* Sackett v. EPA, 132 S. Ct. 1367, 1371 (2012) (applying the *Bennett* test); Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 478–79 (2001) (same); Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 858 (4th Cir. 2002) (stating that "[t]he Court refined its *Standard Oil Co.* finality analysis in *Bennett v. Spear* . . . by narrowing down the inquiry" to the *Bennett* test) (citation omitted); William Funk, Final Agency Action After *Hawkes* 10 (Aug. 21, 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2825443 ("Whatever the weakness of the provenance for *Bennett*'s test for finality, it has been the citation of choice in subsequent Supreme Court decisions assessing finality, including *Hawkes Co.*").

[102] For instance, in *Hawkes*, the Court in a unanimous opinion held that Army Corps of Engineers' jurisdictional determinations are final agency action because they satisfy the two *Bennett* prongs, but also cited *Abbott*, pointing out that the jurisdictional determinations are "definitive" and that finality should be interpreted in a "pragmatic" way. 136 S. Ct. at 1815. Interestingly, in her concurrence, Justice Ginsburg wrote that the jurisdictional determinations are final because they are "definitive" and because they have "an immediate and practical impact." *Id.* at 1817–18 (Ginsburg, J., concurring) (quoting Frozen Food Express v. United States, 351 U.S. 40, 44 (1956)). This may suggest a subtle divide on the Court with respect to the two strands. *See also* 4 CHARLES H. KOCH, JR. & RICHARD MURPHY, ADMINISTRATIVE LAW AND PRACTICE § 12:20 (3d ed. 2017) ("*Hawkes* thus reveals that: (a) the line between legal consequences and practical impacts can be very fine indeed; and (b) the justices do not entirely agree whether that line should matter.").

[103] *See* BREYER ET AL., *supra* note 45, at 916 ("There is an evident connection between [the two tests]—but note that they are not identical.").

[104] *See* Gwendolyn McKee, *Judicial Review of Agency Guidance Documents: Rethinking the Finality Doctrine*, 60 ADMIN. L. REV. 371, 388–89 (2008) ("[C]ourts have begun to interpret the finality requirement . . . through the tests . . . originally created to determine whether courts should consider certain agency actions to be invalidly promulgated legislative rules.").

must be "final" before a court can review it,[105] this difference has significant implications for the pre-enforcement reviewability of nonlegislative rules.

II
The Finality Puzzle

In Part II below, this Note will first discuss whether the GRAS rule mentioned in the Introduction was final agency action. It will then examine the problems with the finality requirement, using the *Center for Food Safety* case as a focal point.

A. The GRAS Rule and Final Agency Action

Recall the dispute in *Center for Food Safety*. In that case, the FDA in 1997 issued a proposed rule through notice-and-comment to replace its older "GRAS 'petition affirmation process'" with a new, less stringent GRAS notification process.[106] The agency then operated under the new process through the Interim Policy for nearly twenty years without ever accepting comments or finalizing the proposed rule.[107]

Did the new process constitute "final agency action" when the Center for Food Safety challenged it in 2014? The answer depends upon whether one looks at the Interim Policy itself or instead at the new GRAS notification process if it had been finalized through the APA's notice-and-comment procedures.[108] The Finalized New Process

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[105] *See* Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt., 460 F.3d 13, 18 (D.C. Cir. 2006) ("Whether there has been 'agency action' or 'final agency action' within the meaning of the APA are threshold questions; if these requirements are not met, the action is not reviewable.").

[106] *See* Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114, 118 (D.D.C. 2015). As the case explains, because GRAS substances are statutorily excluded from the requirement that all food additives be subject to premarket approval, food manufacturers are permitted to bring these substances to market "without FDA's approval and without even notifying FDA." *Id.* at 117 (citing Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,939 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pt. 170)). Because of this exclusion, the FDA need not institute a GRAS program at all and in fact has authority to take enforcement action even without the program. *See* Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,939. Some cases impliedly suggest that rules may be nonlegislative (and thus would not satisfy *Bennett*'s second prong) if agencies have enforcement authority even without the rule. *Cf.* Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993) (explaining that if in the absence of the rule there would *not* be an "adequate legislative basis for enforcement action," the rule is legislative and must undergo notice-and-comment procedures).

[107] *See Ctr. for Food Safety*, 126 F. Supp. 3d at 118 ("FDA has neither responded to any of the comments nor issued a final rule.").

[108] I will refer to this hypothetical final GRAS rule as the "Finalized New Process." Note that the rule was actually finalized in 2016. I refer only to the facts as they existed at the time of the suit.

clearly would satisfy the first prong of the *Bennett* final agency action test; a final rule, by definition, is the consummation of an agency's decisionmaking process because it is no longer tentative or interlocutory in any way.[109] But whether the Interim Policy *itself* satisfies *Bennett*'s first prong is a more difficult question. On the one hand, the Interim Policy may indeed have constituted the "consummation of the agency's decisionmaking process" because under it the FDA had processed hundreds of notices; in fact, the agency appeared to have abandoned the old GRAS affirmation process completely.[110] The new GRAS notification process, as it operated through the Interim Policy, was so well-established, truth be told, that the Government Accountability Office (GAO) penned a report admonishing the FDA for its lax enforcement of GRAS foods well before the FDA even considered finalizing the rule.[111] Crucially, moreover, it had been seventeen years.[112] As William Araiza argues, it may make sense to read *Bennett*'s first prong "as satisfied when an agency's delay is so egregious as to justify a court's conclusion that the agency has effectively defaulted on the question."[113]

On the other hand, however, the Interim Policy may not have been "the consummation of the agency's decisionmaking process," in part because the agency itself characterized it as temporary. By promulgating the new process through a proposed rule, accepting comments on that proposed rule in both 1997 and 2010,[114] and repeatedly insisting to the public and to Congress that the agency intended

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[109] *See* Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (putting forth the first prong of the final agency action test); *In re* Murray Energy Corp., 788 F.3d 330, 336 (D.C. Cir. 2015) ("Put simply, the consummation of the agency's decisionmaking process with respect to a rule occurs when the agency issues the rule.").

[110] GAO REPORT, *supra* note 9, at 6 ("FDA did not formally terminate the petition affirmation process, but has stated it no longer commits resources to the process."). The FDA might therefore have been able to claim that it merely failed to enforce the old GRAS petition affirmation process due to lack of resources, a "failure to act" that would constitute presumptively unreviewable agency *inaction*. *See supra* note 82 and accompanying text (discussing the *Heckler* exception to the presumption of reviewability).

[111] *See* GAO REPORT, *supra* note 9 at 20 ("FDA is not systematically ensuring the continued safety of current GRAS substances."); *see also* Substances Generally Recognized as Safe, 75 Fed. Reg. 81,536 (proposed Dec. 28, 2010) (to be codified at 21 C.F.R. pt. 170) (requesting comments on the proposed rule eight months *after* the GAO report and six years before the FDA finalized the rule).

[112] *Ctr. for Food Safety*, 126 F. Supp. 3d at 122 ("Before the Consent Decree, FDA relied on the Proposed Rule while it contemplated a final rule for seventeen years with no end in sight.").

[113] William D. Araiza, *In Praise of a Skeletal APA:* Norton v. Southern Utah Wilderness Alliance*, Judicial Remedies for Agency Inaction, and the Questionable Value of Amending the APA*, 56 ADMIN. L. REV. 979, 988 (2004).

