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Jeffrey M. Senger

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# EMERGING ISSUES IN FDA REGULATION: WARNING LETTERS, INTERNET PROMOTION, AND TOBACCO

JEFFREY M. SENGER\*

The mission of the United States Food and Drug Administration (FDA) is to protect and promote the public health. The agency is charged with assuring the safety of America's foods; the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and the safety and security of cosmetics and products that emit radiation. Americans spend close to \$1.5 trillion a year on these products—about twenty percent of the entire consumer economy.<sup>1</sup> The FDA's Office of Chief Counsel (OCC) manages the legal work of the agency. This Article will discuss the organization of OCC,<sup>2</sup> along with several important issues now facing the agency: warning letters,<sup>3</sup> Internet promotion,<sup>4</sup> and tobacco.<sup>5</sup>

## I. ORGANIZATION OF OCC

OCC currently has about ninety lawyers and twenty support staff. The lawyers serve as both litigators and counselors. The litigators (about one-third of the office) represent FDA in federal court. OCC participates in both affirmative civil litigation (where the agency sues parties for violating the law) and defensive civil litigation (where parties sue FDA when they believe the agency has violated the law). The litigation team also includes about a dozen lawyers who prosecute criminal matters.

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\* Deputy Chief Counsel for the United States Food and Drug Administration, Department of Health and Human Services. A.B., Harvard College; J.D., Harvard Law School. This Article was adapted from the author's keynote speech for the *Emerging Issues in Food and Drug Law: A National Conference for Lawyers, Policy-Makers, and Corporate Leaders*, which was held at the University of Maryland School of Law on November 16, 2009.

1. U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2010: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 2 (2009), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153491.pdf>.

2. *See infra* Part I.

3. *See infra* Part II.

4. *See infra* Part III.

5. *See infra* Part IV.

OCC lawyers work with the Justice Department on all federal court litigation. Justice Department lawyers generally take the lead in making in-court arguments and serve as “first chair” in trials. OCC lawyers also participate in some arguments and trials, and they often take the lead on brief-writing, as they may have more substantive experience with FDA laws and regulations—particularly when working with an Assistant United States Attorney, as these lawyers must handle a wide variety of subject matters. A more specialized office within the Justice Department, the Office of Consumer Litigation, handles certain FDA-related matters. Because of their greater familiarity with FDA laws, this office often plays a more substantive role in litigation when it is involved.

OCC’s counselors work with each of the FDA’s product centers, advising the agency on legal matters involving drugs, biologic products, devices, foods, animal products, and now tobacco. They handle most agency issues that do not involve litigation and also advise litigators on certain litigation matters. They participate in agency rulemaking, review guidances, advise on legislation, clear press releases, handle administrative law questions, and provide counsel on legal issues involved with agency programs.

OCC is officially part of the Office of General Counsel of the Department of Health and Human Services (HHS). Thus, while OCC advises the FDA on a daily basis, it is not organizationally a part of the FDA. Instead, the office reports to the General Counsel of HHS, with a “dotted-line” relationship to the FDA Commissioner.<sup>6</sup> At the same time, the FDA pays the salaries of OCC employees, and OCC offices are co-located with FDA staff in suburban Maryland, rather than in downtown Washington, D.C., with most HHS staff.

FDA is itself a component of HHS, and the FDA Commissioner reports to the Secretary of HHS, who reports to the President.<sup>7</sup> Thus, the FDA is not an independent agency (like the Securities and Exchange Commission or the Federal Trade Commission), but rather it is a part of the presidential administration. This affects the agency in a number of ways. All testimony that FDA officials give before Congress must be reviewed and approved by the White House Office of Management and Budget, which often sends the testimony to other executive branch agencies for comment.<sup>8</sup> Annual FDA budget requests are made by the President as part of the administration’s formal budget. As mentioned above, all statements the agency makes in court must be approved by the Justice Department.

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6. U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF THE COMMISSIONER: ORGANIZATION CHART, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OrganizationCharts/UCM182115.pdf>; U.S. Dep’t of Health & Human Servs., Office of the General Counsel Organization Chart, <http://www.hhs.gov/about/orgchart/ogc.html> (last visited May 31, 2010).

