JUDICIAL REVIEW OF AGENCY GUIDANCE DOCUMENTS: RETHINKING THE FINALITY DOCTRINE

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INTRODUCTION

Agencies increasingly issue guidance documents—nonbinding documents that typically include detailed instructions for regulatory compliance yet do not clearly provide for judicial review—in lieu of engaging in the more costly, and binding, informal rulemaking process that ultimately affords regulatees with opportunities for judicial review.[1] For example, on April 29, 2004, the Environmental Protection Agency (EPA) issued a document stating why the agency believed it had the authority to regulate prions—a disease-causing agent unlike any the agency had previously regulated and, more importantly, unlike those listed in the Federal Insecticide, Fungicide and Rodenticide Act, the governing statute.[2]

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1. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007) ("[A]gencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs."); Jeff Bowen & Susan Rose-Ackerman, *Partisan Politics and Executive Accountability: Argentina in Comparative Perspective*, 10 SUP. CT. ECON. REV. 157, 196 (2003) ("[E]ven in the United States the president and the administrative agencies try to circumvent procedural requirements. Guidance documents or policy statements are increasingly used by agencies to articulate general policies without needing to follow APA procedures.").

2. *See* Memorandum from Susan B. Hazen, EPA, to the Record, Consideration of Prions As a Pest Under FIFRA (Apr. 29, 2004), *available at* http://www.epa.gov/oppad001/records_of_decision_on_prions.pdf (recording the determination process for the inclusion of prions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) statutory umbrella). All living things are, at a certain level, collections of genetic material and protein. *See* Tami Port, *Cells & Viral Pathogenic Microbes Differences of Living Organisms & Acellular Viruses, Viroids, Prions*, SUITE101.COM, Oct. 14, 2007, http://microbiology.suite101.com/article.cfm/cells_and_viruses. Living things synthesize protein to perform many functions including replication of genetic material. *Cf. id.* (explaining that cells compose all living things and that acellular particles like viruses do not have the ability to synthesize protein). Viruses are not considered living things. *Id.* Although viruses consist of genetic material and protein, viruses cannot use their protein to make new copies of their genetic material. *Id.* Instead, the viral protein is just used for packaging. *Id.* To replicate itself, a virus must use special proteins in a living cell to make new genetic material and packaging protein. *Id.* Prions, like viruses, are also not considered living things. *Id.* However, prions are even more primitive than viruses. *See* Stanley B. Prusiner, *Prion Diseases and the BSE Crisis*, 278 SCI. 245, 245–51 (1997) (discussing the distinguishing features of prion diseases). Prions do not contain any genetic material and instead only consist of normal protein that has become misshapen. *Id.* at 245–47. Prions are misshapen protein that can make normal protein also become misshapen. *Id.* Because of this, prions are distinguishable from both living cells and viruses. *Id.* The FIFRA, which authorizes the Environmental Protection Agency (EPA) to conduct a notice and comment rulemaking to determine whether a virus or a living organism should be considered a pest, would not apply

In April 2005, the Occupational Safety and Health Administration issued a document detailing how to use marine hanging staging, specifying, among other things, the required activities of a rope walker.[3] On October 19, 2007, the Department of Education issued a document detailing how educational institutions are required to collect and report data on race.[4] In March 2007, the Food and Drug Administration (FDA) issued a draft final guidance document governing the processing of fresh-cut produce, containing detailed instructions on everything from plant design to packaging.[5] In each of these cases, regardless of whether the agency issued its decision as a draft or final guidance document, it is unclear whether a challenger would be able to obtain judicial review.[6]

Those affected by the guidances mentioned above have a very real complaint about our system of administrative justice. Their concerns are more manageable, though not necessarily resolved, when the standards for the finality required for judicial review are rational and legitimate. The problem of whether individuals affected by guidance documents can obtain judicial review is the focus of this Article—and a deceptively difficult problem in administrative law.

Before a court will review an agency action, it must first ensure that all statutory and prudential requirements have been met. This Article focuses directly on only one of those requirements, finality, and indirectly on a related issue, ripeness (relating to the maturation of the legal questions presented by the agency action). Stated broadly, a decision is final when an agency concludes its process. A party will experience an agency decision, such as a guidance, as truly final, especially if the substance of that action

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to a prion. The EPA bypassed this statute and the notice and comment process when it issued a guidance document declaring that prions are pests.

3. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, SAFE WORK PRACTICES FOR MARINE HANGING STAGING: AN OSHA GUIDANCE DOCUMENT 1, 4–6 (Apr. 2005), *available at* http://www.osha.gov/dts/maritime/marine_hanging_staging/marine_hanging_staging.pdf.

4. *See* Final Guidance on Maintaining, Collecting, and Reporting Racial and Ethnic Data to the U.S. Department of Education, 72 Fed. Reg. 59,266, 59,266–67 (Oct. 19, 2007) (mandating that agencies use a two part question to determine the origin of Hispanic students).

5. FDA, GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES (Mar. 2007), *available at* http://www.cfsan.fda.gov/~dms/prodgui3.html [hereinafter FDA FOOD GUIDE].

6. Had the EPA issued its decision in a notice and comment rulemaking, a challenger would have had a strong argument that the decision was unlawful because it fell outside the authority granted to the EPA; however, because the decision was issued in an informal guidance document, it is not clear whether it would qualify as "final agency action" under the *Bennett* test and an affected party might not be able to obtain judicial review at all.

In the case of the Food and Drug Administration (FDA) guidance document, although the Federal Food, Drug, and Cosmetic Act contains a specific provision dealing with guidance documents, the provision does not directly grant or deny access to judicial review. *See* 21 U.S.C. § 371(h) (2000). The closest the Act comes to addressing the issue is a provision stating that "[s]uch documents shall not create or confer any rights for or on any person . . . ." *Id.*

reasonably compels that party to make meaningful changes to its conduct. An agency, on the other hand, may have a very different perspective, considering a matter final only when it has exercised any and every regulatory option pertinent to that issuance. These two perspectives do not meld easily into a single, clear test. As this Article demonstrates, many courts have tried—with predictably confusing results.

While the finality requirement originates in the Administrative Procedure Act (APA), the Supreme Court set forth the two prong test used to assess it in *Bennett v. Spear*.[7] To establish finality, the Court required (1) a finding that the agency had reached a point where its action was, for all practical purposes, complete,[8] and (2) a judgment regarding the quality and nature of the issue and impact of the agency action.[9] As this Article demonstrates, while prong one addresses the question of reasonable completion, clearly the core of finality, prong two addresses ripeness, which is a separate, well-developed, elaborate jurisdictional limitation. Merging a duplicate ripeness test into finality is consistent with neither the APA nor the case law prior to *Bennett*, and the merger has given rise to inconsistencies in the field that require a change.

This merger has spawned conflicting and confusing case law that impedes access to the courts, making it difficult if not impossible to challenge agency action at any point prior to an enforcement action. For that reason, this Article advocates eliminating the second prong of the *Bennett* finality requirement.

While the *Bennett* test affects judicial review of all agency action, its effect can be seen most dramatically in review of agency guidance documents, which occupy an ever increasing and important position in the field.[10] To demonstrate how complex the post-*Bennett* analysis has become and to provide a basic understanding of the current state of the law, a large portion of this Article is devoted to direct case analysis and tracing the

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7. 520 U.S. 154, 177–78 (1997) (quoting Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948), and Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)). In *Bennett*, Oregon ranchers and two water districts in Oregon challenged a decision by the Fish and Wildlife Service to protect two species of fish by maintaining higher water levels in the Klamath Irrigation Project, from which the plaintiffs received their water. *Id.* at 157. The case addressed a number of points relevant to administrative law, including questions of standing and what is required to bring suit under the Endangered Species Act. The discussion in this Article concerns only the final point the Court dealt with—that a party may bring a suit under the Administrative Procedure Act (APA), provided the plaintiff meets the two part finality test set forth in the opinion and discussed in this Article beginning in Part II.

8. *See id.* at 177–78 (requiring that the decision under review be the "'consummation' of the agency's decisionmaking process") (citations omitted).

9. *Id.* (requiring that the decision under review be "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow'") (citations omitted).

10. *See* sources cited *supra* note 1.

evolution of conflicting theories and rules. These cases are the only way to see the numerous tests that courts have incorporated into finality, and to point out the inconsistencies and problems with the current application. The focus on guidance documents further serves to highlight these problems, while simultaneously providing an insight into judicial review of this increasingly important method of agency action.

Agencies have expanded their use of guidance documents as the primary method of setting forth agency policy.[11] This expansion occurred in response to the inordinate time and expense required for conventional notice and comment rulemaking.[12] The concept of guidance documents is a relatively recent addition to administrative law; the term "guidance document" does not appear in the APA.[13] It is, however, defined in a recent executive order as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue."[14] While guidance documents are rules within the meaning of the APA, the issuing agency intends the guidance to be exempt from § 553 notice and comment requirements[15] as either general statements of policy or interpretive rules.[16]

Because of the increasing reluctance of agencies to commit the resources required for informal rulemaking,[17] many commentators support agencies' use of guidance documents as a method of keeping their constituencies informed and of ensuring uniform treatment.[18] However, others express

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11. *Id.*

12. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007) ("As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents . . . ."); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1316 (1992) (observing that it is acknowledged, although difficult to prove explicitly, that the use of rules promulgated without the benefit of the APA rulemaking requirements is "widespread"); *see also* M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383, 1411 (2004) (discussing an evolution within agencies from adjudication to rulemaking and eventually to guidance documents as the preferred mode of policymaking).

13. 5 U.S.C. §§ 551–559, 701–706 (2000).

14. Exec. Order No. 13,422 § 3(g), 72 Fed. Reg. 2763 (Jan. 23, 2007).

15. *See* 5 U.S.C. § 553 (setting forth requirements that all rules must meet unless one of the statutory exemptions is applicable).

16. *Id.* § 553(b)(3)(A).

17. In this Article, I use the terms "informal rulemaking" and "notice and comment rulemaking" interchangeably.

18. *See, e.g.*, Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 804 (2001) (describing non-notice and comment rules as "an important element in the hierarchy of agency law"); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159 (2000) (discussing the benefits and tradeoffs of less formal agency action and concluding that agencies need a variety of tools to function most effectively).

concern about the increasingly powerful effect of these often supposedly nonbinding documents and the lack of process given to those affected.[19] In response to these criticisms, and to help bring uniformity to the use of guidance documents, Executive Order 13,422 authorized the Office of Management and Budget (OMB) to require additional procedures for certain types of guidance documents.[20] Following the Executive Order, the OMB issued a final bulletin setting forth requirements agencies must follow when issuing qualifying guidance documents.[21] These new procedures roughly parallel those the OMB previously required only for legislative rules.[22]

While the new Executive Order does add some procedural protection at the agency level, it does nothing to alleviate separation of powers concerns. In fact, by subjecting major guidance documents to OMB review, Executive Order 13,422 effectively tightens the President's control over the agency. Although this Article does not dispute the President's ability to closely monitor agencies within the Executive Branch, it does posit that judicial review of even these documents is the critical protection the APA contemplated.

