

Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx

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PUNISHING PHARMACEUTICAL COMPANIES FOR UNLAWFUL PROMOTION OF APPROVED DRUGS: WHY THE FALSE CLAIMS ACT IS THE WRONG RX

VICKI W. GIRARD*

ABSTRACT

This Article criticizes the shift in focus from correction and compliance to punishment of pharmaceutical companies allegedly violating the Food, Drug, & Cosmetic Act (FD&C Act) prohibitions on unlawful drug promotion. Traditionally, the Food and Drug Administration (FDA) has addressed unlawful promotional activities under the misbranding and new drug provisions of the FD&C Act. Recently, though, the U.S. Department of Justice (DOJ) has expanded the purview of the False Claims Act to include the same allegedly unlawful behavior on the theory that unlawful promotion “induces” physicians to prescribe drugs that result in the filing of false claims for reimbursement. Unchecked and unchallenged, the DOJ has negotiated criminal and civil settlements with individual pharmaceutical companies ranging from just under tens of millions to billions of dollars. Companies settle these cases largely to avoid the potential loss of revenue associated with the exclusion regime administered by the U.S. Department of Health and Human Services, under which companies risk losing the right to have their products reimbursed under federal health care programs. Thus, the willingness of companies to settle claims allows the DOJ to employ an enforcement approach that circumvents judicial review of its legal theories and procedures. This Article discusses the traditional enforcement methods employed by the FDA, as well as the more recent DOJ prosecutions under the False Claims Act. Although it concludes that the FD&C Act should provide the sole means for punishing unlawful drug promotion, it also suggests that when prosecuting pharmaceutical companies under either Act, the government must avoid the temptation to mine companies for large

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settlements in lieu of developing a more coherent and responsible enforcement strategy.

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INTRODUCTION

The promotion and advertising of prescription drugs in the United States is big business. According to one estimate from 2006, spending on pharmaceutical promotion exceeded \$29.9 billion,¹ including more than \$7 billion spent on promotion targeting prescribing physicians and other health care professionals and another \$4.2 billion attributable to direct-to-consumer advertising.² Other estimates calculate promotional expenditures at more than twice that amount.³ Astoundingly large budgets aside, however, pharmaceutical companies are limited in their promotional options. They are not free to operate with Fifth Avenue abandon or to employ the kinds of exaggerated promotional claims associated with cosmetic and other non-health care related products. As purveyors of cures and preventions for serious diseases and health conditions, the pharmaceutical industry is entrusted with obligations far beyond those of whitening teeth, preventing wrinkles, and stopping odor.⁴ We expect public health and safety to come first and demand that companies promote prescription drugs within the parameters established under the federal Food, Drug, and Cosmetic Act (FD&C Act).⁵ When the limits on promotion are exceeded, we rely on the government to step in and ensure compliance. However, the methods used to achieve compliance matter, and the government's most recent efforts to enforce the FD&C Act are troubling. In particular, the government's shift in emphasis from correction and compliance to punishment,⁶ its use of the False Claims Act to prosecute violations of the FD&C Act,⁷ and its reliance on negotiated settlements to circumvent judicial review of its new enforcement approach⁸ deserve careful scrutiny.

1. Estimates are based on those provided by Intercontinental Marketing Services (IMS), one of the primary authorities on pharmaceutical promotional expenditures. See Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 676 tbl.1 (2007). Approximately \$18.4 billion (in retail value) of that amount was devoted to promotional free samples distributed to patients through physicians. *Id.*

2. *Id.* at 676 tbl.1.

3. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 29–31, 30 tbl.1 (2008), available at http://medicine.plosjournals.org/archive/1549-1676/5/1/pdf/10.1371_journal.pmed.0050001-S.pdf.

4. For example, more than 29 million Americans have been prescribed the statin drug Lipitor, used to lower LDL cholesterol and fight the plaque that contribute to heart disease. Research on Lipitor, <http://www.lipitor.com/about-lipitor/clinical-trials.aspx> (last visited Nov. 20, 2009).

5. See 21 U.S.C. §§ 301, 352, 355 (2006), amended by Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 940, 942 (2007). Over-the-counter drugs are also subject to promotional restrictions but are not included within the scope of this Article, which focuses solely on prescription drugs.