7. See U.S. Dep’t of Health & Human Servs., U.S. Department of Health and Human Services Organization Chart, <http://www.hhs.gov/about/orgchart/> (last visited May 31, 2010).

8. Cf. Exec. Order No. 12866, 58 Fed. Reg. 51,735, 51,737 (Oct. 4, 1993) (describing the review function of the Office of Management and Budget).

That said, there are a relatively small number of political appointees at FDA. At noon on January 20, 2009, when President Obama took office, only three political positions changed hands: the Commissioner, the Chief Counsel, and the Special Assistant to the Commissioner.<sup>9</sup> To be sure, these are top positions in the agency, and while only three political positions turned over upon inauguration, some others left before the end of the administration. Nonetheless, the great bulk of the day-to-day work of the agency is done by its roughly 12,000 career employees.<sup>10</sup>

FDA works closely with many other federal agencies to fulfill its mission. Key partners include the Department of Justice on court litigation; the Federal Trade Commission on advertising issues; the Department of Agriculture on food matters; the Environmental Protection Agency on environmental and pesticide issues; the Federal Bureau of Investigation on criminal matters; the Department of State on international issues; the Customs Service on imported products; the Postal Service on mail fraud; the Alcohol and Tobacco Tax and Trade Bureau at the Treasury Department on alcohol and tobacco issues; the Drug Enforcement Administration on controlled substances; and more. Careful coordination is vital to ensure the government takes appropriate positions that meet the needs of all of these agencies.

OCC is headed by the Chief Counsel, who in recent years, and at various times in the past, has been appointed by the President.<sup>11</sup> The Chief Counsel is assisted by the Deputy Chief Counsel, who works on overall management of the office; the Deputy Chief Counsel for litigation, who supervises court-related matters; and the Deputy Chief Counsel for Program Review, who leads the counselors. The management team also includes three Associate Deputy Chief Counsels, one for litigation and two for counseling, and an Executive Officer.

The Chief Counsel (and, from time to time, the Deputy Chief Counsel) participates in a number of daily meetings with FDA leadership. Every Tuesday and Thursday, the Commissioner, Deputy Commissioners, and Chief Counsel meet at 8:45 a.m. in the Commissioner's office at the White Oak complex in Silver Spring, Maryland. Participants report on upcoming events of the day, discuss high-level agency management issues, and strategize about agency priorities. On

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9. S. COMM. ON HOMELAND SECURITY & GOV'T AFF., 110TH CONG., UNITED STATES GOVERNMENT: POLICY AND SUPPORTING POSITIONS 72-74 [hereinafter PLUMBOOK] (Comm. Print 2008), available at [http://www.gpoaccess.gov/plumbook/2008/2008\\_plum\\_book.pdf](http://www.gpoaccess.gov/plumbook/2008/2008_plum_book.pdf).

10. See, e.g., *Nomination of Andrew von Eschenbach and Paul Decamp: Hearing of the Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 11 (2006) (statement of Andrew von Eschenbach, Nominee to be Commissioner of Food and Drugs, Department of Health and Human Services), available at <http://bulk.resource.org/gpo.gov/hearings/109s/30085.pdf> (describing the "over-12,000 incredibly talented and highly trained professionals and staff . . . [as] epitomiz[ing] the true meaning of the word 'public servant'").

11. See PLUMBOOK, *supra* note 9, at 67 (listing the Associate General Counsel, Food and Drug Division as a noncareer appointment).

Mondays, Wednesdays, and Fridays, this group is joined by other senior staff members, including the Associate Commissioner for Regulatory Affairs, the Assistant Commissioner for Public Affairs, the Assistant Commissioner for Legislation, and the Directors of each of the Centers (drugs, biologics, devices, foods, veterinary medicine, and tobacco). Attendees report on activities of their office, including upcoming events. During crisis situations, such as an emerging outbreak, additional meetings are added (such as a recent 7:45 a.m. daily food safety meeting).

