

# THE LITTLE AGENCY THAT COULD (ACT WITH INDIFFERENCE TO CONSTITUTIONAL AND STATUTORY STRICTURES)

Lars Noah<sup>†</sup>

INTRODUCTION .....	901
I. INDIFFERENCE TO STATUTORY BOUNDARIES.....	903
A. Taking Procedural Shortcuts.....	903
B. Making the Most of Limited Tools.....	906
1. <i>Encouraging Product Recalls</i> .....	908
2. <i>Demanding Postapproval Restrictions</i> .....	911
C. Expanding Regulatory Jurisdiction .....	917
II. INDIFFERENCE TO THE CONSTITUTION .....	920
CONCLUSION .....	924

## INTRODUCTION

More than a century ago, Congress inaugurated federal regulation of foods and drugs.<sup>1</sup> By today's standards, the 1906 Act looked terribly anemic, running just five pages in length. Thirty years later, reacting to difficulties with enforcing the original statute (as tragically revealed by a series of fatalities caused by a product called Elixir sulfanilamide), Congress replaced it with the Food, Drug, and Cosmetic Act (FDCA).<sup>2</sup> Although more comprehensive, the new statute continued to eschew details in favor of broad prohibitions against adulteration and misbranding. The original FDCA filled only fifteen pages in the *U.S. Code*. In the intervening years, Congress has both tinkered with the original language and appended brand new powers and requirements, so that the amended version of the FDCA in the latest edition of the *U.S. Code* occupies 230 pages. What started as a fairly

---

<sup>†</sup> Professor of Law, University of Florida. This paper provided the basis for a presentation at the ABA's 2007 Administrative Law Institute in Washington, D.C.

<sup>1</sup> See Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938). Congress had tackled vaccines and other "biologics" a few years earlier. See Biologics Act, Pub. L. No. 57-244, 32 Stat. 728 (1902) (codified as amended at 42 U.S.C. § 262 (2000)). For additional history on the 1906 Act, see Arthur Hull Hayes, Jr., *Food and Drug Regulation After 75 Years*, 246 JAMA 1223 (1981); Marc T. Law, *How Do Regulators Regulate? Enforcement of the Pure Food and Drugs Act, 1907-38*, 22 J.L. ECON. & ORG. 459 (2006).

<sup>2</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331-397 (2000)); see also David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2 (1939); Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS INTERNAL MED. 456 (1995).

simple regime of after-the-fact policing aimed at substandard foods and drugs has morphed into a complex set of product licensing requirements.

In delegating this authority, Congress has demanded much from the Food and Drug Administration (FDA), making the agency responsible for twenty-five percent of all consumer goods sold in the United States,<sup>3</sup> but the legislature has not always supplied the regulatory tools and appropriations needed to fulfill this mandate. Throughout its history, however, the FDA has had an enviable record of success in the courts because judges have shown tremendous deference to its expertise in implementing its public health mission.<sup>4</sup> For this same reason, judges also have given the agency greater leeway than normal on questions of statutory interpretation,<sup>5</sup> and the FDA enjoys largely unreviewable discretion in deciding whether and how to exercise its enforcement powers.<sup>6</sup>

Although it has not fared as well in recent years, the FDA remains one of the most respected agencies in the federal government.<sup>7</sup> This respect translates into important clout for an agency that lacks the size and resources of other regulatory bodies.<sup>8</sup> Nonetheless, because of

---

<sup>3</sup> See Rick Weiss & Ariana Eunjung Cha, *Pet Deaths Spur Call for Better FDA Screening: Imports Raise Concern About Human Foods*, WASH. POST, May 1, 2007, at A1.

<sup>4</sup> See, e.g., *Henley v. FDA*, 77 F.3d 616, 620–21 (2d Cir. 1996); *Schering Corp. v. FDA*, 51 F.3d 390, 399–400 (3d Cir. 1995); see also Lars Noah, *Scientific “Republicanism”: Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1076 (2000).

<sup>5</sup> See *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969) (noting “the well-accepted principle that remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health”); *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

<sup>6</sup> See *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985); see also *United States v. Sage Pharm., Inc.*, 210 F.3d 475, 480 (5th Cir. 2000) (holding that the FDA could target one firm for selling unapproved new drugs even though it had not yet acted against others who distributed substantially similar products). Courts have, however, chastised the agency when it acts inconsistently in regulating similarly situated products. See, e.g., *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997); *United States v. Undetermined Quantities of an Article of Drug Labeled as “Exachol,”* 716 F. Supp. 787, 795–96 (S.D.N.Y. 1989).

<sup>7</sup> See Stephen Barr, *Users Mostly Rate Agencies Favorably*, WASH. POST, Apr. 13, 2000, at A29 (“The FDA came out on top in the survey, with more than 80 percent of medical professionals, business regulatory officers, health and medicine advocates and the chronically ill responding with favorable impressions of the agency.”). Even so, with each widely publicized crisis over the safety of particular foods or drugs, some of this faith has eroded in recent years. See Gardiner Harris, *Potentially Incompatible Goals at F.D.A.*, N.Y. TIMES, June 11, 2007, at A14; William Hubbard, Op-Ed., *The Overwhelmed FDA*, BOSTON GLOBE, June 3, 2007, at C9; Elizabeth Williamson, *FDA Was Aware of Dangers to Food: Outbreaks Were Not Preventable, Officials Say*, WASH. POST, Apr. 23, 2007, at A1.

<sup>8</sup> See Ricardo Alonso-Zaldivar, *FDA Budget Malnourished*, L.A. TIMES, Oct. 7, 2006, at A1; Anna Wilde Mathews, *FDA Chief Is in Budget Bind: Leader Embraces Critics’ Core Views; A Public Departure*, WALL ST. J., Feb. 27, 2008, at A6; see also Mary Olson, *Substitution in Regulatory Agencies: FDA Enforcement Alternatives*, 12 J.L. ECON. & ORG. 376, 404 (1996) (observing that, between 1972 and 1992, “budget reductions and increasing applications for product approval . . . led the agency to reduce its monitoring of FDA-regulated industries and to

the controversial issues that have confronted the agency, it has gone without permanent leadership for much of the last decade.<sup>9</sup> Separately, FDA officials sometimes complain that recent legislative directives and judicial edicts have hamstrung their efforts to protect the public health.<sup>10</sup> Even so, the agency continues to manage fairly well, in part because it has shown little compunction about occasionally crossing a statutory or constitutional line when necessary to accomplish some valuable end.

## I

### INDIFFERENCE TO STATUTORY BOUNDARIES

As elaborated below, the FDA has disregarded legislative directives in at least three different, though interrelated, senses: failing to adhere to procedures specified by Congress; deploying expressly delegated powers in order to achieve ends beyond those envisioned in the legislation; and branching out to reach matters that arguably exceed its jurisdiction. In addition to documenting each of these forms of statutory disregard, this Part notes some of the problems with such indifference.

#### A. Taking Procedural Shortcuts

The FDA was one of the first federal agencies to make extensive use of its initially unclear rulemaking powers. In lieu of bringing enforcement actions under the open-ended provisions of the FDCA and generating adjudicatory precedent for future cases, the FDA began to promulgate more detailed rules to implement its statutory authority.<sup>11</sup>

---

substitute less resource-intensive enforcement actions”). The agency has stretched its limited resources in part by delegating limited authority to private entities. *See* Lars Noah, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. 267, 272 & n.26, 278–79 (2004). The agency’s resource difficulties also have created a peculiar bargaining dynamic with the pharmaceutical and medical device industries when Congress periodically leaves these parties to hash out the terms of new user fee legislation. *See* Anna Wilde Mathews, *Rising FDA Reliance on “User Fees” Boosts Drug Firms Clout in Talks*, WALL ST. J., Sept. 1, 2006, at A1; Cindy Skrzycki, *FDA’s User-Fee Habit*, WASH. POST, Apr. 3, 2007, at D1; *see also* Notice of Public Meeting, Prescription Drug User Fee Act, 72 Fed. Reg. 1743, 1745 (Jan. 16, 2007) (describing the process used for the development of legislative recommendations).

<sup>9</sup> *See* Ricardo Alonso-Zaldivar, *The FDA Awaits a Cure for Its Malaise: Problems Pile Up in the Absence of a Permanent Chief and Political Disputes over Ideology*, L.A. TIMES, Apr. 30, 2006, at A1; Marc Kaufman, *FDA’s Reliance on Unconfirmed Chiefs Is Faulted*, WASH. POST, Dec. 19, 2004, at A1. Shortly after the latest mid-term elections, Andrew von Eschenbach got the post. *See* Stephanie Saul, *New Leader of the F.D.A. Is Confirmed by the Senate*, N.Y. TIMES, Dec. 8, 2006, at A30.

<sup>10</sup> *See, e.g.*, Marion Burros, *F.D.A. Commissioner Is Resigning After 6 Stormy Years in Office*, N.Y. TIMES, Nov. 26, 1996, at A1 (reporting laments about the deregulation of dietary supplements); *see also infra* note 93 (noting struggles to regulate food additives).

<sup>11</sup> *See* Eric R. Claeys, *The Food and Drug Administration and the Command-and-Control Model of Regulation*, 49 ST. LOUIS U. L.J. 105, 117–21 (2004).

Although infractions still required individual enforcement proceedings, the agency would simplify its burden of proof in those proceedings, which, coupled with the greater clarity of expectations, would help to promote improved compliance.