6. See *infra* Part III.A.

7. See *infra* Part II.A.

8. See *infra* Part III.D.

The U.S. Food and Drug Administration (FDA) is the federal agency authorized under the FD&C Act to regulate the promotion of prescription drugs.⁹ Consistent with its mission to protect and promote the public health, the FDA exercises its authority by “assuring [that] prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.”¹⁰ The “labeling and promotional information” referenced by the FDA, on which this Article focuses, falls into two categories: (1) promotional labeling, and (2) advertising.¹¹

Promotional labeling generally refers to everything *except* FDA-approved labeling.¹² FDA-approved labeling for prescription drugs includes professional labeling (i.e., the full prescribing information that accompanies every prescription drug)¹³ and consumer-oriented labeling (i.e., “Medication Guides,” which are required by the FDA to ensure the safe and effective use of certain prescription

9. 21 U.S.C. §§ 352(a), 352(n), 393(a)–(d) (2006). The Federal Trade Commission is responsible for the advertising of over-the-counter drugs. 15 U.S.C. §§ 41, 52 (2006); *Thompson Med. Co. v. Fed. Trade Comm’n*, 791 F.2d 189, 192–93 (D.C. Cir. 1986); Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

10. Div. of Drug Mktg., Adver. & Commc’ns, U.S. Food & Drug Admin., Drug Marketing, Advertising, and Communications Research, <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm> (last visited Nov. 19, 2009). The Food and Drug Administration’s Division of Drug Marketing, Advertising, and Communications (DDMAC) is responsible for the promotion and advertising of drugs. *Id.* The Office of Compliance for Biological Quality (OCBQ) handles the same issues for biological products. OFFICE OF REGULATORY AFFAIRS, U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL 1-4 to -5 (2009), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074345.pdf>.

11. U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., DRAFT GUIDANCE FOR INDUSTRY: “HELP-SEEKING” AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS 2 (2004). The FDA uses these two categories to classify the multitude of promotional and marketing materials that must be submitted to the agency at the time of initial dissemination or publication. See U.S. FOOD & DRUG ADMIN., FORM FDA 2253: TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE (2008), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

12. U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 11, at 2.

13. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006). The requirements for professional labeling are set forth by regulation. 21 C.F.R. § 201.57 (2008). Also included in this category of labeling is the “patient package insert,” which is an extension of the professional labeling in that it is designed for patients using lay language. See *Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs*, 72 Fed. Reg. 11,889 (Mar. 14, 2007); U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., GUIDANCE FOR INDUSTRY: BRIEF SUMMARY: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS 4 (2004), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf>. “Patient package inserts” may be voluntary or required. See, e.g., 21 C.F.R. §§ 310.501, .515, .516 (requiring the provision of a patient package insert for oral contraceptives, estrogens, and progestational drug products).

drugs).¹⁴ As the catch-all for everything except FDA-approved labeling, promotional labeling covers most of the labeling information provided to consumers and healthcare professionals.¹⁵ The FDA's expansive authority over promotional labeling is founded, in part, on the FD&C Act's broad definition of labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."¹⁶ For prescription drugs, which are articles under the FD&C Act,¹⁷ the term *accompanying* does not require the actual physical attachment of information to a drug. Rather, virtually *any* information disseminated by or on behalf of the manufacturer, packer, or distributor that supplements or explains a drug may be said to accompany the product and thus constitute labeling.¹⁸ The form and manner of information encompassed under this view includes all varieties of printed, audio, or visual matter.¹⁹

Promotional materials that do not qualify as labeling are regulated as advertising by the FDA. Although neither *advertisement* nor *advertising* is defined in the FD&C Act, section 352(n) and the implementing regulations demonstrate the broad nature and scope of information regulated as advertising.²⁰ Advertisements subject to section 352(n) include those "in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."²¹ In addition to these traditional media sources, "FDA also regulates advertising conducted by sales representatives, on computer programs, through fax machines, or on electronic bulletin boards."²² Thus, in combination with its authority over promotional labeling, the FDA's regulatory oversight of prescription drug marketing extends to practically every type of material and media imaginable.²³

14. 21 C.F.R. §§ 208.1, .20.

15. *See id.* § 202.1(l) (subjecting prescription drug advertisements, including brochures, booklets, mailing pieces, detailing pieces, bulletins, catalogues, calendars, and film to FDA regulation).

16. 21 U.S.C. § 321(m) (2006).

17. *Id.* § 321(g)(1).

18. *See Kordel v. United States*, 335 U.S. 345, 349–50 (1948).

19. 21 C.F.R. § 202.1(l).

20. 21 U.S.C. § 352(n), *amended by* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 940, 942 (2007); 21 C.F.R. § 202.1(a)(1)–(5). Exemptions from some of these requirements are provided for specific types of promotional material such as "reminder" ads, which are not required to disclose risk information. *See* 21 C.F.R. §§ 200.200, 201.100(f), 202.1(e)(2)(i).

21. 21 C.F.R. § 202.1(l)(1).