The historic importance of judicial review is not debatable. *Marbury v. Madison*[23] firmly established the role of the courts as a check on unconstitutional legislative or executive action, declaring that Article III courts have the final authority to "say what the law is."[24] Nearly a century and a half later, Congress made clear in the APA that courts, not the Executive, were the final arbiter on the meaning of congressional delegations of authority.[25] As others have noted, "[t]he availability of judicial review is the necessary condition, psychologically if not logically, of a system of administrative power which purports to be legitimate, or legally valid."[26] In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[27] a case that redefined the relationship between agencies and

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19. *See* Anthony, *supra* note 12, at 1315–16 (stating that agencies should be required to follow the procedures in § 553 for rules they intend to be binding or explicitly make them nonbinding under the exception for general policy statements). *But see* Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 142 (1997) (deeming unnecessary a move by the FDA to explicitly make guidance documents and similar documents nonbinding).

20. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007).

21. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).

22. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737–38 (Oct. 4, 1993) (discussing the requirements for regulatory planning and review).

23. 5 U.S. (1 Cranch) 137 (1803).

24. *Id.* at 177.

25. *See* 5 U.S.C. §§ 702, 704 (2000) (allowing for judicial review of agency action).

26. LOUIS L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 320 (1965).

27. 467 U.S. 837 (1984).

judicial review, the Court held firm that "[t]he judiciary is the final authority on issues of statutory construction . . . ."[28]

Highly permissive judicial review of guidance documents might potentially limit the willingness of agencies to clarify their views, and facilitating agency action and removing cumbersome limitations on the ability and capacity of agencies to govern is commendable.[29] However, it is one thing to optimize the flow of information from agencies to the public but quite another to irrationally block access to the courts. Moreover, guidance documents have long since ceased to be mere information. They have become process-free vehicles for agency declarations of explicit standards and principles that have a real, direct, and potentially devastating impact. Given the likely presence of aggrieved parties after a guidance document issues, doctrinal confusion and irrational procedural limitations on judicial review are simply bad public policy.

Beyond the statutory and constitutional necessity for measured and reliable rules for judicial review, there are basic pragmatic considerations. In judicial challenges, more often than not, the court upholds the action of the agency, in which case judicial review serves to confirm to members of the public that they should obey the agency's interpretation.[30] Further, in the event the court rejects the agency's view, the likely outcome is a remand to the agency with a directive either to use proper procedures[31] or to produce a reasoned basis for the action or interpretation the agency contemplates. These are hardly onerous consequences. Moreover, when strained and inconsistent interpretations of finality cloud judicial review, it becomes difficult, if not impossible, for private counsel to advise clients adversely affected by a guidance or similar interpretation. Hence, clarifying the case law requires resolving the current uncertainty surrounding *Bennett*.

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28. *Id.* at 843 n.9.

29. *See generally* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1386 (1992) (condemning the "ossification" of the rulemaking process as one of the most "serious problems facing regulatory agencies").

30. Further, in a large number of cases, judicial review simply never occurs. However, the mere possibility of judicial review has a benefit: ensuring that the agency takes the time to provide a basis for each rule such that, were review to occur, the rule would be upheld. Along these lines, academicians have noted that one important function of judicial review is not the review itself but merely "the judiciary's ability to induce the political branches and the public" to ensure proper attention has been given to the conclusion reached. Jonathan T. Molot, *Reexamining* Marbury *in the Administrative State: A Structural and Institutional Defense of Judicial Power over Statutory Interpretation*, 96 NW. U. L. REV. 1239, 1316 (2002) (citing competing interpretations of prior scholarship).

31. For more on the debate over the proper place of judicial review, compare Larry D. Kramer, *Popular Constitutionalism, Circa 2004*, 92 CAL. L. REV. 959 (2004) (describing new uses of judicial review), with Erwin Chemerinsky, *In Defense of Judicial Review: A Reply to Professor Kramer*, 92 CAL. L. REV. 1013 (2004) (responding to Professor Kramer's discussion of judicial review).

Assessment of finality for judicial review of guidance documents differs from that of traditional regulations because an agency issuing a guidance document will not have followed the requirements applicable to classic notice and comment rulemaking. Furthermore, the exact procedures followed may vary from agency to agency and document to document.[32] The less formal nature of guidance documents may make it difficult to determine when the agency has concluded its regulatory process with sufficient permanence to make judicial review appropriate.[33] The lack of clarity in the case law exacerbates this problem by providing a number of alternative tests a court could force a party to use to demonstrate that they meet the finality requirement.

This Article does not question the existence of a finality requirement under the APA and comparable statutory provisions. Instead, the Article asserts that *Bennett*'s delineation of finality is a corruption of prior case law and creates a pointless overlap with ripeness. Furthermore, the Supreme Court so vaguely worded the *Bennett* requirements that lower courts have further confused the doctrine, applying a number of additionally restrictive and unnecessary tests to determine finality.

To provide context for the discussion to follow, the Article begins by describing the previously mentioned FDA guidance document on fresh-cut produce. Part II of the Article then explores the right to judicial review as conditioned by the *Bennett* finality requirement and notes the difference between subject matter jurisdiction, which does not exist under the APA, and the right to judicial review, which the APA does guarantee. This distinction matters because the right to judicial review—the basis for a number of challenges to agency guidance documents—depends entirely on whether the party can meet the *Bennett* finality requirement. Part III begins by discussing the *Bennett* finality standard in context, demonstrating its inconsistent application by courts. Next, the Article describes current tests used in the D.C. Circuit to distinguish legislative from nonlegislative rules. Prior to the articulation of finality in *Bennett*, courts used these tests to review allegedly improperly promulgated guidance documents, a purpose for which they are still used to some extent, possibly because of the confusion surrounding *Bennett*. The tests are also critical because, as demonstrated in Part III.B.2, the courts have used them explicitly to illuminate the *Bennett* finality test, further constricting judicial review. Part IV traces the origin of the second prong of the finality test used in *Bennett* and finds that it originates from a case that predates the APA and

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32. *But see* Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 401 (2006) (describing how the FDA alone has set forth regulations governing the issuance of guidance documents).

33. *See* discussion *infra* Part II.

had never been used to determine "final agency action" prior to *Bennett*. This Part also describes the overlap of ripeness with the second prong of *Bennett*. The Article concludes by recommending a substantial simplification of the field by returning to the plain meaning of finality set forth in the APA and eliminating the overlap with ripeness.

I. A SAMPLE GUIDANCE DOCUMENT

In March 2007, the FDA issued a document titled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables."[34] To emphasize the nonbinding nature of the document, it was subtitled "Draft Final Guidance: Contains Non-Binding Recommendations."[35] For further emphasis, the Agency added a disclaimer, common to all FDA guidance documents, after the table of contents.[36]

In the introduction to the guidance, the FDA referenced the increasing public consumption of fresh produce and the corresponding increase in foodborne illnesses linked to such consumption.[37] As the statutory basis for the regulation of fresh-cut produce, the FDA referenced § 201(gg) of the Federal Food, Drug, and Cosmetic Act, which defines "processed food" as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling."[38] The FDA claimed authority over fresh-cut produce, analogizing slicing pineapple and bagging salad to the "canning, cooking, freezing, dehydration, or milling" required for processing.[39] In the remainder of the guidance, the FDA "suggest[ed] more specific food safety practices for processors of fresh-cut produce."[40] These suggestions included changes to plant construction, plant layout, worker sanitation training, and processing and packaging considerations.[41]

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34. FDA FOOD GUIDE, *supra* note 5.
35. *Id.*
36. *Id.* The disclaimer states:

> This guidance represents the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Id.
37. *Id.* (citing unpublished data from the FDA).
38. *See id.* (referencing 21 U.S.C. § 321(gg) (2000)).
39. *Id.*
40. *Id.*
41. *Id.*

The guidance jumps abruptly from canning, cooking, and other processes mentioned in the statute that dramatically alter the chemical structure of the food and are clearly within FDA jurisdiction, to slicing and bagging—processes that are arguably outside the FDA's reach. This apparent expansion of agency authority would seem to present a strong basis to challenge the FDA's claimed jurisdiction over fresh-cut produce. However, under current case law elaborating *Bennett*'s finality requirements, there is almost no way a producer of fresh-cut produce could challenge the FDA's authority as stated in the guidance at any point before the producer faced a court action for selling adulterated food. As the next section demonstrates, it is not that the producers in question are without a right to judicial review; rather, it is that the current problematic interpretation of the finality limitation on judicial review, particularly in guidance cases, will prevent them from using their right to judicial review to obtain access to the courts.

The FDA is unusual among federal agencies in that it has codified statutory provisions addressing guidance documents.[42] Although these statutory provisions do not address judicial review directly,[43] they specifically disclaim the ability of the agency to bind itself.[44] These provisions could potentially create an additional complication in showing the agency had bound itself to the document, one of the factors courts look at when addressing review of guidance documents. Despite having been codified over ten years ago,[45] however, no one has ever challenged this provision in court,[46] nor would a court likely hold the provision to preclude review were such a challenge to occur.[47]

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42. *See* 21 U.S.C. § 371(h) (giving general guidance to agencies on how to produce documents but not requiring specific provisions).

43. *See supra* note 6.

44. *See* 21 U.S.C. § 371(h)(1)(B) (stating "guidance documents shall not be binding on the Secretary").

45. The bill was signed into law on November 21, 1997. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. § 301 (2000)).

46. As of January 2008, courts have never cited to an FDA guidance document in a judicial challenge since the Act went into effect. *See, e.g.*, Ctr. for Sci. in the Pub. Interest v. FDA, No. 03-1962, 2004 U.S. Dist. LEXIS 18541, at *9-15 (D.D.C. July 30, 2004) (deciding that plaintiffs' claim was not ripe for adjudication because the FDA guidance had not caused an injury separate from an alleged procedural violation, and plaintiffs would not suffer any hardship resulting from the court's decision to withhold judicial review).

47. It is particularly notable that Congress failed to mention judicial review in the provision, which it certainly could have done had it so desired. *See* 21 U.S.C. § 371(h) ("The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents with this subsection.").

II. FINALITY AND THE RIGHT TO JUDICIAL REVIEW UNDER THE APA

Although the Supreme Court has made explicit that the APA does not grant subject matter jurisdiction,[48] the Court has also specifically stated that the APA provides a right to judicial review—parties can bring a case under the APA.[49] These propositions may seem to conflict; however, an examination of their origin makes clear that they readily coexist. This section traces the historical origin of these potentially confusing findings and clarifies the distinction between the two. An understanding of the right to judicial review is critical to this analysis because whether a challenger is able to obtain judicial review under the APA depends on whether the challenger can show the agency action is final. Therefore, the restrictive application of finality directly closes the door to potential agency challenges that parties could only bring under the APA. The starting point for this examination is *Califano v. Sanders*,[50] which foreclosed subject matter jurisdiction under the APA and was the direct precursor to *Bennett*.