In the FDCA, Congress expressly granted the agency the authority to issue regulations governing certain subjects,<sup>12</sup> but it also required that interested parties be allowed to request a public hearing as part of the rulemaking process.<sup>13</sup> For instance, the FDA's power to promulgate prescription drug advertising regulations is subject to this "formal" rulemaking procedure.<sup>14</sup> In practice, these procedures became a source of frustrating delays for the agency.<sup>15</sup>

After courts decided that the residual rulemaking authority in the statute empowered the FDA to issue binding regulations on matters not specifically covered by the formal rulemaking provision,<sup>16</sup> the agency began to utilize "notice-and-comment" procedures for the promulgation of rules. The courts also, however, allowed interested parties to bring pre-enforcement challenges to such rules.<sup>17</sup> Although "informal" rulemaking avoided the cumbersome hearings required with formal rulemaking, searching judicial review on the merits and increasing procedural demands added by all three branches of government have made it increasingly difficult. As a result, the FDA and other agencies have experimented with further shortcuts for issuing regulations.<sup>18</sup>

As informal rulemaking became more difficult, the FDA shifted from promulgating binding rules to issuing nonbinding guidelines. For instance, rather than go to the trouble of amending its then 25-year-old regulations delineating "current" good manufacturing practices (cGMPs) for drugs, the FDA decided to issue guidance for the adoption of innovative quality control technologies by the pharmaceu-

---

<sup>12</sup> See 21 U.S.C. § 371(e) (2000).

<sup>13</sup> See *Pharm. Mfrs. Ass'n v. Gardner*, 381 F.2d 271, 278 (D.C. Cir. 1967).

<sup>14</sup> See 21 U.S.C. § 352(n).

<sup>15</sup> See Robert W. Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132, 1142 (1972) ("[T]he FDA has conducted two major [formal rulemaking] proceedings that have been the subject of wide criticism. Both proceedings have taken (or will take) more than ten years from the formulation of the original proposal to the actual effective date of the regulation.").

<sup>16</sup> See *Nat'l Ass'n of Pharm. Mfrs. v. FDA*, 637 F.2d 877 (2d Cir. 1981); *Pharm. Mfrs. Ass'n v. FDA*, 634 F.2d 106, 108 (3d Cir. 1980) (per curiam).

<sup>17</sup> See *Abbott Labs. v. Gardner*, 387 U.S. 136, 141-48 (1967) (holding that an FDA drug labeling regulation was ripe for judicial review).

<sup>18</sup> See Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401, 409-11 (1999) (describing the FDA's experience with one such technique, which dispenses with the need to publish a proposal before issuing a non-controversial rule); *id.* at 412-28 (questioning the legality of direct final rulemaking).

tical industry.<sup>19</sup> Similarly, even as prescription drug advertising has become increasingly sophisticated,<sup>20</sup> reflecting greater ingenuity and the emergence of brand new media such as the Internet, the FDA has not revised regulations that it issued during the 1960s,<sup>21</sup> relying instead on various types of guidelines.<sup>22</sup>

The agency's growing dependence on guidance documents presents a couple of problems. First, these informal announcements may operate as de facto rules but escape normal procedural safeguards for their promulgation or review.<sup>23</sup> Second, they allow the FDA to take positions that do not even constrain agency officials, which leaves regulated entities guessing about their rights and obligations.<sup>24</sup> Notwithstanding these concerns, in 1997 Congress endorsed (subject to certain limitations) this shift to greater reliance on guidance documents.<sup>25</sup> Thus, the agency has found some convenient shortcuts for communicating its expectations to regulated entities.

---

<sup>19</sup> See Leila Abboud & Scott Hensley, *New Prescription for Drug Makers: Update the Plants*, WALL ST. J., Sept. 3, 2003, at A1; see also Draft Final Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables, 72 Fed. Reg. 11,364 (Mar. 13, 2007).

<sup>20</sup> See Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 430-34 (2002).

<sup>21</sup> See Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 146 n.21 (1997). Only once in the last forty years has the FDA engaged in formal rulemaking to deal with advertising issues, and that came in response to an explicit congressional directive to issue implementing rules for a new statutory provision. See 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 (2007)).

<sup>22</sup> See, e.g., Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004); Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43,197 (Aug. 9, 1999); *infra* notes 107-13 (discussing guidance documents that address industry distribution of article reprints and sponsorship of continuing medical education programs).

<sup>23</sup> See *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 948-49 (D.C. Cir. 1987) (per curiam); *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 was not promulgated through notice-and-comment rulemaking); see also *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C. Cir. 1997) (rejecting the FDA's claim that an interpretive rule was exempt from notice-and-comment requirements).

<sup>24</sup> See Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 140-42 (1997) (criticizing the agency's practice of not taking definitive positions in guidance documents and, thereby, attempting to escape judicial review).

<sup>25</sup> See Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 405, 111 Stat. 2296, 2368 (codified at 21 U.S.C. § 371(h) (2000)) [hereinafter FDAMA]; see also Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 71 Fed. Reg. 15,422 (Mar. 28, 2006) (listing hundreds of guidelines). One decade later, the Executive branch decided to pay closer attention to the proliferation of these nonbinding announcements emanating from all agencies. See Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007); Stephen M. Johnson, *Good Guidance, Good Grief!*, 72 MO. L. REV. 695, 722-26 (2007).

## B. Making the Most of Limited Tools<sup>26</sup>

Congress originally granted the FDA only limited and procedurally cumbersome mechanisms for securing compliance with the statute: product seizures, injunctions, and criminal penalties.<sup>27</sup> The agency has, however, deployed these tools in creative ways: for instance, the FDA may threaten to impose a sanction or withhold a benefit in the hopes of encouraging “voluntary” compliance with a request that the agency could not impose directly on a regulated entity.<sup>28</sup> Often such threats simply represent a more efficient method for achieving ends explicitly authorized by Congress, but in some cases they allow the FDA to pursue extrastatutory goals.

Such “arm-twisting” succeeds, and evades judicial or other scrutiny, in part because companies in pervasively regulated industries believe that they cannot afford to resist agency demands. For instance, some critics have accused the FDA of retaliating against firms that fail to cooperate.<sup>29</sup> Whether or not such charges are accurate, the perception leads companies to accede to the agency’s wishes even though they may lack any basis in law or fact.<sup>30</sup> Whatever the reason, the FDA

---

<sup>26</sup> This section draws extensively from Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873.

<sup>27</sup> See 21 U.S.C. §§ 332–334 (2000).

<sup>28</sup> See Noah, *supra* note 26, at 874. The agency has long relied on such techniques. See H. Thomas Austern, *Expertise in Vivo*, 15 ADMIN. L. REV. 46, 50, 56 (1963) (discussing informal enforcement by the FDA through “jaw-boning” and “lifted eyebrow” techniques, which succeed because of the ever-present threat of criminal sanctions); *id.* at 52 (“[I]n this field what the agency concludes, the court approves; and most of those regulated do not often dare to challenge an informal assertion of power.”); *id.* at 54 (“Every finding is dressed up as a scientific determination. . . . The FDA rule-making process, by and large, has virtual immunity from judicial intervention or correction.”).

<sup>29</sup> See *Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 761 (5th Cir. 1980); *id.* at 767 (criticizing the agency’s “bureaucratic hubris that confuses abuse of power with reason,” and adding that “the FDA’s abuse of its statutory rights of entry and inspection so as to harass and threaten [the parties] can in no way be condoned”); *Allegations of FDA Abuses of Authority: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Commerce*, 104th Cong. 2 (1995) [hereinafter *Hearings*] (statement of Hon. Joe Barton) (suggesting that “these stories are not rare exceptions,” and adding that “the FDA never forgets who its enemies are”); *id.* at 9 (statement of Hon. Thomas J. Bliley, Jr.) (suggesting that “the threat of retaliation is deeply embedded in the culture of this Agency”). *But see id.* at 6 (statement of Hon. Henry A. Waxman) (warning that we should “not base our policy decisions on anecdotes and hyperbole”); *id.* at 83 (statement of Hon. John D. Dingell) (noting that, “upon a fuller review of the five case studies selected by the Majority, claims of FDA retaliation were decidedly premature”).

<sup>30</sup> See, e.g., *Hearings, supra* note 29, at 70 (testimony of Ronald C. Jankelson, Myo-Tronics, Inc.) (describing pressures to enter into a consent decree); see also Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 653 (1996) (“The natural response to such alleged abusive tactics would be to bring suit against the agency, but such a response might not be in the best interests of the affected company.”); Peter Brimelow & Leslie Spencer, *Food and Drugs and Politics*, FORBES, Nov. 22, 1993, at 115, 116 (reporting that 84% of survey respondents had failed to press potentially legitimate complaints against the FDA for fear of retaliation).

has managed to accomplish things that arguably exceed the limits of its delegated authority.

The FDA routinely issues “warning letters” that allege some regulatory infraction and provide the recipient with a limited period of time to take corrective action (coupled with a threat of formal enforcement proceedings).<sup>31</sup> In the case of drugs and medical devices, the FDA used to go further and explain that it had advised government purchasing entities to stop dealing with the firm in the meantime.<sup>32</sup> Because the federal government represents the single largest purchaser of prescription drugs in this country,<sup>33</sup> few manufacturers could afford to risk losing these contracts. If a company dared to disagree with the agency’s allegations and chose to pursue a judicial challenge rather than accede to its demands, the FDA invariably argued that the controversy was not ripe for review.<sup>34</sup> Only once did a court hold that such a challenge was justiciable on the basis of an interim procurement freeze.<sup>35</sup>

If a company voluntarily corrected the violations of federal law alleged in a warning letter, whether or not accompanied by a

---

<sup>31</sup> See Marc Kaufman, *Study Cites Marked Drop in FDA’s Warning Letters*, WASH. POST, June 27, 2006, at A19; see also Mary K. Olson, *Agency Rulemaking, Political Influences, Regulation, and Industry Compliance*, 15 J.L. ECON. & ORG. 573, 573–75 (1999) (noting a decline in FDA inspections coupled with an increase in reported infractions). The FDA’s counterpart in Canada operates almost exclusively in this fashion. See Scott Martin, Note, *Unlabeled “Drugs” as U.S. Health Policy: The Case for Allowing Health Claims on Medicinal Herb Labels; Canada Provides a Model for Reform*, 9 ARIZ. J. INT’L & COMP. L. 545, 568 (1992).

<sup>32</sup> See Noah, *supra* note 26, at 886 n.47.