22. U.S. DEP'T OF HEALTH & HUMAN SERVS. ET AL., *THE CDER HANDBOOK* 56 (2008).

23. Although internet information falls under FDA's regulatory authority, the FDA has equivocated on its precise legal status, suggesting that it may be labeling or advertising depending on the circumstances. *Id.* at 61. Among the policies and guidance currently under development at FDA's Center for Drug Evaluation and Research (CDER), Division of Drug Marketing, Advertising and Communications, is how advertising and promotion of FDA-regulated products will be regulated on the Internet. *Id.*

Given the enormous range of materials regulated as promotional labeling and advertising, the FDA depends heavily on voluntary compliance by pharmaceutical companies to market products according to the requirements of the FD&C Act.²⁴ In designing promotional materials, companies rely on implementing regulations, FDA guidance documents, and other formal and informal consultations with the agency on specific questions about appropriate promotional choices.²⁵ A small percentage of promotional materials are pre-approved by the FDA.²⁶ Companies submit all other promotional materials for prescription drugs to the FDA at the time of first use.²⁷ Additionally, the FDA engages in regular, but limited, surveillance to assess compliance with its promotional standards for prescription drugs and pursues enforcement actions as necessary.²⁸ Despite the FDA's broad authority and genuine efforts to control the promotion and advertising of prescription drugs, and although many pharmaceutical companies act with the best of intentions, by design, mistake, employment of unscrupulous sales representatives, or other means, companies continue to push the outer limits of the law with regard to promotional activities.²⁹

Until fairly recently, the FDA exercised almost exclusive regulatory and enforcement authority over pharmaceutical companies' promotional activities

24. See 21 C.F.R. § 202.1 (k)–(l) (describing the large range of regulated advertisements under the FD&C Act); U.S. GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 17, 24 (2002), available at <http://www.gao.gov/new.items/d03177.pdf> (explaining the efficiency and promotion of industry self regulation) (redesignating the General Accounting Office as the Governmental Accountability Office occurred under the GAO Human Capital Reform Act of 2004, Pub. L. No. 108-271, §§ 1(a), 8(a), 118 Stat. 811, 811, 814 (2004)).

25. See, e.g., 21 C.F.R. § 202.1 (describing advertisement parameters for prescription drugs in detail); DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 1 (1999), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf>; Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Guidance, Compliance, & Regulatory Information, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm> (last visited Nov. 20, 2009) (providing links to numerous regulatory reports, initiatives and activities available to manufacturers and providers).

26. See 21 C.F.R. §§ 314.500, .510, .550 (describing how pre-approval of promotional materials is required for drugs approved under FDA's accelerated approval process).

27. *Id.* § 314.81(b)(3)(i) (requiring companies to report promotional materials at the time of "initial dissemination" and "initial publication").

28. See U.S. GOV'T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES 13–15 (2008), available at <http://www.gao.gov/new.items/d08835.pdf>. The transmittal form is used by FDA as a source of information as to what companies are disseminating and publishing. U.S. FOOD & DRUG ADMIN., *supra* note 11.

29. Some of the more recent willingness to stretch the FDA's promotional boundaries may be traced to companies' growing confidence in their right to disseminate truthful off-label information under the First Amendment following Washington Legal Foundation's successful challenge to the constitutionality of FDA restrictions on speech regarding off-label uses of the FDA-approved products. See *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66, 74 (D.D.C. 1998).

related to prescription drugs.³⁰ Under the FD&C Act, the FDA has a variety of methods to control unlawful promotion, including administrative,³¹ civil,³² and criminal penalties³³ for unlawful promotion. Despite the variety of methods available, the FDA's use of punitive sanctions has been rare.³⁴ Rather, the FDA typically attempts to achieve compliance from companies through less formal means, often relying on "untitled"³⁵ or warning letters to register its objection to promotional activities and provide companies with opportunities to cure misleading messages about the safe and effective use of a product.³⁶ The agency's enforcement approach has not been perceived as completely successful in stopping or preventing unlawful marketing practices.³⁷ Critics argue that companies operate on the premise

30. See *Thompson Med. Co. v. Fed. Trade Comm'n*, 791 F.2d 189, 192–93 (D.C. Cir. 1986); Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

31. See 21 C.F.R. § 7.40(a) (allowing the FDA to issue a recall on drugs that "are in violation of laws administered by the Food and Drug Administration," like the FD&C Act).

32. See, e.g., 21 U.S.C. § 332(a) (2006) (civil punishment of injunction); 21 U.S.C.A. § 333(f)(1) (West Supp. 2008) (civil monetary penalties for misbranding); *id.* § 333(g) (civil penalties for false and misleading direct-to-consumer ads); *id.* § 334(a)(1) (seizure).

33. See 21 U.S.C. § 333(a) (misdemeanor and felony criminal provisions).

34. See U.S. GEN. ACCOUNTING OFFICE, *supra* note 24, at 26 (stating that DDMAC officials did not refer any violations to the Department of Justice for enforcement between 2003 and 2007).