[114] *See Ctr. for Food Safety*, 126 F. Supp. 3d at 118 (hearing from thirty organizations).

to finalize the rule at some point,[115] the FDA made plain that it did not consider its decisionmaking process to be consummated. The caselaw is at least partly on the FDA's side in this matter. Courts often give great weight to an agency's characterization of the finality of its action,[116] and they have also repeatedly held that proposed rules are not final agency action subject to judicial review.[117] Moreover, as a theoretical matter, if a plaintiff were to sue at any time in between 1997 and 2014, the FDA could hypothetically have finalized the rule, and changed a number of procedures, thereby rendering the original suit moot. Under the Fourth Circuit approach, the Interim Policy would therefore be subject to "future uncertainties or intervening agency action,"[118] and thus would be not be final.

The same dichotomy between the Finalized New Process on the one hand and the Interim Policy itself on the other exists when analyzing whether the second prong of the *Bennett* final agency action test was satisfied. The Finalized New Process probably would create "'rights or obligations' from which 'legal consequences will flow'" under *Bennett*'s second prong because it would change the legal regime to which the FDA is subject.[119] Under the "pre-1997 rule," the FDA was legally obligated to undertake a comprehensive regulatory procedure to determine whether substances were or were not GRAS if companies chose to participate.[120] Under the Finalized New Process, by contrast, this legal regime would change because the FDA would

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115 *See* GAO REPORT, *supra* note 9, at 17 ("According to FDA officials, while the agency plans to issue a final rule, the agency has had higher priorities and currently has no specific schedule for doing so.").

116 *See* McKee, *supra* note 104, at 384 (explaining that when guidance documents are labeled "draft" or are treated as future suggestions that "the agency has yet to finalize," courts are unlikely to find them to satisfy *Bennett*'s first prong); *see also* Food & Water Watch v. EPA, 5 F. Supp. 3d 62, 81–82 (D.D.C. 2013) (explaining that courts look in part to "the agency's own characterization of its action" in determining whether agency action is final).

117 *See* Elec. Privacy Info. Ctr. v. FAA, 821 F.3d 39, 44 (D.C. Cir. 2016) ("[W]e do not have authority to review proposed agency rules."); *In re* Murray Energy Corp., 788 F.3d 330, 334–35 (D.C. Cir. 2015) (explaining that proposed rules are not final agency action because they meet neither prong of the *Bennett* test).

118 *See supra* note 100 and accompanying text (describing the Fourth Circuit's gloss on the *Bennett* test).

119 *See* Bennett v. Spear, 520 U.S. 154, 178 (1997) (explaining that the biological opinion in question was final agency action because it changed the legal regime to which the action agency was subject).

120 *See* Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114, 118 (D.D.C. 2015) (describing the procedure); Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,941 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pt. 170) (explaining that under the GRAS petition affirmation process, the FDA would conduct a "comprehensive review" of a petition's data and information).

no longer be legally obligated to undertake such a thorough review.[121] Further, under the old rule, the FDA's decision about the GRAS status of a particular substance was an affirmative determination to which the FDA was bound.[122] Under the Finalized New Process, however, the letters the FDA would send to manufacturers would be nonbinding. They would not, in the FDA's view, "place an agency imprimatur on the substance that is the subject of the notice,"[123] and, in fact, the letters would not be a determination of GRAS status at all.[124] Because these changes from the old process to the new one would constitute a "certain change in the legal obligations of a party"[125]—here, the FDA itself—the Finalized New Process would probably satisfy *Bennett*'s second prong. This illustrates an important point. By the terms of the *Bennett* test, it seems that agency action can be final when legal consequences flow from it, even if those consequences only affect the agency itself.[126] In this sense, if the rule were

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[121] *See* Complaint ¶ 38, *Ctr. for Food Safety*, 126 F. Supp. 3d 114 (No. 1:14-cv-267) ("FDA no longer conducts its own detailed analysis to evaluate the data. In fact, FDA no longer affirms whether or not a substance's use is GRAS at all."); Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,941 (explaining that under the new process, FDA did "not intend to conduct its own detailed evaluation of the data"); *see also Ctr. for Food Safety*, 126 F. Supp. 3d at 125 ("[A]n agency action that 'effectively amends a prior legislative rule' that was previously published in the Code of Federal Regulations is a legislative rule that agencies must promulgate through the notice-and-comment process . . . ." (quoting Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993)).

[122] *See Ctr. for Food Safety*, 126 F. Supp. 3d at 118 (explaining that the FDA in the GRAS "petition affirmation process" would grant parties "official recognition" of their substance's GRAS status); Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,941 (explaining that as part of the FDA's petition affirmation process, it would draft "a detailed explanation" affirming the use of a particular substance as GRAS and publish it in the Federal Register).

[123] Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,946. Moreover, while the FDA lists several reasons why it "*may* question" the GRAS status of the use of a substance and notes that its response *could* identify problems with the company's GRAS notice, the FDA clarifies that "whether [it] chooses to advise a notifier that the agency has identified a problem with the notice, where the notice raises no important public health issues, is a matter *committed to the agency's discretion*." *Id.* at 18,950–51 (emphasis added). The agency might be putting such language in the preamble to persuade a reviewing court that the proposed notification procedure is nonbinding and thus not subject to review.

[124] *See* Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,946 ("[A]n agency response to a GRAS notice would not be equivalent to an agency affirmation of GRAS status.").

[125] *See* Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 15 (D.C. Cir. 2005) ("[I]f the practical effect of the agency action is not a certain change in the legal obligations of a party, the action is non-final for the purpose of judicial review.").

[126] *See, e.g.*, Food & Water Watch v. EPA, 5 F. Supp. 3d 62, 81 (D.D.C. 2013) (explaining that in analyzing *Bennett*'s second prong, courts consider whether the agency has "genuinely left the agency and its decisionmakers free to exercise discretion" (quoting Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 806 (D.C. Cir. 2006))). A formally codified final rule setting forth the new GRAS notification program

finalized, it may not matter that the new process, like the old process, was voluntary. Though the Finalized New Process would not seem to change or create legal obligations for *private parties* because of its voluntary nature, it would change legal obligations for the *agency*, and would thus probably meet *Bennett*'s second prong.[127]

By contrast, the FDA may have been right that the Interim Policy *itself* did not "impose legal consequences" on any parties or determine any rights or obligations. As discussed, the Interim Policy probably did not impose legal consequences on private parties because the process it set forth was completely voluntary for companies, and technically the letters the FDA sent out under it determined nothing but that the agency had no questions or that it did not have enough information.[128] Further, the Interim Policy itself, unlike the Finalized New Process, did not "obligate" the FDA to follow any particular procedures at all. This is exemplified by the FDA's insistence in the Interim Policy that it would follow the GRAS notification process only "in general," and that the agency "would not be bound" by the ninety-day timeframe.[129] Though operating under the GRAS notification process through the Interim Policy, the FDA was refusing to bind itself or anyone else to the procedures set forth in that notification process. Because of this refusal to bind or finalize the process, the Interim Policy may in fact not satisfy *Bennett*'s second prong even though the same process if finalized through notice-and-comment probably would satisfy it.[130]

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would satisfy *Bennett*'s second prong because it would change obligations for and remove discretion from FDA personnel.

