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# THE FDA'S NEW POLICY ON GUIDELINES: HAVING YOUR CAKE AND EATING IT TOO

Lars Noah\*

Under the Administrative Procedure Act (APA),<sup>1</sup> “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” are exempt from notice-and-comment rulemaking requirements.<sup>2</sup> However, courts continue to struggle in their attempts to differentiate such “nonlegislative” rules from binding regulations.<sup>3</sup> Agency efforts to utilize this exemption to evade informal rulemaking requirements have attracted significant scholarly attention in recent years.<sup>4</sup> By comparison, relatively benign uses of interpretative rules and policy statements, especially as a method of providing regulated entities with reliable guidance concerning the acceptability of their conduct, have

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1. Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. §§ 551-559, 701-706 (1994)).

2. 5 U.S.C. § 553(b)(A) (1994). Such rules, however, must be published. *See id.* § 552(a)(1)(D), (2)(C).

3. *See, e.g.,* Lincoln v. Vigil, 508 U.S. 182, 196-97 (1993); *Hocrot v. United States Dep't of Agric.*, 82 F.3d 165, 167-72 (7th Cir. 1996); *Takhar v. Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996); *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595-602 (5th Cir. 1995); *United States v. Yuzary*, 55 F.3d 47, 51-53 (2d Cir. 1995); *Dia Navigation Co. v. Pomeroy*, 34 F.3d 1255, 1264-65 (3d Cir. 1994); *Caraballo v. Reich*, 11 F.3d 186, 194-96 (D.C. Cir. 1993); *White v. Shalala*, 7 F.3d 296, 303-04 (2d Cir. 1993); *Associated Builders & Contractors, Inc. v. Reich*, 922 F. Supp. 676, 680-82 (D.D.C. 1996).

4. *See, e.g.,* 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, 1315 (1992) (“While these nonlegislative rules by definition cannot *legally* bind, agencies often inappropriately issue them with the intent or effect of imposing a *practical* binding norm upon the regulated or benefited public.”); Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1386 (1992) (“[A]gencies are beginning to seek out alternative, less participatory regulatory vehicles to circumvent the increasingly stiff and formalized structures of the informal rulemaking process.”); *see also* Robert A. Anthony & David A. Codevilla, *Pro-Ossification: A Harder Look at Agency Policy Statements*, 31 WAKE FOREST L. REV. 667, 676-80 (1996); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 383-401; Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 82-86 (1995).

generated little commentary. One recent and particularly interesting agency initiative in this area merits discussion.

For almost a century, the United States Food and Drug Administration (FDA) has provided formal advice to persons subject to its jurisdiction. From its earliest beginnings, the FDA found it desirable to issue guidance on which regulated firms could rely. Agency advisory opinions and guidelines provided needed clarification and certainty to persons attempting to comply with statutory and regulatory requirements, and they also benefited the Agency by assuring consistency in actions taken by its employees.

In 1977, the FDA promulgated a regulation providing that any officially issued advisory opinion or guideline would be binding on the Agency.<sup>5</sup> This regulation represented an attempt to codify and structure the Agency's longstanding practice, and its promulgation exemplified the sort of agency self-discipline that courts and commentators long have endorsed. The FDA retained significant flexibility under the regulation: it may decline to follow formal advisory opinions and guidelines if necessary to take action to protect the public health, it may revise or revoke such guidance documents at any time, and it need not issue initial pronouncements in a binding fashion if it prefers not to limit its discretion.<sup>6</sup>

In 1992, the FDA proposed amending this regulation to eliminate the assurance that the Agency would abide by its formal advice to regulated entities.<sup>7</sup> Although the Agency has not yet finalized this proposal, in early 1997 the FDA issued a policy on the use of guidance documents, reiterating its view that formal advisory opinions and guidelines should no longer bind the Agency, and explaining that its proposal would be finalized in the near future.<sup>8</sup> Whether or not that ever happens, the FDA's practice in issuing advisory opinions and guidelines has changed dramatically over the last five years.

The proposed wholesale renunciation of hundreds of formal advisory opinions and guidelines on which regulated firms have come to rely cannot, however, be justified. With the partial rescission of the regulation, regulated entities will no longer be certain that good faith efforts to comply with often ambiguous regulatory requirements will be accepted by the FDA, even though these actions were taken on the basis of formal advisory opinions and guidelines interpreting those requirements.

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5. See 42 Fed. Reg. 4680, 4708-10 (1977) (codified as amended at 21 C.F.R. §§ 10.85, 10.90 (1997)).

6. See *id.*

7. See 57 Fed. Reg. 47,314 (1992).

8. See 62 Fed. Reg. 8961, 8963 (1997); see also 61 Fed. Reg. 9181, 9183 & n.1 (1996).

There are no legal impediments to retaining the regulation in its present form. Although advice provided by FDA employees cannot bar actions to enforce existing legal requirements, the Agency can choose to provide authoritative interpretations of requirements imposed by statute or regulation through formal advisory opinions and guidelines. Similarly, the Agency's failure to utilize notice-and-comment rulemaking procedures before issuing certain advisory opinions or guidelines does not require that the FDA renounce its promise to abide by its formal advice to the industry. To the contrary, by suggesting that past actions taken by regulated entities in reliance on purportedly binding advice may no longer be deemed acceptable, the FDA's proposal countenances an impermissible retroactive effect.

Part I of this Article reviews the Agency's long history of providing reliable advice to regulated entities and explains how the FDA's latest policy and practice represent a substantial break with the past. Part II canvasses the competing policy arguments, concluding that the issuance of reliable advice benefits both the industry and the Agency and that complaints by the FDA that binding guidance unduly constrains its flexibility have no foundation. Finally, Part III considers the Agency's legal arguments, namely, that its past promises to be bound by formal advisory opinions and guidelines violate non-estoppel principles and procedural requirements for rulemaking and that advisory opinions and guidelines should not be deemed final agency action ripe for judicial review. Ultimately, this Article concludes that the FDA's new policy on the issuance of guidelines represents a seriously misguided change in the Agency's practice of promising to stand behind its advice to regulated entities.

### I. THE FDA'S HISTORY OF PROVIDING RELIABLE GUIDANCE

Since the turn of the century, the FDA and its predecessor agencies have issued rulings, decisions, and guidance documents designed to advise regulated parties how they would implement the law and to describe permissible conduct.<sup>9</sup> The promulgation of regulations that implement and elaborate on the statute is, by comparison, a relatively recent phenomenon. Under the Pure Food Act of 1906,<sup>10</sup> the Department of Agriculture's Bureau of Chemistry issued hundreds of Food Inspection Decisions (FIDs).<sup>11</sup> After the enactment of the Federal Food, Drug, and

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9. See 40 Fed. Reg. 40,682, 40,694 (1975) ("Throughout its history, the [FDA] has issued advisory opinions in various forms.").

10. Pub. L. No. 59-384, 34 Stat. 768 (1906) (superseded by Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938)).

11. See Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regula-*

Cosmetic Act (FD&C Act) in 1938,<sup>12</sup> the FDA began publishing Trade Correspondence (TC) to advise regulated firms on how to comply with statutory requirements.<sup>13</sup> Compliance Policy Guides (CPGs) represent a newer incarnation of the TCs. In addition, other types of Agency communications, such as “guidance memoranda” and “points to consider,” have proliferated during the last quarter of a century.<sup>14</sup>

The procedural regulations promulgated by the FDA in 1977 simply codified the Agency’s longstanding practice of issuing advisory opinions and guidelines on which the industry could rely. In large part, by differentiating between formal advisory opinions and informal opinions provided by individual employees, the FDA sought to reaffirm the reliability of advice offered by the Agency in its institutional capacity. In the preamble to its 1975 proposal, the Agency noted that opinion letters sometimes had been provided by FDA employees without being “compiled or reviewed in any comprehensive or systematic way.”<sup>15</sup> The FDA hoped to clarify the authority of different types of Agency opinions, distinguishing between informal opinions provided by Agency employees, which would not estop the government from taking a contrary position, “and the formal opinion of the agency, which represents a position of the [FDA] that is binding and commits the agency to the views expressed until they are formally modified or revoked.”<sup>16</sup> In addition to advisory opinions issued in response to petitions under this regulation, statements of policy or interpretation contained in the *Federal Register*, TCs, CPGs, or other guidelines constituted reliable advisory opinions. However, statements or advice provided by FDA employees did not necessarily represent the formal position of the FDA and would not bind the Agency.<sup>17</sup>

The Agency obligated itself to follow, except in emergency situations, formal positions expressed in advisory opinions or guidelines: “Action

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*tion of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 55 n.435, 56 nn.443 & 447 (1984) (noting that these decisions, along with advice of general interest quoted from Agency correspondence, were collected in periodically updated circulars known as Service and Regulatory Announcements (SRAs)).

12. Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-394 (1994)).

13. See Peter Barton Hutt, *The Transformation of United States Food and Drug Law*, J. ASS’N FOOD & DRUG OFFICIALS, Sept. 1996, at 9, 37; William Van Brunt, *Advisory Opinions*, 32 FOOD DRUG COSM. L.J. 304, 305 (1977).

14. See 61 Fed. Reg. 9181, 9182 (1996) (“Well over a thousand such documents exist.”).

15. 40 Fed. Reg. 40,682, 40,694 (1975).

16. *Id.*

17. See 21 C.F.R. § 10.85(d), (k) (1997).

undertaken or completed in conformity with an advisory opinion [or guideline] which has subsequently been amended or revoked is [or will remain] acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance."<sup>18</sup> Advisory opinions and guidelines may be amended or revoked at any time after issuance so long as notice of this action is given.<sup>19</sup>

The characterization of formal advisory opinions and guidelines as "binding" has engendered confusion.<sup>20</sup> At the outset, it is important to distinguish between the many different respects in which an opinion or guideline might be considered binding. The FDA has made it clear that advisory opinions or guidelines do not represent substantive rules that bind regulated parties.<sup>21</sup> At the other extreme, a formal opinion or guideline does more than simply reflect instructions that Agency personnel are expected to follow. Regulated firms were assured that they could rely on formal opinions and guidelines without fearing that the FDA would take enforcement action or reject conforming submissions—unless necessary to protect the public health. The Agency's decision to "bind"

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18. *Id.* §§ 10.85(h), 10.90(b)(6); *see also id.* §§ 10.85(e), 10.90(b)(2) ("The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion [or guideline] which has not been amended or revoked."); 40 Fed. Reg. at 40,695 ("provid[ing] for sufficient flexibility to permit immediate action where essential to public protection").

19. *See* 21 C.F.R. §§ 10.85(g), 10.90(b)(5); *see also* *Takhar v. Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996).