Attorneys in OCC also meet often with outside parties. Outside lawyers request meetings with our litigators to discuss pending or potential lawsuits, and with counselors to discuss actions they, or the agency, have taken or plan to take. Many times, OCC lawyers will schedule separate meetings with parties on each side of a dispute to ensure everyone has an opportunity to be heard. Meetings with OCC are focused on legal issues. A brief description of all meetings with the Chief Counsel is posted on the internet (consisting of a listing of all attendees and a general description of the topic).<sup>12</sup> Sometimes parties attempt to schedule meetings with OCC on scientific or policy issues, but these are more appropriately referred to the Centers or the Office of Policy.

## II. WARNING LETTER INITIATIVES

A significant recent initiative at FDA involves inspections and warning letters. Upon completion of an inspection of a regulated facility, an FDA form 483 is given to the facility's management to notify them of apparent violations that were observed during the inspection.<sup>13</sup> The form lists observations without constituting a final agency determination of a violation.<sup>14</sup> It requests that the company make any objections to the findings and provide plans to implement corrective action.<sup>15</sup>

When FDA determines that an establishment is in violation of the law, the agency may issue a warning letter.<sup>16</sup> The agency sends a warning letter only for

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12. See U.S. Food & Drug Admin., 2010 Public Calendars, <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/PastMeetingsWithFDAOfficials/2010PublicCalendars/default.htm> (last visited May 31, 2010) (listing "significant meetings held by FDA policy makers with persons outside the executive branch" for 2010).

13. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., INVESTIGATIONS OPERATIONS MANUAL 225-26 (2010), available at <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf> (instructing that the FDA form 483 is to be used to notify the inspected facility in writing of its significant violations that were observed during the inspection).

14. *Id.* at 226.

15. *Id.*

16. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., REGULATORY PROCEDURES MANUAL 4-1 (2010), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf> ("Warning Letters are issued to achieve voluntary compliance and to establish prior notice. . . . The use of Warning Letters and the prior

significant violations that may lead to enforcement action if the company does not promptly and adequately correct them.<sup>17</sup> Senior FDA officials conduct a thorough review of all relevant facts before issuing a warning letter.<sup>18</sup>

In the past, some inspected companies submitted multiple responses to the FDA form 483 inspectional reports, sometimes spanning over many months.<sup>19</sup> Delays sometimes resulted while the agency reviewed these submissions.<sup>20</sup> FDA believes this does not always serve public interest, as prompt issuance of warning letters can promote compliance with the law.<sup>21</sup> Warning letters ensure that top management understand the seriousness and scope of violations and allocate resources to prevent their recurrence.<sup>22</sup>

Therefore, FDA recently implemented a new policy instituting a fifteen-day deadline for company responses.<sup>23</sup> The agency will not ordinarily delay issuance of a warning letter in order to review a response to an FDA form 483 inspection report that the agency receives more than fifteen business days after the 483 report was issued.<sup>24</sup> This program gives a company three weeks to review the report and provide a response, which the agency believes is a reasonable time frame. FDA plans to conduct a detailed review of timely responses before determining whether to issue a warning letter.<sup>25</sup> Further, FDA will address such responses in writing if it subsequently issues a warning letter.<sup>26</sup> FDA will evaluate this program after eighteen months and decide if any changes are appropriate.<sup>27</sup> In the meantime, the agency makes clear that this policy is a guideline only, and it retains the discretion to issue warning letters at any time.<sup>28</sup>

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notice policy are based on the expectation that most individuals and firms will voluntarily comply with the law.”).

17. *Id.* at 4-1 to 4-2.

18. *Id.* at 4-4.

19. Review of Post-Inspection Responses, 74 Fed. Reg. 40,211, 40,212 (Aug. 11, 2009); *see also* Margaret Hamburg, Comm’r of Food & Drugs, U.S. Food & Drug Admin., Remarks at the Food & Drug Law Institute: Effective Enforcement and Benefits to Public Health (Aug. 6, 2009), *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm> (“[M]any of the enforcement actions that the FDA has undertaken have been hampered by unreasonable delays. In some cases, serious violations have gone unaddressed for far too long.”).

20. Review of Post-Inspection Responses, 74 Fed. Reg. at 40,212.

21. *Id.*

22. *Id.*

23. *Id.*; Hamburg, *supra* note 19.