A. Califano *and Subject Matter Jurisdiction*

In *Califano,* the Supreme Court addressed the question of whether the APA conferred subject matter jurisdiction on federal courts to hear alleged violations of agency process requirements.[51] After acknowledging that prior decisions, including *Abbott Laboratories v. Gardner*,[52] might have erroneously assumed subject matter jurisdiction, the Court found that the APA did not confer subject matter jurisdiction on the federal courts.[53] The Court based this conclusion, in part, on the fact that Congress had recently amended 28 U.S.C. § 1331 to remove the "amount in controversy" requirement for actions brought "'against the United States, any agency thereof, or any officer or employee thereof in his official capacity.'"[54] The Court found this amendment indicated that Congress felt it necessary to expressly confer subject matter jurisdiction over claims against federal

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48. *See* Califano v. Sanders, 430 U.S. 99, 107 (1977) (concluding that "the APA does not afford an implied grant of subject-matter jurisdiction permitting federal judicial review of agency action").

49. *See* Bennett v. Spear, 520 U.S. 154, 175 (1997) ("The APA, by its terms, provides a right to judicial review . . . ." (citing 5 U.S.C. § 704 (1994))).

50. 430 U.S. 99 (1977).

51. *Id.* at 100–01.

52. 387 U.S. 136, 141 (1967); *see also infra* Part IV.B (discussing *Abbott Labs.*).

53. *See Califano*, 430 U.S. at 105 (reasoning that congressional action indicated that the "APA is not to be interpreted as an implied grant of subject-matter jurisdiction").

54. *Id.* (quoting Pub. L. No. 94-574, 90 Stat. 2721 (1976) (amending 28 U.S.C. § 1331(a))). Congress has further broadened the language. *See infra* note 61.

agencies, and also served to remove any reservation the Court might have had about denying review of agency action.[55]

In *Califano*, the challenger brought a claim under the Social Security Act (SSA).[56] The SSA's judicial review provision allowed review of final agency decisions if challenged within sixty days.[57] Having missed that deadline, the challenger tried to argue that he could bring his claim under the APA itself.[58] The Court did not allow the APA claim to go forward, finding that allowing this second basis for liability would serve to nullify the strict time limits for judicial review in the SSA.[59] Accordingly, the Court denied review.[60]

Thus, after *Califano*, a party seeking to challenge agency action can assert subject matter jurisdiction under § 1331, provided he or she can identify a federal law, apart from the APA, that the agency action allegedly violated.[61]

Not at issue in *Califano* was whether the APA provided an independent right to judicial review in the absence of an explicit judicial review provision in the enabling legislation or substantive statute. The Court did not need to analyze this issue because the SSA included a statutory review provision.[62] In fact, it was this statutory review provision with its strict statute of limitations that led to the dismissal of the claim.[63] The Court did not address whether the APA provided an independent right to judicial review (that is, whether the APA could form the basis of a claim for nonstatutory review) until *Bennett v. Spear*.[64]

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55. *See Califano*, 430 U.S. at 105–06 (recognizing the new amendment as indication of congressional intent).

56. *Id.* at 102. An administrative law judge had denied the plaintiff's initial claim and the agency's appeals council affirmed. *Id.* While the Social Security Act (SSA) provided for judicial review of final administrative decisions, the plaintiff did not seek judicial review at that time. *Id.* Seven years later, the plaintiff again filed for disability benefits, based on the same claim of disability. *Id.* This time, the administrative law judge found the claim barred by res judicata and decided not to reopen the administrative record, finding no error on the face of the evidence. *Id.* at 102–03. The case was brought seeking judicial review of this decision. *Id.* at 103.

57. *Id.* at 108 (citing 42 U.S.C. § 405(b) (Supp. V 1975)).

58. *See id.* at 103–04 (rejecting the claim that the APA granted subject matter jurisdiction to the Court).

59. *Id.* The plaintiff also argued that he had brought the claim within sixty days of the agency decision not to reopen the case, but the Court refused to allow that action to serve as the relevant agency action, finding that doing so would also wipe out the strict time limits intended in the Act. *Id.*

60. *Id.* at 109.

61. *E.g.*, 28 U.S.C. § 1331 (2000) ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.").

62. *Califano*, 430 U.S. at 108 (citing 42 U.S.C. § 405(b) (Supp. V 1975)).

63. *Id.* at 108–09.

64. 520 U.S. 154 (1997).

B. Bennett v. Spear—*The APA Right to Judicial Review and Finality Requirement*

With little discussion, the Court in *Bennett* found that the APA provides an independent right to judicial review, stating, "[n]o one contends (and it would not be maintainable) that the causes of action against the Secretary set forth in the Endangered Species Act's (ESA) citizen-suit provision are exclusive, supplanting those provided by the APA."[65] Based on this language, some courts refer to this right as an APA cause of action;[66] others use the more common *Bennett* finality requirement or right to judicial review. I will use the latter set. This right arises primarily from §§ 702, 704, and 706 of the APA.[67] Section 704, the section at issue in *Bennett*, allows judicial review of all "final agency action for which there is no other adequate remedy in a court."[68] The APA broadly defines agency action as including "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[69] Thus, agency action effectively encompasses nearly everything an agency does.[70] Given this broad definition, the critical issue a court faces when reviewing such a challenge is whether the agency action is final.[71] *Bennett* set forth a two part conjunctive test to determine when agency action qualifies as "final" under § 704.[72] To be final, the decision under review must be (1) the

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65. *Id.* at 175.

66. *See* Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 806 (D.C. Cir. 2006) ("'The Supreme Court has clearly indicated that the Administrative Procedure Act itself, although it does not create subject-matter jurisdiction, Califano v. Sanders, [430 U.S. 99 (1977)], does supply a generic cause of action in favor of persons aggrieved by agency action.'" (quoting Md. Dep't of Human Res. v. Dep't of Health & Human Servs., 763 F.2d 1441, 1445 n.1 (D.C. Cir. 1985))); Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 185 (D.C. Cir. 2006) ("Although the APA does not confer jurisdiction, what its judicial review provisions, 5 U.S.C. §§ 701–06, do provide is a limited cause of action for parties adversely affected by agency action."); Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt., 460 F.3d 13, 18 & n.4 (D.C. Cir. 2006) (stating that the APA grants a cause of action rather than subject matter jurisdiction); Marceau v. Blackfeet Hous. Auth., 455 F.3d 974, 985 (9th Cir. 2006) ("The APA grants a cause of action to persons injured by administrative action." (citing 5 U.S.C. § 702 (2000)); Utah Shared Access Alliance v. Carpenter, 463 F.3d 1125, 1134 (10th Cir. 2006) ("Because none of the statutory or regulatory provisions in question provide[s] for a private cause of action, the judicial review provisions of the APA govern this suit."); Michael Reese Hosp. & Med. Ctr. v. Thompson, 427 F.3d 436, 440 (7th Cir. 2005) ("[Plaintiff] relies on the APA, which provides a cause of action . . . .").

67. 5 U.S.C. §§ 702, 704, 706 (2000).

68. *Id.* § 704.

69. *Id.* § 551(13).

70. Guidance documents fall within the broad category of "rule" and therefore constitute agency action under the APA. *See id.*

71. *See* Bennett v. Spear, 520 U.S. 154, 177 (1997) (finding that the issue of whether an action is final is a separate and distinct question).

72. *Id*. at 177–78 (quoting Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948), and Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

"consummation of the agency's decisionmaking process" and (2) "one by which 'rights or obligations have been determined,' or from which 'legal consequences flow.'"[73]

Thus, after *Bennett*, where the substantive statute does not contain a judicial review provision, a party seeking relief in federal court from final adverse agency action can challenge the agency in court under the APA, referencing § 1331 and the relevant federal substantive statute. However, what *Bennett* gave to those adversely affected by agency action, it took away from them by expanding finality well beyond the plain meaning of the APA.

Applying the *Bennett* test to the FDA guidance document mentioned in Part I, it is unlikely a court would find the guidance to be the consummation of the agency's decisionmaking process under the first prong of *Bennett* because it is labeled a draft final guidance. The use of the term "draft" indicates that the guidance is still undergoing revision and thus is not the final word from the agency on the subject. However, although the *Federal Register* notice of availability invites the public to submit comments, which people may submit at any time, there is no proposed schedule for future versions.[74] Furthermore, the guidance treats the suggestions given in the document as the current recommendations of the agency, not as a draft of future suggestions the agency has yet to finalize. Consequently, a court could find that, after a significant lapse of time without a future version, the document did indeed give the conclusion reached by the agency. Even if a court found the document to be the consummation of the agency's decisionmaking process, it would not likely qualify as a document from which rights or obligations are determined or from which legal consequences flow—the second prong of the overly complex finality requirements of *Bennett*.[75] This is at least partially because the FDA inserted two disclaimers stating the document is not legally binding, and used nonmandatory terms like "should" instead of "must" when describing suggestions for producers.[76] This seemingly tentative language does not disguise reality; the FDA produced the guidance because it expects that producers will follow its suggestions. The section on scope and use, which references FDA authority to take action

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73. *Id.* (quoting *Chi. & S. Air Lines*, 333 U.S. at 113, and *Rederiaktiebolaget*, 400 U.S. at 71)).

74. Draft Final Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request, 72 Fed. Reg. 11,364 (Mar. 13, 2007).

75. *Bennett*, 520 U.S. at 178.

76. FDA FOOD GUIDE, *supra* note 5.

against those selling harmful fresh-cut produce, makes clear the direct impact of the guidance.[77]

The cases described in the next section expand on the *Bennett* factors mentioned above as related to review of guidance documents. Considering the importance and prevalence of guidance documents, the case law is surprisingly sparse because it is difficult to secure judicial review in the post-*Bennett* era and next to impossible to predict when or whether a court will find a guidance document reviewable.[78] When this uncertainty is combined with the expense of bringing suit and the disfavor such a suit would create for future interactions with the agency, a prudent lawyer may be ethically bound to suggest a client merely comply with the guidance, until the cost of compliance with the document becomes so high that the company has no financial choice but to challenge the action.

III. *BENNETT*'S EVOLUTION—THE CURRENT COMPLICATED TEST FOR FINALITY

A. Bennett *in Context—Direct Application of* Bennett *in Courts*

While this Article argues that the second (legal effect) prong of *Bennett* is unnecessary, it does not claim that all decisions under *Bennett* have been incorrect or that *Bennett* has always blocked judicial review of guidance documents with real and direct effects. In some cases, courts have found challenged agency guidance documents both final and binding, meeting both prongs of the test and allowing judicial review.[79] In other cases, where courts found documents to be final but not binding,[80] the courts might not have found the issue ripe for review, had the analysis proceeded to that point. The Article does suggest, however, that courts should review such documents under a more uniform and coherent standard.

In *Appalachian Power Co. v. EPA*,[81] the challengers sought review of a nineteen page, single spaced EPA "guidance document" that added detailed

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77. *Id.*

78. Given the focus of the Article, it is important to note that the cases discussed herein were not chosen because of the compelling public policy behind the need for review in the case, or because the Article claims that egregious errors were made by the agency, but rather to show the current inconsistencies in the finality doctrine.