[127] *See* Gen. Elec. Co. v. EPA, 290 F.3d 377, 380 (D.C. Cir. 2002) (holding that a guidance document met *Bennett*'s second prong because it was binding on the applicants *and* on the agency). *But see Ctr. for Auto Safety*, 452 F.3d at 811 (holding that voluntary regional recall guidelines did not satisfy the second prong because "the agency has never codified the practices in binding regulations").

[128] *See* GAO Report, *supra* note 9, at 6 (explaining the three types of response letter the FDA would send out under the GRAS notification process); *see also* Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,942 (explaining that because both the older and newer procedures are voluntary, the "substitution" of the new program for the old is "neutral" from a "legal and regulatory perspective"). The FDA's codified definition of a "guidance document" may also indicate that the Interim Policy was not final agency action. *See* 21 C.F.R. § 10.115 (2016) ("Guidance documents include, but are not limited to, documents that relate to . . . the processing, content, and *evaluation or approval of submissions*." (emphasis added)).

[129] Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,954.

[130] To be sure, it also may be the case that Interim Policy itself satisfies *Bennett*'s second prong. The fact that the FDA proceeded via notice-and-comment suggests that the FDA thought that it *had* to proceed this way. Moreover, the Interim Policy seems to "effectively amend[ ]" a prior legislative rule—the old GRAS process—which also indicates the Interim Policy may itself be a legislative rule. *See* Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993) (explaining that if a rule "effectively

The point of this exercise, however, is not to decide the specific outcome of this case, but rather to illustrate the problems that the finality requirement causes.[131] Section II.B will discuss how the *Bennett* test creates a doctrinal overlap that undermines the presumption of reviewability and other background principles of administrative law. It will then explain the negative consequences of this doctrine.

B. The Problems with the Finality Requirement

First, as the above analysis shows, the finality requirement creates incentives for agencies to strategically abuse the prongs of the *Bennett* test to avoid judicial review. Had the FDA finalized its new process, the final rule would likely constitute a final agency action. But by proposing a rule, operating under it, and then not finalizing it, the FDA may be able to use the finality requirement to insulate its new rule from legal challenge. Indeed, as a result of cases giving great deference to agency claims that rules were only "draft," that the agency only intended to follow rules "in general," or that rules did not impose legal consequences because the agency used words like "should" instead of "must," agencies like the FDA have learned what language to use to avoid satisfying the two prongs of the *Bennett* test.[132]

Second, though *Bennett*'s second prong is not supposed to merely duplicate the tests for distinguishing between legislative and nonlegislative rules,[133] as described in Part I above, in practice it does just that.[134] Courts ask, in essence, whether the challenged rule is legally

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amends" a legislative rule, it is a legislative rule and must go through notice-and-comment).

[131] The case ended on a consent decree without resolving the merits. *See* Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114, 119 (D.D.C. 2015). This Note examines this case because: 1) it shows a particularly egregious and interesting example of an agency using the finality prerequisite to its advantage; 2) it highlights the thin line between legislative and nonlegislative rules; 3) it shows how the very same rule that could likely be subject to pre-enforcement challenge if finalized may be immune from review if left in a "temporary" state; 4) it involves a deregulatory action and a regulatory beneficiary as plaintiff; 5) it can also be potentially characterized as inaction and thus presumptively unreviewable; 6) it is a voluntary and comprehensive program, which are less likely than are discrete actions to be final agency action; and 7) the result may differ depending upon which strand of finality doctrine a reviewing court follows. The case thus brings the problems with the doctrine into full focus.

[132] McKee, *supra* note 104, at 391.

[133] *See* Funk, *supra* note 49, at 1337 ("To say that nonlegislative rules do not make 'law' or have binding legal effect, however, is not to say that they cannot have legal consequences."); Funk, *supra* note 101, at 11–12 (explaining that though *Bennett*'s legal consequences inquiry seems to contemplate practical impacts, it nonetheless is unclear whether interpretive rules and policy statements can ever be final agency action).

[134] *See, e.g.*, Nat. Res. Def. Council v. EPA, 643 F.3d 311, 321 (D.C. Cir. 2011) ("[T]he inquiries into whether the agency action was final and whether the agency action was a rule

binding, carries legal effects, or whether it speaks with the "force of law."[135] Because courts ask this, and because the satisfaction of this prong is a prerequisite to judicial review in all cases,[136] nonlegislative rules seem to be effectively immune from pre-enforcement judicial review. This is the case even though "interpretive rule[s] . . . would certainly appear to fall within the final agency action category for which judicial review is allowed under the APA,"[137] because private parties can indeed be adversely affected by them.[138]

Because of this doctrinal overlap, the *Bennett* test conflicts with the *Standard Oil* strand of the finality doctrine and undermines *Abbott*'s ripeness test and presumption of reviewability. The Supreme Court seems aware of these conflicts, but has provided little guidance and confusingly seems to apply both the *Bennett* and *Standard Oil* tests at the same time.[139] The *Abbott* and *Standard Oil* formulations posit that actions are ripe and final, respectively, if they are definitive and pose significant "day-to-day effects" on the business of private parties.[140] Under these tests, the GRAS Interim Policy would likely be both ripe and final because 1) the FDA's position is for practical purposes definitive; 2) there are day-to-day effects on manufacturers who can now much more easily obtain tacit FDA approval of their substances; and 3) there at least may be day-to-day effects on the Center for Food Safety's members because they may have, for example, eaten harmful substances which would have been denied GRAS status had the FDA examined them more thoroughly. But *Bennett*'s second prong undercuts *Abbott*'s flexible and fact-driven ripeness inquiry by

[are] essentially the same." (citing Cement Kiln Recycling Coal. v. EPA, 493 F.3d 207, 226 (D.C. Cir. 2007))); Broadgate, Inc. v. U.S. Citizenship & Immigration Servs., 730 F. Supp. 2d 240, 243 (D.D.C. 2010) ("Legislative or substantive rules are, by definition, final agency action, while interpretive rules and general policy statements are not."); *see also* McKee, *supra* note 104, at 398 ("[A]ll the legislative/nonlegislative tests . . . have been incorporated as an alternative to the second prong of the *Bennett* test."); Seidenfeld, *supra* note 2, at 376 ("[T]he dual inquiry that governs finality predisposes courts to determine that guidance documents are not final [agency action] more often than is warranted."); *infra* note 163 (explaining that one D.C. Circuit case seemed to conflate the two tests accidentally).

135 *See supra* notes 49–63 and accompanying text (describing the tests for distinguishing legislative from nonlegislative rules).

136 5 U.S.C. § 704 (2012). Technically, the final agency action requirement is not jurisdictional. *See* Sundeep Iyer, Comment, *Jurisdictional Rules and Final Agency Action*, 125 YALE L.J. 785, 785–86 (2016). However, because courts have interpreted it as necessary to survive a motion to dismiss, finality is effectively required for a suit to go forward.

137 McKee, *supra* note 104, at 396.

138 *See* Funk, *supra* note 49, at 1337 (illustrating that legal consequences can flow from nonlegislative rules).

139 *See supra* note 102 and accompanying text (discussing the internal divide on the Supreme Court with respect to the two strands of finality doctrine).

140 *See supra* notes 87–97 and accompanying text (discussing *Abbott* and *Standard Oil*).

effectively requiring any policy to be a legislative rule before suit can be brought. Thus, even if a rule has real effects, and even if the issues involved are "purely legal"—here, a question of whether the FDA's new process complies with its statute—that rule *still* may not be reviewable unless it passes the notoriously convoluted legally binding test,[141] which as discussed above is a test the GRAS Interim Policy may not pass.