20. *Cf.* Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1464 (1992).

We can imagine cases [where only the government is bound]—historically perhaps not numerous in litigation, but nonetheless central to one's sense of what it means to have a government of laws—in which citizens who are not themselves bound by a governmental policy instrument seek to hold the government to the promise that the instrument seems to contain.

*Id.*; *see also id.* at 1466 ("What is needed is an analysis that also takes into account the traditions of holding government accountable to the law it creates for itself."); *id.* at 1483 (explaining that policies designed only to bind the agency are rarely challenged and that courts therefore fail to distinguish them from policy statements designed to bind others). In a related context, one court suggested that "[a] binding policy is an oxymoron." *Vietnam Veterans of Am. v. Secretary of the Navy*, 843 F.2d 528, 537 (D.C. Cir. 1988); *see also* OFFICE OF THE CHAIRMAN, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, A GUIDE TO FEDERAL AGENCY RULEMAKING 65 (2d ed. 1991) ("Any form of binding effect will take an agency pronouncement out of the policy statement exemption . . .").

21. *See* 21 C.F.R. §§ 10.85(j), 10.90(b)(8) ("An advisory opinion [or guideline] may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement."); 42 Fed. Reg. 4680, 4694 (1977) ("Guidelines ordinarily represent agency interpretations of formal legal requirements, not binding legislative rules.").

itself in this fashion meant, however, only that it promised to abide by its formal interpretation of the requirements imposed by statute or regulation, *not* that it promised to excuse violations of these requirements in certain instances. The regulation does nothing more than bind the FDA in the sense that it agrees to issue reliable advice about how it interprets the requirements imposed by the statute and regulations. Formal advisory opinions and guidelines would not, for instance, give third parties the right to object to Agency decisions accepting submissions by a regulated firm that are allegedly inconsistent with those opinions or guidelines.<sup>22</sup>

The FDA's decision in 1977 to create different categories of advice represented an attempt to clarify the otherwise ambiguous status of various Agency pronouncements. In 1997, the Agency continued this effort by issuing its "Good Guidance Practices" (GGP) policy,<sup>23</sup> which defined guidance documents to include:

documents prepared for FDA staff, applicants/sponsors, and the public that: (1) Relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures.<sup>24</sup>

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22. For example, when the Center for Science in the Public Interest filed objections to the FDA's decision to approve the food additive petition for acesulfame potassium, it argued that the Agency should not have accepted toxicity studies that had failed to achieve a maximum tolerated dose as provided by the "*Redbook*." The FDA responded that the *Redbook* does not "bind" the Agency. See 57 Fed. Reg. 6667, 6669 & n.2 (1992); see also *Simpson v. Young*, 854 F.2d 1429, 1435 (D.C. Cir. 1988) (holding that the FDA need not demand adherence to the guidelines set out in the *Redbook* given the "permissive language in the manual"); cf. *American Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 538-39 (1970) (holding that an agency could ignore a procedural rule that was not intended to confer any benefits on competitors objecting to another company's application). One would assume, however, that the Agency would have been "bound" to accept from a sponsor of a food additive petition toxicity studies that fully complied with the *Redbook*, putting aside for the moment the fact that the "guidelines that provide suggested protocols" are part of a "draft" document. 47 Fed. Reg. 46,141, 46,142 (1982); see also 58 Fed. Reg. 16,536 (1993) (announcing the availability of a revised draft of the *Redbook*).

23. See 62 Fed. Reg. 8961, 8967 (1997). Less than a year earlier, the FDA had published a notice of its proposed policy inviting comments and announcing a public meeting on the subject. See 61 Fed. Reg. 9181 (1996); see also 61 Fed. Reg. 15,080 (1996) (announcing the meeting). The FDA reform bill recently passed by Congress would obligate the Agency to promulgate its GGP policy as a regulation by July 1, 2000. See S. 830, 105th Cong. § 405 (1997), in 143 CONG. REC. H10,452, H10471 (daily ed. Nov. 9, 1997).

24. 62 Fed. Reg. at 8967 (adding that the term "do[es] not include documents relating to internal FDA procedures, agency reports, general information documents provided

The GGP policy calls for uniformity in format, the use of standardized nomenclature, explicit language disavowing any binding legal effect, assurances of access to these documents by interested parties, opportunities for public input, and procedures for internal review.<sup>25</sup> The original impetus for, and much of the focus of, this new policy were complaints that the FDA inappropriately had used guidance documents as if they constituted binding rules that regulated entities had to follow.<sup>26</sup> Although the policy expresses symmetry in emphasizing that neither companies nor Agency officials are bound, evidently no one other than the FDA itself had complained about the operation of the 1977 regulation to bind the Agency.

In the GGP notice, the FDA explained that it remains committed to finalizing its 1992 proposal.<sup>27</sup> In fact, the proposed revision would codify only what has become the Agency's consistent practice during the last five years. Essentially every guidance document announced since 1992 includes a disclaimer that it reflects only the FDA's current (and sometimes only tentative) thinking on the subject and binds no one.<sup>28</sup> In contrast, earlier guidelines might have advised regulated entities that they remained free to deviate from the Agency's guidance.<sup>29</sup> Thus, the FDA's

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to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms").

25. See *id.* at 8968-70. For instance, guidance documents should not use mandatory words unless describing existing obligations under the statute and regulations, and a disclaimer provides that a "guidance document represents the agency's current thinking on [the policy under consideration]. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public." *Id.* at 8969.

26. See *id.* at 8961 (explaining that the policy represented a response to a citizen petition filed by an association of medical device companies that had objected to the FDA's mandatory application of nonbinding guidelines); *id.* at 8963 (discussing comments alleging past misuses of guidance documents by Agency employees); see also *United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 83-84 (D. Md. 1987) (rejecting the FDA's effort to require that device manufacturers adhere to a sterility guideline that had not been promulgated through notice-and-comment rulemaking).

27. See 62 Fed. Reg. at 8961, 8963. In the meantime, consistent with GGP policy, officials already have begun the process of compiling and updating the FDA's numerous guidance documents. See, e.g., 62 Fed. Reg. 14,912 (1997) (requesting comment on guidance documents relating to prescription drugs issued by the Division of Drug Marketing, Advertising, and Communications); 62 Fed. Reg. 34,480 (1997) (giving notice of how the National Shellfish Sanitation Program intends to apply its policy on guidance documents).

28. See, e.g., 62 Fed. Reg. 36,836, 36,836 (1997) ("This guidance document represents the agency's current thinking . . . and does not operate to bind FDA or the public."); 62 Fed. Reg. 31,118, 31,121 (1997) (same); 62 Fed. Reg. 32,351, 32,351 (1997) (same); 62 Fed. Reg. 32,352, 32,352 (1997) (same); 62 Fed. Reg. 33,094, 33,094 (1997) (same); see also 61 Fed. Reg. 67,557, 67,557 (1996) (explaining that CPGs do not bind the Agency); 60 Fed. Reg. 32,159, 32,159 (1995) (same).

29. See, e.g., 57 Fed. Reg. 33,201, 33,202 (1992) (noting that "[a] manufacturer may choose to use alternative procedures even though they are not described").

policy against providing binding advice already is firmly entrenched, and finalization of its proposal simply would confirm that policy and apply it retroactively to withdraw prior assurances that regulated entities could continue to rely on any advisory opinions and guidelines published before 1993 and not yet specifically withdrawn.

The 1992 proposal and the Agency's subsequent practice of routinely disclaiming the binding effect of guidance documents blur, if not eliminate, the distinction between formal advice and the informal opinions of FDA employees. If the Agency announces that it no longer guarantees that an advisory opinion represents the FDA's formal policy, or that a person may no longer rely upon a guideline with the assurance that it will be acceptable to the FDA, then formal advisory opinions and guidelines will be largely indistinguishable from oral assurances provided by individual employees.<sup>30</sup> The former would remain somewhat more reliable only in the sense that they were issued by higher level officials. In effect, the FDA has proposed segregating its pronouncements into only two categories: those that bind both regulated firms and the Agency (i.e., regulations promulgated through notice-and-comment or more formal rulemaking procedures), and, at the other extreme, those that bind no one and on which no one can safely rely. As explained in the discussion that follows, it is unwise to implement such a change.

## II. THE ADVANTAGES OF BINDING ADVICE

The FDA's practice of issuing advisory opinions and guidelines, a hallmark of agency behavior for nearly a century, has advantages for both regulated firms and the Agency. Formal opinions and guidelines elicit conduct desired by the FDA, while allowing firms to plan activities and undertake useful investments without fearing that the Agency will change its mind on issues such as the appropriate design of toxicity studies and reject previously acceptable protocols.

Principles of good government require that persons responsible for implementing and enforcing legislative enactments apprise regulated entities and the public about the meaning of applicable legal requirements. In his famous book on the subject of administrative discretion, Professor Kenneth Culp Davis emphasized the importance of both structuring and

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30. The Agency conceded as much in its 1992 proposal, "acknowledg[ing] that there may be little difference between formal agency advisory opinions and informal advice from agency employees." 57 Fed. Reg. 47,314, 47,316 (1992). Just like informal opinions from employees, advisory opinions "would still [only] represent the agency's best advice on the matter at issue *at the time they are rendered.*" *Id.* at 47,314 (emphasis added).

confining discretionary power exercised by administrative agencies.<sup>31</sup> Professor Davis explained that a number of methods exist for accomplishing these two goals, including the use of policy statements and guidelines:

[S]omething in the nature of guidelines seems essential to fairness, for otherwise businessmen are governed by policy or law that is inaccessible to them. Not only does fairness require clarification of prosecution policy, but efficiency does. . . . One fundamental is that the typical businessman normally complies with law that is clear. Continuing uncertainty of law or policy is a needless barrier to voluntary compliance.<sup>32</sup>

He added that policy statements are less binding than regulations but more binding than informal remarks by officials.<sup>33</sup> It was in response to recommendations of this sort that the FDA, in 1975, originally proposed to codify and clarify its longstanding practice of providing meaningful and reliable advice to regulated firms: "The Commissioner recognizes that such guidelines, which do not have the legal status of regulations, are increasingly important in providing assistance both to the regulated industry and to agency employees who are charged with consistent and fair administration of the law."<sup>34</sup>

Courts also have recognized that FDA "guidelines have the not inconsiderable benefits of apprising the regulated community of the agency's intentions as well as informing the exercise of discretion by agents and officers in the field."<sup>35</sup> Both industry and the FDA benefit, therefore,

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31. See KENNETH CULP DAVIS, *DISCRETIONARY JUSTICE: A PRELIMINARY INQUIRY* 88 (1969) (describing the "system [a]s atrociously unsound under which an individual policeman has unguided discretionary power").