79. *See, e.g.*, Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021–23 (D.C. Cir. 2000) (holding that the document at issue met both prongs of *Bennett*'s two-part test).

80. *See, e.g.*, Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 14–17 (D.C. Cir. 2005) (holding that the document at issue met *Bennett*'s first prong of consummation, but rejecting the claim that it was binding).

81. 208 F.3d 1015 (D.C. Cir. 2005).

monitoring requirements in a number of situations.[82] Applying the first prong of *Bennett*, the court found the document marked the consummation of the EPA's decisionmaking process, as the EPA issued it after circulating two earlier versions, one of which the Agency made available only months earlier, titled "EPA Draft Final Periodic Monitoring Guidance."[83] Applying the second prong of *Bennett*, the court found that certain portions of the guidance set forth particular requirements that states were required to follow.[84] Requiring states to comply with the guidance document was a legal effect.[85] The court next rejected an argument that the guidance document could not be final as it was subject to change, reasoning that even the U.S. Constitution can be changed, a fact irrelevant to whether it is presently binding.[86] The court also rejected an argument that the guidance was merely a disclaimer, stating that, though the document was not binding, it was enough to cure any doubts about the document's legal significance.[87]

National Ass'n of Home Builders v. Norton,[88] in contrast, underscores the inconsistency in this field, and is best read in opposition to *Appalachian Power*.[89] At issue in *Home Builders* was a guidance document setting forth survey procedures to detect a species of endangered butterfly.[90] The protocols specified that the butterfly would be presumed to be present in the areas subject to the survey.[91] The only way to disprove this presumption was to follow the exact survey procedures described in the policies and submit the results to the agency, which could choose whether

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82. *Id*. at 1019. Petitioners brought this case under the judicial review provisions of the Clean Air Act, 42 U.S.C. § 7607 (2000), rather than directly under the APA, but the case is still the most thorough analysis of *Bennett*'s two-prong requirement. *Id.* at 1028.

83. *Id.* at 1022. The court also disagreed with the government's argument that merely categorizing the document as a "guidance document" inherently meant the document could not be final as required for judicial review. *Id.* at 1021.

84. *See id.* at 1023 (explaining that the guidance at issue read like "a ukase" because "[i]t commands, it requires, it orders, it dictates").

85. *See id.* (stating that the guidance document had legal consequences for both state agencies and companies who must obtain permits to continue their operations).

86. *Id.* at 1022.

87. *Id.* at 1023. The court rejected as mere boilerplate the following disclaimer, placed at the end of the document: "The policies set forth in this paper are intended solely as guidance, do not represent final [EPA] action, and cannot be relied upon to create any rights enforceable by any party." *Id.* (quoting EPA, PERIODIC MONITORING GUIDANCE 19 (1998), *available at* http://www.epa.gov/Region7/programs/artd/air/title5/t5memos/pmguide.pdf). The FDA similarly relies heavily on the use of disclaimers to signify the nonbinding nature of FDA guidance documents. *See* FDA FOOD GUIDE, *supra* note 5 (classifying the guidance documents as a "draft final guidance," which is not binding on the public).

88. 415 F.3d 8 (D.C. Cir. 2005).

89. *See id*. at 16 (distinguishing the statutory scheme in *Appalachian Power* from that at issue in this case).

90. *Id.* at 9.

91. Appellants' Opening Brief at 13, *Home Builders*, 415 F.3d 8 (No. 04-5048) (D.C. Cir. June 10, 2004).

or not to accept the results.[92] The agency did not accept any survey that did not precisely follow the requirements of the guidance.[93] Building on a butterfly habitat could result in large fines for both the homeowner and the county issuing the building permit.[94] While the homeowner had a personal incentive to build, the county did not. Thus, counties began to require approved surveys as part of the building permit process, as the agency expected.[95]

The court quickly concluded that the protocols met *Bennett*'s first prong of consummation, as the agency issued them after reviewing data and consulting with specialists.[96] However, the court then proceeded to reject a number of arguments drawn from prior cases on *Bennett*—including the legislative/nonlegislative rule tests discussed in the next section—that the protocols met *Bennett*'s second prong of legal effects.[97]

The court first rejected the argument that the protocols were binding on their face.[98] Although the court acknowledged that the protocols used mandatory language when describing how to conduct the butterfly survey, it deemed this language irrelevant because the document made clear that the parties need not conduct the survey at all—it merely provided instructions if a landowner were to undertake such a survey.[99] Additionally, no one had yet brought an action against a landowner for failing to follow the protocols.[100]

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92. *See id.* (proclaiming the protocol the exclusive method to survey). According to the survey procedures, only agency licensed biologists could detect the presence of the butterfly during the annual four to six week flight cycle that begins between late February and May of each year. *Id.* at 5. Surveys, such as weekly checks for adults during the potential flight cycle, were to take place over an extended period of time. *Id.* at 23.

93. *Id.* at 25. In addition, surveys in which no butterflies were found could be, and were, rejected as false negatives if they were near a known butterfly habitat. *Id.* at 6. When this happened, the landowner would need to wait an additional year and compete yet again for one of the few trained butterfly surveyors. *Id.*

94. Building on a butterfly habitat would count as "taking" an endangered species. *Id.* at 29–30. "Taking" an endangered species, which includes destroying the habitat of the species, can result in civil and criminal penalties. *Id.* at 28.

95. *Id.* at 33. The EPA expected homeowners and counties to use required surveys since it listed the survey procedures as one of the actions it was taking as part of its required recovery plan for the butterfly. *Id.* at 25–26.

96. Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 14 (D.C. Cir. 2005).

97. *See id.* at 15–17 (rejecting a finding of justiciability such as that found in *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002), *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317 (D.C. Cir. 2002), *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), and *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987) and distinguishing these cases from the case at hand).

98. *See id.* at 14 (reasoning that the agency had previously referred to the protocols as nonmandatory).

99. *Id.* The court next discounted the argument that the protocols should be considered practically binding, rationalizing that the protocols neither created a safe harbor nor changed the burden faced by the government. *Id.* at 14–15.

100. *Id.* at 15.

The court also rejected the argument that, as had been the case in *Appalachian Power*, the protocols were binding because they "exert[ed] a coercive effect on local governments."[101] Although two counties in California adopted the protocols as part of their building permit requirements, the court chose to find that this was not due to coercion by the agency, stating that the local governments' reasons for adopting the protocols were unknown.[102] The only agency action the court appeared to view as possibly coercive was a letter the agency sent to one of the local governments pointing out that a proposed golf course was within the butterfly's potential habitat area.[103] The court discounted this as well, reasoning that since issuing such a letter was within the power of the agency under the enabling statute, the action could hardly be evidence of coercion.[104]

The counties in *Home Builders* did what rational counties would do—comply rather than risk adverse agency action, particularly after the agency expressed a specific concern about butterfly habitat. This is precisely what the agency expected the counties to do, as it indicated in its recovery plan for the species. This was also the response of the states in *Appalachian Power*.[105] And, it will be the likely response of many producers of fresh-cut produce based on the previously mentioned FDA guidance document.[106] However, rather than finding these compliance actions to be a sufficient legal effect of the agency action, thus allowing the court to at least examine the right of the agency to recommend these survey procedures, the court denied all hope of agency review and access to the courts.[107] The sheer number of arguments as to why the protocols had legal effect arises from the numerous and confusing tests being applied in this area; as the case law under *Bennett* has evolved, courts have begun to interpret the finality requirement for guidance documents through the tests (described in the following section) originally created to determine whether

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101. *Id.* at 16.
102. *Id.*
103. *Id.*
104. *Id.* Finally, the court rejected a reiteration of the safe harbor argument made through analogy to *Cmty. Nutrition*, citing the lack of mandatory language in the protocols. *Id.* at 17 (citing Cmty. Nutrition Inst. v. Young, 818 F.2d 943 (D.C. Cir. 1987) (discussed *infra* Part III.B.1.a)).
105. *See* Appalachian Power Co. v. EPA, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (noting that although the EPA argued that the policy at issue was not final, the EPA created procedures that it forced the states to implement and follow).
106. FDA FOOD GUIDE, *supra* note 5.
107. Would this outcome have been different had the analysis proceeded to the factors for ripeness? Perhaps not, as no agency action had even been brought for failing to follow the protocols, but it does begin to demonstrate some of the inconsistency in applications of *Bennett* and the need to more rationally delineate ripeness and finality.

courts should consider certain agency actions to be invalidly promulgated legislative rules.

B. The Influence of the Distinction Between Legislative and Nonlegislative Rules on the Second Prong of Bennett*'s Finality Test*

1. Tests Used to Distinguish Legislative from Nonlegislative Rules

The APA considers guidance documents rules, which it defines broadly as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy . . . ."[108] The APA requires agencies to promulgate rules through notice and comment rulemaking unless one of the listed exceptions applies.[109] Included among the exceptions are interpretive rules and agency policy statements.[110] Therefore, a court deciding whether to consider a particular document a legislative rule is frequently concerned only with distinguishing legislative rules from nonlegislative rules (that is, interpretive rules and policy statements), rather than with determining specifically in which of these three categories the document most properly fits.

In the case of guidance documents, the need to distinguish legislative from nonlegislative rules has arisen in two contexts, creating two different tests, although both originate from and are still used by the D.C. Circuit.[111] The first situation is a challenge to a guidance document alleging that the document is effectively a legislative rule that the agency should only have promulgated through the notice and comment requirements of § 553. I will call this a procedural sufficiency question to distinguish it from a true merits-based challenge, which analyzes the validity of the position chosen by the agency based on an appropriate level of judicial deference. If the court finds that the guidance document in question qualifies as a legislative rule, and the agency failed to follow the required procedures, the court generally vacates the guidance document. This analysis occurs at the end of the case, after the court has answered preliminary questions on justiciability. A challenger who wins this argument wins the case.

The legislative/nonlegislative distinction is also critical in the second situation, where the challenger seeks relief based on a specific statutory judicial review provision authorizing review only of "regulations" or "final

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108. 5 U.S.C. § 551(4) (2000).

109. *Id.* § 553. This occurs unless a party invokes the formal rulemaking requirements of §§ 556 and 557. *Id.* §§ 556–557.

110. *Id.* § 553(b)(3)(A). The statute also allows for exceptions to agency procedural rules, which are generally not implicated when a document is alleged to be an invalidly promulgated rule.