35. DEP'T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 22, at 53.

Untitled letters address promotion violations that are less serious than those addressed in warning letters. A reviewer's untitled letter is peer-reviewed and has the concurrence of the branch chief. In such letters, DDMAC usually requests that a company take specific action to bring the company into compliance within a certain amount of time, usually 10 working days. There is no requirement that the agency take enforcement action, although the letters may serve as a basis for additional regulatory action.

Id.

36. Warning letters are reserved for activity FDA perceives as raising more serious health concerns and require that companies take corrective action. See *id.* at 53–54; OFFICE OF REGULATORY AFFAIRS, *supra* note 10, at 4-1 to -18. Warning Letters often include sending *Dear Doctor* letters to physicians the company has provided with questionable promotional materials in order to correct false or misleading messages about a particular product. See, e.g., Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver., and Comm'ns, U.S. Food & Drug Admin., to Brian A. Markison, Chairman, President, & Chief Executive Officer, King Pharmaceuticals (March 24, 2008), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048362.htm>; Letter from Lisa M. Hubbard, Regulatory Review Officer, U.S. Food & Drug Admin., to Dennis Ahern, Assoc. Dir. of Regulatory Affairs, Shire Dev., Inc. (May 1, 2008), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054102.pdf>.

37. See, e.g., U.S. GEN. ACCOUNTING OFFICE, *supra* note 24, at 4 (recognizing that despite FDA oversight some pharmaceutical companies "repeatedly disseminat[ed] new misleading advertisements"); U.S. GOV'T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: TRENDS IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 1, 13 (2008), available at <http://www.gao.gov/new.items/d08758t.pdf>; Jonathan H. Marks, *The Price of Seduction: Direct-to-Consumer Advertising of Prescription Drugs in the U.S.*, 64 N.C. MED. J. 292, 292–94 (2003) ("The [GAO Study] makes clear that although regulatory letters halt the dissemination of misleading advertisements, they do not deter

that the benefits of questionable promotional tactics outweigh the risk that the FDA will take action or that the consequences of any action will be significant.³⁸ In part, that perception and critique are probably fueled by the FDA's overall approach to unlawful promotional activity, which has traditionally addressed claims on an individual basis, focusing on specific pieces of labeling, advertisements, or activities, rather than considering the overall context and collective impact of claims made as part of companies' broader marketing schemes.³⁹

The FDA's enforcement restraint has undoubtedly contributed to the emergence of the U.S. Department of Justice (DOJ) as a more strident crusader against FD&C Act violations arising from the promotion of off-label uses. Looking beyond the FDA's traditionally narrow emphasis on individual claims and activities, the DOJ asserts that when viewed collectively, individual promotional claims and activities may support broader charges that a pharmaceutical company is engaged in a scheme of fraudulent marketing.⁴⁰ In 1999, for example, the DOJ brought its first ever criminal prosecution against a drug company (Genentech, Inc.) for violating FDA rules against promoting a drug for unapproved uses.⁴¹ Faced with the DOJ's allegation that discernible "patterns" of off-label promotion amounted to a misbranding scheme, Genentech paid \$50 million to settle charges that it illegally promoted its approved drug Protropin (human growth hormone) for unapproved uses related to the treatment of children who were undersized for reasons other than the lack of adequate growth hormone, the treatment children with a rare form of juvenile obesity, and the treatment of burn patients.⁴² More recently, the DOJ's continued focus on the overall impact of promotional marketing schemes rather than on individual labeling and advertising claims was exemplified by its 2004 settlement with Warner-Lambert following the decision in *United States ex rel. Franklin v. Parke-Davis*.⁴³ The DOJ based its charges against

pharmaceutical companies from making misleading claims in subsequent advertisements, even those for the same drug.").

38. See Marks, *supra* note 37, at 293–94.

39. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 5 (“[T]he extent and variety of promotional activities that occur make it difficult for [the] FDA to oversee them in a *comprehensive* manner.”) (emphasis added). The Government Accountability Office's recent report provides a detailed discussion of FDA's oversight approach and its shortcomings regarding off-label promotional activity. *Id.* at 13–16.

40. See *id.* at 24 tbl.3, 26–27 (contrasting the FDA's narrow regulatory letters with the DOJ settlements and actions based on alleged marketing schemes).