32. *Id.* at 201; see also *The Second Citizens Advisory Committee Report*, 17 *FOOD DRUG COSM. L.J.* 581, 598 (1962) (encouraging the FDA to promote voluntary compliance through increased attention to educational efforts). For a criticism of the Agency's reliance on "voluntary" concessions from regulated entities, see Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 *WIS. L. REV.* (forthcoming 1998).

33. See DAVIS, *supra* note 31, at 103 ("At some point policy statements shade into interpretative rules which in turn shade into legislative rules. Interpretative rules are considered slightly more formal than policy statements, and they usually have a slightly greater degree of binding effect on the agency—a degree that is seldom clear."). "Plans, policy statements, and rules are three facets of essentially the same thing; all are designed to clarify and to regularize the purpose of the governmental activity." *Id.* at 98. For an assessment of the influential impact of Professor Davis's book, see Barry Boyer, *From Discretionary to Bureaucratic Justice*, 82 *MICH. L. REV.* 971, 973 (1984).

34. 40 *Fed. Reg.* 40,682, 40,695 (1975).

35. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 949 (D.C. Cir. 1987) (*per curiam*); see also Strauss, *supra* note 20, at 1465 ("Procedural rules that would inhibit reliable advice-giving, are, from this point of view, to be frowned upon."); Richard M. Tho-

from the issuance of advisory opinions and guidelines that the Agency agrees to follow. Indeed, the Agency still seems to appreciate these dual benefits, acknowledging “the value of guidance documents in providing consistency and predictability.”<sup>36</sup> Nonetheless, it believes that these benefits will not be sacrificed by renouncing the binding effect of advisory opinions and guidelines.<sup>37</sup> As explained below, such confidence seems misplaced.

### A. Benefits to Regulated Entities

Advisory opinions and guidelines provide regulated entities with important clarification about how to comply with statutory and regulatory requirements.<sup>38</sup> Formal opinions and guidelines create predictability about how the FDA plans to enforce these requirements and assures regulated entities that actions taken in conformity with these opinions and guidelines will comply with the law.<sup>39</sup> The availability of guidelines on which entities may rely is of particular importance with respect to the development and testing of substances that are subject to the FDA’s premarket review. In 1977, a special committee, convened to evaluate the Agency’s new drug approval (NDA) process, recommended that the FDA issue a greater number of guidelines to provide sponsors of new

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mas, *Prosecutorial Discretion and Agency Self-Regulation: CNI v. Young and the Aflatoxin Dance*, 44 ADMIN. L. REV. 131, 155 (1992) (“[I]f regularity of agency enforcement action, centralized control of agency personnel, and imposition of public, agency-wide policy are desired . . . then a rule that essentially penalizes an agency for restricting the discretion of its own personnel would appear to be counterproductive.”).

36. 62 Fed. Reg. 8961, 8963 (1997); *see also id.* (“A company wants assurance that if it chooses to follow a guidance document, FDA generally will find it to be in compliance with the statute and regulations. Moreover, FDA issues guidance to its staff so that they will apply the statute and regulations in a consistent manner.”); 61 Fed. Reg. 9181, 9182 (1996) (endorsing the same concept).

37. *See* 62 Fed. Reg. at 8963 (“FDA’s decisionmakers will take steps to ensure that their staff do not deviate from guidance documents without appropriate justification and without first obtaining concurrence from a supervisor. This practice will provide assurance to companies that choose to follow a guidance, yet will not legally bind the agency . . .”); *id.* at 8967 (endorsing the same concept).

38. *See* Peter L. Strauss, *From Expertise to Politics: The Transformation of American Rulemaking*, 31 WAKE FOREST L. REV. 745, 749 (1996) (“Those subject to regulation often solicit this advice-giving activity eagerly, as an efficient means of resolving uncertainties that could be quite costly to them.”).

39. One particularly significant new guideline, though issued in the form of a “draft” guidance document, clarifies the application of the FDA’s rules on broadcast prescription drug advertising to promotional campaigns appearing on television. *See* 62 Fed. Reg. 43,171 (1997); *see also* Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. (forthcoming 1997); Bruce Ingersoll & Yumiko Ono, *FDA to Clear the Way for Blitz of TV Drug Ads*, WALL ST. J., Aug. 8, 1997, at B1.

drug products with reliable advice for the preparation of NDA submissions.<sup>40</sup> During the last two decades, the FDA has issued detailed guidelines to assist manufacturers of drugs, biologics, and medical devices in assembling applications for premarket approval.<sup>41</sup>

In the medical device area, for example, the reviewing divisions of the Office of Device Evaluation (ODE) have published dozens of important guidance documents and draft guidelines that address many of the issues that arise in preparing investigational device exemption applications, premarket notifications under section 510(k) of the Act, and premarket approval applications for particular types of devices.<sup>42</sup> These guidelines, compiled and periodically updated as "ODE Guidance Memoranda," provide sponsors with important advice for submitting applications to the Agency. In addition, in 1990, Congress specifically directed the FDA to develop and disseminate such guidelines for certain types of medical devices.<sup>43</sup> Without reliable guidance, companies would have difficulty anticipating what types of information ODE reviewers might demand. The submission of applications using non-standard formats or containing extraneous information would waste the FDA's time and unnecessarily delay the review of applications.

The recommendation that the FDA issue formal guidelines was

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40. See United States Dep't of Health, Educ., and Welfare, *Final Report: Review Panel on New Drug Regulation* 67 (May 1977) ("Formal release of up-to-date preclinical and clinical guidelines should improve the quality of research and increase the acceptability and reliability of test data by clarifying what FDA believes constitutes a well-controlled study and by providing investigators with generalized standards and procedures for conducting animal and human testing."); see also Christopher L. Hagenbush, *How the Food and Drug Administration and Industry Use Guidelines in Defining and Interpreting Statutory Requirements*, 38 FOOD DRUG COSM. L.J. 177, 178-79 (1983) (describing the FDA's decision to issue guidelines rather than regulations concerning clinical testing); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1778-81, 1779 n.79, 1848 (1996) (discussing the importance to applicants of reliable FDA guidance on acceptable clinical study designs).

41. See, e.g., 61 Fed. Reg. 56,243 (1996) (rDNA products); 61 Fed. Reg. 43,934 (1996) (acute toxicity testing); 61 Fed. Reg. 26,191 (1996) (pediatric labeling); 59 Fed. Reg. 64,094 (1994) (supplements for nonsterile products); 58 Fed. Reg. 63,996 (1993) (sterilization process validation); 58 Fed. Reg. 39,406 (1993) (clinical testing for gender differences in drug safety and effectiveness); see also Center for Drug Evaluation & Research, FDA, *Guidance Documents* (last modified Oct. 23, 1997) <<http://www.fda.gov/cder/guidance>> (collecting guidelines relevant to the pharmaceutical industry); 58 Fed. Reg. 17,413 (1993) (listing guidelines issued by the FDA's Center for Veterinary Medicine).

42. See Center for Devices & Radiological Health, FDA, *Device Evaluation Information* (last modified Apr. 14, 1997) <<http://www.fda.gov/cdrh/device.html>> (collecting guidance documents about FDA review of applications to market medical devices).

43. See Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 5(a)(2), 104 Stat. 4511, 4517-18 (codified at 21 U.S.C. § 360c(a)(1)(B) (1994)).

equally relevant to other Agency activities, including its regulation of the food and cosmetics industries. In preparing food and color additive petitions, for example, regulated firms benefit greatly from knowing in advance what types of toxicological studies the Agency will deem acceptable.<sup>44</sup> Research and development (R&D) efforts would be hindered substantially if sponsors could no longer conduct chronic animal studies with the assurance that these studies would be acceptable to FDA reviewers years later if the studies were performed in accordance with announced guidelines.<sup>45</sup> Although persons remain free to use procedures other than those identified as acceptable in guidelines, the FDA encourages them to “discuss the matter in advance with FDA to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.”<sup>46</sup>

Agencies should be able to issue opinions and guidelines that imply greater reliability than the oral advice of individual employees. Although existing case law may not clearly define the status of intermediate pronouncements such as advisory opinions and guidelines, the FDA should not discard these useful documents by taking the position that such pronouncements are as meaningless as the oral advice received from a single agency employee in the field. In its 1992 proposal, the Agency suggested that its formal opinions and guidelines would continue to provide a dependable sign of the FDA’s expectations.<sup>47</sup> However, if this is true, it is hard to fathom why the proposed revision is necessary. In fact, the Agency’s apparent desire to free itself of its promise to be bound by formal opinions and guidelines belies its reassurances that such pronouncements will continue to represent reliable advice.<sup>48</sup>

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44. See *supra* note 22 (discussing the FDA’s *Redbook*, which specifies acceptable protocols for toxicological testing of food-use substances); see also Center for Food Safety & Applied Nutrition, FDA, *Information Materials for the Food and Cosmetics Industries* (last modified Oct. 27, 1997) <<http://vm.cfsan.fda.gov/~dms/industry.html>> (collecting guidance documents relevant to food processors).

45. See Lars Noah & Richard A. Merrill, *Starting From Scratch? Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. (forthcoming 1998).

46. 21 C.F.R. § 10.90(b)(1)(i) (1997); see also *id.* § 170.20 (reiterating this policy specifically with respect to food additive petitions).

47. See 57 Fed. Reg. 47,314, 47,315 (1992).

48. Cf. Anthony, *supra* note 4, at 1340 (explaining that “agenc[ies] may try to have it both ways—that is, to hold affected parties to the standards set in the enforcement policy, but deny the document a role as a safe harbor, thereby reserving the freedom to proceed against persons who conform to it”); *id.* at 1360-61 (“suspecting that the agencies consider it easy to fool the courts on these points,” and objecting to agency efforts to disclaim any binding effect because it “would leave the private party in the worst of possible worlds: The private party is bound but the agency retains full freedom to act at variance with its stated position”).

### B. Benefits to the Agency

It is also in the FDA's best interest to issue formal advisory opinions and guidelines on which regulated firms are invited to rely.<sup>49</sup> Courts have recognized the importance of holding agencies to their formal policy statements. Declining to rule that an agency may announce a policy and "then be free to disregard that policy with impunity," one court observed that the agency's "own interests in public cooperation are not served by such a public assertion of freedom from accountability."<sup>50</sup> Professor Michael Asimow, in a report prepared for the Administrative Conference of the United States (ACUS), has expressed a view endorsed by other commentators:

[I]nterpretive rules and policy statements are indispensable to proper administration. Agencies cannot perform effectively unless they clarify the law through interpretive rules and channel their discretion through policy statements. Both kinds of rulemaking are needed to guide the staff in administering the statute and in assisting regulated persons to comply with the law.<sup>51</sup>

The issuance of formal advisory opinions and guidelines provides useful guidance to FDA employees responsible for enforcing statutory and regulatory requirements.