111. *See* discussion *infra* Part III.B.1.a–b.

regulations." The specific provision giving rise to the most litigation, and the origin of the second test, involves the Resource Conservation and Recovery Act (RCRA).[112] This analysis occurs at the beginning of the case, when the court addresses whether it has jurisdiction. If the court does not consider the document to be a legislative rule, the court lacks jurisdiction and dismisses the case. In contrast, if the challenger prevails on this test, he or she has shown only that the court may properly hear the case; he or she has not necessarily won the suit. The challenger will win if the argument is that the document is essentially a legislative rule that the agency should not have promulgated without notice and comment. If that is the case, the court does not further analyze the document, as it did under the preceding test. If, however, the challenger is seeking review of the substance of the document, the court will analyze the document using the appropriate level of deference separately from the legislative/nonlegislative test. The remainder of this section describes the origin of these two tests and their recent merger.

a. Community Nutrition *and the Procedural Sufficiency Test*

One line of cases uses the legislative/nonlegislative test to determine procedural sufficiency, further complicating the case law. *Community Nutrition Institute v. Young*,[113] while not the first to develop or apply the test, is frequently cited on procedural sufficiency grounds, and is important to understanding the current standard facing potential challengers who seek judicial review under *Bennett*. The case arose after the FDA issued an informal "action level" stating that the agency would take enforcement action against any person selling corn contaminated by more than twenty parts per billion of aflatoxin.[114] The court relied on two factors to help distinguish legislative from nonlegislative rules: whether the statement (1) has a present day binding effect, and (2) leaves the agency "free to exercise discretion."[115]

Applying the first prong, the court found the action level was binding.[116] The court first looked at the language of the FDA's previously published and codified regulations announcing that action levels "may be established to define the level of contamination at which food *will be deemed to be*

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112. *See* 42 U.S.C. § 6976 (2000) (establishing the circumstances in which judicial review of final regulations may take place).

113. 818 F.2d 943 (D.C. Cir. 1987).

114. *See id.* at 945 (explaining that the Community Nutrition Institute filed a suit in which it claimed that the FDA's action level violated the APA and the Federal Food, Drug, and Cosmetic Act).

115. *Id.* at 946 (quoting Am. Bus. Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980)).

116. *See id.* at 947 ("The language employed by FDA in creating and describing action levels suggests that those levels both have a present effect and are binding.").

adulterated."[117] The court read the initial condition as merely indicating that the FDA retained discretion whether to issue action levels at all, and the italicized language as indicating that the Agency viewed action levels, once established, as binding.[118] The court next pointed out that the FDA required producers to seek exceptions to the action levels to allow marketing of what the Agency would otherwise consider to be adulterated food under the relevant action level.[119] Finally, the court noted that the FDA indicated in a telegram and in the published notice of the action level at issue that it would automatically consider corn with aflatoxin levels greater than twenty ppb to be adulterated, again using binding language.[120]

Applying the second prong, the court found that the agency had effectively "bound itself."[121] This was despite a finding that the FDA could not bind members of the public to the action level, and would need to prove in any prosecution that the corn was adulterated rather than that the level of aflatoxin in the corn was above that specified in the action level. The court noted that the agency conceded at oral argument that it would be "daunting indeed" to try to bring a claim against a producer with corn contaminated at a level lower than twenty parts per billion.[122]

The court therefore determined that the FDA properly categorized the action levels as a legislative rule.[123] As all parties agreed that the action levels had not gone through the formal notice and comment process, the court held them to be an invalidly promulgated rule.[124]

Even a nominally final version of the fresh-cut produce guidance document would not likely qualify as a legislative rule under this analysis. Given the number of disclaimers in the document, and the language used, a court would not find the document to be binding. The FDA has learned from *Community Nutrition* what language it can and cannot use in a guidance document. As to the second part of the test, it is unclear whether

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117. *Id.* (quoting 21 C.F.R. § 109.4 (1986)).

118. *See id.* (finding that the language used in the regulation "clearly reflects an interpretation of action levels as presently binding norms").

119. *See id*. (determining that the need to secure an exception to the action level confirms the fact that action levels have a present, binding effect).

120. *See id.* at 947–48 (quoting the telegram as stating that any shipment exceeding the level of twenty parts per billion would "be considered adulterated and subject to condemnation").

121. *Id.* at 948.

122. *Id.*

123. *See id.* (finding that the action level narrowly limits administrative discretion and thus will be taken as a "binding rule of substantive law").

124. *See id*. at 949 ("Having accorded such substantive significance to action levels, FDA is compelled by the APA to utilize notice-and-comment procedures in promulgating them."). The court did note, however, that were the FDA to change the manner in which it treated the action levels, it could potentially reissue them as policy statements in the future. *Id.*

a court would find it "daunting indeed"[125] for the FDA to bring an action against a producer who had complied with all the suggestions in the guidance document; this would lead to an argument that the FDA had at least bound itself when publishing the document, despite the disclaimer to the contrary. However, since a court would not find the document to be binding, a court would not consider it to be a legislative rule under *Community Nutrition*.

b. Molycorp *and Restricted Statutory Review*

Restricted statutory review is the other situation in which the legislative/nonlegislative distinction has been incorporated into the *Bennett* analysis. It is yet another barrier that a challenger seeking judicial review of a guidance document could face in bringing a claim. As mentioned in the introduction to this section, judicial review under RCRA is allowed only for "final regulations."[126] Thus, to determine whether a RCRA claim can be brought at all, a court must determine whether the guidance document at issue qualifies as a final regulation. While courts could interpret the RCRA's provisions to allow review only of codified sections of the *Code of Federal Regulations*, or in other instances where the agency claimed to have issued a regulation, the D.C. Circuit has adopted a more pragmatic approach. The Circuit has instead examined whether the guidance document has the effect of a regulation, rather than whether it has met all the technical hurdles required to be a regulation.

In *Molycorp, Inc. v. EPA*,[127] a case frequently cited for this test, a mining company brought suit after the EPA issued a "Technical Background Document" that appeared to compel the mining company to dispose of its waste rock in a significantly more burdensome manner than the company believed necessary.[128] The EPA previously issued the document in draft form, and Molycorp commented on the draft, explaining why it believed alternative disposal methods would be adequate.[129] Despite these comments, the final EPA document recommended the same disposal

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125. *Id.* at 948.

126. 42 U.S.C. § 6976 (2000). While the statute allows review of "final regulations promulgated pursuant to this chapter and the Administrator's denial of any petition for the promulgation, amendment, or repeal of any regulation under this chapter," a guidance document put out by the Agency would not be considered a denial of a petition for review and does not figure in the analysis. *Id.* § 6976(a).

127. 197 F.3d 543 (D.C. Cir. 1999).

128. *See id.* at 544–45 (describing the distinction between beneficiation waste, which agencies exclude from certain regulations, and processing waste, which agencies regulate more heavily).

129. *See id.* at 545 (arguing that the EPA mischaracterized Molycorp's operations as processing and explaining that these operations were extraction or beneficiation).

methods as the draft.[130] In response, the company brought suit, claiming both that the document was improperly issued and that it was inconsistent with the statute it purported to interpret.[131]

To determine whether to consider the document a regulation (as required for judicial review under the statute), the court looked at "(1) the Agency's own characterization of the action; (2) whether the action was published in the *Federal Register* or the *Code of Federal Regulations*; and (3) whether the action has binding effects on private parties or on the agency."[132] The court noted that the most significant requirement was the third: whether the supposed regulation has the force of law.[133] The court found this binding effects/force-of-law element lacking in *Molycorp* because the document had disclaimers stating it did "not impose legally-binding requirements on any party, including [the] EPA, States[,] or the regulated community."[134] The court concluded the document did not set out an interpretation of the EPA regulations or impose new obligations, but merely shared the Agency's "view of how it plans to regard particular activities relating to the production of mineral commodities."[135]

As was the case under *Community Nutrition*, the fresh-cut produce guidance document would also fail to qualify as a legislative rule under the *Molycorp* test. The FDA characterized the document as a nonbinding guidance document. It did not publish the entirety of the document in the *Federal Register*, but rather a mere notice of availability, and it will not publish the document in the *Code of Federal Regulations*. In light of the numerous disclaimers and lack of publication through conventional means, a court would likely refuse to find the document legally binding.

Thus, *Community Nutrition* and *Molycorp* resulted in two distinct tests to determine when an agency document qualifies as a legislative rule. *Community Nutrition* looks at (1) whether the statement has a present day binding effect and (2) whether the statement leaves the agency "free to exercise discretion."[136] In contrast, *Molycorp* examines "(1) the agency's own characterization of the action; (2) whether the action was published in

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130. *Id.*

131. *See id.* (claiming that the agency should have issued the document in accordance with notice and comment rulemaking, and that the document was unlawfully vague in its definition of disposal methods).

132. *Id.* (citing Fla. Power & Light Co. v. EPA, 145 F.3d 1414, 1418 (D.C. Cir. 1998)).

133. *See id.* at 545 (noting that the third factor is the "ultimate focus of the inquiry" and that the first two criteria "serve to illuminate" it).

134. *Id.* at 546.

135. *Id.*

136. 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)).

the *Federal Register* or the *Code of Federal Regulations*; and (3) whether the action has binding effects on private parties or on the agency."[137]

c. The Emergence of the Combined Test

Although an understanding of both the *Community Nutrition* and *Molycorp* tests is important to understand the current state of *Bennett*, the combined test is particularly important as courts have recently used it to clarify *Bennett*'s second prong. Realizing that both *Community Nutrition* and *Molycorp* are aimed at answering the same fundamental question of whether a document issued by an agency is in effect a legislative rule, the D.C. Circuit has begun to apply the fundamental "binding" inquiry from both tests simultaneously to distinguish legislative from nonlegislative rules. Originally this combined approach was used to determine whether review should be allowed under relatively obscure statutory judicial review provisions. The first instance of this application was in *General Electric Co. v. EPA*,[138] where the court addressed whether a challenge to an EPA-issued guidance document should be allowed to proceed under § 19(a)(1)(A) of the Toxic Substances Control Act—a provision that only allows challenges to a "rule."[139] The court determined that both the *Community Nutrition* and *Molycorp* tests assess the same thing—whether the document has a binding effect.[140] Applying this new, more fundamental analysis, the court sidestepped the question of the meaning of "rule" and concluded the document was facially binding on both the Agency and public, thus effectively making it a legislative rule and reviewable.[141] Because the EPA conceded it had not followed the procedures required for legislative rules under the APA, the court vacated the document.[142]

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137. *Molycorp*, 197 F.3d at 545 (citing *Fla. Power & Light*, 145 F.3d at 1418) (emphasis added).

138. 290 F.3d 377 (D.C. Cir. 2002).

139. 15 U.S.C. § 2618(a)(1)(A) (2000). The two sides argued over whether courts should give "rule" the broad construction that it has in the APA (encompassing legislative and interpretive rules as well as policy statements) or the narrow construction that it has in RCRA and similar statutes (encompassing only legislative rules). *See Gen. Elec. Co.*, 290 F.3d at 381 (discussing the meaning of "rule"). The court found that it need not decide the issue, since the document in question qualified as a legislative rule. *Id.* at 382.

140. *See Gen. Elec. Co.*, 290 F.3d at 382 (reasoning that the two tests overlap at the third prong of *Molycorp*).

141. *See id.* at 385 (concluding that the guidance document's requirement that applicants submit a specific type of application for risk-based cleanup plans was enough to render it a legislative rule).