41. Tamar Nordenberg, *Maker of Growth Hormone Feels Long Arm of Law*, FDA CONSUMER, Sept.–Oct. 1999, at 33.

42. *Id.*

43. See Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm. The settlement followed the District Court of Massachusetts' denial of Parke-Davis' motion for summary judgment, allowing allegations of False

Warner-Lambert on the company's off-label promotion for its drug, Neurontin, including activities related to sales representatives, medical liaisons, paid consultants' meetings and advisory boards, and teleconferences.⁴⁴ As part of its guilty plea, Warner-Lambert agreed to pay a \$240 million criminal fine for violating the FD&C Act and an additional \$190 million to settle civil liabilities under the False Claims Act.⁴⁵

The DOJ's increased enforcement role and interest in pursuing violations of the FD&C Act have precipitated several major changes in its approach to unlawful promotion by pharmaceutical companies. First, the DOJ's focus on punishing broad marketing schemes and strategies has resulted in an overall expansion in enforcement and penalties against companies that engage in unlawful promotion, encompassing more aggressive application of the criminal misbranding and felony intent provisions of the FD&C Act.⁴⁶ Second, the DOJ has extended its prosecutorial reach over unlawful promotion by applying the False Claims Act to violations of the FD&C Act under the theory that pharmaceutical companies, by promoting their products for off-label uses, cause the filing of false requests for reimbursement with Medicare, Medicaid, and other federal health care programs.⁴⁷ Third, by negotiating settlements under the FD&C Act and the False Claims Act, the DOJ has avoided judicial review of its enforcement theories and procedures, increasing the likelihood that its significantly altered approach to unlawful drug promotion will continue unchecked.⁴⁸

For the reasons described below, this Article criticizes the manner in which the DOJ has expanded its application of the False Claims Act and broadened the remedies available to punish pharmaceutical companies whose advertising and promotional labeling activities violate the FD&C Act. By shifting the focus from correction and compliance to punishment, the DOJ has stumbled upon not just one goose but an entire flock of geese, each of which is capable of laying the proverbial golden egg at the government's doorstep.⁴⁹ Indeed, within the last five years, the DOJ negotiated criminal and civil settlements with individual pharmaceutical companies, ranging in dollar amounts from just under ten million to more than a

Claims Act violations to proceed to trial. United States *ex rel.* Franklin v. Parke-Davis, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *1, *20. (D. Mass. Aug. 22, 2003).

44. See Press Release, U.S. Dep't of Justice, *supra* note 43.

45. *Id.*

46. See *infra* Part II.

47. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *1, *4-5, *10-15; see *infra* Part II.A.

48. See *infra* Part III.D.

49. The attraction may be impossible to resist as nobody much cares for these geese who are already maligned from every direction as dirty, dishonest, price-gouging crooks. See, e.g., Scott Gottlieb, *Stop the War on Drugs*, WALL ST. J., Dec. 17, 2007, at A21 ("Drug firms are persona non grata in Washington, a result of the industry's own excesses, but also of a lot of political targeting. The result is an anything-that-bashes-pharma goes mentality in policy making.").

billion.⁵⁰ In the face of such profound financial success, there has been little incentive for the government to question either the legality or wisdom of its approach. Nor are companies willing to litigate against the DOJ because of the potential costs associated with the exclusion remedy administered by the U.S. Department of Health and Human Services (HHS),⁵¹ under which the HHS may exclude a company's products from federal health care reimbursement programs. There are genuine concerns raised by the DOJ's focus on punishment, its application of the False Claims Act to unlawful promotion cases, and its readiness to negotiate settlements that stretch remedies available under the False Claims Act and the FD&C Act.

First, to the extent that the DOJ's enforcement approach to unlawful promotion reaps large monetary recoveries, the DOJ is likely to continue focusing on the rewards of punishment without regard to the benefits associated with the FDA's more traditional aims of correction and compliance. Such a shift is problematic in the context of pharmaceutical labeling and advertising, where the FDA's long-standing reliance on industry self-regulation (with Agency guidance) legitimately serves the public health and is consistent with the goals of the FD&C Act and the amount of enforcement resources available. The DOJ should consider the benefits of the FDA's enforcement approach and its expertise in issues related

50. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 26–27; Press Release, U.S. Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (Sept. 2, 2009), available at <http://www.justice.gov/opa/pr/2009/September/09-civ-900.html>; Press Release, U.S. Dep't of Justice, Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa (January 15, 2009), available at <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html>; Press Release, U.S. Attorney's Office E. Dist. of N.Y., Jazz Pharmaceuticals, Inc. Agrees to Pay \$20 Million to Resolve Criminal and Civil Allegations in "Off-Label" Marketing Investigation (July 13, 2007), available at <http://www.usdoj.gov/usao/nye/pr/2007/2007jul13a.html>; Press Release, U.S. Attorney's Office W. Dist. of Va., The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay over \$600 Million (May 10, 2007).