Binding guidelines also help ensure consistency in decisionmaking. In the past, Congress has "chastised FDA for the absence of written policies that led to inconsistent Agency actions."<sup>52</sup> If the Agency decides

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49. See 40 Fed. Reg. 40,682, 40,695 (1975) (recognizing that the development of binding guidelines was "imperative for efficient administrative implementation of the law").

50. *United States v. Tobins*, 512 F. Supp. 308, 315 (D. Mass. 1981).

51. Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520, 529 (1977) [hereinafter Asimow, *Public Participation*]; see also HENRY J. FRIENDLY, *THE FEDERAL ADMINISTRATIVE AGENCIES: THE NEED FOR BETTER DEFINITION OF STANDARDS* 145-46 (1962) (explaining that "one of the values of the policy statement [is] the education of agency members in the agency's work"); Michael Asimow, *California Underground Regulations*, 44 ADMIN. L. REV. 43, 43 (1992) (explaining that, in addition to reducing transaction costs for regulated parties, clear guidance about what the law requires also helps agency staff "apply the law consistently, fairly, and efficiently"); *id.* at 59 ("There cannot be too many nonlegislative rules.").

52. Edward John Allera, *FDA's Use of Guidelines, Notices of Proposed Rulemaking, and Compliance Policies as De Facto Rules: An Abuse of Discretion*, 36 FOOD DRUG COSM. L.J. 270, 276 (1981); see also *FDA's Regulation of Zomax: Hearings Before a Subcomm. of the House Comm. on Gov't Operations*, 98th Cong. 159 (1983). Courts have intervened when it appears that the FDA has taken inconsistent actions toward similarly situated products. See *United States v. Diapulse Corp.*, 748 F.2d 56, 62 (2d Cir. 1984); *Rhodia, Inc. v. FDA*, 608 F.2d 1376, 1379 (D.C. Cir. 1979); *United States v. Undeter-*

that formal advisory opinions and guidelines no longer can be relied upon by regulated firms, then FDA employees might feel less compelled to follow the policies announced by the Commissioner's office. Agency employees would be free to ignore formal positions previously taken by FDA officials, adding further uncertainty for persons in regulated industries and raising the specter of arbitrary enforcement action.<sup>53</sup> As Professor Peter Strauss once cautioned, "*ad hoc* decisionmaking by low-level bureaucrats must be avoided. The regrettable and perverse impact of strongly discouraging publication rulemaking [of formal opinions and guidelines] would be to sharply diminish the effective resources available to control the exercise of low-level discretion."<sup>54</sup>

Nor should the Agency expect that the proposed revisions will lead to any reduction in its administrative workload. In all likelihood, the FDA will face greater demands on its time and resources once it disclaims the continued reliability of formal advisory opinions and guidelines. Persons will continue to submit petitions requesting advisory opinions, and the Agency's obligation to process these requests will not be lessened simply because the opinions have no lasting assurance of reliability. The FDA may save a small amount of time by dispensing with the need to announce changes to previously issued advisory opinions and guidelines, but this insignificant saving of time will be more than offset by the FDA's need to litigate more cases where regulated parties believe that they have been treated in an arbitrary fashion whenever the Agency deviates from its formal advice.

Moreover, the FDA can expect more citizen petitions requesting the issuance or revision of binding regulations from persons seeking reliable

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mined Quantities of . . . "Exachol," 716 F. Supp. 787, 794 (S.D.N.Y. 1989). Although the court in the *Exachol* case referred to a policy that the FDA had expressed in the preamble to the proposed health claims rule, the decision rested on the Agency's failure to apply that policy to the claimant's products in the same fashion as it had done for two other products. *See id.* at 795-96.

53. District offices could, for example, issue warning letters threatening imminent seizure of a product even though it was being marketed in reliance upon a formal advisory opinion or guideline. *See* 56 Fed. Reg. 27,026 (1991) (discussing procedures for the issuance of warning letters). Inconsistencies also could arise in situations where states are authorized to enforce federal requirements, as is the case with certain restrictions on food labeling, *see* 21 U.S.C. § 337(b) (1994), but the states choose to ignore FDA interpretations of the law because these are expressed in statements of policy no longer considered to be binding by the Agency.

54. Strauss, *supra* note 20, at 1489. "Staff instructions, manuals, and other forms of publication rules are essential tools of bureaucratic management, by which the expertise of an agency is shared throughout its structure, and staff operatives are kept under the discipline necessary to the efficient accomplishment of agency mission." *Id.* at 1482.

clarification about what the law requires of them.<sup>55</sup> The Agency then will face the significantly more difficult task of either initiating a rulemaking proceeding or defending a refusal to do so if challenged in court. By comparison, reliable advisory opinions and guidelines are flexible and efficient regulatory mechanisms that should not be discarded without good reason.

### C. Flexibility Does Not Require Retroactivity

The FDA has issued advisory opinions and guidelines for the last twenty years, fully cognizant of their status under the regulations. The Agency always has been free to avoid the consequences of these provisions by qualifying the opinions and guidelines that it issues. If it desires greater freedom in the future, the FDA can issue guidance in forms that avoid the guarantees contained in the existing procedural regulations. For example, the Agency can publish "draft" guidelines that will not have any binding effect. Indeed, it has done so repeatedly in recent years.<sup>56</sup> Even for previously announced advisory opinions and guidelines, the existing regulations give the Agency adequate flexibility. The FDA may choose not to abide by formal advisory opinions or guidelines when necessary to protect the public health, and it may revise or revoke these opinions and guidelines at any time.

The FDA contends that it is "anomalous" that preambles of proposed rules should bind the Agency.<sup>57</sup> This ignores the fact that notices of proposed rulemaking are issued only after the Agency has given considerable attention to an issue. For most of the past generation, preambles to

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55. Cf. 21 C.F.R. §§ 10.20-30 (1997); see also *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (rejecting a challenge to the Agency's decision to deny a citizen petition); William V. Luneburg, *Petitioning Federal Agencies for Rulemaking: An Overview of Administrative and Judicial Practice and Some Recommendations for Improvement*, 1988 WIS. L. REV. 1, 56 (noting that the FDA receives more than 200 petitions annually); Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 9 (1995) (describing anticompetitive uses of the FDA's citizen petition procedures).

56. See, e.g., 62 Fed. Reg. 32,351, 32,351 (1997) ("The draft guidance document announced in this notice represents the agency's tentative thinking of the subjects discussed therein." (emphasis added)); 62 Fed. Reg. 13,649, 13,650 (1997) (same); 61 Fed. Reg. 64,755, 64,755 (1996) (same); see also *supra* note 28 and accompanying text (describing the FDA's consistent practice in the last five years of publishing guidelines with an explicit disclaimer that the guidance does not bind the Agency).

57. See 57 Fed. Reg. 47,314, 47,315 (1992). "By virtue of its preamble, a proposed rule, under these circumstances, would have the effect of a final rule, and § 10.85 might limit the enforcement action that FDA could take." *Id.* (adding that "this result would be inconsistent with the intent of the notice and comment provisions of the APA, because the purpose of a proposed rule is to provide opportunity for public comment before the tentative judgments reflected in the proposal are given binding effect").

proposed rules have served as important vehicles for the announcement of policy.<sup>58</sup> They were, and still are, the product of thorough internal deliberation and thus, more than many documents, reflect the considered collective judgment of the Agency. When the FDA is unprepared to take a binding position on an issue that is the subject of a rulemaking proceeding, it can either publish an advance notice of proposed rulemaking or make it clear in the preamble that it does not intend to bind itself to any policy expressed in the proposal. If the FDA changes its mind at a later date, it can amend the proposal or clarify its views in the preamble to the final rule.<sup>59</sup> Under its 1992 proposal, however, the FDA can announce what appears to be a formal position in a preamble or other document and then freely ignore that statement of policy whenever it likes.

Under the proposed amendment to the regulation, the FDA seeks to free itself from all formal advisory opinions and guidelines that it has issued in the past by announcing that it will no longer feel constrained to abide by its advice. The Agency is not simply announcing that it will stop issuing formal advisory opinions and guidelines or that it is rescinding particular ones. Instead, the FDA effectively is rescinding all previously published opinions and guidelines without any explanation to justify individual revocations.<sup>60</sup> The proposal is thus tantamount to a renunciation of the FDA's long-standing policy to stand by the formal advice that it offers, amounting to an assertion that it has a right to act in an arbitrary fashion.<sup>61</sup>

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58. See Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PRODS. & TOXICS LIAB. 139, 143 & n.16, 154 & n.75 (1994) (discussing different courts' treatment of the FDA's never-finalized notice of proposed rulemaking on off-label uses of prescription drugs).

59. This is precisely how the Agency dealt with what it viewed as problematic about the proposed health messages rule. See 55 Fed. Reg. 5176, 5177 (1990) (converting the proposed rule into advance notice of proposed rulemaking); see also 56 Fed. Reg. 67,440 (1991) (withdrawing nearly 100 notices of proposed rulemaking that were more than five years old).

60. In fact, the FDA explicitly declined to revoke existing opinions and guidelines, preferring instead to renounce their status as binding advice. See 57 Fed. Reg. at 47,315 (explaining that "advisory opinions and guidelines currently in effect will remain in effect but will not bind the agency").

61. Professor Strauss characterized the use of disclaimers to accompany formal opinions as a "charade," effectively putting guidance "in a form that cannily reserves the possibilities for future lawlessness." Strauss, *supra* note 20, at 1485; see also Anthony, *supra* note 4, at 1361 (noting the one-sided nature of guidelines that appear binding to individuals but which preserve agency discretion); Thomas, *supra* note 35, at 152-53 (noting the danger in promoting hiddenness). Another commentator warned that courts should not be "asking agencies to bend over backwards to demonstrate their lack of commitment to the positions they set forth in policy statements. If we want to encourage agencies to

The existing regulation provides that “[a]ction[s] undertaken or completed in conformity with a guideline [or an advisory opinion] which has subsequently been amended or revoked will remain acceptable to FDA unless [it] determines that substantial public interest considerations preclude continued acceptance.”<sup>62</sup> The proposed amendment would obliterate this assurance:

[A]n advisory opinion [or guideline] does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. FDA may, in its discretion, recommend or initiate legal or administrative action against a person or product with respect to an action taken in conformity with an advisory opinion [or guideline], provided that the legal or administrative action is consistent with applicable statutes and regulations.<sup>63</sup>

Such a wholesale reversal of the status of advisory opinions and guidelines could have serious consequences for past actions, such as chronic animal toxicity studies for food and color additives or large-scale clinical trials for new drugs, taken in reliance on the assurance that advisory opinions and guidelines were binding and would remain so even if subsequently amended or revoked.