142. *Id.* A similar result occurred in *Croplife Am. v. EPA*. 329 F.3d 876 (D.C. Cir. 2003). Here, review was sought under 21 U.S.C. § 346a(h)(1), a judicial review provision like RCRA that allowed review only of regulations, although the statute specified "regulations" rather than "final regulations." The challengers sought review of a press release issued by the EPA announcing that it would no longer accept the results of third party toxicity studies when evaluating pesticides. *Croplife*, 329 F.3d at 878. Prior Agency

Recently, courts have applied this fundamental binding test as an expanded procedural merits test in place of *Community Nutrition* alone, adding further confusion to an already muddled field. In *Wilderness Society v. Norton*,[143] the D.C. Circuit used the test to determine whether an environmental group could compel the Park Service to develop "wilderness management plans" as the Service said it would do in a document titled "Management Policies."[144] The court noted that the agency had not published the Policies in either the *Federal Register* or *Code of Federal Regulations*, indicating the agency did not wish to bind itself with the Policies.[145] Further evidence of the agency's intent not to bind itself came from a description of the document in a *Federal Register* notice of availability calling the Policies merely "a reference source" for agency personnel.[146] The document itself also reserved unlimited discretion for top Agency officials.[147] The court found the document's lack of a requirement to develop wilderness management plans in the form of a statute to be final evidence of the nonbinding nature of the Policies.[148] Apparently believing that the two choices for categorizing the document were either as a legislative rule or a policy statement, the court deemed the document a policy statement.[149] Having found the document a nonbinding policy

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policy had been to consider such studies on a case-by-case basis, and previous pesticides had been approved, at least in part, on the basis of third party studies. *Id.* at 880. These approval decisions had prompted public criticism that led to the press release in question. *Id.* The Agency responded to this criticism by asking the National Academy of Scientists to comment on the use of such studies. *Id.* The Agency then issued a press release saying that, while waiting for a response from the Academy, the Agency would no longer consider third party studies unless legally required to do so. *Id.* at 881. The court found that this statement indicated the agency was binding both itself and parties submitting pesticide statements. *Id.* at 883. The court reiterated the importance of the two tests to determine whether a given document functioned as a legislative rule, and, noting its binding nature, held the press release to be a reviewable regulation. *Id.* at 884. As the Agency again conceded that it had not completed the procedures required for the promulgation of legislative rules, the document was vacated, and the court reinstated the agency policy of allowing evidence from third party studies. *Id.* at 884–85.

143. 434 F.3d 584 (D.C. Cir. 2006).

144. *Id.* at 587.

145. *See id.* at 595–96 (concluding that the document was not binding because the agency failed to publish it).

146. *Id.* at 596.

147. *See id.* (noting that the document required adherence by low level personnel unless waived by "the Secretary, the Assistant Secretary, or the Director" (quoting NAT'L PARK SERV., DEP'T OF INTERIOR, NPS D1416, MANAGEMENT POLICIES 2001, at 4 (2000), *available at* http://www.nps.gov/refdesk/mp/cover.pdf)).

148. *See id.* (reasoning that the fact that the document did not arise from a congressional mandate presents proof of its nonbinding nature).

149. *Id.* at 596–97. However, the court in the prior paragraph had called the Management Policies a "nonbinding, internal agency manual," indicating that in fact, it felt the document should fall under the § 553 exception for "rules of agency organization, procedure, or practice." *Id.* at 596; 5 U.S.C. § 553(b)(3)(A) (2000).

statement, the court denied the claim to compel the formation of wilderness management plans.[150]

Despite the confusion created by the number of different tests, in none of the cases discussed above did the court effectively broaden the legislative/nonlegislative tests beyond what they were designed to do—distinguish agency statements that should be treated as legislative rules from interpretive rules and policy statements.[151] Part III.B.2 discusses the application of the combined test to the *Bennett* analysis.

d. Other Methods of Determining When a Rule Should Be Considered a Legislative Rule

Courts do not always analyze guidance documents by one of the previously mentioned methods. The D.C. Circuit has also dealt with challenges to whether an agency should have issued a particular rule only after notice and comment by attempting to determine which of the three classifications (legislative rule, interpretive rule, or policy statement) the agency action should be considered, rather than simply whether the action qualified as a legislative rule. This subsection briefly discusses two cases where the D.C. Circuit focused on whether courts should consider the document in question as an interpretive rule. Courts require this type of analysis when the agency admits that the rule has legal effect, but nevertheless argues that it should not have been required to undergo the standard notice and comment process in producing the rule. In distinguishing legislative from interpretive rules, these cases focus on how closely the agency interpretation follows the authorizing statute or regulation. This has led to little doctrinal development, which could explain the D.C. Circuit's reluctance to abandon the bright line legislative/nonlegislative tests described previously.

These cases highlight one of the most overt flaws in the previous tests—that interpretive rules can have direct legal consequences for those regulated by the agency. Interpretive rules are merely exempt from the notice and comment requirements of § 553 because they are so closely linked to the statutory or regulatory language. An interpretive rule with legal effect would certainly appear to fall within the final agency action category for which judicial review is allowed under the APA, and would

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150. *See Wilderness Soc'y*, 434 F.3d at 597 (denying the Wilderness Society's statutory claims as "predicated on unenforceable agency statements of policy").

151. While making this distinction is technically not what the court was doing in *General Electric Co. v. EPA*, any error would have been harmless. This is because the court did not transform the statute to require a legislative rule to obtain review; it merely reserved the question of the type of rule required under the statute, holding instead that agency action qualifying as a legislative rule was affirmatively entitled to review. Gen. Elec. Co. v. EPA, 290 F.3d 377, 385 (D.C. Cir. 2002).

likely even qualify under the traditional *Bennett* analysis as final action with a binding effect. That same rule, however, could fail to meet the additional legislative/nonlegislative rule tests now being incorporated into *Bennett*. Such a result would prevent a party from ever getting into court to contest whether the legal effectiveness of the interpretation is valid before facing charges for violating it.

In *Syncor International Corp. v. Shalala*,[152] the D.C. Circuit cited *Community Nutrition* and bemoaned the tendency of courts to lump policy statements and interpretive rules together in contrast to legislative rules, "a tendency to which we have ourselves succumbed on occasion."[153] In *Syncor*, the FDA issued a guidance document reversing prior agency policy and stated that positron emission tomography (PET) nuclear pharmaceuticals would henceforth be subject to the requirements of the Federal Food, Drug, and Cosmetic Act.[154] As the FDA claimed the document in *Syncor* was an interpretive rule, the court concentrated on the distinction between interpretive and legislative rules, finding the critical factor to be "how tightly the agency's interpretation is drawn linguistically from the actual language of the statute."[155] Finding that the guidance did not purport to interpret any language, the court declared it a legislative rule.[156] For this reason as well, the court rejected an alternative argument by the FDA that the focus should be on whether there would be an adequate statutory basis for enforcement in the absence of the guidance, concluding that the court needed no alternative analysis when the document cited no interpretation.[157]

In contrast, the D.C. Circuit found for the agency and declared the rule at issue an interpretive rule in *Air Transportation Ass'n of America, Inc. v. FAA*.[158] Air Transportation Association of America (ATA) challenged a letter issued by the FAA requiring that airlines determine the minimum rest period for flight crew members based on the actual flight time, not the published flight time.[159] The FAA later published this rule in the *Federal*

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152. 127 F.3d 90 (D.C. Cir. 1997).
153. *Id.* at 93–94 (citing Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987)).
154. *See id.* at 92 (noting the FDA announcement called for regulation under the statute's drug provisions).
155. *Id.* at 94 (citing Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579, 588 (D.C. Cir. 1997)). The agency made this argument because the document mandated that positron emission tomography (PET) drugs follow general drug requirements, and was therefore a definite statement of agency expectations, rather than suggested behavior. *Id.* at 92.
156. *See id.* at 95 (concluding that the FDA's wording used terminology consistent with rulemaking).
157. *See id.* at 96 (reasoning that the rule lacked characteristics of interpretive rules).
158. 291 F.3d 49 (D.C. Cir. 2002).
159. *See id.* at 52–53 (outlining the specific determinations contained in the letter).

Register as a notice, and the FAA stated it would begin strictly enforcing the requirement in six months.[160] ATA claimed that notice and comment was required, either because the rule was a legislative rule or because it contradicted a previous interpretation.[161] The court disagreed, finding that the requirement was encompassed within the regulatory language it purported to interpret, and was consistent with past interpretations because the FAA had never previously addressed this particular question.[162] Consistent with *Syncor*, the court noted that in the absence of the rule, there would be an adequate basis in the regulation for enforcement, which required airlines to compute rest time based on "scheduled flight times."[163]

Of particular relevance to this Article, in *Air Transportation Ass'n of America* the Agency did not dispute that the rule had a direct legal consequence for the parties.[164] Under the combined test (which merely asks whether the rule is binding) this alone could have qualified it as a legislative rule, further demonstrating the inconsistency of current judicial review standards. As an additional measure of inconsistency, the court never addressed the finality requirement. Had it done so, the notice would appear to qualify as a document from which legal consequences flow, since the agency stated an intent to begin enforcement. However, had the court interpreted finality under the latest iteration of *Bennett*, discussed more fully in Part III.C, the failure of the court to find the document a legislative rule would have completely prevented the challenger from meeting the finality requirement needed to bring the claim.

2. Application of the Legislative/Nonlegislative Tests to the Finality Analysis

Further adding to the confusion surrounding *Bennett*, the finality requirement, the right to judicial review, and all the legislative/nonlegislative tests discussed in Part III.B.1 have been incorporated as an alternative to the second prong of the *Bennett* test. In *Center for Auto Safety v. National Highway Traffic Safety Administration*,[165] the Center for Auto Safety (Center) filed a petition for

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160. *Id.* at 53.

161. *See id.* at 53–54 (pointing out the inconsistency between the letter and a previous regulation).

162. *See id.* at 56–58 (declaring that the letter's interpretation of the previous regulation was exempt from notice and comment requirements).

163. *See id.* at 56 (concluding that the FAA's interpretation of the required rest regulation was reasonable).

164. *See id.* at 53 (citing Flight Crewmember Flight Time Limitations and Rest Requirements, 66 Fed. Reg. 27,548, 27,549 (May 17, 2001)) (stating that six months after publishing notification of the letter at issue in the *Federal Register*, the Agency would begin enforcing the requirements in the letter).