This is improper. To be sure, the Court has sometimes denied pre-enforcement judicial review on various grounds,[142] but as Justice Thomas has rightly opined, when the question is "now-or-never instead of now-or-later," the presumption of reviewability ought to have more force.[143] This makes sense, as under *Abbott* courts ought to consider "the hardship to parties [that results from] withholding court consideration."[144] It is one thing, in other words, to deny review under *Bennett* to a regulated company when it receives a letter from an agency with a preliminary determination that the company's products do not comply with various statutory requirements.[145] Although the letter poses real hardship to the company, the agency has not yet made any definitive determination or taken enforcement action[146]—the company can thus always sue at that time if it cannot sue now. It is quite another matter, however, to deny review when the plaintiff could never otherwise get its day in court. This is often the case when the plaintiff is a beneficiary of regulation rather than a regulated business. For instance, in *Center for Auto Safety v. National Highway Traffic Safety Administration*, when the National Highway Traffic

141 *See supra* notes 45–47 and accompanying text (explaining that courts struggle to distinguish between legislative and nonlegislative rules). To be sure, the crux of the Center for Food Safety's argument was that the GRAS Interim Policy was a legislative rule that had been improperly promulgated without notice-and-comment procedures. *See* Complaint ¶ 8, Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114 (D.D.C. 2015) (No. 1:14-cv-267) ("This Court should declare that FDA has violated the APA by operating under a proposed rule that did not undergo the rulemaking procedures required by the APA."). Under this claim, of course, the rule would need to be legally binding for the Center for Food Safety to receive relief even in the absence of the *Bennett* test, as a properly promulgated guidance document is exempt from section 553 procedures.

142 *See supra* notes 89–93 and accompanying text (describing situations where the Court has denied pre-enforcement review and explaining that the Court has recently "cut back" on the presumption of reviewability).

143 Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 45 (2000) (Thomas, J., dissenting) ("While it is true that the presumption may not be quite as strong when the question is now-or-later instead of now-or-never . . . .").

144 *See supra* note 84 and accompanying text (discussing the ripeness test).

145 Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n, 324 F.3d 726, 731 (D.C. Cir. 2003) (holding that a CPSC letter to sprinkler company with a preliminary determination that its sprinklers failed to comply with certain product safety requirements was not final agency action).

146 *Id.* at 731–32.

Safety Administration (NHTSA) issued "policy guidelines" allowing regional instead of national recalls in certain circumstances, the court denied review to an auto safety organization challenging the guidelines as violating the authorizing statute.[147] Though the guidelines did constitute the "'consummation' of the agency's decisionmaking process" under the first prong, they did not "impose[ ] any rights and obligations" because they were not a legislative rule, and as such the court would not review the case.[148] But like in *Center for Food Safety*, the NHTSA will not be taking enforcement action against the auto safety group. As is the case with all regulatory beneficiaries who seek to challenge deregulatory agency action, if the auto safety group cannot challenge the guidelines now, it can never challenge them because the guidelines will never impose legal consequences sufficient to satisfy *Bennett*'s second prong.[149]

The *Center for Auto Safety* example also illustrates another problem with the finality doctrine: When the challenged action is a program or policy, as opposed to a discrete action, it is much more difficult to obtain judicial review.[150] This is the case for two reasons. First, unlike with a basic license or a hearing, as discussed in Part I, it is difficult to say when an agency has finalized a program. If an agency fully proceeds through the notice-and-comment process, of course, the requisite finality would be established, but if, as in *Center for Food Safety*, an agency indicates that a program "is still under meaningful refinement and development," that is often enough to defeat finality under *Bennett*'s first prong.[151] Thus instead of merely proceeding via

147 452 F.3d 798, 803–04 (D.C. Cir. 2006).

148 *Id.* at 806 (quoting CropLife Am. v. EPA, 329 F.3d 876, 883 (D.C. Cir. 2003)).

149 *See, e.g.*, Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 420–21 (2007) (explaining that "regulatory beneficiaries" are often denied "the opportunity for judicial review that is eventually afforded to a regulated entity" in part because "a guidance document may not be considered final agency action"). *But see* Funk, *supra* note 49, at 1340 (explaining that the ripeness now-or-later versus now-or-never inquiry grants beneficiaries judicial review more frequently). If Funk is right, then *Bennett*'s second prong further undercuts the ripeness doctrine because the finality and ripeness inquiries would lead to opposite results even though the two doctrines ought to be essentially the same. *See supra* notes 94–95 and accompanying text (explaining that the doctrines blend together and that section 704 of the APA can be understood to have codified the ripeness doctrine).

150 *See* E. Gates Garrity-Rokous, Note, *Preserving Review of Undeclared Programs: A Statutory Redefinition of Final Agency Action*, 101 YALE L.J. 643, 653 (1991) (arguing that *Lujan v. National Wildlife Federation*, 497 U.S. 871 (1990), significantly undermined judicial review of undeclared programs); Gregory, *supra* note 94, at 620–21 (explaining that "the determination of finality is more difficult" when the challenged action is a program rather than a discrete action).

151 Nat'l Automatic Laundry & Cleaning Council v. Shultz, 443 F.2d 689, 703 (D.C. Cir. 1971) (explaining that when an agency states that "a matter is still under meaningful

guidance document, proceeding via notice-and-comment and then not finishing the process gives an agency significant cover to suggest that its policy is still undergoing refinement and reconsideration. Second, programs might not meet the final agency action requirement because they might not count as "agency action" at all. As E. Gates Garrity-Rokous argues, one Supreme Court precedent appears to declare that comprehensive policies and programs are not reviewable as final agency action because they are not discrete agency determinations.[152] But as the dissent in that case points out—a point with which the majority seems to agree—"declared" programs enacted through notice-and-comment rulemaking would likely be final and reviewable.[153] By contrast, the same exact programs enacted through guidance documents—what Garrity-Rokous calls "undeclared" programs—might not be sufficiently discrete to warrant review.[154] The above analysis of the GRAS notification process accords with this: If the process were finalized, it would likely be reviewable, but if it remained in an "interim" state, a court might not consider it a "declared" program sufficiently discrete to be reviewable in court.

Further, when programs or policies are "voluntary," the finality doctrine also poses obstacles to review. For instance, in *National Ass'n of Home Builders v. Norton*, the EPA put forth a guidance document stipulating that an endangered butterfly was "presumed to be present" in certain areas.[155] This presumption could only be challenged if the landowner followed the exact survey procedures that the EPA laid out.[156] When an association filed suit challenging the EPA's survey

refinement and development, [it] will likely provide the element of tentativeness and reconsideration that should negative finality").

[152] Garrity-Rokous, *supra* note 150, at 644–45, 653.

[153] *Compare Lujan*, 497 U.S. at 914–15 (Blackmun, J., dissenting) (arguing that if the Bureau of Land Management published a final regulation implementing the same exact program, the National Wildlife Federation could challenge it), *with id.* at 890 n.2 (majority opinion) ("If there is in fact some specific order or regulation, applying some particular measure across the board to all individual classification terminations and withdrawal revocations, and if that order or regulation is final . . . it can of course be challenged under the APA.").