Case law suggests that such shifts in an agency's position may not have the effect of undermining reliance interests of regulated entities. The United States Supreme Court has cautioned that “an administrative agency may not apply a new rule retroactively when to do so would unduly intrude upon reasonable reliance interests.”<sup>64</sup> Professor Davis has

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provide guidance, we should not be too quick to criticize them for stating their views with confidence.” Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497, 1499 (1992).

62. 21 C.F.R. §§ 10.90(b)(6), 10.85(h) (1997); *see also* 40 Fed. Reg. 40,682, 40,696 (1975) (“Where the guideline consisted of a protocol for an animal study which was simply being revised to reflect the latest knowledge about appropriate scientific procedures rather than because of any concern about the scientific validity of prior results under the former protocol, the old work would undoubtedly remain acceptable.”).

63. 57 Fed. Reg. at 47,317-18.

64. *Heckler v. Community Health Servs.*, 467 U.S. 51, 60 n.12 (1984); *see also* *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988) (explaining the presumption against agency authority to promulgate retroactive rules); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 295 (1974) (explaining that “this is not a case in which some new liability is sought to be imposed on individuals for past actions which were taken in good-faith reliance on Board pronouncements”); *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 745-46 (D.C. Cir. 1986) (“When parties rely on an admittedly lawful regulation and plan their activities accordingly, retroactive modification or rescission of the regulation can cause great mischief.”); *International Union v. Brock*, 783 F.2d 237, 248 (D.C. Cir. 1986) (“[A]n agency may not impose liability retroactively when the individual has acted in accordance with the agency's own announced interpretation of the statute.”).

echoed these concerns, arguing that "changes that operate against private parties who have properly relied upon old guidelines should in general be limited to prospective operation."<sup>65</sup> Thus, the FDA's proposal to renounce all existing advisory opinions and guidelines would violate legal prohibitions against the retroactive application of revised agency rules and policies.

### III. THE LAWFULNESS OF BINDING ADVICE

Even if, as a matter of policy, agencies *should* promise to abide by their formal advisory opinions and guidelines, the FDA has argued that it lacks the power to agree to be bound by such pronouncements. In its 1992 proposal, the Agency suggested that non-estoppel principles and notice-and-comment rulemaking requirements rendered its existing regulation unlawful.<sup>66</sup> Moreover, the FDA concluded that formal advisory opinions and guidelines should not be regarded as final agency actions considered ripe for judicial review. None of the Agency's legal arguments withstands close scrutiny.

#### A. Estoppel Concerns

In explaining its 1975 proposal, the FDA recognized that, "[a]bsent specific regulations to the contrary, the statements of a government employee do not bind the government."<sup>67</sup> Advice provided by an FDA employee will not estop the government from enforcing statutory or regulatory requirements.<sup>68</sup> The decisions cited by the Agency in its 1992 proposal to amend this regulation do not stand for any different proposition.<sup>69</sup> The case law on this issue has not changed appreciably in the last

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65. DAVIS, *supra* note 31, at 202; *see also* 1993 A.B.A. ANNUAL MEETING REP. pt. 2, 120C (The ABA's House of Delegates adopted a recommendation that, "[w]hen an agency proposes to act at variance with a policy or interpretation contained in an established nonlegislative rule on which a private party has reasonably relied . . . the agency [must] explain why it is departing from its established policy or interpretation.").

66. *See* 57 Fed. Reg. at 47,315.

67. 40 Fed. Reg. at 40,694; *see also* *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384 (1947) ("Whatever the form in which the Government functions, anyone entering into an arrangement with the Government takes the risk of having accurately ascertained that he who purports to act for the Government stays within the bounds of his authority."); Raoul Berger, *Estoppel Against the Government*, 21 U. CHI. L. REV. 680, 680 & n.6 (1954); Frank C. Newman, *Should Official Advice be Reliable?—Proposals as to Estoppel and Related Doctrines in Administrative Law*, 53 COLUM. L. REV. 374, 374-75 (1953).

68. *See, e.g.*, *AMP Inc. v. Gardner*, 275 F. Supp. 410, 412 n.1 (S.D.N.Y. 1967), *aff'd*, 389 F.2d 825, 826 n.1 (2d Cir. 1968); *United States v. 354 Bulk Cartons \* \* \* Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 853-54 (D.N.J. 1959).

69. *See* 57 Fed. Reg. at 47,315.

two decades,<sup>70</sup> and, if the FDA's revised analysis of the estoppel decisions is correct, then it need not fear that the current regulation might jeopardize otherwise legitimate enforcement actions. Apart from questions concerning the applicability of estoppel principles, however, the FDA may agree voluntarily to be bound by its formal opinions and guidelines, just as legislative rules properly adopted by the Agency bind both its personnel as well as persons in the regulated industry.

The FDA asserted that courts have been "reluctant" to follow its regulation on this subject, arguing that they narrowly construe advisory opinions and guidelines as not binding "despite the language" of the regulation.<sup>71</sup> In fact, both decisions cited by the FDA suggest that the regulation *by its own terms* did not purport to establish any judicially enforceable requirements.<sup>72</sup> Although there is only sparse discussion of the issue, neither decision reflects a reluctance to apply advisory opinions and guidelines on non-estoppel grounds.<sup>73</sup>

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70. See Jean F. Rydstrom, Annotation, *Modern Status of Applicability of Doctrine of Estoppel Against Federal Government and Its Agencies*, 27 A.L.R. FED. 702 (1976 & Supp. 1997). The Supreme Court, at least implicitly or in dicta, has rejected the suggestion that the government can never be estopped. See, e.g., *Office of Personnel Management v. Richmond*, 496 U.S. 414, 434 (1990) ("Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address."); *Heckler v. Community Health Servs.*, 467 U.S. 51, 60-61 (1984) (hesitating "to say that there are *no cases* in which the public interest in ensuring that the Government can enforce the law free from estoppel might be outweighed by the countervailing interest of citizens in some minimum standard of decency, honor, and reliability in their dealings with their Government"); see also Joshua I. Schwartz, *The Irresistible Force Meets the Immovable Object: Estoppel Remedies for an Agency's Violation of Its Own Regulations or Other Misconduct*, 44 ADMIN. L. REV. 653, 665 (1992) ("While generally hostile to the application of estoppel against government agencies, the Court also has been reluctant categorically to preclude such relief."); *id.* at 725-26 (discussing the scope of the *Richmond* decision).

71. See 57 Fed. Reg. at 47,315.

72. See *United States v. Articles of Drug . . . Promise Toothpaste*, 594 F. Supp. 211, 218 (N.D. Ill. 1984); *McIlwain v. Hayes*, 530 F. Supp. 973, 977-78 n.8 (D.D.C. 1981) (citing 21 C.F.R. § 10.85(j)), *aff'd*, 690 F.2d 1041 (D.C. Cir. 1982).

73. In *Promise Toothpaste*, the district court decided that those portions of a Compliance Policy Guide relied upon by the claimant did not represent "statement[s] of policy or interpretation" that qualified as advisory opinions under the regulation. See 594 F. Supp. at 216. As an afterthought, and without taking a position on the matter, the court mentioned the decision in *McIlwain* as providing "some authority to the effect that advisory opinions are not binding in court, despite the apparent meaning of 21 C.F.R. § 10.85(e)." *Id.* at 218. The discussion in *McIlwain* was itself dicta; furthermore, the court there did not suggest that non-estoppel principles would prevent an agency from volunteering to be bound by its own formal opinions and guidelines. See 530 F. Supp. at 977-78 n.8. Apart from misinterpreting § 10.85(j), a provision which merely confirms that advisory opinions do not establish substantive legal requirements binding on persons regulated by the FDA, the courts have not suggested a disinclination to hold the Agency

Informal advice provided by subordinates will not estop the government from taking a contrary position in enforcing the law. However, agencies are bound to follow their own regulations even when these regulations are more generous than required by Congress.<sup>74</sup> For example, agencies sometimes voluntarily decide to abide by more demanding procedural requirements than mandated by statute. Once an agency chooses to restrict its flexibility in this fashion, it cannot escape the requirements that it has agreed to follow.<sup>75</sup>

Just as such regulations are binding on agencies, formal advisory opinions and guidelines may have the same effect if that is the agency's intent. "[I]t is a familiar principle of federal administrative law that agencies may be bound by their own substantive and procedural rules and policies, whether or not published in the Federal Register, if they are intended as mandatory."<sup>76</sup> The Supreme Court has held, for example,

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to its advisory opinions and guidelines on non-estoppel grounds.

74. See, e.g., *United States v. Nixon*, 418 U.S. 683, 696 (1974) ("So long as this regulation remains in force the Executive Branch is bound by it."); *Vitarelli v. Seaton*, 359 U.S. 535, 540 (1959) (deciding that "the Secretary . . . was bound by the regulations which he himself had promulgated for dealing with such cases, even though without such regulations he could have discharged petitioner summarily"); *id.* at 546 (Frankfurter, J., concurring in part and dissenting in part) ("An executive agency must be rigorously held to the standards by which it professes its action to be judged."); *Service v. Dulles*, 354 U.S. 363, 372 (1957) (explaining that "regulations validly prescribed by a government administrator are binding upon him as well as the citizen"); *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 267 (1954) (holding that, "as long as the regulations remain operative, the Attorney General denies himself the right to sidestep the Board"); see also Schwartz, *supra* note 70, at 668-74 (discussing ambiguities in this line of decisions); Rodney A. Smolla, *The Erosion of the Principle That the Government Must Follow Self-Imposed Rules*, 52 *FORDHAM L. REV.* 472, 476-81 (1984) (same).

75. See *Webster v. Doe*, 486 U.S. 592, 602 n.7 (1988) (noting that the CIA's failure to follow its own procedural rules would be amenable to judicial review even if its decision was otherwise unreviewable as committed to agency discretion); *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 542 (1978) (suggesting that "a totally unjustified departure from well-settled agency procedures of long standing might require judicial correction"); *Algonquin Gas Transmission Co. v. FERC*, 948 F.2d 1305, 1315 (D.C. Cir. 1991) ("It is axiomatic that an 'agency is legally bound to respect its own regulations and commits procedural error [if it] fails to abide [by] them.'"); *Gardner v. FCC*, 530 F.2d 1086, 1090 (D.C. Cir. 1976) ("Once having stated that it will give such notice, the [FCC] has created a reasonable expectation in the parties to the proceeding that such notice will be received."); *Abbs v. Sullivan*, 756 F. Supp. 1172, 1188 (W.D. Wis. 1990) ("As a result of this voluntary election by the Secretary to abide by the rulemaking provisions of the [APA], courts have held [HHS] to strict compliance with the notice and comment requirements when promulgating regulations."), *vacated*, 963 F.2d 918 (7th Cir. 1992).