165. 452 F.3d 798 (D.C. Cir. 2006). In *Ctr. for Auto Safety*, the problem started when the court held that the APA required the challenger to demonstrate that the document in

review in the D.C. Circuit after the National Highway Traffic Safety Administration (NHTSA) issued a document (referred to in the opinion as the "1998 policy guidelines") setting forth how the agency would approve statutorily required automotive recalls for defects created after exposure to various environmental conditions.[166] At the time the guidelines were issued, car manufacturers had been conducting only limited regional recalls when the condition causing the defect occurred regionally as well.[167] The guidelines differentiated between problems created through short-term exposure to an environmental condition and problems that could only occur after long term exposure,[168] and declared that the agency would allow regional recalls only for long-term exposure defects.[169] The Center challenged this as an invalidly promulgated legislative rule under the APA.[170]

The court began its analysis with *Bennett*, finding that the NHTSA issued the guidelines after the consummation of the agency decisionmaking process, therefore meeting the first prong, but that the guidelines failed to meet the second.[171] To determine whether the documents were legally binding, the court looked at many of the factors used in the legislative/nonlegislative cases and noted that the agency had not published the guidelines in the *Code of Federal Regulations*, nor claimed the guidelines carried the force of law.[172] Further, the court found the language nonbinding on its face, focusing on statements like "*in general*, it is not appropriate for a manufacturer to limit the scope of the recall to a particular geographic area where the consequences of the defect can occur after a

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question was final agency action under 5 U.S.C. § 704 or that the document constituted a legislative rule in order to have a right to judicial review. *Id.* at 806. While the court noted in its statement of the alternative analysis that meeting the legislative rule test was merely sufficient, rather than necessary, to qualify as final agency action, importing the two legislative/nonlegislative tests as an alternative analysis effectively elevates the legislative rule to a necessary requirement. *Id.* Although this alternative analysis appears to be similar to what *Bennett* actually requires, as discussed in the analysis, this is also one of the problems with *Bennett*. The court then cited the two-part analysis in *Bennett*, and, after laying this foundation, brought in the "two lines of inquiry" that had developed to determine when agency action should be considered a legislative rule. *Id.* at 806–07.

166. *Id.* at 800–01 (citing 49 U.S.C. § 30,118(c)); *id.* at 803–04.

167. *See id.* at 802 (describing the regional recalls policy). An example of such a regional recall would be fixing parts prone to corrosion from salt only in areas of the country where it snowed. *Id.* at 803–04.

168. *Id.* at 803 (quoting Generic Version of 1998 Letter from NHTSA to Manufacturers [hereinafter Letter] at 1, *reprinted in* Joint Appendix at 80, Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798 (No. 04-5402) (D.C. Cir. Sept. 7, 2006)).

169. *Id.* (citing Letter, *supra* note 168, at 2).

170. *See id.* at 804 (arguing that the agency's policy constituted a "*de facto* legislative rule issued without the opportunity for public notice and comment").

171. *See id.* at 807–08 (holding that the guidelines did not constitute "final agency action" because they were "general policy statements with no legal force").

172. *See id.* at 808–09 (explaining why the guidelines do not have any force of law).

short-term exposure to a meteorological condition."[173] In addition, the court noted there was nothing in the guidelines to constrain the agency's discretion in any way, nor was there any evidence that the public could rely on the guidelines as a safe harbor.[174] Finally, the court also noted that the person issuing the guidelines (the Associate Administrator for Safety Assurance) did not have sufficient authority to issue a binding rule.[175]

The court rejected the Center's contention that the guidelines were legally binding because they effectively altered the legal regime under which car manufacturers operated,[176] holding instead that complete adoption of the guidelines by the car manufacturers merely showed that the guidelines were practically binding, not legally binding as the APA requires.[177] The court found that although a car maker's decision to institute only regional recalls likely disadvantaged some car owners, the guidelines had not altered the legal standard under which the car manufacturers operated because this practice had also been in place prior to the issuance of the guidelines.[178] The court thus found the guidelines were nonbinding and unreviewable.[179]

The requirements the court incorporated into the second prong of *Bennett* in *Center for Auto Safety* would make it difficult, if not impossible, to secure judicial review of almost any guidance document, including a final version of the fresh-cut produce guidance mentioned earlier. Despite the profound economic consequences of the FDA's produce guidance, its use of only nonmandatory language, similar to the guidelines in *Center for Auto Safety*, would render the guidance unreviewable.

C. The Current State of Bennett*'s Second Prong*

Bennett today stands as a major barrier to judicial review of documents promulgated by any means less formal than a published regulation due to the difficulty of stating its precise requirements and the resulting uncertainty. *Bennett* blocks judicial review for potential challenges and a

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173. *Id.* at 809.
174. *See id.* (stating that the agency may exercise discretion in evaluating possible recalls).
175. *See id.* at 810 (concluding that the author of the guidelines did not have the "authority to issue guidelines with binding effect").
176. *See id.* at 810–11 (classifying automakers' adherence to the practices established by guidelines as a practical consequence).
177. *See id.* ("[D]e facto compliance is not enough to establish that the guidelines have had legal consequences.") (emphasis omitted).
178. *Id.* at 811 (reasoning why the "adverse effects flowing from the regional recall practices . . . are not a *legal consequence* of the guidelines").
179. *See id.* ("The adverse effects flowing from the regional recall practices surely are not a *legal consequence* of the guidelines, not only because the effects preceded the guidelines, but, more importantly, because the agency has never codified the practices in binding regulations.").

potentially important alternative argument for the challenger. Under the cases previously described in Part III.B.1.c, a challenger seeking review of a guidance document must demonstrate that the document at issue qualifies as a legislative rule. This not only sets the bar higher than that required by § 704 of the APA, but also forecloses a vital argument for the aggrieved party: that the document in question is an interpretive rule based on an invalid reading of the governing statute—a claim that parties have made only occasionally.[180]

Preventing such a challenge both forecloses the argument that the agency failed to follow proper procedures (because courts do not permit review) and eliminates a challenge to the merits of the rule based on a *Mead*[181] or *Skidmore*[182] lower level deference assessment.[183] This type of content-based non-*Chevron* analysis might be more important than a procedural challenge if the agency has not adequately explained its position in the guidance document and the challenger hopes to prevent issuance of the same interpretation following proper procedures, and to avoid future litigation.

In addition, the ability to challenge the interpretation adopted through these procedures presents one solution to the concern that agencies are increasingly foregoing the opportunity to formulate binding regulations. Basic principles of accountability suggest that courts should not only subject an agency that uses less formal rulemaking procedures to judicial review, but also subject the agency to review at a reduced level of deference. However, the current case law provides agencies with an incentive to make their views known through any method other than notice and comment rulemaking, resulting in a reduction of public input and accountability. This leads to the powerful and unfortunate anomaly that the less procedure an agency implements, the less it needs to concern itself with judicial deference; the less procedure there is, the greater the likelihood a court will simply find that the document does not qualify as a legislative rule. Such a finding would prevent challenges and negate the

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180. The fact that relatively few cases have attempted to challenge both the procedure and the merits does not mean that foreclosing this argument has been simply harmless error. Instead, it merely reflects the fact that the case law has increasingly indicated this is not a viable argument.

181. United States v. Mead Corp., 533 U.S. 218 (2001).

182. Skidmore v. Swift & Co., 323 U.S. 134 (1944).

183. *See Mead*, 533 U.S. at 228–29, 234–38 (recognizing varying levels of deference by finding that although an agency ruling may not claim judicial deference under *Chevron*, *Skidmore* entitles the ruling to some deference); *Skidmore*, 323 U.S. at 139–40 (holding that an agency's rulings, interpretations, or opinions under a statute deserve some level of respect given the information available to an agency and its specialized experience compared to a court).

need for the agency to explain its reasoning when the agency publishes the document or defends its decision in court.[184]

This presents a paradoxical situation in which a strained interpretation of finality can result in agency action that would be subject to more penetrating review—becoming a de facto legislative rule simply because parties can never challenge it.[185] Returning to the original language in *Bennett* cannot and will not solve this paradox because the case law in this area is problematic precisely because of the language used in *Bennett*. As the next section suggests, a solution will require more radical surgery.

IV. *BENNETT*'S SECOND PRONG SHOULD BE ELIMINATED

Bennett severely restricts judicial review in cases where parties are, in any honest assessment of the wording of the APA, aggrieved. Too frequently, the judicial system denies this basic entitlement—despite the apparent intent of the APA—to those needing the independent and objective review that only a court can provide. Even worse, subsequent precedent based on the original text of *Bennett* has produced limitations on review that are even more confining than those articulated by the Court when it decided *Bennett*.[186] To fully understand the problems *Bennett* has caused, it is necessary to probe the origin of *Bennett*'s two-part test. The first prong, consummation, appears to be drawn directly from the language of the APA; however, the second prong of legal effect in *Bennett* is a corruption of a line of cases that predates the APA. Furthermore, the courts in these cases never intended to determine whether the actions in question were final agency actions.[187] This Part discusses the origin of the test and explains why the second prong is little more than an extrapolation of the ripeness test. To the extent that the considerations inherent in the second prong have legitimacy, it is in the compulsory ripeness analysis and not in finality.

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184. Other commentators have also noted this phenomenon. *See, e.g.*, Anthony, *supra* note 12, at 1317–18 (noting the numerous advantages an agency obtains by foregoing the notice and comment process, including the possibility of completely avoiding judicial review).

185. The exact level of deference would depend on the court's interpretation of the deference due under *Skidmore* and *Mead*. *See Mead*, 533 U.S. at 228–29, 234–38 (according a Customs ruling letter a lower level of deference under *Skidmore* despite its failing to qualify under *Chevron*); *Skidmore*, 323 U.S. at 139–40 (giving weight to administrative decisions and interpretations due to the administrative body's experience and informed judgment, despite not being "controlling upon the courts by reason of their authority").

186. *See* discussion *supra* Part III.B.

187. *Id.*

A. The Unfortunate History of the Second Prong of Bennett *or the Origins of the Second Prong of* Bennett*: An Unintended Application*

The test used in *Bennett* traces back to *Rochester Telephone Corp. v. United States*,[188] a ruling issued seven years before Congress enacted the APA. In that case, the Court held an order reviewable because it was not "a mere abstract declaration regarding the status of the [challenger] under the Communications Act, nor was it a stage in an incomplete process of administrative adjudication."[189] A quarter century later, in *Interstate Commerce Commission v. Atlantic Coast Line Railroad Co.*,[190] the Court summarized this sentence from *Rochester* as recognition that "Commission *orders* determining a 'right or obligation' so that 'legal consequences' will flow therefrom are judicially reviewable."[191]

The *Atlantic Coast Line Railroad* Court addressed reviewability under the Administrative Orders Review Act.[192] The Administrative Orders Review Act allows review of only certain types of final agency orders.[193] However, an "order" is merely one of the terms listed in the APA definition of agency action and differs from the separately listed term "rule," which includes guidance documents.[194] Therefore, final agency orders inherently constitute a much smaller category than the "final agency action" standard for reviewability under the APA and comprise a category that Congress never intended to encompass: guidance documents or other APA rules.[195] It was this final orders test, however, that the Court contorted in the second prong of *Bennett* to the now familiar "'rights or obligations have been determined[]' or from which 'legal consequences will flow'" requirement used to determine what qualifies as final agency action under the APA.[196]

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188. 307 U.S. 125 (1939).
189. *Id.* at 143 (footnote omitted).
190. 383 U.S. 576 (1966).
191. *Id.* at 602 (emphasis added).
192. *See* 28 U.S.C. § 2342 (2000 & Supp. V 2005) (providing the court of appeals exclusive jurisdiction over rules, regulations, and final orders for specific federal agencies as well as for all final agency actions described in 49 U.S.C. § 20,114(c)).
193. *See id.* (establishing review of certain final agency orders arising from the Federal Communications Commission, the Secretary of Agriculture, the Secretary of Transportation, the Federal Maritime Commission, the Atomic Energy Commission, the Surface Transportation Board, and § 812 of the Fair Housing Act).
194. *See* 5 U.S.C. § 551(4) (2000) (defining "rule"); *id.* § 551(13) (2000) (defining "agency action"); *see also supra* text accompanying note 70.
195. *See* 5 U.S.C. § 704 (establishing that final agency actions are subject to judicial review, and that preliminary, procedural, or intermediate agency actions are subject to review during the review of the final agency action).
196. Bennett v. Spear, 520 U.S. 154, 178 (1997) (quoting Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

In sharp contrast to the current interpretation of the second prong of *Bennett*, the legislative history of the APA[197] and prior Supreme Court case law[198] suggest the widest possible review through use of the term "final agency action." Moreover, as lower courts have sought to clarify the test, *Bennett*'s nebulous finality language has moved away from the final agency orders from which it descended by requiring a constrained standard of review for "final regulations." This creates both confusing and unnecessary results because a court will address the content of *Bennett*'s second prong in the hardship component of ripeness, where there is a more coherent review.