[154] Garrity-Rokous, *supra* note 150, at 644–45. The GRAS notification process, to be sure, could not have been implemented via guidance document because of the existence of the old regulation. *See* Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114, 125 (D.D.C. 2015). But had the FDA been able to pursue the guidance route, and especially had it pursued that route informally and without official documentation with sufficient indicia of finality, the GRAS notification process could be seen as a nondiscrete agency "pattern or practice" that would not constitute reviewable agency action. Garrity-Rokous, *supra* note 150, at 646; *see also Lujan*, 497 U.S. at 890 (holding the land withdrawal program nonreviewable because it was not a program and it was not "agency action").

[155] McKee, *supra* note 104, at 386 (citing Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8 (D.C. Cir. 2005)).

[156] *Id.*

procedures as beyond the agency's statutory power, the court held that the procedures were not final: Though they did constitute the "consummation of the agency's decisionmaking process," they did not "impose legal rights or obligations" because the survey procedures—like the GRAS notification process in *Center for Food Safety*—were purely voluntary.[157] But as a practical matter, of course, the EPA expected landowners to comply with these procedures, and they did just that.

It is not news, to be sure, that it is more difficult for beneficiaries of regulation to obtain judicial review, especially when they challenge a nonlegislative rule or a voluntary program or policy.[158] These issues are not unique to the finality doctrine,[159] and they may also not be as problematic as they seem. The analysis of *Center for Food Safety* in Section II.A may suggest that the doctrine is sufficiently flexible to allow a court to find agency action to be final where it merits judicial review. And in fact there are significant drawbacks to pre-enforcement review of agency action. Agencies should be able to experiment temporarily to determine best practices without every last action being subject to court challenge. As Professor Nicholas Bagley points out, pre-enforcement review can "introduce delay, divert agency resources, and limit agency flexibility."[160] It can drastically increase the costs of rulemaking.[161] Pre-enforcement review may also encourage agencies to proceed by inaction rather than rulemaking. If the FDA in *Center for Food Safety* simply decided not to enforce the old GRAS process, for instance, its *inaction* would be presumptively *un*reviewable.[162] This advantages neither the agency nor the public, both of whom benefit from clear rules and procedures. And indeed, in *National Park Hospitality Ass'n v. U.S. Department of the Interior*, the Court, by requiring a "concrete action applying the regulation to the

157 *Nat'l Ass'n of Home Builders*, 415 F.3d at 15–16.

158 *See, e.g.*, Mendelson, *supra* note 149, at 414–20 (describing multiple doctrines that make it difficult for regulatory beneficiaries to challenge deregulatory actions in court).

159 The changes that *Lujan* made to judicial review of programmatic action, for instance, are outside the scope of the *Bennett* doctrine. *See Lujan*, 497 U.S. at 892–94. Accordingly, any changes to the *Bennett* doctrine would not affect *Lujan*'s premise. Nonetheless, as described below, *Lujan* should properly be placed within the APA's exception for action "committed to agency discretion by law," rather than functioning as a prerequisite to review. *See infra* note 176 and accompanying text (arguing that *Bennett*'s second prong should be conceptualized as part of the exception).

160 Bagley, *supra* note 77, at 1329–30.

161 PIERCE, *supra* note 37, at 108.

162 *See supra* note 82 and accompanying text (discussing *Heckler*).

claimant's situation," seems to suggest a new direction in ripeness doctrine away from the presumption of pre-enforcement review.[163]

But one frequently asserted argument against pre-enforcement review—that it may encourage agencies to "rely more heavily on guidance documents"[164]—actually shows the problem with the current finality doctrine. As discussed, because *Bennett*'s second prong appears to be the same exact test as is used to distinguish between legislative and nonlegislative rules, interpretive rules and policy statements seem effectively immune from pre-enforcement judicial review.[165] However, guidance documents can indeed be reviewable for consistency with their authorizing statute; actually, in that context they are subject to more exacting scrutiny than are legislative rules.[166] Some scholars,[167] in fact, have advocated the aforementioned "short-cut"—classifying rules as legislative or nonlegislative solely based upon whether they were promulgated through the notice-and-comment process—precisely because of the differing *Mead* and *Chevron* standards of deference for the two types of rules.[168] If an agency issues a guidance document, they argue, the benefits the

163 *See supra* notes 91–93 and accompanying text. Note that in *National Park Hospitality Ass'n*, the plaintiffs, a trade group representing concessioners doing business in national parks, were challenging a final regulation that interpreted concession contracts in such a way as to preclude plaintiffs from taking advantage of favorable dispute resolution procedures. 538 U.S. 803, 804–05 (2003). The Court held that the rule was a nonbinding policy statement and *also* that it was "final agency action." *Id.* at 812. This seems to contradict current finality doctrine. *See infra* note 165 and accompanying text. It is important to note too that "nothing in the regulation prevent[ed] concessioners from following the [dispute] procedures . . . once a dispute over a concession contract actually arises." *Nat'l Park Hosp. Ass'n*, 538 U.S. at 804. Thus, unlike in *Center for Food Safety* or in *Center for Auto Safety*, this was a "now-or-later" and not a "now-or-never" situation.

164 Bagley, *supra* note 77, at 1329–30.

165 *See* Funk, *supra* note 49, at 1340 ("[T]he finality of a nonlegislative rule for purposes of pre-enforcement judicial review . . . is hardly assured."). Funk understates it; read literally, the *Bennett* test actually precludes pre-enforcement review of nonlegislative rules entirely. As McKee points out, the finality doctrine is not in fact supposed to work this way. In *Center for Auto Safety*, the court noted that meeting the legislative rule test is "merely sufficient, rather than necessary, to qualify as final agency action." McKee, *supra* note 104, at 398 n.165 (quoting Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 798 (D.C. Cir. 2006)). Nonetheless, she argues, "importing the two legislative/nonlegislative tests . . . effectively elevates the legislative rule to a necessary requirement." *Id.*; *see also* Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 795 (2010) ("Though guidance documents generally receive less deference than legislative rules, bringing a legal challenge to guidance documents is actually more difficult.").

166 *See supra* notes 70–75 and accompanying text (explaining *Chevron* and *Mead* deference).

167 *See* Funk, *supra* note 57, at 663 (arguing for the short-cut); Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1720–21 (2007) (same); Manning, *supra* note 57, at 929 (same).

168 *See supra* notes 70–75 and accompanying text.

agency receives from avoiding the burdensome notice-and-comment procedures at the front-end are balanced out by the more exacting standard of review it would receive at the litigation stage.[169] Because of this "trade-off," they assert, the choice for agencies is simply to "pay now or pay later."[170]

Bennett's conception of the finality doctrine, however, undermines this "trade-off." By issuing guidance documents, agencies will never have to "pay later" at all. If the agency avoids the notice-and-comment process, its action is less likely to be final and will more easily allow the agency to avoid judicial review altogether.[171] If it initiates the process and does not complete it, as in *Center for Food Safety*, the agency can possibly even avoid finality by arguing that its decisionmaking process is not consummated under *Bennett*'s first prong. In fact, as the above discussion of *Center for Food Safety* shows, it may be the case that a program could be subject to pre-enforcement review if issued via notice-and-comment procedures, but would not be final agency action if issued as guidance, thus denying a challenger its day in court.[172]

Accordingly, *Bennett*'s two-part test for final agency action poses many problems and in some cases leads to results that seem not to make sense. Part III below will briefly explain why the *Bennett* test is doctrinally problematic before recommending a limited solution that would help to unify the final agency action test with other areas of administrative law.