76. *Lucas v. Hodges*, 730 F.2d 1493, 1504 n.20 (D.C. Cir.), *vacated as moot*, 738 F.2d 1392 (D.C. Cir. 1984); see also *Padula v. Webster*, 822 F.2d 97, 100 (D.C. Cir. 1987) ("[I]nternal guidelines and rules not formally promulgated have occasionally been held to bind agency conduct."); *Doe v. Hampton*, 566 F.2d 265, 281 (D.C. Cir. 1977) (explaining that unpublished provisions of the Federal Personnel Manual "may be binding if so in-

that an agency must publish a notice whenever it modifies eligibility criteria for unemployment benefits, even if its promise to do so appears only in a staff manual.<sup>77</sup> "It is well settled that an agency, even one that enjoys broad discretion, must adhere to voluntarily adopted, binding policies that limit its discretion."<sup>78</sup> Even policy statements that have no independent binding effect because they use only precatory language may obligate the agency to explain departures from that policy if it is the established practice of the agency to take action based on the policy statement.<sup>79</sup>

Whether or not an agency purports to bind itself by the formal advice that it issues, courts routinely place significant reliance on agency statements of policy or interpretations contained in documents other than final regulations. Precisely because final regulations leave important issues of their application unclear or unresolved, courts must resort to administrative history<sup>80</sup> or subsequent opinions and guidelines<sup>81</sup> as aids to

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tended by the Commission").

77. See *Morton v. Ruiz*, 415 U.S. 199, 235 (1974); see also *United States v. Heffner*, 420 F.2d 809, 812 (4th Cir. 1969) ("The arbitrary character of such a departure [from internal IRS procedures] is in no way ameliorated by the fact that the ignored procedure was enunciated as an instruction in a 'News Release.'"); *United States v. Tobins*, 512 F. Supp. 308, 315 (D. Mass. 1981) (explaining that, because an announced policy statement concerning audits by the Department of Energy "was a deliberate commitment by the agency . . . to constrain its broad investigatory discretion," the agency "should be required to honor its public representations").

78. *Padula*, 822 F.2d at 100; see also Peter Raven-Hansen, *Regulatory Estoppel: When Agencies Break Their Own "Laws,"* 64 TEX. L. REV. 1, 4 (1985) (arguing that "estoppel should be available if the private reliance interest in agency obedience to its own law outweighs the public interest in those legislative policies that would be affected by regulatory estoppel in a given case"); *id.* at 69-75 (applying this proposed interest balancing approach to a hypothetical agency failure to honor a promise to advise regulated businesses of what they can do to comply with applicable regulatory requirements); Schwartz, *supra* note 70, at 743-44 (concluding that estoppel-like relief is appropriate in those cases where an agency has obligated itself to follow a particular course).

79. See *Vietnam Veterans of Am. v. Secretary of the Navy*, 843 F.2d 528, 539 (D.C. Cir. 1988); *Telecommunications Research & Action Ctr. v. FCC*, 800 F.2d 1181, 1184 (D.C. Cir. 1986). *But cf.* *Chen Zhou Chai v. Carroll*, 48 F.3d 1331, 1341 (4th Cir. 1995) (stating that the requirement for providing a reasoned explanation "applies only to revocations of substantive rules, not to revocations of interpretive rules or general statements of policy"). This was the basis for the court's decision in *United States v. Undetermined Quantities of . . . "Exachol,"* 716 F. Supp. 787, 794 (S.D.N.Y. 1989). *Cf.* *Rhodia, Inc. v. FDA*, 608 F.2d 1376, 1378-79 (D.C. Cir. 1979) (barring the FDA from applying a new policy in a fashion inconsistent with its established practice in handling applications for approval of new animal drugs).

80. See *Vermont v. Thomas*, 850 F.2d 99, 103 (2d Cir. 1988) (relying on the preamble to construe regulation). The APA mandates that final regulations be accompanied by "a concise general statement of their basis and purpose." 5 U.S.C. § 553(c) (1994).

81. See, e.g., *Reno v. Koray*, 515 U.S. 50, 60-61 (1995) (deferring to an internal guideline of the Bureau of Prisons); *NationsBank of North Carolina v. Variable Annuity*

interpretation. In the preamble to its 1977 final regulation governing advisory opinions and guidelines, the FDA took the position that the Supreme Court's opinion concerning the interpretive value of guidelines issued by the Equal Employment Opportunity Commission (EEOC) "can be read as support for administrative agencies interpreting statutory provisions under their jurisdiction through guidelines developed without formal public participation."<sup>82</sup>

The FDA is not the only agency to have taken the position that advisory opinions and guidelines may be relied upon by persons in the industry until revised or revoked. A number of agencies agree to be bound by their own informal advice.<sup>83</sup> For example, the Federal Trade Commission (FTC) "will not proceed against the requesting party with respect to

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Life Ins. Co., 513 U.S. 251, 263-64 (1995) (deferring to letters issued by the Comptroller of the Currency); *Davis v. United States*, 495 U.S. 472, 484 (1990) (deferring to IRS interpretive rulings); *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 431 (1975) (explaining that EEOC guidelines were "entitled to great deference" in interpreting a statute even though the guidelines were not adopted through notice-and-comment rulemaking); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("[T]he rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance."). In recent years, the Supreme Court has been particularly deferential to agency interpretations of ambiguous regulations and guidelines. See *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 98-100 (1995); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 517-18 (1994); *Stinson v. United States*, 508 U.S. 36, 41-47 (1993).

82. 42 Fed. Reg. 4680, 4694 (1977) (rejecting a comment suggesting that notice-and-comment rulemaking was mandatory for the development of guidelines). Subsequent Supreme Court decisions have displayed little or no deference to EEOC guidelines. See, e.g., *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 257 (1991). In fact, the Court has yet to resolve the extent to which nonlegislative rules interpreting ambiguous statutory provisions deserve deference. See *City of Chicago v. Envtl. Defense Fund*, 511 U.S. 328, 339 n.5 (1994).

83. See GARY J. EDLES & JEROME NELSON, *FEDERAL REGULATORY PROCESS: AGENCY PRACTICES & PROCEDURES* § 7.4, at 185 (2d ed. 1989); see also Asimow, *Public Participation*, *supra* note 51, at 524-28 (describing the rulemaking practices of the Internal Revenue Service, the Immigration and Naturalization Service, the Federal Communications Commission, and the Federal Trade Commission); Burnele V. Powell, *Sinners, Supplicants, and Samaritans: Agency Advice Giving in Relation to Section 554(e) of the Administrative Procedure Act*, 63 N.C. L. REV. 339, 354-56 (1985) (reporting a willingness by some agencies to be estopped from sanctioning those who follow their informal advice). For example, the Office of Government Ethics has published regulations implementing limitations on the acceptance of honoraria pursuant to which government employees may request an advisory opinion and be assured that good faith reliance on such an opinion will protect them from disciplinary action. See 5 C.F.R. § 2636.103(c) (1997). Even Congress has, in some instances, provided that reliance on administrative rulings or interpretations will excuse liability for alleged violations of a statute. See 29 U.S.C. §§ 258-259 (1994) (minimum wage and overtime compensation requirements applicable to certain employers).

any action taken in good faith reliance upon the Commission's advice."<sup>84</sup> In 1996, the FTC issued revised guidelines concerning acceptable environmental marketing claims, providing "safe harbors" for certain claims describing product attributes such as recyclability.<sup>85</sup> These guidelines do not bind regulated entities in the sense that a failure to comply would constitute a regulatory infraction, but they do bind the FTC in the sense that it would not initiate enforcement action for false or misleading advertising against persons who have chosen to adhere to these guidelines.

Although agencies generally are not bound by opinions and guidelines that they issue, courts will hold agencies to such pronouncements when they were intended to have binding effect. For instance, where the Internal Revenue Service issued both "a general guideline, deliberately devised, aiming at accomplishing uniform conduct of officials," and "an equally deliberate public announcement, made in response to inquiries, on which many taxpayers and their advisors could reasonably and expectably rely," one court held that "the agency had a duty to conform to its procedure, that citizens have a right to rely on conformance, and that the courts must enforce both the right and duty."<sup>86</sup> Similarly, in a challenge to an action taken by the Bureau of Indian Affairs, the United States Court of Appeals for the Eighth Circuit held that the Bureau's failure "to make any real attempt to comply with its own policy of consultation" with certain tribes "violates those general principles which govern administrative decisionmaking."<sup>87</sup> Yet another court has observed that an "agency is not free to declare one policy publicly, . . . and then follow a different practice in its dealings with regulated entities and

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84. 16 C.F.R. § 1.3(b) (1997); *see also* 62 Fed. Reg. 16,809, 16,810-12 (1997) (describing the various forms of FTC guidance); WILLIAM F. WEST, *ADMINISTRATIVE RULEMAKING: POLITICS AND PROCESSES* 111-12 (1985) (describing the history behind the FTC's use of guidelines and advisory opinions).

85. *See* 61 Fed. Reg. 53,311, 53,316 (1996) (codified at 16 C.F.R. pt. 260 (1997)); *see also* Kevin M. Bank, *How Green is My Product and Package: The Federal Trade Commission's Environmental Marketing Guidelines*, 49 *FOOD & DRUG L.J.* 499 (1994); Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 *FLA. L. REV.* 63, 101-02 & n.194 (1995).

86. *United States v. Leahey*, 434 F.2d 7, 11 (1st Cir. 1970); *see also* *LeCroy Research Sys. Corp. v. Commissioner*, 751 F.2d 123, 127 (2d Cir. 1984) ("[I]t is clear that there are judicially enforceable limits on the Commissioner's discretion to ignore prior assurances given to taxpayers.").

87. *Oglala Sioux Tribe of Indians v. Andrus*, 603 F.2d 707, 721 (8th Cir. 1979) ("[W]here the Bureau has established a policy requiring prior consultation with a tribe [concerning personnel decisions], and has thereby created a justified expectation on the part of the Indian people that they will be given a meaningful opportunity to express their views before Bureau policy is made, that opportunity must be afforded.").

individuals.”<sup>88</sup> Thus, non-estoppel principles do not compel the FDA’s change in policy.