51. See 42 U.S.C. § 1320a-7 (2006) (describing the statutory authority of the Department of Health and Human Services to exclude individuals and companies from the Medicare and State health care programs); Ronald H. Clark et al., *HHS Expanded Use of Fraud Law's "Corporate Death Sentence" Is Legally Suspect*, LEGAL BACKGROUNDER, June 6, 2003, at 1–3, available at http://www.arentfox.com/pdf_notReady/content1117.pdf.

The Office of Inspector General (OIG) often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. False claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law give rise to the OIG's permissive exclusion authority under 42 U.S.C. § 1320a-7(b)(7) (2000). Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.

Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Corporate Integrity Agreements, <http://www.oig.hhs.gov/fraud/cias.asp> (last visited Nov. 20, 2009).

to public health, and ensure that the FDA's role in assessing the legitimacy of promotional claims under the FD&C Act is not too diminished.

Second, applying the False Claims Act to unlawful promotion cases raises significant legal questions. The DOJ's position that unlawful promotional activity by pharmaceutical companies "induces" physicians to write prescriptions, resulting in the filing of false claims for reimbursement⁵² relies on a questionable theory of causation. Given that the penalty provisions in the FD&C Act, in conjunction with the doctrine of equitable disgorgement,⁵³ provide sufficient means to punish unlawful promotional activity, reliance on the questionable theory of causation required to prosecute cases under the False Claims Act is unnecessary. Instead of using the False Claims Act, the DOJ should address unlawful promotional activity solely under the FD&C Act, which is the statutory scheme established by Congress specifically for that purpose and provides adequate remedies and punishment.

Third, even if the shift from compliance to punishment is warranted, and even if the use of the False Claims Act against unlawful promotional claims is legitimate, the DOJ's enforcement approach under both the False Claims Act and the FD&C Act has culminated in negotiated settlements with individual companies.⁵⁴ The amounts of these settlements are large,⁵⁵ suggesting an expansion of remedies that deserves a closer look. Having, for the most part, avoided judicial scrutiny of its enforcement activity in the area of unlawful promotion of approved drugs,⁵⁶ it is unclear whether the significant legal and policy decisions related to the DOJ's interpretation and application of the FD&C Act and False Claims Act are valid. Thus, at the very least, if the government is going to continue to employ the False Claims Act in these types of cases, it must exercise its discretion carefully and resist the temptation to extract inappropriate and unsubstantiated monetary settlements. When relying on the FD&C Act to punish unlawful promotion by pharmaceutical companies, similar restraint should be exercised.

Under neither scenario should the DOJ negotiate large monetary settlements based on threats related to loss of government business. Ultimately, by creating an environment that encourages companies to settle unlawful promotional claims at any cost, the DOJ's "recovery" of what it views as companies' "ill-gotten gains"

52. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *15-17; Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 FOOD & DRUG L.J. 653, 658 (2006).

53. Disgorgement in this context refers to the courts' traditional equitable authority to order restitution for reimbursement and deterrent purposes and has been found within the scope of remedies allowed under the FD&C Act. *See, e.g.*, *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1053-54, 1061-62 (10th Cir. 2006); *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 220, 222, 225 (3d Cir. 2005); *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 754, 760, 762 (6th Cir. 1999).

54. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 26-27.

55. *See* sources cited *supra* note 50.

56. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 28 tbl.4 (listing several large settlements over the past four years); *see infra* Part III.D.

may enrich the United States Treasury at the expense of consumers from whom such costs will be extracted.

I. RESTRICTIONS ON DRUG PROMOTION UNDER THE FD&C ACT

As a prerequisite to the lawful promotion of a prescription drug, the drug must be legally on the market pursuant to an approved new drug application (NDA).⁵⁷ The success of an NDA depends, in part, on the drug sponsor's ability to prove that the drug is "safe and effective for its intended use(s)."⁵⁸ The intended use of an approved drug is carefully restricted and must be properly reflected in the labeling that accompanies the drug, which is also subject to FDA approval.⁵⁹ Together, these approval mechanisms ensure that drugs are approved only for those uses for which safety and effectiveness have been established, and that approved drugs will be properly understood and used by the physicians who prescribe them.

A prescription drug with an approved NDA offers a pharmaceutical company a wide variety of promotional options. Promotion may be directed toward health care professionals (including physicians and pharmacy benefit managers), consumers, or both.⁶⁰ While the majority of promotional labeling and advertising efforts fall within the regulatory parameters set by the FDA, not all pharmaceutical companies are able to resist the temptation to increase sales through unlawful promotional activities. When pharmaceutical companies cross the line from lawful to unlawful promotion, two potential charges commonly arise under the FD&C Act: that the company introduced a new drug into interstate commerce,⁶¹ or that the company misbranded a drug.⁶²

57. 21 U.S.C. § 355(a) (2006) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). The limited exceptions to the approved NDA route to market are not reviewed here, as they do not impact the application of the promotion and advertising restrictions imposed on prescription drugs.