<sup>33</sup> See Scott Hensley, *Big Buyers Push for Steep Price Cuts from Drug Makers*, WALL ST. J., June 22, 2006, at B1 (explaining that, as the health insurer for over five million individuals, the Department of Veterans Affairs can exercise significant leverage in procurement deals); Robert Pear, *Medicare Law Prompts a Rush for Lobbyists*, N.Y. TIMES, Aug. 23, 2005, at A1 (reporting that “Medicare and Medicaid will account for 37 percent of all spending on prescription drugs next year, up from 20 percent this year” and that “Medicare will spend more than \$1 trillion on prescription drugs in the next 10 years”).

<sup>34</sup> See, e.g., *Dietary Supplement Coal., Inc. v. Kessler*, 978 F.2d 560, 563 (9th Cir. 1992) (noting that an FDA regulatory letter does not constitute final agency action); *Prof’ls & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) (explaining that warning letters do not constitute final agency action but instead “merely establish a dialogue between the FDA and the pharmacist and do not necessarily lead to further sanctions”), *aff’d*, 56 F.3d 592, 599–600 (5th Cir. 1995). But see *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 29–30, 34–36 (D.D.C. 1995) (holding that a challenge to the FDA’s unofficial policy against drug industry sponsorship of scientific symposia was ripe for review based in part on warning letters alleging the unlawful promotion of off-label uses at such meetings).

<sup>35</sup> See *Den-Mat Corp. v. United States*, No. MJG-92-444, 1992 U.S. Dist. LEXIS 12233, at \*13 (D. Md. Aug. 17, 1992) (“Such action by the FDA would effectively ‘seize’ all products that normally would be sold to federal agencies.”). The court also expressed concern that “the FDA may have targeted Den-Mat . . . for a publicity campaign designed to coerce Den-Mat (and others) into complying with the agency’s decision.” *Id.* at \*14. “[I]t would be inherently unfair to allow the FDA to continue to ‘enforce’ its determination [through indirect means] without allowing the affected party an opportunity to prove that the FDA’s position is wrong.” *Id.* at \*15 & n.6.

threatened procurement freeze, it lost any opportunity to challenge the legal basis for the FDA's objections. In this manner, as explained in the sections that follow, the agency has managed to exercise a recall power not delegated by Congress. In addition, and without the need to allege any wrongdoing or threaten formal enforcement action, the agency has conditioned the granting of licenses on various postapproval restrictions not contemplated in the statute.

### 1. *Encouraging Product Recalls*

The FDA generally lacks the statutory authority to order a recall of potentially dangerous products subject to its regulatory jurisdiction.<sup>36</sup> Although Congress has granted the agency such authority with regard to limited classes of products,<sup>37</sup> and government reports have recommended providing it with broader recall powers,<sup>38</sup> the FDA generally has resisted proposals to provide it with explicit recall authority.<sup>39</sup> Instead, the agency prefers encouraging voluntary recalls, and it even has promulgated detailed regulations setting forth its recall procedures and policies.<sup>40</sup>

This strategy has succeeded because firms know that a failure to cooperate with an agency request would invite more draconian en-

---

<sup>36</sup> See *Nat'l Confectioners Ass'n v. Califano*, 569 F.2d 690, 694 (D.C. Cir. 1978); *United States v. Superpharm Corp.*, 530 F. Supp. 408, 410 (E.D.N.Y. 1981); *United States v. C.E.B. Prods., Inc.*, 380 F. Supp. 664, 667-72 (N.D. Ill. 1974). *But cf.* *United States v. K-N Enter., Inc.*, 461 F. Supp. 988, 990-91 (N.D. Ill. 1978) (reading the FDCA broadly as authorizing a court-ordered recall of adulterated drugs). In recent years, however, courts have construed the FDA's power to request injunctive relief more broadly to include remedies not delineated in the statute. See, e.g., *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1058-63 (10th Cir. 2006); *United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 233-36 (3d Cir. 2005) (upholding a district court order that the seller of unapproved new drugs pay restitution to consumers).

<sup>37</sup> See, e.g., *Safe Medical Devices Act of 1990*, Pub. L. No. 101-629, § 8, 104 Stat. 4511, 4520-21 (codified at 21 U.S.C. § 360h(e) (2000)); *Infant Formula Act of 1980*, Pub. L. No. 96-359, § 2, 94 Stat. 1190, 1190-91 (codified as amended at 21 U.S.C. § 350a(f) (2000)).

<sup>38</sup> See, e.g., H.R. REP. NO. 102-1030, at 12-13, 15 (1992); *Recommendations of the Administrative Conference Regarding Administrative Practice and Procedure*, 49 Fed. Reg. 29,937, 29,940-41 (July 25, 1984).

<sup>39</sup> See Eugene M. Pfeifer, *Enforcement, in FOOD AND DRUG LAW* 72, 101 (1984) ("It realistically fears that Congress would legislate burdensome, time-consuming procedural requirements . . . . Because requests for recalls—backed by the implicit threa[t] of court actions and publicity—are generally complied with, the agency has been unwilling to jeopardize what it regards as an efficient, albeit voluntary, recall system.").

<sup>40</sup> See *Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibilities*, 43 Fed. Reg. 26,202, 26,218 (June 16, 1978) (codified as amended at 21 C.F.R. pt. 7(C) (2007)); see also 21 C.F.R. § 7.40(a) ("This [subpart] recognize[s] the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities."). For one recent example of a "voluntary" (though grudging) product withdrawal, see Marc Kaufman, *Another Pain Reliever Pulled: FDA Warns of Risk in Entire Class of Anti-Inflammatories*, WASH. POST, Apr. 8, 2005, at A1 (Bextra®).

forcement measures authorized by statute.<sup>41</sup> Because these necessitate judicial proceedings, however, the issuance of adverse publicity may represent a still more effective way of prompting action.<sup>42</sup> Companies often prefer a voluntary recall because it allows them to exercise greater control over the nature and extent of public notification about any hazards associated with their particular product.<sup>43</sup>

The FDCA expressly authorizes the issuance of adverse publicity, though only in limited circumstances.<sup>44</sup> Even then, targets of an information campaign often have no meaningful opportunity to respond to the charges or seek judicial review.<sup>45</sup> In recognition of the risk of improper use, the FDA once proposed a policy to limit the issuance of such publicity.<sup>46</sup> The agency never finalized this proposal, and it continues to rely on explicit or implicit threats of disseminating bad press as a method of encouraging voluntary compliance with its recall and other demands.<sup>47</sup>

---

<sup>41</sup> See 21 C.F.R. § 7.40(c) (“Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the [FDA] . . . .”); Proposed Rule, Enforcement Policy, Practices and Procedures: Recall Policy and Procedures, 41 Fed. Reg. 26,924, 26,924 (June 30, 1976) (“While the act does not explicitly mention recalls, the statutory sanctions available to FDA have a vital role in a firm’s willingness to recall and support the development of recall as a major FDA regulatory tool.”).

<sup>42</sup> See Ernest Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380, 1408 (1973) (“Since [recalls] cannot be required by law, the FDA ensures compliance by threatening seizure, injunction, and the issuance of publicity. Of these, the threat of publicity is usually the most potent persuader.”); *id.* at 1415 (noting that the FDA apparently “cannot resist the temptation of using [public] warnings to operate an extrastatutory recall program”).

<sup>43</sup> Cf. *Heart Device Warning May Change: The FDA Is Considering a Physician Group’s Request Not to Use the Word “Recall” Because It May Cause Undue Alarm*, L.A. TIMES, Sept. 29, 2006, at C3.

<sup>44</sup> See 21 U.S.C. § 375(b) (2000) (“The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer.”); see also *Ajay Nutrition Foods, Inc. v. FDA*, 378 F. Supp. 210, 216–19 (D.N.J. 1974) (refusing to enjoin adverse publicity issued by the FDA), *aff’d mem.*, 513 F.2d 625 (3d Cir. 1975); *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376, 378 (D.D.C. 1957) (same).

<sup>45</sup> See H. Thomas Austern, *Sanctions in a Silhouette*, in WALTER GELLHORN & CLARK BYSE, *ADMINISTRATIVE LAW* 671, 674 (4th ed. 1960) (“Never forget that the publicity sanction—that omnibus condemnation by press release—goes forward without formal evidence, without any opportunity for hearing, without counsel and, of course, without the remotest possibility of court review.”); Gellhorn, *supra* note 42, at 1424 (“Publicity is quicker and cheaper; it is not presently subject to judicial review or other effective legal control; and it involves the exercise of pure administrative discretion.”); *id.* at 1441 (“Adverse agency publicity is a powerful and often unruly nonlegal sanction.”).

<sup>46</sup> See Proposed Rule, Administrative Practices and Procedures: Publicity Policy, 42 Fed. Reg. 12,436, 12,440–41 (Mar. 4, 1977), *withdrawn*, 56 Fed. Reg. 67,446 (Dec. 30, 1991).

<sup>47</sup> See Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563, 567–68 (2004). Agency publicity may serve to inform the public or sanction a wrongdoer. See Gellhorn, *supra* note 42, at 1383 (“Occasionally publicity which informs or warns also functions to punish law violators, to deter unlawful conduct, or to force a transgressor to negotiate and settle.”); *id.* at 1424

During the early 1990s, the FDA negotiated consent decrees with pharmaceutical companies that it had accused of unlawfully promoting certain prescription drugs. In one of these cases, a manufacturer agreed to undertake an extensive corrective advertising campaign and also to preclear all of its promotional materials with the agency for a period of two years,<sup>48</sup> even though the statute generally prohibits mandatory preclearance of pharmaceutical advertising.<sup>49</sup> In another case, a company agreed to establish an FDA-approved training program for its pharmaceutical sales representatives,<sup>50</sup> even though the agency does not appear to have the power to regulate such communications.<sup>51</sup> In these and other cases, explicit FDA threats of especially burdensome product seizures or injunctions prompted the companies to accept these unprecedented requirements.<sup>52</sup>

---

n.177 (noting that “the FDA’s use of publicity in its recall program is paradigmatic” of this dual use). In effect, the government threatens to engage in product disparagement in order to shame the seller into altering its behavior.