### B. Notice-and-Comment Concerns

The FDA suggested in its 1992 notice of proposed rulemaking that the decision in *Community Nutrition Institute (CNI) v. Young*<sup>89</sup> invalidates any effort by the Agency to issue advice on which private parties may rely.<sup>90</sup> In *CNI*, the United States Court of Appeals for the D.C. Circuit held that the FDA could not cabin its prosecutorial discretion by promising not to enforce the adulteration provisions of the FD&C Act in certain circumstances, unless it had issued an appropriate regulation after notice-and-comment rulemaking.<sup>91</sup> The court added an important caveat, however, noting that its holding would not prevent agencies from “develop[ing] written guidelines to aid their exercise of discretion.”<sup>92</sup> In essence, the court viewed the safe harbor for the food industry as a potential burden on other constituencies of the FDA, namely, the consuming public.<sup>93</sup> Not all safe harbors, however, inevitably threaten the interests of persons other than the beneficiary of the agency’s assurance, such as formal guidelines setting forth acceptable testing protocols for a substance. In response to *CNI*, the FDA revised its regulation governing

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88. *United States v. Tobins*, 512 F. Supp. 308, 314 (D. Mass. 1981).

89. 818 F.2d 943 (D.C. Cir. 1987) (per curiam).

90. See 57 Fed. Reg. 47,314, 47,315 (1992).

91. See *CNI*, 818 F.2d at 948-49.

92. *Id.* at 949. The dissenting judge persuasively argued that a guideline which only binds an agency but does not create a substantive rule enforceable against regulated firms should be exempt from APA requirements under the court’s precedent. See *id.* at 950-53 (Starr, J., concurring in part and dissenting in part) (relying on *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974)); see also KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* § 6.2, at 233 (3d ed. 1994) (“Fortunately, [*CNI*] is so totally inconsistent with the Supreme Court’s approach to administrative law that the holding is likely to be short-lived.”); Daniel A. Kracov & Robert P. Brady, *Food and Drug Administration Advisory Opinions and Guidance Documents After Community Nutrition Institute v. Young*, 48 *FOOD & DRUG L.J.* 47, 53-56 (1993) (criticizing the FDA for overreacting to *CNI*); Thomas, *supra* note 35, at 152 (“To the extent that the agency’s own statement of prosecutorial policy is in some sense ‘binding’ on the agency, then the policy only serves the function of regularizing agency behavior and reducing case-specific arbitrariness all the more. Yet the rule of *CNI II* penalizes agencies just as they approach this degree of salutary self-regulation.”).

93. See Strauss, *supra* note 20, at 1484-85 (suggesting that the *CNI* court sought to split the difference between the interests of the industry and the public); see also *Alaska v. United States Dep’t of Transp.*, 868 F.2d 441, 445-47 (D.C. Cir. 1989) (holding that a safe harbor for advertising by the tour industry operated to the detriment of the public by preempting state efforts to regulate deceptive advertising and therefore had to be promulgated as a regulation).

action levels to make it clear that these guidelines were not legislative rules but only "prosecutorial guidelines."<sup>94</sup>

The FDA has asserted that its 1992 proposal would make the Agency's treatment of advisory opinions and guidelines consistent with the *CNI* decision.<sup>95</sup> But the court surely did not prohibit the Agency from issuing formal advisory opinions and interpretative guidelines. *CNI* required adherence to informal rulemaking requirements only to the extent that guidelines "bind" the FDA by restricting its freedom to bring enforcement actions for violations of existing general requirements.<sup>96</sup> The APA does not require notice-and-comment rulemaking for advisory opinions or guidelines that merely interpret existing requirements,<sup>97</sup> nor does it prevent the issuance of binding instructions to agency personnel about how they are to enforce existing requirements.<sup>98</sup> Moreover, the APA allows agencies to issue binding advice in the form of declaratory orders

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94. See 54 Fed. Reg. 16,128, 16,129 (1989); see also 21 C.F.R. § 109.4(c) (1997); 55 Fed. Reg. 20,782 (1990); 53 Fed. Reg. 5043 (1988) (announcing that action levels "are not binding on the courts, the public (including food producers) or the agency (including individual FDA employees)").

95. See 57 Fed. Reg. at 47,315; see also 62 Fed. Reg. 8961, 8963 (1997) (reiterating the Agency's view that "the principle that guidance documents are binding on FDA is inconsistent with [*CNI*]").

96. See *CNI*, 818 F.2d at 949. The court did not prohibit the establishment of such "binding" guidelines by informal rulemaking. See *id.* Other courts have suggested that guidelines adopted after notice-and-comment rulemaking may bind an agency. See *United States v. Tobins*, 512 F. Supp. 308, 315 (D. Mass. 1981) ("Both the substantive context in which the policy was promulgated and the procedural formalities attending its publication distinguish the audit policy statement from the type of interpretive rules, guidelines, general policy statements, and instructions to staff sometimes held not to be binding on the issuing agency.").

97. See *Clarry v. United States*, 85 F.3d 1041, 1049 (2d Cir. 1996); *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1307-08 (D.C. Cir. 1991) (finding that interpretation of a statutory term in the preamble does not require informal rulemaking); *International Union v. Brock*, 783 F.2d 237, 249 n.15 (D.C. Cir. 1986) (contrasting "a prosecutor's statement that his office will no longer prosecute possession of *de minimis* amounts of marijuana, with a prosecutor's statement that he interprets the state's statute as *permitting* possession of small amounts of marijuana"); *Interport, Inc. v. Magaw*, 923 F. Supp. 242, 245 (D.D.C. 1996).

98. See *Vietnam Veterans v. Secretary of the Navy*, 843 F.2d 528, 538 (D.C. Cir. 1988) ("Internal procedures . . . are exempt from the coverage of § 553 . . . quite independent of whether the procedures will be binding."); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1049-52 (D.C. Cir. 1987) (holding enforcement manuals exempt as procedural rules). *But cf.* *Benten v. Kessler*, 799 F. Supp. 281, 289 (E.D.N.Y. 1992) (holding that the FDA's import alert requiring automatic detention of RU-486 constituted a substantive rule requiring notice-and-comment rulemaking because it imposed a nondiscretionary duty on Agency personnel); *Bellarno Int'l Ltd. v. FDA*, 678 F. Supp. 410, 412-15 (E.D.N.Y. 1988) (same holding with regard to another group of pharmaceuticals).

without abiding by notice-and-comment rulemaking requirements.<sup>99</sup>

Even if *CNI* requires notice-and-comment procedures for the issuance of formal advisory opinions and guidelines, the FDA need not respond by rescinding the assurances contained in the existing regulations. The Agency has afforded interested persons advance notice and an opportunity to comment on many of the guidelines and policy statements that it has issued over the last two decades. For example, policy statements contained in preambles to final regulations represent the culmination of notice-and-comment rulemaking proceedings and would, therefore, satisfy the *CNI* requirement.

Moreover, until 1991, the FDA's administrative procedure regulations provided that interpretive rules and general statements of policy should be promulgated in accordance with the APA's informal rulemaking requirements.<sup>100</sup> Although this rule no longer exists, the Agency has continued to provide notice and an opportunity for comment on policy statements and proposed guidelines, typically by announcing the availability of a draft guideline and inviting public input.<sup>101</sup> The Agency occa-

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99. See 5 U.S.C. § 554(e) (1994); *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 626 (1973) ("Section 554(e), however, does not place administrative proceedings in that straitjacket."); *Merchants Fast Motor Lines, Inc. v. ICC*, 5 F.3d 911, 914-17 (5th Cir. 1993); *Central Freight Lines v. ICC*, 899 F.2d 413, 415-19 (5th Cir. 1990); *New York State Comm'n on Cable Television v. FCC*, 749 F.2d 804, 815 (D.C. Cir. 1984); *British Caledonian Airways, Ltd. v. Civil Aeronautics Bd.*, 584 F.2d 982, 989-94 (D.C. Cir. 1978); see also Burnele V. Powell, *Administratively Declaring Order: Some Practical Applications of the Administrative Procedure Act's Declaratory Order Process*, 64 N.C. L. REV. 277, 279, 297-300 (1986); Burnele V. Powell, *Regular Appellate Review, Direct Judicial Review, and the Role of Review of the Declaratory Order: Three Roads to Judicial Review*, 40 ADMIN. L. REV. 451, 453 (1988) ("[D]eclaratory orders facilitate resolution of disagreements in situations where agencies, regulated entities, and the courts share (or, at least, should share) the desire for an efficient means of resolving disagreements."); *id.* at 477-79, 500 (distinguishing the issuance of interpretive rules and advisory opinions).

100. See 21 C.F.R. § 10.40(d) (1990), *revoked*, 56 Fed. Reg. 13,757 (1991). This voluntary adherence to notice-and-comment procedures conformed to an ACUS recommendation on the subject. See 41 Fed. Reg. 56,767, 56,769-70 (1976) (urging agencies to provide notice and an opportunity for comment on interpretive rules or policy statements likely to have a substantial impact on the public, either before finalization or immediately afterward); see also 57 Fed. Reg. 30,101 (1992) (noting similar ACUS recommendation); Charles H. Koch, Jr., *Public Procedures for the Promulgation of Interpretative Rules and General Statements of Policy*, 64 GEO. L.J. 1047, 1078-79 (1976). In revoking its regulation, the FDA objected to the "substantial impact" test originally proposed by ACUS. See 56 Fed. Reg. at 13,758.

101. See, e.g., 62 Fed. Reg. 41,397 (1997) (draft guidance on labeling of medical devices); 62 Fed. Reg. 40,099 (1997) (draft guidance on principles of software validation); 62 Fed. Reg. 32,351 (1997) (draft guidance on diagnostic ultrasound devices); 62 Fed. Reg. 13,649 (1997) (draft guidance on approval of new cancer treatments); 62 Fed. Reg. 12,832 (1997) (draft guidance on immunotoxicity testing of medical devices); 59 Fed. Reg. 6279 (1994) (interim guidance on voluntary rBST labeling); 57 Fed. Reg. 56,412 (1992) (draft

sionally even publishes a subsequent notice to extend the comment period.<sup>102</sup> Requests for advisory opinions also are sometimes announced in the *Federal Register* with an invitation for public comment.<sup>103</sup> The new GGP policy formalizes this FDA practice.<sup>104</sup>

Finally, even when pre-publication notice and opportunity for comment are not provided, existing regulations require post-publication notice and an opportunity to comment so that the Agency may determine whether further modification of an opinion or guideline is warranted.<sup>105</sup> For example, the FDA has issued several guidance documents revised in light of sometimes extensive public comments on earlier versions.<sup>106</sup> Thus, revised versions of FDA guidelines arguably comply with the APA's informal rulemaking requirements even if initially issued without advance notice and an opportunity for comment.<sup>107</sup>

policy on industry-supported scientific and educational activities); 57 Fed. Reg. 22,984 (1992) (policy statement on genetically engineered foods).