58. *Id.* § 355(b)(1)(A) (requiring submission of full reports of investigations that have been made on the safety and effectiveness of the drug as part of the NDA); 21 C.F.R. § 314.50(c)(2)(i) (2008) (describing the proposed text of labeling that must be submitted as part of the application to market a new drug).

59. *See* 21 U.S.C. § 355(b)(1)(F) (requiring submission of labeling specimens for the drug as part of the NDA); 21 C.F.R. §§ 314.50(c)(2), 601.2(a). "For prescription products, the FDA-approved labeling must be included in or within the package from which the drug or device is to be dispensed, or else the product is deemed misbranded on the ground that it lacks adequate directions for use." U.S. DEP'T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 11, at 2–3; *see also* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.100(c)(1).

60. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 24, at 9.

61. 21 U.S.C. § 331(d) (prohibiting the introduction or delivery for introduction into interstate commerce of a "new drug" as defined under section 355 of the FD&C Act). The prohibition applies to biologics, 42 U.S.C. § 262(a) (2006), and any reference to drugs in this Article also includes biological products.

62. 21 U.S.C. § 331(a) (prohibiting the introduction or delivery for introduction into interstate commerce of any drug that is misbranded); *id.* § 352(a) (defining a drug as misbranded if its labeling is

A. Creating a “New Drug” Through “Off-Label” Promotion

The FD&C Act limits drugs sold in the United States to those that are proven to be “safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.”⁶³ Because approved applications for drugs identify the specific uses for which a drug may be marketed,⁶⁴ promoting an approved drug for an unapproved use (i.e., for an “off-label” use) renders the drug “new” under the FD&C Act.⁶⁵ Whether the expanded claims for use are truthful representations of the drug’s efficacy is irrelevant, as such claims must still be approved by the FDA before the drug can be promoted for an unapproved purpose.⁶⁶ When a pharmaceutical company promotes an approved drug for a use that is not specifically identified in the drug’s approved NDA, the FDA may charge the company with unlawfully introducing a new drug into interstate commerce under the FD&C Act.⁶⁷

While off-label promotion of lawfully marketed drugs is generally prohibited under the FD&C Act, not all communications about off-label uses of approved drugs are banned. Scientists, physicians, consumers, and other entities or individuals unrelated to the company or to the marketing of a product generally are free to consider and discuss off-label uses of approved drugs.⁶⁸ Permitting such entities to engage in dialogue about off-label uses is critical to the public health. In 2005, the National Comprehensive Cancer Network estimated that fifty to seventy-five percent of all uses of drugs and biologics in cancer care in the United States were off-label.⁶⁹ Allowing some exchange of scientific and educational information is consistent with physicians’ prescribing authority.⁷⁰ Regardless of whether the

false or misleading); *id.* § 352(f)(1) (defining a drug as misbranded where its labeling lacks adequate directions for use).

63. *Id.* § 321(p)(1).

64. *Id.* § 355(b)(1).

65. *Id.* § 321(p).

66. See 21 C.F.R. § 202.1(e)(4)(i)(a) (2008) (prohibiting the recommendation of a use that is not covered by the labeling in the approved new-drug application).

67. See 21 U.S.C. § 331(d); 21 C.F.R. § 202.1 (e)(4)(i)(a).

68. See 21 C.F.R. § 201.128. Claims made in these contexts are not regulated by FDA because they fall outside the scope of the “intended use” of a drug, which refers to the objective intent of the persons legally responsible for the labeling of the product as suggested by the circumstances surrounding its distribution and marketing. *Id.*

69. Michael Soares, “Off-Label” Indications for Oncology Drug Use and Drug Compendia: History and Current Status, *J. ONCOLOGY PRAC.*, Sept. 2005, at 102–04. Off-label uses are even more prevalent in the pediatric population. *Id.* at 104.

70. This professional discretion is granted to physicians under the “practice of medicine” exception to FDA’s drug approval process, which permits the off-label use of approved drugs. See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 *FOOD & DRUG L.J.* 71, 76–80 (1998); U.S. Food & Drug Admin., “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices (1998), available at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheets andNotices/ucm116355.htm>.

FDA has approved a particular use for a drug, if the drug is legally on the market a physician may prescribe it for any safe and effective use that will benefit a patient.⁷¹ Thus, the opportunity to increase sales by marketing off-label uses to physicians provides much of the impetus for unlawful promotion that may result in a “new drug” charge against a pharmaceutical company.⁷²

Beyond the dialogue between disinterested entities, the public health value of exchanging off-label information is so critical that even companies and others who are responsible for marketing an approved drug are granted some ability to communicate about off-label uses without violating the FD&C Act.⁷³ Under those circumstances, the value of exchanging off-label information is balanced against the risk of unlawful promotion by carefully circumscribing the conditions under which the information is delivered to ensure that such information is scientifically valid and not presented in a promotional manner.⁷⁴ Thus, the limited exceptions to

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement [sic]. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the “practice of medicine” does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB).