<sup>48</sup> See *Syntex Will Run Naprosyn Corrective Ads in 18 Medical Journals and on “Lifetime” TV in Court-Filed Consent Decree to Halt Arthroprotective Claims*, F-D-C REP. (“The Pink Sheet”), Oct. 14, 1991, at 6, 8 [hereinafter *Syntex Decree*] (reporting that “[t]he comprehensive scope and breadth of FDA scrutiny set out in the consent agreement are unprecedented”); see also *Bristol Oncology Promotions Will Be Precleared by FDA for Two Years: Automatic Go-Ahead May Protect Company from Delays in Agency Ad Reviews*, F-D-C REP. (“The Pink Sheet”), June 3, 1991, at 6, 6 (describing a preclearance requirement covering about a dozen products in a consent decree negotiated with Bristol-Myers Squibb, and adding that “[t]he agency has extracted similar agreements in recent years”).

<sup>49</sup> See 21 U.S.C. § 352(n) (providing that, “except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement”); see also 21 C.F.R. § 202.1(j) (2007) (calling for FDA preclearance of proposed advertisements only if unexpected fatalities or other serious side effects come to light); Request for Comments, Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24,314–15 (May 14, 1996) (disavowing any intent to require routine preclearance of prescription drug ads).

<sup>50</sup> See *Kabi Pharmacia’s Dipentum Consent Decree Requires FDA-Approved Training Program for Sales Reps; July 30 Order Is FDA’s First “Significant” Detailing Case*, F-D-C REP. (“The Pink Sheet”), Aug. 9, 1993, at 17, 17 (noting that the “FDA’s involvement in developing a training program is unprecedented”). Other provisions of this consent decree required corrective advertising, preclearance of all promotional materials for one year, and reimbursement of the costs of the FDA’s investigation. See *id.* at 18.

<sup>51</sup> See Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 FOOD & DRUG L.J. 309, 322–26 (1992).

<sup>52</sup> See, e.g., *Syntex Decree*, *supra* note 48, at 8 (“To get the Syntex agreement, FDA is understood to have threatened to seize all of the company’s stocks of Naprosyn.”); see also *FDA’s Generic Drug Enforcement Policies Will Be Reviewed*, F-D-C REP. (“The Pink Sheet”), Aug. 31, 1992, at T&G-1 (reporting congressional concerns about the “FDA’s recent approach to pressuring firms for corrections of alleged violations. In one case, involving Barr Laboratories, FDA has offered the firm the choice of signing a consent decree and agreeing to correct alleged deficiencies or facing an injunction that would shut down operations.”).

## 2. *Demanding Postapproval Restrictions*

Product licensing gives the FDA even greater leverage for extracting concessions from sellers. In 1996, for instance, the agency approved Procter & Gamble's food additive petition for the non-caloric fat substitute olestra, though only for use in certain snack foods.<sup>53</sup> Nearly twenty-five years had elapsed between the company's initial contacts with agency officials and final approval, and Procter & Gamble spent more than \$200 million in the product development process.<sup>54</sup> Indeed, the FDA approved olestra just days before the expiration of the company's previously extended patents.<sup>55</sup> The final regulation conditioned use of the additive on special labeling, vitamin fortification, and the submission of follow-up reports to allow for further agency review.<sup>56</sup>

The requirement for postmarket surveillance represented one of the most curious features of the approval. The regulation itself did not mandate further testing by the petitioner; it only provided that the FDA "will review and evaluate all data and information bearing on the safety of olestra received by the agency."<sup>57</sup> In the preamble accompanying the regulation, however, the agency explained that "as a condition of approval, Procter and Gamble is to conduct the studies that it has identified in its letter to FDA,"<sup>58</sup> and it warned that, "if Procter and Gamble does not conduct the identified studies and does not conduct them according to the articulated timetable, FDA will

---

<sup>53</sup> See Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 61 Fed. Reg. 3118, 3171-72 (Jan. 30, 1996) (codified as amended at 21 C.F.R. § 172.867 (2007)).

<sup>54</sup> See Marian Burros, *Intensifying Debate on a Fat Substitute*, N.Y. TIMES, Jan. 17, 1996, at C1.

<sup>55</sup> See Sally Squires, *FDA Decision Nears on Fat Substitute*, WASH. POST, Jan. 23, 1996, at F8. Upon approval, the company became eligible for limited patent term restoration. See Determination of Regulatory Review Period for Purposes of Patent Extension, 62 Fed. Reg. 763 (Jan. 6, 1997); see also Raju Narisetti, *Anatomy of a Food Fight: The Olestra Debate*, WALL ST. J., July 31, 1996, at B1.

<sup>56</sup> See 21 C.F.R. § 172.867(d)-(f) (2004) (repealed 2004).

<sup>57</sup> *Id.* § 172.867(f). Eight years later, after conducting this further review, the agency amended the rule. See Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 69 Fed. Reg. 29,428, 29,432 (May 24, 2004) (codified at 21 C.F.R. § 172.867).

<sup>58</sup> 61 Fed. Reg. at 3168 ("Procter and Gamble has notified FDA that the company will be conducting additional studies of olestra exposure (both amounts consumed and patterns of consumption) and the effects of olestra consumption . . ."); see also U.S. GEN. ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY: INNOVATIVE STRATEGIES MAY BE NEEDED TO REGULATE NEW FOOD TECHNOLOGIES, No. RCED-93-142 (1993), at 61 [hereinafter GAO] (According to one official, the "FDA may try to negotiate requirements for firms to conduct postmarket surveillance, including the collection and reporting of data on dietary use and on any adverse effects, as a condition for approving novel macro-ingredients as food additives.").

consider the approval set forth in this document to be void *ab initio* and will institute appropriate proceedings.”<sup>59</sup>

By making this threat, the agency incorrectly implied that food additive approval served as a private license rather than as a public regulation available, subject only to patent limitations, to any firm wishing to manufacture and sell the additive.<sup>60</sup> The FDA’s threat also seemingly ignored the procedures specified by Congress for withdrawing an approval.<sup>61</sup> The agency responded that its postmarket surveillance condition “is not without precedent,” citing the more limited data collection requirement imposed fifteen years earlier on the manufacturer of the food additive aspartame,<sup>62</sup> but this also had reflected a nominally voluntary undertaking by the sponsor.<sup>63</sup>

Even more so than it does in the case of food additives, the FDA carefully reviews all new drug products prior to marketing. Until recently, the FDCA made no mention of postmarket (so-called “Phase IV”) study requirements,<sup>64</sup> but the agency long ago issued regulations governing such clinical trials.<sup>65</sup> As a condition of product approval, the FDA often has demanded that applicants undertake postapproval

---

<sup>59</sup> 61 Fed. Reg. at 3169. The preamble provided little information about the nature of this correspondence, though the letter from the company referenced by the agency—dated one month after the close of the public comment period and less than one week before publication of the approval—suggested last minute negotiations.

<sup>60</sup> See GAO, *supra* note 58, at 27 (“Unlike approvals for new drugs, food additives regulations are not licenses. Once FDA has issued a regulation specifying the uses and conditions of use for a food additive, any company is free to market the additive as long as the additive is in compliance with the regulation and is not patented.”).

<sup>61</sup> See 21 U.S.C. § 348(h) (2000); 21 C.F.R. § 171.130.

<sup>62</sup> 61 Fed. Reg. at 3169. The final decision approving aspartame included the following additional condition: “Searle is to monitor the actual use levels of aspartame and to provide such information on aspartame’s use to the Bureau of Foods as the Bureau may deem necessary by an order, in the form of a letter, to Searle.” Aspartame: Commissioner’s Final Decision, 46 Fed. Reg. 38,285, 38,303 (July 24, 1981).

<sup>63</sup> See GAO, *supra* note 58, at 61 (“In at least one instance, FDA has been able to obtain *voluntary* postmarket surveillance for a food additive (Aspartame, an artificial sweetener) as part of the approval process for this substance. However, FDA does not have the statutory authority to *require* surveillance for food products, as it does for human drugs . . .”).

<sup>64</sup> See Robert L. Fleshner, *Post-Marketing Surveillance of Prescription Drugs: Do We Need to Amend the FDCA?*, 18 HARV. J. ON LEGIS. 327, 329–31 (1981). In 1997, Congress authorized such requirements, though only for drugs eligible for “fast track” review. See FDAMA, Pub. L. No. 105-115, §§ 112, 130, 111 Stat. 2296, 2309–10, 2331–32 (codified as amended at 21 U.S.C. §§ 356(b), 356b(a) (2000)); see also Curt D. Furberg et al., *The FDA and Drug Safety: A Proposal for Sweeping Changes*, 166 ARCHIVES INTERNAL MED. 1938, 1940–41 (2006) (recommending, among other things, routine Phase IV trials). One decade later, it broadened the agency’s authority in this area. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, tit. IX, 121 Stat. 823, 922.

<sup>65</sup> See Approved New Drugs That Require Continuation of Longterm Studies, Records, and Reports, 35 Fed. Reg. 14,784 (Sept. 23, 1970) (codified as amended at 21 C.F.R. § 310.303(a) (2007)).

research,<sup>66</sup> though it has done a poor job of holding pharmaceutical manufacturers to these promises.<sup>67</sup>

In 1992, in response to complaints about excessive delays in approving AIDS drugs, the agency promulgated regulations to establish an accelerated approval procedure for new drugs and biologics intended to treat serious or life-threatening illnesses.<sup>68</sup> Before approving a new drug, the FDA must find that it is both safe and effective, but under the accelerated approval procedures it accepted weaker evidence of effectiveness than normally required.<sup>69</sup> If a pharmaceutical company wanted to utilize this expedited licensing procedure, it had to agree to several conditions on approval not originally authorized by Congress. For example, an applicant would have to accept any necessary postmarketing restrictions, including distribution only through certain medical facilities or by specially trained physicians, distribution conditioned on the performance of specified medical procedures, and advance submission of all promotional materials for FDA review.<sup>70</sup> At the time that the agency issued the rule, however, the governing statute did not authorize the imposition of any of these conditions.<sup>71</sup> Moreover, the FDA insisted that a company waive its statutory right to demand an evidentiary hearing in the event that the agency later chose to withdraw the approval.<sup>72</sup>

In response to industry complaints about such conditions, the FDA explained that any “applicants objecting to these procedures may forego approval under these regulations and seek approval under the

---

<sup>66</sup> See Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 325–27 (2006).