24. Review of Post-Inspection Responses, 74 Fed. Reg. at 40,212.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

As another part of this initiative, OCC will no longer review every warning letter before issuance.<sup>29</sup> In 2001, the HHS Deputy Secretary had required OCC to review every FDA warning letter to “further consistency and accountability.”<sup>30</sup> The number of warning letters the agency issued dropped after this policy began.<sup>31</sup> FDA now believes this change will benefit the public health by permitting letters to move forward through a more streamlined process.<sup>32</sup> OCC will continue to review certain categories of letters involving controversial or sensitive issues. This change in policy will also be evaluated in the future to see if modifications are appropriate.

A third important change in this area is FDA’s creation of a formal warning letter “close-out” process.<sup>33</sup> Following the issuance of a warning letter, FDA will seek to determine whether a company has fully corrected the violations raised in the letter.<sup>34</sup> This will usually involve a re-inspection. If the company meets the appropriate standards, FDA will provide a “close-out” letter, indicating that they have successfully addressed the issues in the warning letter.<sup>35</sup> To keep the public informed, FDA will indicate on its website when a firm has received a “close-out” letter.<sup>36</sup>

### III. PROMOTION USING THE INTERNET AND SOCIAL MEDIA

Another priority area for FDA is the regulation of product promotion involving the Internet and social media tools. More and more companies are using the Internet to disseminate information about their products.<sup>37</sup> Social media— websites whose content is primarily created by site-users rather than site-owners— are playing an increasing role as well.<sup>38</sup> Many FDA laws and regulations were

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29. See Hamburg, *supra* note 19 (stating that the FDA will limit warning letter review only to the critical legal issues).

30. Memorandum from Claude Allen, Deputy Secretary, U.S. Dep’t of Health & Human Servs., to Bernard Schwetz, Acting Comm’r of Food & Drugs, U.S. Food & Drug Admin. (Nov. 29, 2001).

31. Mike Mitka, *Report Criticizes Lack of FDA Oversight*, 296 JAMA 920, 920 (2006) (“[T]he number of warning letters issued . . . decreased from 1154 in 2000 to 535 in 2005 and represented a 15-year low.”); see also U.S. Food & Drug Admin., Inspections, Compliance, Enforcement, and Criminal Investigations: Warning Letters, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (documenting the warning letters issued since 1996) (last visited May 31, 2010).

32. Hamburg, *supra* note 19.

33. See *id.* (explaining the formal warning letter “close-out” process as an official determination that a business has successfully complied with all the necessary corrective measures raised in the FDA correspondence).

34. *Id.*

35. *Id.*

36. *Id.*

37. E.g., Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting, 61 Fed. Reg. 48,707, 48,707 (Sept. 16, 1996) (“With the recent dramatic increases in the number of users on the Internet . . . companies, including manufacturers and distributors of products regulated by FDA, are looking at the Internet as a medium for disseminating information about their products.”).

38. Tony Blank, Vice Pres., Cardiovascular Reg. Affairs, Boston Scientific Corp., Presentation at the FDA Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and

created before this technology was prevalent or even before it existed at all. The agency is now evaluating how its statutes, regulations, and policies should be applied (or changed) to meet these challenges.

Existing laws provide an initial framework for FDA's approach to these issues. Under the Food, Drug, and Cosmetic Act,<sup>39</sup> the agency has the responsibility for regulating the labeling of prescription drugs and medical devices and the advertising of prescription drugs and restricted medical devices.<sup>40</sup> The Act defines *labeling* as "all labels and other written, printed, or graphic" materials "upon" or "accompanying" an article.<sup>41</sup> The Supreme Court interpreted the term "accompanying" broadly in the landmark case, *Kordel v. United States*.<sup>42</sup> Following this broad interpretation, FDA's regulations state that labeling may include brochures, mailing pieces, detailing pieces, calendars, price lists, letters, motion picture films, and sound recordings.<sup>43</sup> Labeling must be truthful and non-misleading.<sup>44</sup> FDA also regulates the *advertising* for prescription drugs, biologics, and restricted devices.<sup>45</sup> The Act does not define the word *advertisement*, but FDA interprets the term to include information (other than labeling) that is intended to promote a product, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."<sup>46</sup>

A prescription drug is misbranded unless its advertising includes a "true statement of . . . information in brief summary relating to side effects, contraindications, and effectiveness" of the product.<sup>47</sup> FDA's regulations require that a "true statement" must not be false or misleading about side effects and it must disclose relevant material facts.<sup>48</sup> These regulations also require

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Social Media Tools (Nov. 12, 2009), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM193462.pdf> ("[S]ocial media . . . is a growing space and a space of great interest to the medical device industry . . .").