B. The Second Prong of Bennett*: Ripeness Redux*

Ripeness is one of the fundamental considerations of justiciability—along with mootness, standing, and the political question doctrine.[199] As a fundamental consideration, an opposing party can raise the issue of ripeness at any time during the litigation, and a court can raise it sua sponte.[200] Ripeness has both constitutional and prudential aspects.[201] Constitutionally, ripeness demands an injury in fact, which originates in the "same case or controversy" language that forms the basis for all justiciability considerations and which is generally treated under the standing analysis.[202] Therefore, when evaluating challenges to administrative action, courts focus on the prudential ripeness requirements. Courts designed these requirements to protect the Judicial Branch from wasting time and resources on questions that may never actually arise, and to protect the

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197. *See* H.R. REP. NO. 79-1980, at 43 (1946) ("'Final' action includes *any* effective or operative agency action for which there is no other adequate remedy in any court.") (emphasis added); S. REP. NO. 79-752, at 27 (1945) ("'Final' action includes *any* effective agency action for which there is no other adequate remedy in any court.") (emphasis added).

198. *See* Abbott Labs. v. Gardner, 387 U.S. 136, 140–41 (1967) (stating "the Administrative Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation. . . . [O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review.") (citations omitted).

199. *See* DaimlerChrysler Corp. v. Cuno, 126 S. Ct. 1854, 1867 (2006) ("The doctrines of mootness, ripeness, and political question all originate in Article III's 'case' or 'controversy' language, no less than standing does.").

200. *See* Utah v. Dep't of the Interior, 210 F.3d 1193, 1196 n.1 (10th Cir. 2000) ("[R]ipeness can be raised at any time, even by the court sua sponte for the first time on appeal.").

201. *See* United States v. Lazarenko, 476 F.3d 642, 649 (9th Cir. 2007) (explaining that ripeness has a "constitutional component, rooted in the Constitution's case-or-controversy requirement, and a prudential component, which embraces judicially self-imposed restraints on federal jurisdiction").

202. *See* Thomas v. Anchorage Equal Rights Comm'n, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc) (analogizing a ripeness inquiry to a standing inquiry in that jurisdiction under both concepts requires "a constitutional 'case or controversy,' that the issues presented are 'definite and concrete, not hypothetical or abstract'" (quoting Ry. Mail Ass'n v. Corsi, 326 U.S. 88, 93 (1945))).

Executive Branch—and more specifically, the agencies—from premature judicial entanglement before an agency has had an opportunity to fully consider the issue and apply its expertise.[203]

In a pre-enforcement challenge, a challenger must satisfy the basic elements of prudential ripeness as enumerated in *Abbott Laboratories*. The two part test requires a showing of (1) the fitness of the issue for judicial review and (2) the hardship to the parties if review is withheld.[204] Under the fitness prong, the court must find the issue predominantly legal and final.[205] Furthermore, the court must find that pre-enforcement review is preferable to waiting for the specific facts present in a particular enforcement action.[206] The second prong, hardship, focuses on whether the challenged action will create "adverse effects of a strictly legal kind" or otherwise result in practical hardship for the challenger, which is particularly relevant to this discussion.[207] The Court illuminated this prong in *Ohio Forestry Ass'n v. Sierra Club*,[208] where it elaborated on the meaning of adverse legal effects, holding the provisions of a forestry plan were not ripe because:

> [T]hey do not command anyone to do anything or to refrain from doing anything; they do not grant, withhold, or modify any formal legal license, power, or authority; they do not subject anyone to any civil or criminal liability; they create no legal rights or obligations. Thus, for example, the Plan does not give anyone a legal right to cut trees, nor does it abolish anyone's legal authority to object to trees being cut.[209]

The Court also found that the provisions at issue would not create practical hardship effects because the provisions still required the Forest Service to go through numerous steps before logging could begin, giving the Sierra Club ample opportunity to challenge specific applications of the plan.[210]

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203. *Abbott Labs.*, 387 U.S. at 148 (providing the basic rationale for the ripeness doctrine).

204. *See id.* at 149 (expressing that ripeness is best determined in a two part analysis); *see also* United States v. Loy, 237 F.3d 251, 257 (3d Cir. 2001) (stating that these ripeness factors are prudential); Simmonds v. INS, 326 F.3d 351, 359 (2d Cir. 2003) (applying the two part ripeness test to "analyz[e] the prudence of hearing a claim of future injury").

205. *See Abbott Labs.*, 387 U.S. at 149 (finding the issue before the court to be "purely legal" and the regulations at issue to be a "final agency action").

206. Although this finality requirement also originates from § 704 of the APA, there is surprisingly no overlap in the case law between the finality requirement in *Bennett* and the finality requirement that is part of the fitness prong of the ripeness test. The best explanation for this lack of overlap is that after *Bennett*, the finality requirement in ripeness generally receives very little analysis, if any; instead, courts address this requirement as part of the regular *Bennett* analysis.

207. Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998).

208. 523 U.S. 726 (1998).

209. *Id.* at 733.

210. *See id.* at 734 ("[B]efore the Forest Service can permit logging, it must focus upon a particular site, propose a specific harvesting method, prepare an environmental review,

Ripeness, therefore, ensures that courts will not waste time and resources analyzing cases that have no immediate legal impact on the conduct of the challenger. More specifically, in analyzing the hardship prong of ripeness, a court examines whether the challenger will suffer adverse legal effects if it does not hear the case.[211] *Bennett*'s finality test asks precisely the same question regarding the legal consequences of the agency action.[212] This redundancy serves no meaningful purpose; instead, it fractures review by providing two instances for a court to address how much it matters to the challenger that the court allow the case to proceed. Once a court determines finality is lacking, it is unlikely to assess whether the requirements for ripeness are satisfied, compounding the difficulty of eliminating the overlap and harmonizing finality and ripeness, as well as stultifying the promise of judicial review in the APA.

This redundancy also eliminates the beneficial development of precedent to guide behavior. Where the same question regarding access to judicial review is addressed in multiple contexts and answered in a highly varied manner, the common law goal of predictability is lost. Parties cannot be assured of even vaguely similar treatment because they cannot anticipate whether the court will apply the hardship analysis of ripeness or that of finality, as the two analyses continue to evolve separately and erratically.

Integrating the two analyses cannot solve this problem; rather, it would further confuse the analysis. Ripeness is a concern in all cases, not just in administrative law, and continues to evolve independently of *Bennett*. Therefore, removing the hardship prong from *Bennett*'s finality criteria and allowing courts to address it exclusively through ripeness is the most effective approach.

C. The Solution

To bring judicial review under the APA back in line with the APA itself, courts should limit the test for finality to only the first prong of *Bennett*, which asks whether the agency action being challenged is final. The purpose of APA judicial review is to provide interested parties an opportunity to challenge adverse agency action. Agency accountability

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permit the public an opportunity to be heard, and (if challenged) justify the proposal in court."). While the Court admitted this would be more burdensome than a single challenge to the validity of the plan, it was unwilling to find a case ripe based on increased litigation costs alone. *See id.* at 734–35 (suggesting that one initial site-specific victory would have the same effect as a single challenge against the entire Land and Resource Management Plan).

211. *See id.* at 733 (finding that the provisions of the challenged plan did not create "adverse effects of a strictly legal kind, that is, effects of a sort that traditionally would have qualified as harm").

212. More specifically, *Bennett* asks whether legal consequences flow, presuming that if legal consequences do not flow, the party is not actually harmed.

was a primary concern when Congress enacted the APA.[213] Reading unnecessary requirements into § 704, as courts have done through *Bennett* and its progeny, unnecessarily restricts this review. Therefore, the test for whether a challenger has met the finality requirement of the APA should ask merely whether the agency action at issue is the conclusion of the agency's decisionmaking process. If the agency issued a temporary rule while beginning to undertake notice and comment rulemaking, the temporary rule is not final. However, a document issued after notice and comment and labeled a final guidance document would presumably meet the finality test. This distinction should also be clearer in the future, when many major guidance documents will be subject to the new OMB circular requirements that require notice and an opportunity for public input before agencies can release even nonbinding documents.[214]

Merely meeting the finality requirement, however, would not mean that parties would flood courts with agency challenges. Regardless of finality, all cases brought in federal court must be ripe. If the challenger does not face imminent harm, the court could still properly refuse to hear the case.[215] Separating the doctrines of finality and ripeness would enhance fairness and clarity to the agency and its regulatees. Challengers would know the inquiry they face when seeking review of a guidance document, rather than wondering which of the many tests the court might choose to apply—or if the court would even address the finality requirement at all. Currently, confusing and overlapping decisions in ripeness and finality constrain judicial review of guidance documents; clearer separation of the two doctrines could solve this.

CONCLUSION

The Supreme Court appropriately found a right to judicial review for final agency actions within the framework of the APA. This right will become increasingly important as supposedly nonbinding guidance documents take on a greater role in the regulatory state. However, the current test for determining judicial review has strayed too far from that

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213. *See* Matthew Diller, *The Revolution in Welfare Administration: Rules, Discretion, and Entrepreneurial Government*, 75 N.Y.U. L. REV. 1121, 1188–89 (2000) (stating the APA was a compromise intended to address the accountability concerns present during the New Deal).

214. *See supra* notes 20–21 and accompanying text.

215. This Article only addresses finality, attempting to create a more streamlined approach to the review of documents. Documents that pass finality could still fail to obtain review under ripeness, particularly since there is also case law that appears to unnecessarily restrict what is considered ripe.

intended by the APA itself. The test for whether the challenger has met the requirements set forth in the APA for final agency action should ask just that: Is the agency action final?