<sup>67</sup> See Jennifer Corbett Dooren, *Review Finds Gap in Required Study of Approved Drugs*, WALL ST. J., June 1, 2005, at D4; *65% of Promised Drug Studies Pending*, WASH. POST, Mar. 4, 2006, at A4.

<sup>68</sup> See New Drug, Antibiotic, and Biological Drug Product Regulations: Accelerated Approval, 57 Fed. Reg. 58,942, 58,958–60 (Dec. 11, 1992) (codified at 21 C.F.R. pts. 314(H), 601(E) (2007)).

<sup>69</sup> For instance, the FDA will accept evidence of drug effectiveness in attaining “surrogate endpoints” (e.g., reductions in CD4 cell counts or tumor shrinkage) in lieu of the more difficult to prove “clinical endpoints” (e.g., improved survival). See 21 C.F.R. §§ 314.510, 601.41 (2007); 57 Fed. Reg. at 58,943–44. Approval predicated on surrogate endpoints requires that the applicant agree to conduct postmarketing studies relating to the clinical endpoints. See 21 C.F.R. §§ 314.510, 601.41.

<sup>70</sup> See 21 C.F.R. §§ 314.520(a), 314.550, 601.42(a), 601.45.

<sup>71</sup> See *supra* note 49 (describing limits on the power to preclear advertising); *infra* note 78 (discussing limitations on the power to restrict distribution). The FDA responded that the statute provided it with sufficient flexibility to impose these various conditions for accelerated approvals. See 57 Fed. Reg. at 58,949, 58,951 (alluding to the “spirit” of the statute); *id.* at 58,953–54 (citing its broad rulemaking authority); see also Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 308–15 (2001) (defending these initiatives).

<sup>72</sup> See 21 C.F.R. §§ 314.530, 601.43 (providing the applicant with only an informal hearing prior to revocation).

traditional approval process.”<sup>73</sup> With potentially millions of dollars in revenue foregone for each additional month awaiting approval,<sup>74</sup> eligible drug companies could not afford to decline the invitation to make use of these accelerated procedures, and the industry never challenged the rules in court. Five years later, Congress belatedly authorized these special procedures for what it called “fast track” review,<sup>75</sup> and, thanks to these initiatives, the agency has succeeded in rapidly approving important new therapies.<sup>76</sup>

In the last decade, as the pendulum has swung from complaints about excessive agency caution in approving critically needed treatments to criticisms about excessive haste in approving sometimes less-than-critical (a.k.a. “lifestyle”) drugs that turn out to pose undue risks, the FDA has shown interest in developing more tailored risk management strategies. These efforts might include restricting distribution to certain specialists,<sup>77</sup> patient informed consent requirements, struc-

<sup>73</sup> 57 Fed. Reg. at 58,955. The FDA also explained that no court had interpreted the statute as requiring a formal evidentiary hearing before withdrawing approval, but that its own regulations provided for such a hearing. *See id.* Although the agency may utilize a summary judgment procedure to deny hearing requests when it withdraws its approval of a new drug, *see Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–22 (1973), it must provide a hearing when genuine issues are in dispute, *see id.* at 623; *Edison Pharm. Co. v. FDA*, 513 F.2d 1063, 1072 (D.C. Cir. 1975); *Sterling Drug Inc. v. Weinberger*, 503 F.2d 675, 680–83 (2d Cir. 1974). The FDA also argued that the less formal hearing procedure that it provided for withdrawals of accelerated approvals would give the applicant adequate notice and opportunity to be heard. *See* 57 Fed. Reg. at 58,955.

<sup>74</sup> *See User Fees for Prescription Drugs: Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 102d Cong. 10 (1992) (statement of David A. Kessler, Comm’r, FDA) (“For a drug that raises \$200 million a year in annual sales, assuming an 80 percent gross margin, every additional month of delay the Agency takes to review an application would cost the company about \$10 million in lost opportunity.”); *see also* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 160–61 (2003); Peter Landers, *Drug Firms See Costs Increase to Bring a Product to Market*, WALL ST. J., Dec. 8, 2003, at B4 (\$1.7 billion).

<sup>75</sup> *See* FDAMA, Pub. L. No. 105-115, § 112, 111 Stat. 2296, 2309–10 (codified at 21 U.S.C. § 356 (2000)); *see also id.* § 103, 111 Stat. at 2299–304 (codified as amended at 21 U.S.C. §§ 379g–379h) (reauthorizing the imposition of user fees); Deborah G. Parver, Comment, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 ADMIN. L. REV. 1249 (1999); Diedtra Henderson, *Drug Makers Lobby US to Hike FDA Funds*, BOSTON GLOBE, July 13, 2006, at E1 (reporting that in FY2004 the agency collected \$232 million in user fees, which accounted for more than half of its budget for new drug reviews, and had doubled its review staff since 1992).

<sup>76</sup> *See, e.g.*, Mary K. Olson, *Managing Delegation in the FDA: Reducing Delay in New-Drug Review*, 29 J. HEALTH POL. POL’Y & L. 397, 406, 426 (2004); Marc Kaufman, *FDA Clears Once-a-Day AIDS Drug: Single-Pill Regimen Hailed as Milestone*, WASH. POST, July 13, 2006, at A1 (“The FDA has approved 28 products in the United States to treat HIV infection—most of them as high-priority applications.”); *cf.* Gardiner Harris, *F.D.A. Responds to Criticism with New Caution*, N.Y. TIMES, Aug. 6, 2005, at A1; Anna Wilde Mathews & John Hechinger, *Are Too Many Unproven Drugs Receiving FDA Early Approval?: Process Comes Under Scrutiny*, WALL ST. J., Mar. 1, 2005, at B1.

<sup>77</sup> *See* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 654 (2003) (suggesting that only reproductive endocrinologists should get access to fertility drugs); Lars Noah, *Challenges in the Federal Regulation*

tured postmarket surveillance, and mandatory concomitant therapy or patient monitoring. In addition, the agency might seek to prohibit certain off-label uses, perhaps in those situations where the labeling specifically contraindicates a use. Whether or not drugs qualify for fast track status, serious questions exist about the FDA's power to impose such restrictions under its current statutory authority,<sup>78</sup> but the agency generally has managed to encourage pharmaceutical manufacturers to accept such limitations as a condition of product approval.<sup>79</sup>

In some cases, physicians must register with the manufacturer—attesting that they understand the risks and benefits of a particular drug—before they may prescribe it.<sup>80</sup> For instance, when it approved Thalomid® (thalidomide) for the treatment of leprosy patients, the FDA conditioned approval on extremely strict marketing controls because of the serious risk of birth defects: distribution only through specially registered physicians and pharmacists, and tracking of patients, who must agree to use two forms of contraception and undergo frequent pregnancy tests.<sup>81</sup> The agency secured comparable distribu-

---

*of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 64 (2003) (“[T]he government might limit access to those medical specialists who usually encounter persons suffering severe or chronic pain—including, for instance, oncologists and orthopedic surgeons along with pain specialists—in the hopes that such specialists would better resist the tendency to prescribe Schedule II analgesics for patients for whom milder agents would work equally well.”); Scott B. Markow, Note, *Penetrating the Walls of Drug-Resistant Bacteria: A Statutory Prescription to Combat Antibiotic Misuse*, 87 GEO. L.J. 531, 546–47 (1998) (suggesting that only infectious disease specialists in hospitals be permitted to use the latest antibiotics). In approving the expanded use of a biosynthetic growth hormone to treat very short children, the FDA persuaded the manufacturer to market this new use only to pediatric endocrinologists. See Jeff Swiatek, *FDA OKs Lilly Growth Drug*, INDIANAPOLIS STAR, July 26, 2003, at 1C.

<sup>78</sup> See *Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974) (invalidating FDA restrictions on the distribution of methadone as a condition of approval), *aff'd per curiam*, 530 F.2d 1054 (D.C. Cir. 1976); Mark A. Hurwitz, Note, *Bundling Patented Drugs and Medical Services: An Antitrust Analysis*, 91 COLUM. L. REV. 1188, 1192–95 (1991); see also Anna Wilde Mathews & Leila Abboud, *FDA Approves Generic OxyContin*, WALL ST. J., Mar. 24, 2004, at A3 (“[T]he FDA has never limited any opioid to certain pharmacies, and agency officials say they don’t have the authority to block certain physicians from prescribing a drug.”).

<sup>79</sup> See Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 153, 188–91 (2004). In a recent commentary, one former FDA official (who had just left his post as a deputy commissioner) explained that risk-management plans “already guide the use of about 30 marketed drugs as part of ‘voluntary’ arrangements with drug companies.” Scott Gottlieb, Op-Ed., *Prescription for Trouble*, WALL ST. J., Mar. 6, 2007, at A19.

<sup>80</sup> See Francesca Lunzer Kritz, *Still Irritable, Still Waiting: After Return to Market, Lotronex Can Be Hard to Get*, WASH. POST, Feb. 11, 2003, at F1 (discussing restrictions on access to a drug used for the treatment of irritable bowel syndrome, and explaining that similar physician registration requirements apply to felbamate (used for epilepsy) and clozapine (used for schizophrenia)).