39. 21 U.S.C. §§ 301–399a (2006 & West Supp. 2009).

40. See *id.* § 352 (describing the labeling requirements for drugs and devices); *id.* § 353b ("The Secretary may require the submission of any television advertisement for a drug . . . for review . . . before dissemination . . ."); *id.* § 360e(c)(1)(F) (requiring submission of "specimens of the labeling proposed to be used" for a device subject to premarket approval).

41. *Id.* § 321(m).

42. 335 U.S. 345, 349 (1948) ("[T]he phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported.").

43. 21 C.F.R. § 202.1(l)(2) (2009).

44. 21 U.S.C. § 352(a).

45. 21 C.F.R. § 202; see also Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting, 61 Fed. Reg. 48,707, 48,708 (Sept. 16, 1996) ("The Federal Food, Drug, and Cosmetic Act . . . and its implementing regulations define the conditions under which human and animal drugs, biologics, and medical devices shall be advertised and otherwise promoted . . .").

46. 21 C.F.R. § 202.1(l)(1).

47. 21 U.S.C. § 352(n).

48. 21 C.F.R. § 202.1(e)(5)(i), (iii).

advertisements “to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug . . . .”<sup>49</sup> *Fair balance* means that the information provided in each of these categories must be “comparable in depth and detail . . . .”<sup>50</sup> The Act similarly regulates advertising for restricted devices.<sup>51</sup>

How to apply these principles to Internet promotion is not always obvious. No existing FDA statutes or regulations specifically address Internet promotion. While some Internet promotional efforts are substantially similar in presentation and content to promotional materials in traditional media, others are not. The Internet’s unique technological features include presentation and content options that may have important implications in this area.

Since the agency first examined these issues at a public meeting in 1996,<sup>52</sup> new Internet tools and technologies have multiplied.<sup>53</sup> Internet platforms now include blogs (diary or journal-type entries), microblogs (short blogs, such as Twitter), podcasts (audio/video files), social networks (Facebook, LinkedIn, etc.), video sharing (hosting services such as YouTube), widgets (on-screen live content such as weather reports and news updates), chatrooms (forums for multiple users to ask questions and post comments), and wikis (web content that users can edit).<sup>54</sup>

FDA has called for public comment into regulatory issues surrounding these matters.<sup>55</sup> The agency requests input on a number of specific questions. For what communications should companies be held accountable? As a general matter, FDA holds manufacturers, packers, and distributors responsible for any communications they create, or that anyone acting on their behalf influences or controls, in whole or in part (this covers, for example, statements made by advertising agencies).<sup>56</sup> How should these principles apply to an Internet chatroom a company creates for members of the public to post comments on their products? Should it matter whether a company reviews and edits the comments or simply posts them automatically? Should it matter whether a company affirmatively reaches out to specific people to request comments or merely provides an open public forum for anyone to comment?

Another significant question involves how companies can meet their regulatory obligations given the real-time nature and space limitations of certain

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49. *Id.* § 202.1(e)(5)(ii).

50. *Id.*

51. 21 U.S.C. § 352(q).

52. Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting, 61 Fed. Reg. 48,707 (Sept. 16, 1996).

53. Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Fed. Reg. 48,083, 48,085 (Sept. 21, 2009).

54. *Id.*

55. *Id.*

56. *Id.* at 48,086.