III
Solving the Finality Puzzle

Regardless of one's views as to the role of the federal courts in the administrative process, the question of whether Congress delegated to the agency the power to speak with the "force of law" should be relevant to whether the court decides to apply *Mead* or *Chevron*, not to whether the agency's action is final, and thus reviewable, in the first place. Even if one believes that nonlegislative rules generally

169 *See, e.g.*, Fraser, *supra* note 39, at 1325–29 (arguing for the short-cut).

170 *See* Franklin, *supra* note 23, at 280 ("The trade-off asserts that agencies—recognizing that they must either 'pay now or pay later' in terms of defending their substantive policy choices—would decide, at least much of the time, to submit their rules to notice and comment . . . .").

171 *See supra* note 60 and accompanying text (explaining that the *Appalachian Power* court suggested that the EPA issued a guidance document for the express purpose of immunizing its lawmaking from judicial review).

172 The FDA in *Center for Food Safety* could not have issued the GRAS notification program as pure guidance because of its prior regulation. But if the prior rule had never existed then perhaps the agency could have operated in this manner.

ought to be unreviewable when challenged for consistency with statutes,[173] it would still be conceptually and doctrinally more logical to place any such presumption within the APA's reviewability exception for actions "committed to agency discretion by law."[174] This is because finality and ripeness are about *timing* while the section 701(a)(2) exception is about *discretion*. When courts apply the exception, they decide for practical and institutional reasons to defer to the agency's discretion and not review the action even though the usual prerequisites to judicial review are met.[175] The question of whether agency action is legally binding is more related to these practical and institutional concerns than it is to timing. For example, court review of certain nonbinding guidance documents—an employee handbook governing internal agency procedures, for instance—has little to do with timing but would seem to be both practically difficult and institutionally to encroach upon matters that should be left to the agency itself.

Conceptualizing *Bennett*'s legally binding inquiry as part of the "committed to agency discretion by law" exception is accordingly more logical than including it in the final agency action test.[176] It is also more "pragmatic": Because it is an exception rather than a prerequisite to review in every single case, using it would grant the courts more flexibility in individual cases.[177] For example, a court could use the exception to hold an employee handbook unreviewable while

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173 As explained in Part I, when a rule is ostensibly nonlegislative, plaintiffs can argue 1) that the rule is actually a legislative rule required to undergo notice-and-comment procedures; and/or 2) that the rule violates the authorizing statute. *See supra* notes 73–75 and accompanying text. By definition, in the first type of claim discussed above a plaintiff cannot obtain judicial relief unless the challenged rule is in fact legislative. Further, only legislative rules can be challenged as arbitrary and capricious. *See supra* notes 66–75 and accompanying text (explaining that plaintiffs can make arbitrary and capricious challenges to legislative rules but not nonlegislative rules). Accordingly, the second prong of the *Bennett* final agency action test only can operate to preclude judicial review when a plaintiff challenges a nonlegislative rule as outside an agency's statutory power. Other challenges will fail on other grounds.

174 5 U.S.C. § 701(a)(2) (2012).

175 For instance, consider why agency inaction is presumptively unreviewable under section 701(a)(2). First, it is *practically* difficult to discern an appropriate legal standard by which to judge an agency's failure to act; by what standard would a court make judgments? *See supra* note 82 (explaining that the FDA's inaction in *Heckler* was not reviewable because there were no judicially manageable standards by which to judge how the FDA exercised its discretion). Moreover, because agencies often fail to act simply because they lack resources, it would pose *institutional* separation of powers concerns for the court to intervene in policy decisions about how to spend money.

176 *Cf.* Seidenfeld, *supra* note 2, at 380 (explaining that *Bennett*'s second prong bears little relation to the policy concerns underlying the finality requirement).

177 *See supra* note 96 and accompanying text (pointing out that the Supreme Court has indicated that final agency action should be interpreted in a pragmatic way).

finding another guidance document reviewable where there were, in fact, judicially manageable standards in the statute by which to judge the agency's discretion. Moving the legally binding inquiry to the section 701(a)(2) exception would also dovetail well with Gwendolyn McKee's suggestion to eliminate *Bennett*'s second prong from the finality inquiry entirely,[178] and would perhaps be the doctrinally most straightforward way to address the final agency action puzzle.[179] Many cases, to be sure, might come out the same way regardless of how these questions are analyzed, but the finality doctrine as it is currently constituted can operate to deny review where it might otherwise be available.

But until and unless the Supreme Court acts, the doctrine is what it is. Courts must find a way to analyze these questions using the current framework. And because there are both many different tests for whether a rule is legislative or nonlegislative, and multiple strands of finality and ripeness doctrine, there is sufficient support in the caselaw for courts to find the "pragmatic" approach to finality that *Abbott* advocates. Sections III.A and III.B will discuss such possible pragmatic solutions.

A. Unreasonable Delay?

One potential solution, at least to the narrow section of cases like *Center for Food Safety* that involve long delays in the notice-and-comment process, is a limited exception to the finality prerequisite in section 706(1) of the APA that authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed" before actions are final.[180] The Supreme Court in *Norton v. Southern Utah Wilderness Alliance*, however, strictly interpreted this authority by holding that courts can only compel agencies to take action under section 706(1) when the agency fails to take discrete action that it is statutorily required to take.[181] As the Court put it, "a delay cannot be

178 McKee, *supra* note 104, at 406–07.

179 The problems with finality discussed in Section II.B, *supra*, could also be resolved through this framework. Courts could, for instance, find certain nonlegislative rules nonreviewable under the exception if the question was "now-or-later"—perhaps to review the agency action "now" would encroach too heavily on the agency's discretion—but find the same rules reviewable if the question was "now-or-never." *See supra* note 143 and accompanying text (explaining that the presumption of reviewability is stronger when the question is "now-or-never instead of now-or-later").

180 § 706(1); *see* DANIEL T. SHEDD, CONG. RESEARCH SERV., R43013, ADMINISTRATIVE AGENCIES AND CLAIMS OF UNREASONABLE DELAY: ANALYSIS OF COURT TREATMENT 2 (2013) ("A court may hear a claim for unreasonable delay despite the fact that the agency has yet to take a final action on the subject.").

181 542 U.S. 55, 63 (2004).

unreasonable with respect to action that is not required."[182] Accordingly, in *Center for Food Safety*, the FDA would probably argue that because no statute compelled it to propose a rule in 1997[183]—the FDA could have left the previous rule in place or decided to only selectively enforce the GRAS standard as a matter of its own discretion—a court could not compel the FDA to finalize it. If a court were to accept this argument, then the APA's "unreasonable delay" provision would not serve as a solution to the finality problem in that case.

A statutory provision within the APA itself, however, may satisfy the *Southern Utah Wilderness Alliance* requirement that the action to be compelled be legally required. Section 555(b) of the APA provides that "within a reasonable time, each agency shall proceed to conclude a matter presented to it."[184] To be sure, the FDA could potentially argue that because it decided to initiate its own rulemaking process, the matter was not "presented to it." But some cases suggest that though an agency has no general obligation to make rules (absent a statutory duty), section 555(b) creates an obligation to proceed within a reasonable time once the agency "decides to take a particular action."[185] Thus though in one case the FDA was not legally required to promulgate a tampon labeling regulation, "[i]n deciding that a regulation was necessary, the FDA took on a duty to promulgate one in a reasonable time. It cannot hide behind the argument that no duty to do so existed."[186]

While it is unclear how much this dicta survives *Southern Utah Wilderness Alliance*—in particular, a broad requirement authorizing courts to compel finalization every time an agency "decides to take a particular action" seems to infringe upon *Southern Utah Wilderness Alliance*'s requirement that that action be legally required—a court would probably be able to use this APA provision to force the FDA to finalize the GRAS proposed rule.[187] But if the FDA had proceeded via guidance document, further action would likely not be legally

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[182] *Id.* at 63 n.1.