<sup>81</sup> See Rita Rubin, *Thalidomide Could Guide Use of Drugs That Risk Birth Defects*, USA TODAY, July 22, 1998, at 7D; see also Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1 (“If any doctors or pharmacists refuse to comply with the distribution rules, their privileges to prescribe or dispense the drug

tion restrictions in connection with Accutane® (isotretinoin)<sup>82</sup> and Mifeprex® (mifepristone).<sup>83</sup>

Perhaps the power to license implies a power to impose conditions on approval. Congress has, for instance, invited the FDA to impose such other conditions on product approvals as it may deem necessary in certain limited circumstances.<sup>84</sup> Beyond such situations, however, courts should hold agencies to the limits of their enabling statutes.<sup>85</sup> Congress has authorized the FDA to impose certain conditions on food additive and new drug approvals (e.g., warning requirements); it has not explicitly authorized other requirements (e.g., recalls or postmarketing surveillance); and it implicitly or explicitly forbade the imposition of still other requirements (e.g., preclearance of drug advertising)—the latter category should be off limits, leaving parties at most to bargain over commitments about which Congress expressed no intent one way or another.

might be revoked.”); Jamie Talan, *Thalidomide’s Legacy*, WASH. POST, Jan. 4, 2000, at F10 (reporting that physicians who prescribe the drug receive from the manufacturer an “education kit, including a consent form to be signed by both doctor and patient”).

<sup>82</sup> See Ami E. Doshi, Comment, *The Cost of Clear Skin: Balancing the Social and Safety Costs of iPLEDGE with the Efficacy of Accutane (Isotretinoin)*, 37 SETON HALL L. REV. 625, 630–45 (2007); see also Gardiner Harris, *F.D.A. Imposes Tougher Rules for Acne Drug*, N.Y. TIMES, Aug. 13, 2005, at A1 (“The new program is the latest and by far most drastic of more than 40 efforts by the agency in the last 22 years to reduce harm from Accutane . . . while allowing its continued use.”); *Anti-Pregnancy Effort Fails*, WASH. POST, July 31, 2007, at A10 (“The new figures show the 122 pregnancies reported in the first year of the iPledge program are about the same as the number reported annually before the FDA tightened restrictions on the drug . . .”).

<sup>83</sup> See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 584–86 (2001); *id.* at 581–82 (“Mifepristone’s eligibility to use such [accelerated review] procedures remains something of a mystery: the drug did not provide the type of therapeutic benefit over existing treatments for a serious illness that the regulations contemplated as justifying an expedited approval process. . . . Apparently the agency took this route so that it could better justify imposing otherwise unauthorized restrictions on the use and distribution of the drug . . .”); Gina Kolata, *Ready in 4 Weeks: Woman Will Be Able to End Early Pregnancy in Her Own Home*, N.Y. TIMES, Sept. 29, 2000, at A1 (“A woman will be given written instructions . . . , and her doctor must sign a statement saying they have read the instructions and will comply with them exactly.”). The FDA has not, however, enforced these restrictions. See Marc Kaufman, *Death After Abortion Pill Reignites Safety Debate*, WASH. POST, Nov. 3, 2003, at A3; see also Rob Stein, *As Abortion Rate Drops, Use of RU-486 Is on the Rise*, WASH. POST, Jan. 22, 2008, at A1.

<sup>84</sup> See 21 U.S.C. § 348(c)(1)(A) (2000) (food additives); *id.* § 360j(e)(1)(B) (restricted devices).

<sup>85</sup> “One may well ask how far an agency might go in conditioning licenses. In addition to postmarketing studies and the waiver of hearing rights, . . . could the FDA condition product approvals on agreements not to engage in broadcast advertising or not to raise drug prices faster than the rate of inflation?” Noah, *supra* note 26, at 883; see also *id.* (“Could the Agency demand waivers of patent rights or promises to contribute some percentage of profits to a public health agency (or perhaps the Republican National Committee)?”); *id.* at 933 (“[T]he FDA presumably understands that it cannot condition product approvals on voluntary price controls or charitable contributions, even though Congress has not expressly prohibited such demands.”).

### C. Expanding Regulatory Jurisdiction

The FDA has shown tremendous creativity in construing the reach of its authority, as, for example, it did one decade ago in announcing that it would control human cloning experiments.<sup>86</sup> The agency must, of course, grapple with advances in science and technology that Congress could not have anticipated many decades earlier, including the advent of genetically modified foods,<sup>87</sup> bioengineered drugs,<sup>88</sup> nanotechnology,<sup>89</sup> tissue engineering and regenerative medicine,<sup>90</sup> gene therapy,<sup>91</sup> and pharmacogenomics.<sup>92</sup> Conversely, the FDA has at times tried to escape the occasionally precise (and, to its mind, inflexible) directives issued by Congress.<sup>93</sup>

---

<sup>86</sup> See Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85, 97–100 (2001); see also Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical “Devices” from Medical “Devices” Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 831–50 (1993) (discussing the FDA’s creativity in using its power to regulate medical devices to reach other types of products). See generally FRED H. DEGNAN, *FDA’S CREATIVE APPLICATION OF THE LAW* (2d ed. 2006).

<sup>87</sup> See Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 405–13 (1998); see also *id.* at 332, 401–05, 413–21 (discussing the challenges posed by other novel food additives such as the artificial sweetener aspartame and the fat-substitute olestra).

<sup>88</sup> See Lars Noah, *Managing Biotechnology’s [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4 (2006); *id.* at 37–38 (describing difficulties with attempts to extend to biotech drugs the FDA’s authority to approve cheaper generics); *id.* at 39–43 (discussing “pharming,” which refers to the engineering of crops or livestock to produce pharmaceuticals); see also *id.* at 50–51 & nn.234, 236 (applauding the FDA’s decision not to subject a bioengineered aquarium fish to its new animal drug approval authority as “an exercise of healthy institutional restraint by declining uncertain jurisdiction”).

<sup>89</sup> See *id.* at 61 (“If biotechnology rendered untenable the traditional distinction between drugs and biologics, then nanomedicine may do the same to the line separating devices and biologics.”); Keay Davidson, *FDA Urged to Limit Nanoparticle Use in Cosmetics and Sunscreens*, S.F. CHRON., May 17, 2006, at A4; Rick Weiss, *Nanotechnology Risks Unknown: Insufficient Attention Paid to Potential Dangers, Report Says*, WASH. POST, Sept. 26, 2006, at A12.

<sup>90</sup> See Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1146–47 & n.66 (2004); Michael Leachman, Comment, *Regulation of the Human Tissue Industry: A Call for Fast-Track Regulations*, 65 LA. L. REV. 443 (2004); Rick Weiss, *First Bladders Grown in Lab Transplanted: Breakthrough Shows Promise for Creating Other Human Organs*, WASH. POST, Apr. 4, 2006, at A1.

<sup>91</sup> See Noah, *supra* note 88, at 17; Rick Weiss, *Death Points to Risks in Research: One Woman’s Experience in Gene Therapy Trial Highlights Weaknesses in the Patient Safety Net*, WASH. POST, Aug. 6, 2007, at A1.

<sup>92</sup> See Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients’ Genetic Profiles*, 43 JURIMETRICS J. 1, 12–24 (2002); *id.* at 11 (“Federal regulators—accustomed to large clinical trials using a diverse subject population and designed to test drugs with significant market potential, centralized manufacturing facilities, and uniform labeling—will have to cope with a radically altered model of drug development and use.”); Janet Woodcock, *FDA Policy on Pharmacogenomic Data in Drug Development*, 66 LA. L. REV. 91 (2005); Symposium, *Pharmacogenomics*, 46 JURIMETRICS J. 237 (2006); Gina Kolata, *A Tale of Two Drugs Hints at Promise for Genetic Testing*, N.Y. TIMES, July 11, 2006, at F1.

<sup>93</sup> See Noah & Merrill, *supra* note 87, at 443 (“Out of necessity, the [FDA] has been forced to improvise, sometimes evading its unrealistic directives from Congress.”); *id.* at 395–401 (discussing application of the Delaney clause to suspected carcinogens); *id.* at

In the early 1970s, the FDA's Chief Counsel expressed the view that the agency's enabling statute represented a broad "constitution," authorizing it to protect the public health by any necessary and proper means, rather than a limited and precise delegation of power from Congress.<sup>94</sup> Accordingly, unless explicitly prohibited, "the fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the [FDA] exerting initiative and leadership in the public interest."<sup>95</sup> His successor in that office, though writing many years after leaving government service, analogized the FDCA to an unfinished set of architectural blueprints.<sup>96</sup> As explained by one of the chief congressional "architects" of detailed amendments to the original statutory provisions governing medical devices, however, the greater specificity of this legislation sought "to make clear that Congress wanted the agencies to follow the Congressional mandate more carefully and not go off on bureaucratic binges pursuing bureaucratic whims."<sup>97</sup>

---

422–28 (identifying persistent agency failures to meet deadlines for taking action); *see also id.* at 382–85 (describing the FDA's creation of a category of "interim" food additives); *id.* at 411–13, 433–35 (comparing abbreviated premarket notification procedures that the agency has applied to medical devices and other products in order to avoid the difficulties associated with full premarket review).

<sup>94</sup> *See* Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 178 (1973) ("[T]he Act must be regarded as a constitution. . . . The mission of the [FDA] is to implement [the Act's fundamental] objectives through the most effective and efficient controls that can be devised.").

<sup>95</sup> *Id.* at 179; *see also* United States v. Dotterweich, 320 U.S. 277, 280 (1943) (suggesting that the FDA's enabling statute be treated as "a working instrument of government and not merely as a collection of English words"); *cf.* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 248 n.10 (2d Cir. 1977) ("[W]e think Mr. Hutt's language to be conscious hyperbole. The test is . . . whether delegation may be fairly inferred from the general purpose."). Agency officials have, at times, continued to take this expansive view of their jurisdiction. *See, e.g.*, David A. Kessler & Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising and Promotion*, 264 JAMA 2409, 2411 (1990) ("Until further judicial decisions or congressional action clarifies the FDA's specific authority in the area of [drug product] promotion, the FDA will continue to assert broad jurisdiction.").