Internet communication tools. FDA regulations require that promotional communications must provide a “fair balance” between risk and benefit information (unless the communication is a “reminder” advertisement that mentions the name of the product without making any claims about it).<sup>57</sup> Further, each part of a communication must contain risk information necessary to qualify any representations made about the drug in that part.<sup>58</sup>

What are the implications of these provisions to Internet tools that have limited space? Twitter, for example, requires its messages to be 140 characters or less, and Google limits “sponsored links” (short advertisements on search results pages with links to company web pages) to twenty-five characters for the title and seventy characters for the ad text. On this issue, FDA issued fourteen letters on April 2, 2009, to companies that advertised products by way of “sponsored links.”<sup>59</sup> The letters said these links misbranded the products by making representations about efficacy without communicating associated risk information.<sup>60</sup>

The agency would also like comment on the situation where misinformation about a company’s products (including discussion of unapproved uses) exists on a website outside its control, such as a blog, social networking site, or wiki.<sup>61</sup> Some companies have attempted to correct such misinformation, but others have expressed concern that doing so could make them responsible for all other information on the website.<sup>62</sup> A related issue involves the use of links.<sup>63</sup> Does the law permit a company to sponsor a website that links to websites owned by other organizations (such as support groups) that contain information about unapproved uses of the company’s products?

Finally, there are important questions about adverse event reporting involving the Internet.<sup>64</sup> The law requires companies to provide information about adverse events involving their products to FDA.<sup>65</sup> In March 2001, FDA issued a draft guidance for industry entitled *Postmarketing Safety Reporting for Human Drug and*

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57. 21 C.F.R. § 202.1(e)(5)(ii) (2009).

58. *Id.* § 202.1(e)(3)(i).

59. See U.S. Food & Drug Admin., U.S. Dep’t of Health & Human Servs., Drugs: Warning Letters 2009, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773> (last visited May 31, 2010) (showing specific companies that received warning letters).

60. *E.g.*, Letter from Shefali Doshi, Regulatory Review Officer, U.S. Food & Drug Admin., to Amit Patel, Associate Dir., Regulatory Advertising & Promotion, Johnson & Johnson Pharmaceutical Services, L.L.C. (Apr. 2, 2009), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM143484.pdf>.

61. Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Fed. Reg. at 48,086.

62. *Id.* at 48,087.

63. See *id.* (discussing the appropriate use of links to product information).

64. *Id.*

65. 21 C.F.R. §§ 310.305, 314.80, 314.98, 514.80, 600.80, 803.1–.58 (2009).

*Biological Products Including Vaccines*.<sup>66</sup> This document stated that companies with postmarketing reporting obligations must report to FDA any adverse events that they learn about on Internet sites that they sponsor if they have knowledge of four things: an identifiable reporter, an identifiable patient, a suspect drug, and an adverse experience suspected to be due to the drug.<sup>67</sup> Companies are not responsible for reviewing Internet sites they do not sponsor, but if they become aware of an adverse event on such a site, they should review it to determine if they should report it to FDA.<sup>68</sup> The agency is interested in learning about companies' experiences in this regard, what their practices have been, what challenges they face, and what uncertainties remain.

#### IV. TOBACCO REGULATION

One of the most important recent developments at FDA is the enactment of the Family Smoking Prevention and Tobacco Control Act.<sup>69</sup> Tobacco use is the leading preventable cause of death and disease in the United States.<sup>70</sup> Smoking and exposure to second-hand smoke cause approximately 443,000 deaths every year.<sup>71</sup> Smokers die thirteen to fourteen years earlier than nonsmokers.<sup>72</sup> Seventy percent of smokers want to quit.<sup>73</sup> Tobacco causes \$193 billion in lost productivity and medical costs each year.<sup>74</sup> More deaths are caused each year by tobacco use than by

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66. CTR. FOR DRUG EVALUATION & RESEARCH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: POSTMARKETING SAFETY REPORTING FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS INCLUDING VACCINES (2001), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm092257.pdf>.

67. *Id.* at 8.

68. *Id.* at 21.

69. Pub. L. No. 111-31, 123 Stat. 1776 (2009).

70. *E.g.*, Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *High School Students Who Tried to Quit Smoking Cigarettes—United States, 2007*, 58 MORBIDITY & MORTALITY WKLY. REP. 428, 428 (2009), available at <http://www.cdc.gov/mmwr/pdf/wk/mm5816.pdf>. See also NAT'L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, PUB. NO. 2009-1232, HEALTH, UNITED STATES, 2008, at 84–85 (2009), available at [http://www.cdc.gov/nchs/data/08.pdf](http://www.cdc.gov/nchs/data/hus/08.pdf) (discussing tobacco use in the United States).

71. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004*, 57 MORBIDITY & MORTALITY WKLY. REP. 1226, 1226 (2008), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf>.

72. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs—United States, 1995–1999*, 51 MORBIDITY & MORTALITY WKLY. REP. 300, 301 (2002), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5114.pdf>.

73. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Cigarette Smoking Among Adults—United States, 2000*, 51 MORBIDITY & MORTALITY WKLY. REP. 642, 642 (2002), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5129.pdf>.

74. Ctrs. for Disease Control & Prevention, *supra* note 71, at 1228.

all deaths from human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, suicides, and murders combined.<sup>75</sup>

Cigarette smoking rates have been declining, but the decline may be reaching a plateau. In 1955, 54% of men and 24% of women smoked; by 2007, these rates had dropped to 22% of men and 17% of women.<sup>76</sup> For youth, however, recent smoking rates have fluctuated. In 1991, 28% of high school students smoked; in 1997, this figure rose to 36%; in 2007, it was 20%.<sup>77</sup> The number of youth who smoke is crucial, as nearly 90% of smokers start by the age of eighteen.<sup>78</sup>

FDA's goals in regulating tobacco are to reduce youth tobacco use, promote public understanding of contents and consequences of tobacco use, develop a base of scientific knowledge, and begin meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death.<sup>79</sup> The Act provides the agency with important tools to accomplish this mission: the authority to establish tobacco product standards,<sup>80</sup> the requirement that manufacturers receive pre-market approval for certain products,<sup>81</sup> a requirement that manufacturers report ingredient and constituent data for their products,<sup>82</sup> the authority to promulgate advertising standards and require warning labels,<sup>83</sup> and the power to enforce violations of the law.<sup>84</sup>

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75. Ali H. Mokdad, *Actual Causes of Death in the United States, 2000*, 291 JAMA 1238, 1240 tbl.2 (2004).

76. JOHN R. PLEIS & JACQUELINE W. LUCAS, CTNS. FOR DISEASE CONTROL & PREVENTION, PUB. NO. 2009-1568, SUMMARY HEALTH STATISTICS FOR U.S. ADULTS: NATIONAL HEALTH INTERVIEW SURVEY, 2007, at 71 tbl.25 (2009), available at [http://www.cdc.gov/nchs/data/series/sr\\_10/sr10\\_240.pdf](http://www.cdc.gov/nchs/data/series/sr_10/sr10_240.pdf); Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Surveillance for Selected Tobacco-Use Behaviors—United States, 1900–1994*, 43 MORBIDITY & MORTALITY WKLY. REP. (SURVEILLANCE SUMMARIES) 35 (1994), available at <http://www.cdc.gov/mmwr/PDF/ss/ss4303.pdf>; see also GARY A. GIOVINO ET AL., ROBERT WOOD JOHNSON FOUND., CIGARETTE SMOKING PREVALENCE AND POLICIES IN THE 50 STATES: AN ERA OF CHANGE 11 fig.3 (2009), available at [http://www.impactteen.org/generalarea\\_PDFs/chartbook\\_final071009.pdf](http://www.impactteen.org/generalarea_PDFs/chartbook_final071009.pdf) (showing the reduction in cigarette smoking from 1955 to 2007).

77. Danice K. Eaton et al., Ctrs. for Disease Control & Prevention, *Youth Risk Behavior Surveillance—United States, 2007*, 57 MORBIDITY & MORTALITY WKLY. REP. (SURVEILLANCE SUMMARIES) 32 (2008), available at <http://www.cdc.gov/mmwr/pdf/ss/ss5704.pdf>.

78. Donald W. Garner & Richard J. Whitney, *Protecting Children from Joe Camel and His Friends: A New First Amendment and Federal Preemption Analysis of Tobacco Billboard Regulation*, 46 EMORY L.J. 479, 533 (1997); Nancy A. Rigotti et al., *The Effect of Enforcing Tobacco-Sales Laws on Adolescents' Access to Tobacco and Smoking Behavior*, 337 NEW ENG. J. MED. 1044, 1044 (1997).

79. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, sec. 3, 123 Stat. 1776, 1781 (2009).

80. *Id.* sec. 101, § 907, 123 Stat. at 1799 (to be codified at 21 U.S.C. § 387g).

81. *Id.* sec. 101, § 903(b), 123 Stat. at 1788 (to be codified at 21 U.S.C. § 387c).

82. *Id.* sec. 101, § 904(a)(3), 123 Stat. at 1781 (to be codified at 21 U.S.C. § 387d).

83. *Id.* secs. 201–202, 123 Stat. at 1842–46 (to be codified at 15 U.S.C. §§ 1333–1334).

84. *Id.* sec. 105(a), 123 Stat. at 1841 (to be codified at 21 U.S.C. § 387f-1).

FDA's tobacco program will be funded entirely by user fees paid by industry.<sup>85</sup> Companies will pay based upon their share of the United States market.<sup>86</sup> The Act sets the FY2010 budget at \$235 million and provides for annual 5.8% raises until 2019, when the budget will be set at \$712 million.<sup>87</sup>

FDA has been very active since the law's passage. Agency representatives have met with State and local officials, tobacco industry representatives, and public health advocates to learn more about the field.<sup>88</sup> The agency is well on its way to staffing a new Center for Tobacco Products, with a Center Director and dedicated office facilities.<sup>89</sup>

Interagency cooperation will be crucial. In particular, FDA will be working closely with the Centers for Disease Control on public health issues, including their Office on Smoking and Health and National Center for Environmental Health. The National Institutes of Health will be an important partner in tobacco research. The Substance Abuse and Mental Health Services Administration will be invaluable in outreach and surveillance issues. FDA plans to work with state and local agency partners to create a unified approach to tobacco control.

In the legal arena, on September 22, 2009, the statutory ban on cigarettes containing certain characterizing flavors went into effect.<sup>90</sup> The ban on candy and fruit-flavored cigarettes recognizes the importance of reducing the number of youth who smoke and then become addicted.<sup>91</sup> On September 30, 2009 FDA issued a draft guidance document covering the prohibition against marketing a tobacco product in combination with another FDA-regulated product.<sup>92</sup> In October, the agency issued two draft guidance documents to assist industry, one on statutory registration and product listing requirements, and the other on requirements for ingredient listing.<sup>93</sup>

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85. *Id.* sec. 101, § 919(a), 123 Stat. at 1826 (to be codified at 21 U.S.C. § 387s).

86. *Id.* sec. 101, § 919(b)(2)(B)(ii), 123 Stat. at 1827.

87. *Id.* sec. 101, § 919(b), 123 Stat. at 1826–27.

88. See U.S. Food & Drug Admin., Tobacco Products: Center for Tobacco Products Update, <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm189487.htm> (last visited May 31, 2010).

89. See Press Release, U.S. Food & Drug Admin., FDA Launches New Center for Tobacco Products (Aug. 19, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm179410.htm> (introducing the newly implemented program, including the new director position and facility location).

90. U.S. Food & Drug Admin., *supra* note 88.

91. Press Release, U.S. Food & Drug Admin., Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step Is First Under New Tobacco Law (Sept. 22, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm183211.htm>.

92. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE: THE SCOPE OF THE PROHIBITION AGAINST MARKETING A TOBACCO PRODUCT IN COMBINATION WITH ANOTHER ARTICLE OR PRODUCT REGULATED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2009), <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm184283.htm>.

93. CTR. FOR TOBACCO PRODUCTS, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: REGISTRATION AND PRODUCT LISTING FOR OWNERS AND OPERATORS OF DOMESTIC TOBACCO

## CONCLUSION

FDA's mission takes on new meaning as regulatory issues emerge. Developing technologies, a changing legislative landscape, and evolving public needs require the agency to adapt to serve its purpose. Working with the public, the courts, the Congress, and other government agencies, FDA seeks to maximize its effectiveness in protecting and promoting the public health.