102. See, e.g., 59 Fed. Reg. 16,655 (1994); 59 Fed. Reg. 11,080 (1994); 58 Fed. Reg. 6126 (1993); 57 Fed. Reg. 42,588 (1992).

103. See, e.g., 57 Fed. Reg. 22,772 (1992) (genetically engineered plants); 56 Fed. Reg. 20,004 (1991) (same). In other cases, advisory opinions are likely to be disseminated widely by other means. See 42 Fed. Reg. 4680, 4693-94 (1977) (disagreeing with the claim that "the right to comment on advisory opinions is illusory" because "[s]ufficiently wide publicity will be given to FDA advisory opinions so that any person with even a casual interest in the agency will be likely to learn of them"); 40 Fed. Reg. 40,682, 40,695 (1975) (endorsing the same concept).

104. See 62 Fed. Reg. 8961, 8965 (1997) (differentiating between two levels of guidance documents: providing advance notice and an opportunity to comment on significant proposals before finalization and a post-issuance opportunity to comment on all other guidance documents); see also Strauss, *supra* note 20, at 1488 ("Undoubtedly, it is desirable for agencies to engage in consultation as they develop important interpretations . . . and indications are that this is often done.").

105. See 21 C.F.R. §§ 10.85(i), 10.90(b)(7) (1997); see also Asimow, *Public Participation*, *supra* note 51, at 578-84 (recommending post-adoption notice and comment for nonlegislative rules).

106. See, e.g., 62 Fed. Reg. 38,567 (1997) (guidance on medical device reporting); 62 Fed. Reg. 31,118 (1997) (guidance on contact lens care products); 62 Fed. Reg. 19,580 (1997) (guidance on PET drug products); 62 Fed. Reg. 8024 (1997) (guidance on premarket notifications for modified medical devices); 61 Fed. Reg. 52,800 (1996) (guidance on industry advertising); 61 Fed. Reg. 26,182 (1996) (guidance on animal drug bioequivalence); 61 Fed. Reg. 3043 (1996) (guidance on testing for antimicrobial drug residues in food). In addition, defect action levels (DALs) for food are issued on an interim basis through publication in the *Federal Register*, and the public then is provided a full year to submit comments before a final DAL is published. See 47 Fed. Reg. 41,637, 41,638 (1982).

107. Cf. 60 Fed. Reg. 43,110 (1995) (ACUS recommendation that agencies issue final regulations without first issuing notices of proposed rulemaking on routine and noncontroversial subjects, providing that such regulations take effect only if a specified period of time passes without the receipt of any adverse comments); Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1, 10-18 (1995) (explaining the legality of this expe-

In short, *CNI* provides no basis for revoking the formal status of advisory opinions and guidelines on which regulated firms have been invited to rely. The court's decision applies only to policy statements or guidelines that promised not to enforce existing requirements. Moreover, many FDA guidance documents have been issued in accordance with notice-and-comment procedures or their rough equivalent. In any event, the FDA could not excuse a failure to abide by advisory opinions and guidelines that it has agreed to follow by arguing that the failure to utilize notice-and-comment procedures now has obviated its promise to be bound by them.<sup>108</sup>

### C. Finality and Ripeness Issues

Lastly, there is no justification for the FDA's proposal to delete formal opinions and guidelines from the list of final agency actions subject to judicial review. Although the FDA proposes to retreat from its promise that advisory opinions and guidelines bind the Agency, it insists that these will continue to represent a reliable indication of the FDA's current thinking on a particular issue, but then it concludes that advisory opinions and guidelines should not be subject to judicial review.<sup>109</sup> The Agency cannot have it both ways. Either formal advice will continue to be reliable and have an impact on persons in the regulated industry, in which case judicial review is appropriate, or it will become indistinguishable from the informal advice issued by individual FDA employees. It would be inconsistent to alter the Agency's longstanding practice, as reflected in the current regulation,<sup>110</sup> of not interposing ripeness arguments as a defense to judicial challenges concerning formal advisory opinions and guidelines.

Generally, parties may seek judicial review only of "final" agency action.<sup>111</sup> Even then, courts may decline to consider challenges to agency

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dited form of rulemaking, based either on the good cause exception when public participation is considered "unnecessary" or on a claim of substantial compliance with notice-and-comment requirements). In addition, the APA's requirement that legislative rules become effective no sooner than 30 days after publication does not apply to a "rule which grants or recognizes an exemption or relieves a restriction." 5 U.S.C. § 553(d)(1) (1994).

108. See *Cubanski v. Heckler*, 781 F.2d 1421, 1428 (9th Cir. 1986) ("The APA procedural requirements exist to protect the public's interests, not to shelter the Secretary."), *vacated*, *Bowen v. Kizer*, 485 U.S. 386 (1988); *Vigil v. Rhoades*, 746 F. Supp. 1471, 1481 (D.N.M. 1990) (holding that the government's "suggestion that the original promulgation of the Program was procedurally faulty . . . even if true, has no effect on the applicability of the notice and comment requirement" for its termination), *aff'd*, 953 F.2d 1225, 1231 (10th Cir. 1992).

109. See 57 Fed. Reg. 47,314, 47,316 (1992).

110. See 21 C.F.R. § 10.45(d) (1997).

111. See 5 U.S.C. § 704 (1994) ("Agency action made reviewable by statute and final

action that are not yet "ripe" for review. To determine whether a challenge is ripe, courts balance whether an issue is fit for immediate review against the hardship to the parties of delaying review until the agency rule or policy has been given some concrete application. When the challenge poses primarily legal questions, and regulated entities can pursue judicial review only by refusing to comply with a costly agency requirement, courts have agreed to undertake pre-enforcement review of an agency rule or policy.<sup>112</sup> If, however, questions of fact predominate, and regulated entities would not face any real dilemma when deciding whether or not to comply, courts have declined to engage in premature review.<sup>113</sup>

Courts have held that formal advisory opinions issued by the head of an agency are final action subject to judicial review. As one federal court explained a quarter of a century ago:

When a published interpretation represents the initial views of an agency, approved by the Commission or person who heads the agency, when it is the product of the process provided by the agency for taking into account the position of agency staff as well as the outside presentation, when the interpretation is not labeled as tentative or otherwise qualified by arrangement for reconsideration, it [is] . . . "final" for purposes of the APA and judicial review.<sup>114</sup>

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agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."); *Dalton v. Specter*, 511 U.S. 462, 469-70 (1994) (holding that reports and recommendations submitted to the President by the Secretary of Defense and the Defense Base Closure and Realignment Commission were not "final" agency actions); *FTC v. Standard Oil Co.*, 449 U.S. 232, 243 (1980) (holding that the issuance of a complaint did not constitute final agency action).

112. See, e.g., *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 200-02 (1983); *Abbott Lab. v. Gardner*, 387 U.S. 136, 149-56 (1967); *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 857 F. Supp. 1137, 1140-45 (M.D.N.C. 1994).

113. See, e.g., *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 58-59 (1993); *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 162-65 (1967); *Municipality of Anchorage v. United States*, 980 F.2d 1320, 1325 (9th Cir. 1992); *Public Citizen, Inc. v. NRC*, 940 F.2d 679, 682-84 (D.C. Cir. 1991); *Arkansas Power & Light Co. v. ICC*, 725 F.2d 716, 725-26 (D.C. Cir. 1984).

114. *National Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 702 (D.C. Cir. 1971); see also *Franklin Fed. Sav. Bank v. Director, Office of Thrift Supervision*, 927 F.2d 1332, 1337 (6th Cir. 1991); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435-38 (D.C. Cir. 1986) (holding that letter from the head of the EPA's Pesticide Division was sufficiently final to be ripe for review); *Eagle-Picher Indus. v. EPA*, 759 F.2d 905, 917 (D.C. Cir. 1985); cf. *Frozen Food Express v. United States*, 351 U.S. 40, 44-45 (1956) (holding that an ICC order specifying which commodities were exempt from supervision was reviewable); *Columbia Broad. Sys., Inc. v. United States*, 316 U.S. 407, 422 (1942)

The FDA's regulation adheres to this precedent by providing that formal advisory opinions and guidelines represent final agency action.<sup>115</sup>

The Agency asserted in its 1992 proposal that, "[g]iven the changed status of advisory opinions and guidelines, it would be inconsistent for these documents to be considered final agency action for the purpose of judicial review."<sup>116</sup> The fact that the FDA may consider itself no longer bound by expressions of policy contained in formal advisory opinions and guidelines does not, however, alter the finality calculus used by the courts.<sup>117</sup> Moreover, there is no compelling reason for shielding advisory opinions and guidelines from judicial scrutiny.<sup>118</sup> Courts have not limited their review to final agency actions that technically bind an agency, and the FDA should not attempt to escape the responsibility of justifying formal positions it takes on important issues even if it now believes that these pronouncements are devoid of any lasting effect.

#### IV. CONCLUSION

The FDA's proposed revision to the regulation that accords binding effect to formal advisory opinions and guidelines is justified neither by the case law concerning estoppel nor by the policy arguments offered in the preamble. Indeed, there are compelling practical and legal reasons for maintaining the regulations in their current form. Regulated firms have been invited to rely on formal advisory opinions and guidelines, and the Agency's promise to be bound by these pronouncements is equally beneficial to its own activities. The proposed revisions and recent practice have, for no good reason, undermined a sensible and legally permissible system.

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(holding that FCC's chain broadcasting pronouncement was ripe for review).

115. See 21 C.F.R. § 10.45(d) (1997); 42 Fed. Reg. 4680, 4688 (1977).

116. 57 Fed. Reg. 47,314, 47,316 (1992).

117. See *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 93 (D.C. Cir. 1986) (holding that guidelines issued without engaging in notice-and-comment rulemaking were final agency action subject to review); *Independent Bankers Ass'n of Am. v. Smith*, 534 F.2d 921, 929 (D.C. Cir. 1976) (holding that an interpretive ruling issued without engaging in notice-and-comment rulemaking was final agency action).

118. Although it may seem "anomalous" that persons should be able to rely on statements of policy contained in preambles to proposed rules, the current regulation does not suggest that such preambles are final agency action subject to review. Although statements of policy contained in preambles may "constitute" advisory opinions, see 21 C.F.R. § 10.85(d) (1997), they are not "issued" under that provision. Only those advisory opinions that are "issued under § 10.85" are deemed final agency action. See *id.* § 10.45(d).