<sup>96</sup> *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1757 (1996) ("[A]s in any long-running regulatory program, FDA officials have served as both general contractors and sub-contractors in constructing the modern legal framework from the legislature's working drawings."); *cf. id.* at 1864 ("Nor are FDA's decisions—to grant, withhold, or delay approval—commonly challenged in court. . . . The FDA product approval system is, in short, remarkably free from conventional legal constraint.").

<sup>97</sup> Paul G. Rogers, *Medical Device Law—Intent and Implementation*, 36 FOOD DRUG COSM. L.J. 4, 4 (1981) (noting that "the philosophy behind the writing of the Medical Device Amendments [of 1976] was to be so specific in language that less discretion was left to the agency"); *see also* 62 Cases More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 600 (1951) ("In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.") (quoted with approval in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000)); *United States v. Parkinson*, 240 F.2d 918, 921 (9th Cir. 1956) ("The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. A passion and a

During the 1990s, the FDA asserted the authority to regulate tobacco products as medical devices, and some commentators invoked the constitutional metaphor to defend this creative effort against claims that the agency had overstepped the limits on its jurisdiction.<sup>98</sup> One scholar took the idea a step further and argued that enabling statutes express little more than broad goals to pursue, much like common law norms that judges explicate in the course of resolving private disputes.<sup>99</sup> Elsewhere, I have argued at length against these positions,<sup>100</sup> especially as used in an attempt to justify the FDA's assertion of jurisdiction over tobacco products.<sup>101</sup> In the course of invalidating the agency's restrictions on cigarette advertising, the Supreme

---

zeal to crusade affects their operations."); H. Thomas Austern, *Philosophy of Regulation: A Reply to Mr. Hutt*, 28 FOOD DRUG COSM. L.J. 189, 191 (1973) (criticizing the suggestion that "a well-motivated administrative agency can legally do what it alone deems desirable unless Congress has *in advance* specifically prohibited it").

<sup>98</sup> See, e.g., James T. O'Reilly, *Tobacco and the Regulatory Earthquake: Why the FDA Will Prevail After the Smoke Clears*, 24 N. KY. L. REV. 509, 515 (1997) ("If the statute is a constitution then the FDA can reach anywhere and regulate anything not proscribed by Congress.").

<sup>99</sup> See Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1062 (1998) ("In applying the FDCA to tobacco, the FDA performed a lawful common law function, one that also has a high degree of democratic legitimacy."); see also *id.* at 1019 ("Operating as common law courts, agencies have, as they should, considerable power to adapt statutory language to changing understandings and circumstances."); *id.* at 1060 (describing dynamic interpretation of statutes as "an administrative task, not a judicial one," and calling the common law decision making of agencies "an omnipresent feature of the modern legal landscape"); *id.* at 1068 ("As a matter of simple practice, administrative agencies have become America's common law courts. . . . In view of agency self-interest and the exercise of power by self-interested private groups, this development is not without risks. On balance, however, it is highly salutary.").

<sup>100</sup> See Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1530 (2000) ("The rush to defend seemingly desirable regulatory initiatives should not blind us to the potentially serious institutional consequences of adopting a stance of excessive faith in administrative agencies."); *id.* at 1498 ("As creatures of statutes lacking any independent constitutional pedigree, agencies cannot invoke some kind of inherent authority to justify actions that find no warrant in their enabling legislation."); *id.* at 1504 ("In the end, no single metaphor accurately captures the variety of organic acts, and Congress may have shifted from the open-ended and aspirational delegations of earlier this century to the somewhat more precise and constrained enabling statutes of today.").

<sup>101</sup> See Lars Noah, *Regulating Cigarettes: (Non)sense and Sensibility*, 22 S. ILL. U. L.J. 677, 691 (1998) (arguing that the FDA "should not be free to ignore the outer boundaries of its delegated authority in pursuit of a well-meaning crusade against a public health problem"); *id.* at 685–86 (criticizing the FDA's request for serial *Chevron* deference, with each step compounding the initial error); see also Lars Noah, *Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules*, 51 HASTINGS L.J. 255, 305–06 & n.193 (2000) ("[R]egulatory officials [are] busy cloaking themselves in that safe haven from the outset of a rulemaking or other proceeding, instead of attempting to offer persuasive explanations defending the reasonableness of their preferred interpretations and then only later, in defending against a judicial challenge, invoking *Chevron* as a kicker.").

Court sensibly declined to view the FDCA as akin to an adaptable constitution.<sup>102</sup>

## II

### INDIFFERENCE TO THE CONSTITUTION

Although courts expect agencies to take the Constitution into account,<sup>103</sup> at times the FDA has shown a marked indifference to constitutional limits on its range of actions.<sup>104</sup> During the 1990s, for instance, the Washington Legal Foundation (WLF) challenged the agency's efforts to limit the dissemination of information by manufacturers of drugs and medical devices.<sup>105</sup> Once a new drug or device receives marketing clearance from the FDA, the manufacturer can promote it only for those indications set forth in the approved labeling, though physicians remain free to use the product for other purposes.<sup>106</sup> The FDA had become concerned that some sellers had

---

<sup>102</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (emphasizing that “an administrative agency’s power to regulate in the public interest must always be grounded in a valid grant of authority from Congress”); see also *id.* at 165 (Breyer, J., dissenting) (unsuccessfully invoking the constitutional metaphor); Marcia Coyle, *More to FDA Ruling Than Tobacco?*, NAT’L L.J., Apr. 3, 2000, at A4. In recent years, lower courts also have become less willing to countenance expansive interpretations of the agency’s jurisdiction. See, e.g., *Nutritional Health Alliance v. FDA*, 318 F.3d 92, 98–101 (2d Cir. 2003) (holding that the agency’s authority to prevent adulteration, including through the issuance of GMPs, did not authorize the promulgation of a rule—that the agency had made in response to incidents of poisoning in children—requiring sellers of certain iron-containing products to distribute those products in unit-dose packages); *Ass’n Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (“Section 371 does not constitute an independent grant of authority that permits FDA to issue *any* regulation the agency determines would advance the public health. Rather, § 371 permits the FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress.”).

<sup>103</sup> See *Nat’l Treasury Employees Union v. Fed. Labor Relations Auth.*, 986 F.2d 537, 539–40 (D.C. Cir. 1993) (noting that an agency should consider First Amendment constraints when interpreting its enabling act); see also Trevor W. Morrison, *Constitutional Avoidance in the Executive Branch*, 106 COLUM. L. REV. 1189, 1215, 1223–26, 1237 (2006).

<sup>104</sup> See Lars Noah, *What’s Wrong with “Constitutionalizing Food and Drug Law”?*, 75 TUL. L. REV. 137, 139–46 (2000) [hereinafter Noah, *What’s Wrong*]; see also Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 243–58 (2007) (questioning the constitutionality of requirements that patients use contraceptives as a condition of access to drugs that carry a risk of causing birth defects); Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 385–91 (2006) [hereinafter Noah, *Treat Yourself*] (arguing that an involuntary Rx-to-OTC drug switch might raise a Takings problem).

<sup>105</sup> See *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 27–28 (D.D.C. 1995); see also Edmund Polubinski III, Note, *Closing the Channels of Communication: A First Amendment Analysis of the FDA’s Policy on Manufacturer Promotion of “Off-Label” Use*, 83 VA. L. REV. 991, 1019–34 (1997).

<sup>106</sup> See Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PRODS. & TOXICS LIAB. 139, 140–44 (1994); see also David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1025 (2006) (finding “that about 21% of all estimated uses for commonly prescribed medications were off-label, and that 15% of all estimated uses lacked scientific evidence of therapeutic efficacy”).

promoted such “off-label” uses indirectly, for instance by sponsoring continuing medical education (CME) programs and scientific symposia featuring discussions about unapproved uses of their products and by providing health care professionals with “enduring materials” (namely, textbooks or reprints of published articles) mentioning such uses. In 1992, the agency issued a “draft policy statement” to inform the industry that it might regard such activities as unlawful product promotions unless manufacturers took certain steps to ensure editorial independence.<sup>107</sup> Although characterized at the time as a “safe harbor,”<sup>108</sup> these announcements reflected an agency crackdown on perceived industry excesses rather than an enlightened effort to liberalize existing prohibitions that seemed unduly restrictive.

The FDA formulated its off-label promotion policies in a manner designed to evade normal administrative law constraints. The draft policy statement evolved into a pair of “draft guidance” documents on enduring materials published in 1995,<sup>109</sup> which were finalized one year later,<sup>110</sup> and into a “final guidance” document on CME programs published in 1997.<sup>111</sup> Although not formally binding, even in their final form,<sup>112</sup> these various FDA guidelines unmistakably sought to alter the behavior of pharmaceutical and medical device companies. The federal district court understood these realities when, in the first phase of the WLF litigation, it rejected the FDA’s claim that the challenge to the draft policy statement was not ripe for judicial review; Judge Lamberth speculated that the FDA would “threaten[ ] (but never actually initiat[e]) enforcement procedures against companies which failed to comply with the agency’s *de facto* policy.”<sup>113</sup>

After the agency replaced its draft policy statement with guidance documents, the district court held them unconstitutional, and it enjoined any agency attempts to apply these restrictive policies.<sup>114</sup> Only

---

<sup>107</sup> See Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412 (Nov. 27, 1992).

<sup>108</sup> See David G. Adams, *FDA Regulation of Communications on Pharmaceutical Products*, 24 SETON HALL L. REV. 1399, 1409–17 (1994) (describing the origins of this policy, and defending its constitutionality).

<sup>109</sup> See Advertising and Promotion; Draft Guidances, 60 Fed. Reg. 62,471 (Dec. 6, 1995).

<sup>110</sup> See Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

<sup>111</sup> See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997).