[183] *See supra* note 106 (describing the statutory scheme behind the GRAS rule).

[184] § 555(b).

[185] Pub. Citizen Health Research Grp. v. FDA, 724 F. Supp. 1013, 1020 (D.D.C. 1989) (citing Cutler v. Hayes, 818 F.2d 879, 895 (D.C. Cir. 1987)); *see also Cutler*, 818 F.2d at 895 ("Once FDA elected to respond to its legislative directive . . . the APA imposed an obligation to proceed with reasonable dispatch."); Telecomms. Research & Action Ctr. v. FCC, 750 F.2d 70, 79–80 (D.C. Cir. 1984) (explaining that section 555(b) requires agencies to decide matters within a reasonable time).

[186] *Pub. Citizen Health Research Grp.*, 724 F. Supp. at 1020.

[187] *See, e.g.*, Ctr. for Sci. in the Pub. Interest v. FDA, 74 F. Supp. 3d 295, 299–301 (D.D.C. 2014) (rejecting plaintiff's unreasonable delay claim but definitively stating that courts may compel the completion of agency rulemaking if agencies fail to respond to citizen rulemaking petitions).

required as *Southern Utah Wilderness Alliance* demands. And for the many cases that do not turn on long delays in completing the notice-and-comment process, the unreasonable delay provision would not only be unavailable but would also be inadequate to resolve the finality puzzle.[188] The unreasonable delay provision therefore does not provide a complete solution, but it does suggest a framework that might help courts to conceptualize the finality problem. Section III.B will describe such a framework.

B. Towards a Pragmatic Approach to Finality

First, where courts *can* compel the agency to finalize its action, they should interpret *Bennett*'s second prong more formally by using the "legally binding" or "legal effects" tests described in Part I instead of the more functional "substantial impact" or "impact on agencies" tests.[189] Under this formal approach, the court would demand a more searching inquiry into whether the agency's rule imposed legal obligations. As an example, in *Center for Food Safety*, a court following this approach would hold that the GRAS Interim Policy was not final agency action because the FDA technically retained discretion as to whether to abide by the notification process, and because the program's voluntary nature bound neither the agency nor private parties. At the same time, however, the court could compel the FDA to finish the rulemaking process and promulgate a final GRAS rule, because FDA's seventeen-year delay would be unreasonable.

By contrast, where the reviewing court *cannot* compel the agency to finish its process—if for example the agency has issued a guidance document as in *National Ass'n of Home Builders*—the court should construe *Bennett*'s second prong functionally by using the same "practically binding" approach that the D.C. Circuit used in *Appalachian Power*.[190] Under this approach, the reviewing court would look to whether the agency in practice always abided by the criteria or policies set forth in the document regardless of whether or not the agency technically disclaimed legal effect.[191] In *National Ass'n of Home*

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[188] *See supra* Section II.B (discussing other finality cases that do not turn on unreasonable delay in the rulemaking process).

[189] *See supra* notes 49–63 and accompanying text (discussing the various tests courts use to distinguish the two types of rules).

[190] *See supra* notes 58–63 and accompanying text (explaining the "practically binding" standard).

[191] *See* Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021 (D.C. Cir. 2000) ("If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule . . . the agency's document is for all practical purposes 'binding.'"). This approach can also be used in the agency *inaction* context. *See, e.g.*, Texas v. United States, 86 F. Supp. 3d 591, 653–54 (S.D. Tex. 2015)

Builders, the EPA butterfly survey protocols case, a court applying this test would ask 1) if some private parties choose not to participate in the "voluntary" survey protocols, or if all parties always abide by them in practice; and 2) if the EPA always applies the survey protocols in practice regardless of what it states.[192] And in *Center for Food Safety*, if a court could not compel the FDA to finalize the GRAS rule, then it would apply this test and find that FDA as a practical matter had operated under the GRAS notification process since the issuance of the Interim Policy.[193] Thus, because the GRAS Interim Policy was "practically binding," the court would conclude that *Bennett*'s second prong was met, and accordingly that the GRAS Interim Policy was final agency action.

This proposed framework provides a limited solution to the finality puzzle. First, it restores the "trade-off" between process and deference. Under the proposed framework, agencies again face incentives to follow the notice-and-comment process: While their rules are still under development they will be subject to a stricter final agency action inquiry that forms a higher bar to judicial review. By contrast, if agencies elect instead to issue guidance documents, they risk a looser finality inquiry and consequently a greater risk that their rules will be subject to review. Second, the proposed framework is more consistent than is current doctrine with *Abbott*'s presumption of reviewability and with other areas of administrative law. The "practically binding" standard, for instance, more closely considers "day-to-day effects" of any action on both the agency and on private parties, as the *Standard Oil* formulation of the finality inquiry commands.[194] Moreover, the proposed framework takes into account the "hardship to the parties of withholding court consideration" in the *Abbott* ripeness test.[195] When plaintiffs can sue to compel an agency to complete its unreasonably delayed rulemaking, they suffer less hardship. Accordingly, the proposed framework imposes a stricter legal consequences test "now" because plaintiffs can always challenge the final rulemaking "later."

(holding that the DAPA program was not entitled to the *Heckler* presumption because the Department of Homeland Security gave it practically binding effect).

[192] *See* Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 15 (D.C. Cir. 2005) (holding that the survey procedures failed *Bennett*'s second prong).

[193] By 2008, the FDA had sent 274 letters to companies under this "interim" policy. GAO REPORT, *supra* note 9, at 10. At the time of the Center for Food Safety suit, the number had reached almost 500. Complaint ¶ 45, Ctr. for Food Safety v. Burwell, 126 F. Supp. 3d 114 (D.D.C. 2015) (No. 1:14-cv-267).

[194] *See supra* notes 97–100 and accompanying text (discussing the two strands of finality doctrine).

[195] *See supra* notes 84–88 and accompanying text (describing the two prongs of the *Abbott* ripeness test).

The reverse is of course also true. Third, because the proposed framework incentivizes notice-and-comment rulemaking, and it is easier for plaintiffs to challenge "declared" programs issued in this manner than it is to challenge "undeclared" programs issued via guidance document, plaintiffs may be more likely to obtain judicial review of voluntary programs than is the case now.

This framework's standards of review also promote sincere agency experimentation while discouraging the strategic abuse of the finality requirement. Under the formalist finality inquiry in the proposed framework, proceeding via notice-and-comment would buy the agency time and become a strategy to allow agencies to undertake needed experiments to determine when approaches work best without the threat of an immediate lawsuit. At the same time, if agencies use the notice-and-comment process to strategically avoid litigation by delaying for unreasonably long amounts of time, courts could force them to finish their processes, at which point their rules would be final and reviewable. Further, if agencies instead choose to enact programs via guidance document in an effort to strategically avoid judicial review, the functional "practically binding" test would not allow the agencies to hide behind "boilerplate" claims that their rules were not final.[196] The proposed framework, however, also protects agency discretion—even if the agency enacts a program by issuing a guidance document, the document still would not count as "practically binding" unless the agency actually treated it as controlling in practice and abided by it consistently.[197] Thus while the GRAS Interim Policy in *Center for Food Safety*, for example, would count as practically binding because the FDA always followed it in practice, SEC no-action letters would likely not because they are isolated statements of policy applied in particular cases rather than a comprehensive program applied in every case.

