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Guidance Gone Wild?: FDA's Regrettable Retreat from Legislative Rulemaking

by Professor Lars Noah

Over the last few decades, as it became harder to promulgate binding rules, the U.S. Food and Drug Administration (FDA) has come to rely on the issuance of nonbinding guidance documents to make its wishes known to the various industries that it regulates.[1] Although the Administrative Procedure Act (APA) plainly allows for the practice, the agency may have gotten a little carried away with this mechanism, and, at times, it improperly treats these guidance documents as if they were regulations adopted after notice-and-comment rulemaking.

Efforts to circumvent procedural requirements can have serious consequences for the quality of FDA's work and those subject to its commands. Nonetheless, Congress has endorsed and even encouraged this development; in 1997, it directed the agency to promulgate its then newly released guidance on "Good Guidance Practices" (GGPs) as a legislative rule.[2] Three years later, FDA issued such a regulation.[3]

Good Guidance Practices as Distinguished from Notice-and-Comment Rulemaking

The GGPs rule differentiates between "Level 1" and "Level 2" guidance documents, defining the former category as those that "(i) set forth initial interpretations of statutory or regulatory requirements; (ii) set forth changes in interpretation or policy that are of more than a minor nature; (iii) include complex scientific issues; or (iv) cover highly controversial issues."[4] Arguably, this definition describes subjects that FDA previously would have handled through notice-and-comment rulemaking, while only those less consequential matters viewed as appropriate for Level 2 guidance would have avoided APA requirements as interpretive rules or general statements of policy (or nowadays perhaps as candidates for what it calls "direct final" rulemaking[5]).

Level 1 guidance documents must undergo a truncated notice-and-comment procedure, while Level 2 guidance documents only provide an opportunity for post-publication comment.[6] Particularly insofar as FDA need not provide detailed responses to public comments, these procedures contemplate a "lite" form of informal rulemaking, at least for Level 1 guidance documents. Then again, the APA's requirement for a "concise general statement of the [rule's] basis and purpose" plainly never meant to impose such a requirement for legislative rules though courts later so interpreted it.[7] Thus, Level 1 guidance documents produced consistent with the GGPs—coupled with the absence of routine opportunities for "pre-enforcement" judicial review (technically, of course, a misnomer in this context) or close scrutiny by the other two branches of government—may reflect something of a throwback to informal rulemaking as originally conceived.

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A comprehensive list published in 2010 revealed almost two thousand FDA guidance documents, in both draft and final form,[8] and in recent years the agency has produced more than a hundred new ones annually,[9] easily outpacing the frequency of notice-and-comment rulemaking.[10] It did not take long for complaints to surface about "ossification" of FDA's guidance-making process. Perhaps that explains why Level 1 guidance documents often remain in draft form, which makes the procedures for their issuance (as drafts) the same as those reserved for Level 2 guidance.

Congressional Calls for Guidance Documents from FDA

In amendments to the agency's enabling statute enacted during the last couple of decades, Congress included more than thirty separate provisions that invite or require guidance-making by FDA. In 2006, for instance, it ordered the agency to issue guidance on adverse event reporting for nonprescription drugs and dietary supplements.[11] In contrast, when decades earlier it gave FDA the power to require such reporting for prescription drugs and medical devices, Congress required that the agency use notice-and-comment rulemaking to spell out the details.[12]

Similarly, in 2010, when Congress created an approval pathway for generic biologics ("biosimilars"), it directed FDA to implement the provision using Level 1 guidance documents.[13] In contrast, when it codified an approval pathway for generic versions of conventional pharmaceuticals a quarter of a century earlier, Congress demanded that the agency engage in notice-and-comment rulemaking to craft implementing regulations.[14]

Several commentators have discussed the degree of deference owed by courts when evaluating agency interpretations of ambiguous statutory language that appear in guidance documents instead of binding regulations.[15] No one appears to have considered the extent to which an explicit congressional order to issue guidance on a particular matter should factor into the analysis, but it seems that such a delegation of authority might justify granting an agency interpretation significant deference even if the policy announcement emerged without the exact procedures required for legislative rules. If that happens, however, then nonbinding guidance documents would have an even stronger de facto binding effect on regulated entities.

FDA Guidance Spreading Like Kudzu

FDA does not reserve guidance documents for narrow and technical facets of its work. Large swaths of important agency activities depend entirely on such nonbinding pronouncements, and in areas other than those where Congress has expressly called for guidance-making. Nowadays, it seems, legislative rulemaking only happens when Congress insists on that course of action.