<sup>112</sup> See, e.g., *id.* at 64,094 n.1 (“This guidance represents the Agency’s current thinking . . . and does not operate to bind FDA or the industry . . .”); see also *supra* note 24 and accompanying text (discussing the limited force of FDA guidelines).

<sup>113</sup> Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 34 (D.D.C. 1995); see also *id.* at 36 (“[F]ew if any companies are willing to directly challenge the FDA in this manner. . . . [M]anufacturers are most reluctant to arouse the ire of such a powerful agency.”).

<sup>114</sup> See Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 74 (D.D.C. 1998), *amended* by 36 F. Supp. 2d 16, 19–20 (D.D.C. 1999), *amended sub nom.* Wash. Legal Found. v. Hen-

after Congress enacted relevant provisions in 1997 did the FDA bother to undertake notice-and-comment rulemaking to promulgate formally binding requirements to control the dissemination of enduring materials describing off-label uses of drugs and medical devices.<sup>115</sup> After further briefing, Judge Lamberth held that even these less onerous restrictions violated the First Amendment.<sup>116</sup>

The FDA's string of setbacks in the courts must have come as something of an unpleasant surprise to agency officials. The deference that judges historically have shown the FDA, bordering on the position that the agency could do no wrong, did not surface in newer opinions that express some impatience with the FDA's seeming disregard for the First Amendment. As these courts pointed out, some of the agency's responses to the constitutional objections bordered on the frivolous.<sup>117</sup> Nonetheless, the appellate court lifted most of Judge Lamberth's injunction.<sup>118</sup> During oral argument, the government had offered a fanciful interpretation of the relevant statutory provision as creating no directly enforceable restrictions but instead a "safe harbor,"<sup>119</sup> suggesting that a company not moored in this safe harbor still might not run afoul of the preexisting prohibitions against off-label drug promotion.<sup>120</sup>

---

ney, 56 F. Supp. 2d 81, 87 (D.D.C. 1999), *vacated in part and appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

<sup>115</sup> See *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 (2007)).

<sup>116</sup> See *Henney*, 56 F. Supp. 2d at 87.

<sup>117</sup> See *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (calling "almost frivolous" the FDA's argument that health claims for dietary supplements were inherently misleading); *Henney*, 56 F. Supp. 2d at 85 (calling "preposterous" the FDA's argument that FDAMA need not comply with the First Amendment because it affirmatively permits truthful speech); *Friedman*, 13 F. Supp. 2d at 59 ("This court is hard pressed to believe that the agency is seriously contending that 'promotion' of an activity is conduct and not speech, or that 'promotion' is entitled to no First Amendment protection."); *id.* at 66 (dismissing as "tautological" the FDA's argument that off-label promotion gets no constitutional protection because it violates statute); see also *id.* at 67 ("In asserting that any and all scientific claims about . . . prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.").

<sup>118</sup> See *Wash. Legal Found. v. Henney*, 202 F.3d 331, 336–37 (D.C. Cir. 2000).

<sup>119</sup> See *id.* at 335 ("In response to questioning at oral argument, the government definitively stated that it subscribed to the 'safe harbor' interpretation and further explained that, in its view, neither the FDAMA nor the CME Guidance independently authorizes the FDA to prohibit or to sanction speech."); see also Noah, *What's Wrong*, *supra* note 104, at 146–48 (explaining the flaws in this interpretation).

<sup>120</sup> Although perhaps reflecting a plausible characterization of the agency's earlier guidance documents, this reading seemingly ignored the effect of FDAMA's provision that makes violations a distinct "prohibited act" under the statute that can trigger the imposition of formal sanctions, see 21 U.S.C. § 331(z) (2000), and it also disregarded the practical consequences of any such safe harbor. After remand, Judge Lamberth concluded that nothing remained of the injunction. See *Wash. Legal Found. v. Henney*, 128 F. Supp. 2d

At other times, when it happens to suit the purposes of the incumbent administration, the FDA has seemed overly attentive to possible constitutional limits on its authority—one might say that this amounts to a selective preoccupation with constitutional constraints to justify indifference to statutory directives.<sup>121</sup> In *Thompson v. Western States Medical Center*,<sup>122</sup> the Supreme Court invalidated a statutory prohibition on advertising by pharmacists about compounded drugs. As an exercise in constitutional jurisprudence, the case hardly broke new ground—the members of the Court evaluated the question using a well-worn form of intermediate scrutiny, differing in their respective assessments of whether the government had demonstrated a sufficient nexus between the means selected and its asserted interest in preventing the risks associated with the commercialization of unapproved new drugs under the guise of pharmacy compounding.<sup>123</sup> The decision did stand out as the first time that the Supreme Court had invalidated a recently enacted congressional restriction on advertising, thereby showing little deference to the judgments of a coordinate branch of government, and it certainly solidified a trend evident over the last decade of taking seriously the constitutional rights of entities wishing to engage in commercial speech.

---

11, 15 (D.D.C. 2000). In 2006, because of a sunset provision in FDAMA, the FDA became free again to formulate its own policies governing the dissemination of enduring materials that discussed off-label uses. See Gardiner Harris, *F.D.A. Seeks to Broaden Range of Use for Drugs*, N.Y. TIMES, Feb. 16, 2008, at B1 (reporting that the agency had proposed even more flexible guidelines).

<sup>121</sup> Cf. Morrison, *supra* note 103, at 1236–37, 1259; *id.* at 1195 (explaining that in some instances, “we may fairly suspect that the government has invoked avoidance in an effort to cover a fundamentally political decision with the veneer of legal obligation”); *id.* at 1229 (recognizing that “the executive’s use of avoidance to construe a speech-restrictive statute would generally redound to the benefit of a private actor at the expense of the executive branch”). The FDA also has deployed make-weight statutory arguments when seeking to resist taking action that it finds distasteful. See Noah, *Treat Yourself*, *supra* note 104, at 375 n.88 (discussing inexplicable delays in switching an emergency contraceptive product to nonprescription status).

<sup>122</sup> 535 U.S. 357 (2002).

<sup>123</sup> Justice O’Connor’s opinion for the majority offered a somewhat cramped reading of the government’s asserted interest—as simply wanting to draw a line between large-scale drug manufacturing and small-scale pharmacy compounding—and then rejected the government’s argument that the act of advertising the availability of particular drugs served as a proxy for commercial activity that should have to comply with the FDA’s premarket approval requirements. See *id.* at 369–77. She suggested a number of other alternatives for making such a distinction without needing to restrict speech. See *id.* at 372–73. The majority’s unforgiving application of the nexus requirement mimicked the least restrictive means test normally reserved for strict scrutiny cases and demanded a probably unattainable level of legislative precision. The majority also failed to concede that the legislation had not in fact prevented pharmacists from advertising the fact that they offered compounding services in general or that they offered particular types of drugs—Congress simply insisted that, before doing the latter, pharmacists satisfy the FDA’s demanding new drug approval requirements or face the risk of sanctions identical to those applicable to other entities that might attempt to sell unapproved new drugs.

In some ways, the FDA's reaction to the Court's fairly narrow decision represented the most startling aspect of this litigation. Instead of a grudging response, the agency took it as an occasion to reconsider its entire approach to regulation. Traditionally, the FDA has depended on its ability to control product information.<sup>124</sup> Less than three weeks after the Court announced its decision in *Western States*, however, the agency published a notice inviting public comments on a series of questions that, while carefully framed in neutral terms, implied that it might welcome suggestions favoring the deregulation of labeling and advertising.<sup>125</sup> The agency almost never moves with such dispatch.

The FDA's announcement represented a dramatic about-face for an agency that until recently had taken the position that it need not concern itself with the First Amendment.<sup>126</sup> Although an admirable act of self-examination, the announcement also reflected a significant shift in personnel at the agency in 2001: the new Chief Counsel had spent a number of years representing the WLF in its challenges to other FDA policies. The agency's suggestion that it might deregulate labeling and advertising attracted substantial attention.<sup>127</sup> Nothing, however, ever came of the FDA's remarkable proposal to get out of the business of controlling the dissemination of information, and in recently revising the format and content requirements for prescription drug labeling, the agency offered a brief constitutional defense without ever mentioning *Western States*.<sup>128</sup>

#### CONCLUSION

Necessity may be the mother of invention, but over the course of a century of struggling to protect the public health with its limited statutory powers and often inadequate resources, the FDA evidently has institutionalized a practice of cavalierly ignoring legal constraints. At times, the agency's creativity has received belated endorsement from Congress or the courts, though, on other occasions, members of

---

<sup>124</sup> LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 317 (2d ed. 2007).

<sup>125</sup> See Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002). It took another three weeks before the FDA responded to the Court's more limited holding by issuing a revised guidance document to govern pharmacy compounding. See Pharmacy Compounding Compliance Policy Guide; Availability, 67 Fed. Reg. 39,409 (June 7, 2002).

<sup>126</sup> See *supra* note 117.

<sup>127</sup> See, e.g., Marc Kaufman, *FDA Seeks Public Comment on Rules' Constitutionality: Advocates Worry Agency Might Loosen Its Oversight*, WASH. POST, May 15, 2002, at A25; Gina Kolata, *Stung by Courts, F.D.A. Rethinks Its Rules*, N.Y. TIMES, Oct. 15, 2002, at F1.

<sup>128</sup> See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3964 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314 & 601 (2007)); see also Julie Schmit, *Drug Ads to Get More FDA Scrutiny*, USA TODAY, Feb. 25, 2008, at 1B.

these branches have condemned it for showing excessive initiative. Most of the FDA's decisions, however, escape any such scrutiny, which means that nothing other than humility and self-restraint stand in the way of regulatory overreaching. It seems that whenever, in the course of pursuing its vision of the public good, this little agency found that it could get away with doing something, the FDA blithely disregarded its obligation of fidelity to constitutional and statutory constraints. Even if we applaud the ends that the agency sought to achieve, such a pattern of behavior represents a serious affront to the rule of law.