But the proposed framework does have some potential drawbacks. First, it does not easily answer the question of whether the agency has "consummated its decisionmaking process" under *Bennett*'s first prong. However, this is likely to be inherently fact-specific. The reviewing court in any case would have to examine the specific context to determine whether the agency had in fact finished developing its policy; a bright-line rule would be difficult to apply. The fact that plaintiffs can sometimes force an agency to finalize a rule can also provide an answer in particularly egregious situations. Second, the proposed framework is in some tension with *National Park*

[196] *See supra* notes 58–63 and accompanying text (discussing *Appalachian Power*).
[197] *See supra* notes 58–63 and accompanying text.

Hospitality Ass'n, which cut back on the presumption of pre-enforcement reviewability, and with cases suggesting that plaintiffs can only challenge discrete actions rather than broad programs.[198] By and large, however, this tension merely reflects inconsistencies in the doctrine itself. The Supreme Court has oscillated between both broad and narrow approaches to when agency actions should be reviewable—an inconsistency the final agency action doctrine, with its two conflicting strands, itself demonstrates. This Note advocates as a policy matter wider availability of pre-enforcement review, especially when plaintiffs are regulatory beneficiaries like the Center for Food Safety who will never otherwise be able to challenge deregulatory agency programs in court. But even if *National Park Hospitality Ass'n* and other cases suggest that the Court disagrees with this as a policy matter, current doctrine can lead to strange results. The same agency program, for example, might be reviewable if promulgated through notice-and-comment procedures but immune from challenge if issued in a more informal manner.[199] Further, under current caselaw the finality and ripeness inquiries can lead to different results, even though both result from similar policy and doctrinal concerns.[200] The proposed framework would at least help to resolve these doctrinal inconsistencies.

A third potential drawback of the proposed framework stems from the "practically binding" standard itself. Some commentators argue that the "practically binding" standard is problematic because it induces agencies to move away from "firm, hard-edged rules in the direction of tentative, open-ended standards."[201] Indeed, this is a real risk: The FDA could have instituted a more vague GRAS program

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198 *See* Nat'l Park Hosp. Ass'n v. Dep't of the Interior, 538 U.S. 803, 812 (2003) (cutting back on the *Abbott* presumption of reviewability); *supra* notes 152–54 and accompanying text (discussing *Lujan* and its implications).

199 *See supra* note 172 and accompanying text (explaining that the reviewability of a program like the GRAS Interim Policy might depend upon how it is issued).

200 *See supra* note 95 and accompanying text (explaining that ripeness and finality blend together).

201 Cass R. Sunstein, *"Practically Binding": General Policy Statements and Notice-and-Comment Rulemaking*, 68 ADMIN. L. REV. 491, 502 (2016). Pierce also criticizes the practically binding standard as "far too broad" and "extremely difficult to apply" because, he argues, it is better for agencies to consistently apply their enforcement discretion in the same manner rather than randomly decide what policies to apply on a case-by-case basis. PIERCE, *supra* note 44, § 6.3, at 323. The "practically binding" standard can also be difficult to apply because it requires hindsight—courts must know how the agency has operated in practice over some period of time. Fraser, *supra* note 39, at 1313. But this is not a concern for the finality inquiry: If there is no record on which a court can find a policy to be practically binding, it would simply hold that final agency action is not present because *Bennett*'s second prong is not satisfied. In this way, the standard still allows the agency some time to experiment before its policy is treated as final.

with less clear steps or in fact could have chosen to not enact a GRAS program at all. But these commentators criticize the way courts use the "practically binding" approach to determine whether a rule is legislative or nonlegislative. The proposed framework advocated herein does not address this distinction; it only addresses the *finality* doctrine. The proposed framework would not force agencies to promulgate all "practically binding" policies through notice-and-comment procedures, nor would it mandate that all such policies be reviewable. Courts could still limit judicial review using other doctrines such as the exception to the presumption of reviewability for actions "committed to agency discretion by law."[202]

Fourth, others might argue that the finality doctrine works well as it is by giving lower courts discretion to decide which strand to follow depending upon the specific case. Indeed, as the decision in *Appalachian Power* itself hints, the doctrine can be quite flexible; the current "inconsistency" of the finality inquiry may suggest its fundamental pragmatism.[203] But the framework this Note promotes helps litigants and agencies predict when a court will apply which strand of doctrine. Such predictability would be valuable for agencies, regulated companies, and beneficiaries of regulation alike.

Finally, as stated above, McKee argues that simply eliminating *Bennett*'s second prong would be the most efficient solution to the finality puzzle. Her approach, possibly combined with the above suggestion to move any "legal consequences" inquiry a court might conduct to the APA's reviewability exception for actions "committed to agency discretion by law," is a long-term proposal for doctrinal change that the Supreme Court should consider. The combined approach would help fulfill McKee's goals of promoting simplicity, avoiding overlap, and fostering the "common law goal of predictability."[204] For the time being, however, the framework herein promotes predictability too, is relatively simple to apply, and can be applied now using approaches supported by current caselaw.

Conclusion

All of these doctrines, from the legislative rule/nonlegislative rule distinction to the *Abbott* presumption of reviewability to the presump-

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[202] *See supra* notes 174–78 and accompanying text (suggesting that it would make more sense doctrinally to place any presumptions curtailing judicial review into the "discretion" exception rather than to intertwine them with final agency action doctrine).

[203] *See supra* notes 97–100 and accompanying text (discussing the two strands of finality doctrine and the contradiction between the practical and legal effects tests); *supra* note 20 and accompanying text (explaining how the finality doctrine contradicts itself).

[204] McKee, *supra* note 104, at 402–06.

tion of nonreviewability for agency inaction, promote the same goal: to grant affected parties—especially beneficiaries of regulation—real opportunities for participation and judicial review while at the same time giving agencies the discretion they need to operate in a resource-limited world where litigation is expensive and time-consuming. Currently, however, the puzzling final agency action inquiry undercuts this goal. The proposals in this Note would start to solve the puzzle by harmonizing the final agency action requirement with these other doctrines. The proposed framework formally construes *Bennett*'s "legal consequences" test when an agency proceeds by notice-and-comment procedures (or other statutory processes), but more functionally construes the test when the remedy of compelling the agency to finalize its action would be unavailable. In so doing, it promotes balancing the interests of all parties in a logical manner that depends upon the context. Thus in a case like *Center for Food Safety*, the proposed framework for finality would ensure that while the FDA would have flexibility to experiment with possible policies, the plaintiff food safety organization could potentially challenge the new GRAS program at least at some point in time. Especially because some foods that have achieved GRAS status might be dangerous, such opportunity for judicial review would provide the public with important protection. Moreover, by alternatively proposing longer-term doctrinal changes, this Note helps to harmonize a confusing area of administrative law. If applied, these proposals may advance the "pragmatic" interpretation of finality the Supreme Court has encouraged since its *Abbott* decision some fifty years ago.