In some cases, FDA uses guidance to update regulations promulgated long ago. For instance, rather than go to the trouble of amending its then-25-year-old regulations delineating "current" good manufacturing practices for drugs, FDA decided to issue guidance for the adoption of innovative quality control technologies by the pharmaceutical industry.[16]

Similarly, even as prescription drug and device advertising has become increasingly sophisticated, FDA has not revised regulations that it issued during the 1960s, relying instead on various guidance documents.[17] In particular, direct-to-consumer advertising of prescription products has expanded over the last quarter of a century. In 1995, FDA conceded that "[t]here are no regulations that pertain specifically to consumer-directed promotional materials."[18] Two decades later, that statement remains true, though numerous guidance documents now address different aspects of the practice.[19]

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In 1997, Congress granted drug and device manufacturers limited permission to distribute to physicians textbooks and reprints of articles discussing "off-label" uses, and it required that FDA promulgate regulations for this purpose.[20] When the statutory provision lapsed in 2006, however, the agency opted to rescind rather than amend this rule,[21] which it then replaced with a substantially similar guidance document.[22] Five years later, it further diminished the authoritative status of this policy by issuing a "revised draft" guidance.[23] It seems at least mildly curious that the agency would think it appropriate to use such a format to address a complex and contentious issue of this sort after the matter previously had required a special legislative amendment coupled with implementing regulations.[24]

Responsiveness to scientific advances represents a common justification for not prematurely rushing into rulemaking. For instance, the agency has relied exclusively on guidance documents to address the various issues that have arisen with foods derived from genetically engineered sources.[25] FDA has responded in a similar fashion to advances in pharmacogenomics, nanotechnologies, and xenotransplantation. At some point, however, the initially steep learning curve should begin to plateau, and a maturing industry might benefit from the greater clarity provided by binding and more stable pronouncements from the agency. Nonetheless, so long as guidance documents manage to communicate FDA's evolving expectations reasonably well and secure voluntary adherence,[26] the agency has little reason to formalize its policies and subject them to unwelcome external scrutiny.

A Better Way Forward?

Some commentators have urged courts to entertain substantive challenges to agency guidance documents.[27] No doubt, this would serve to bring guidance-making full circle back to legislative rulemaking with all of the difficulties that process has entailed for agencies. Perhaps a better strategy would move in precisely the opposite direction, seeking to discourage reviewing courts from even referencing guidance documents, which in turn might make them less appealing to FDA. Similar efforts to prevent parties from citing unpublished judicial opinions have triggered objections,[28] but surely Congress could add to the GGPs provision in FDA's enabling statute a rule of construction designed to leave no doubt about the fundamental flimsiness of these agency pronouncements. At the very least, why not dictate that drafts become inoperative if more than a year or two old?[29]

For a relatively small agency with a lot on its plate, FDA's reliance on such procedural short cuts should come as no great surprise. Congress generally has condoned the agency's shift to guidance-making, though it also sought to impose some procedural requirements. Nonetheless, FDA has managed to escape even these modest constraints, for instance by leaving Level 1 guidance perpetually in draft form. Guidance documents clearly have a place in the portfolio of any agency, but FDA arguably has overused this format for policy announcements that previously would have emerged after notice-and-comment rulemaking. Congress may well want to rethink its rush to embrace this development, or at least counterbalance its growing acceptance of guidance-making with a greater willingness to insist that FDA go to the extra trouble of engaging in legislative rulemaking whenever that seems to represent the more appropriate course.

Endnotes

[1] *See* K.M. Lewis, *Informal Guidance and the FDA*, 66 Food & Drug L.J. 507, 509–23 (2011) (tracing the evolution in the agency's use of guidance); *id*. at 537, 549–50 fig.5 (enumerating the annual production of guidance at FDA over the last quarter of a century).
[2] *See* Food and Drug Administration Modernization Act (FDAMA), Pub. L. No. 105-115, § 405, 111 Stat. 2296, 2369 (1997) (codified as amended at 21 U.S.C. § 371(h)(5) (2012)).
[3] *See* Final Rule, Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56,477 (Sept. 19, 2000) (codified at 21 C.F.R. § 10.115 (2015)).
[4] 21 C.F.R. § 10.115(c)(1).

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[5] *See* Notice, Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466 (Nov. 21, 1997); *see also* Lars Noah, *Doubts About Direct Final Rulemaking*, 51 Admin. L. Rev. 401, 412–28 (1999) (explaining why that procedure runs afoul of the APA).
[6] 21 C.F.R. § 10.115(g).
[7] *See* Lars Noah, *Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules*, 51 Hastings L.J. 255, 308–10 (2000).
[8] *See* Notice, Comprehensive List of Guidance Documents at the Food and Drug Administration, 75 Fed. Reg. 48,180 (Aug. 9, 2010). Current lists (divided by subject matter) appear on the agency's website. *See* Regulatory Information, Guidances, http://www.fda.gov/RegulatoryInformation/Guidances/ (last visited Sept. 7, 2015).
[9] *See* Notice of Availability, Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency, 76 Fed. Reg. 82,311, 82,312 (Dec. 30, 2011).
[10] *See* Erica Seiguer & John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 Food & Drug L.J. 17, 25–26 (2005).
[11] *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, §§ 2(e)(3), 3(d)(3), 120 Stat. 3469, 3472, 3475 (2006).
[12] *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 103(a), 76 Stat. 780, 782–83 (codified as amended at 21 U.S.C. § 355(k)(1) (2012)); Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 564–65 (codified as amended at 21 U.S.C. § 360i(a) (2012)).
[13] *See* Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, § 7002(a)(2), 124 Stat. 119, 808 (2010) (codified at 42 U.S.C. § 262(k)(8) (2012)).
[14] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 105(a), 98 Stat. 1585, 1597.
[15] *See, e.g.*, Kristin E. Hickman, *Unpacking the Force of Law*, 66 Vand. L. Rev. 465, 484–90, 511–25 (2013).
[16] *See* Leila Abboud & Scott Hensley, *Factory Shift: New Prescription for Drug Makers*, Wall St. J., Sept. 3, 2003, at A1.
[17] *See* Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 Ga. L. Rev. 141, 146 n.21 (1997).
[18] Notice of Public Hearing, Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).
[19] *See, e.g.*, Notice of Availability, Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004).
[20] *See* FDAMA, Pub. L. No. 105-115, § 401(a), 111 Stat. 2296, 2356–64 (1997) (codified at 21 U.S.C. § 360aaa (2006)); *see also* Final Rule, Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 64,556 (Nov. 20, 1998) (codified at 21 C.F.R. pt. 99 (2006)).
[21] *See* Notice of Availability, Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. 9342 (Feb. 20, 2008).
[22] *See* Notice of Availability, Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed. Reg. 1694 (Jan. 13, 2009); *see also* Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 Health Matrix 31, 70–72 & n.174, 80–82 (2011).
[23] *See* Notice of Availability, Revised Draft Guidance for Industry on Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices, 79 Fed. Reg. 11,793 (Mar. 3, 2014).
[24] *See* Lars Noah, *Permission to Speak Freely?*, 162 U. Pa. L. Rev. Online 248, 253 (2014) ("FDA's increasingly popular practice of issuing technically nonbinding guidance documents while counting on its power to cajole—a cagey if not always successful effort to shield its dubious policies from judicial scrutiny and avoid other forms of accountability—seems to represent the least defensible method of all when First Amendment rights hang in the balance.").
[25] *See, e.g.*, Lars Noah, *Genetic Modification and Food Irradiation: Are Those Strictly on a Need-to-Know Basis?*, 118 Penn. St. L. Rev. 759, 761–64 & n.20 (2014) (focusing on guidance related to disclosures in labeling).
[26] For a discussion of FDA's power to "twist arms," see Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 Cornell L. Rev. 901, 906–16 (2008).
[27] *See, e.g.*, Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 Tex. L. Rev. 331, 373–94 & n.265 (2011).
[28] *See, e.g.*, Patrick J. Schiltz, *The Citation of Unpublished Opinions in the Federal Courts of Appeals*, 74 Fordham L. Rev. 23 (2005); Rafi Moghadam, Note, *Judge Nullification: A Perception of Unpublished Opinions*, 62 Hastings L.J. 1397 (2011) (criticizing this practice in the California state courts).
[29] Recently, one of FDA's centers recognized that it had dozens of drafts that were more than three years old. *See* Notice, Retrospective Review of Draft Guidance Documents Issued Before 2010, 78 Fed. Reg. 48,175 (Aug. 7, 2013) (promising to either withdraw or finalize them).

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