Id. (emphasis in original).

71. See Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 HASTINGS L.J. 967, 976–77 (2007); U.S. Food & Drug Admin., *supra* note 70.

72. MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 137 (2004); see U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 21 fig.2 (detailing that 50% of off-label promotion was directed at medical professionals alone while 33% at both medical professionals and consumers).

73. See 21 C.F.R. § 99.101; Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. 9342 (Feb. 20, 2008); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES 2–5 (2008), available at <http://www.fda.gov/ohrms/dockets/98fr/fda-2008-d-0053-gdl.pdf>.

74. There are a number of methods by which a company, its employees, or its agents may disseminate information about off-label uses of an approved drug. See 21 C.F.R. § 99.101. The exchange of scientific information in a non-promotional context is permitted by regulation. *Id.* § 312.7(a). FDA also sanctions discussions about off-label uses in the context of industry-supported scientific and educational activities that are otherwise independent and non-promotional as where, for example, a company provides financial support for independent Continuing Medical Education activities. See U.S. FOOD & DRUG ADMIN., *supra* note 73, at 2–6. An informal policy of allowing companies to respond to unsolicited requests from healthcare personnel for information about off-label uses also exists. *Id.* Under very limited circumstances, companies may also disseminate peer-reviewed journal articles and medical texts that include references to off-label uses of approved drugs. See Draft

the rules against off-label dissemination of information recognize that dialogue is vital to the continued development and improvement of pharmaceutical options for controlling and preventing disease.

*B. Promotion that “Misbrands” a Drug*⁷⁵

The types of unlawful promotion that may result in new drug charges under the FD&C Act are often combined with the FD&C Act’s misbranding prohibitions. When a pharmaceutical company labels a drug in a way that is false or misleading,⁷⁶ advertises a drug in a way that fails to meet the requirements for a true statement of information set forth in the FD&C Act,⁷⁷ or suggests uses for a drug for which no adequate directions are provided,⁷⁸ the company may face misbranding charges. Generally speaking, the parameters for promotional labeling and advertising of a prescription drug are dictated by the labeling approved by the FDA in conjunction with the drug’s NDA.⁷⁹ A manufacturer may promote only those claims relating to the intended uses for which the drug has been approved (i.e., “on-label” uses).⁸⁰ Promotional claims relating to on-label uses violate the FD&C Act prohibitions on misbranding when they are “false or misleading.”⁸¹ Among the types of claims commonly meeting those criteria are claims that a drug is safer or more effective than the substantial evidence submitted to the FDA for approval of the drug supports.⁸² In addition to affirmative statements that are false

Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. at 9342; *see also* Washington Legal Found. v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999) (discussing dissemination of truthful off-label information as protected speech under the First Amendment to the United States Constitution). The statutory authority for these informal FDA policies that existed under sections 551 and 552 of the Food and Drug Modernization Act of 1997 expired pursuant to sunset provisions in September 2006. Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, §§ 551–52, 557(e), 111 Stat. 2296, 2356–59, 2364.

75. While there are many other ways to misbrand a product, methods that are not related to the promotional labeling or advertising for a product are not included in this discussion.

76. 21 U.S.C. § 352(a) (2006).

77. *Id.* § 352(n), amended by Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 940, 942 (2007).

78. 21 U.S.C. § 352(f).

79. *See* 21 C.F.R. § 202.1(a)–(b), (e) (2008).

80. *See id.* § 202.1(e)(4)(i)(a).

81. 21 U.S.C. § 352(a) (“A drug shall be deemed misbranded if its labeling is false or misleading in any particular.”). The Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the misbranding provisions of section 352 to provide that a violation of the new safety labeling requirements in section 355 also results in the misbranding of the drug product. Food and Drug Administration Amendments Act of 2007 § 902(a), 21 U.S.C.A. § 352(z) (West Supp. 2008).

82. *See* 21 C.F.R. § 202.1(e)(6)(i). Claims of this type, which are made in the context of the approved uses for a drug, violate FDA’s requirement that advertisements include a “true statement” of information. *See* 21 U.S.C. § 352(n). Such claims may also arise in the context of comparative claims, i.e. where greater efficacy or safety than another approved drug is alleged without substantial evidence to support such claim. 21 C.F.R. § 202.1(e)(6)(ii).

or misleading, misbranding also encompasses what a company fails to say about its product.⁸³ For example, a manufacturer may misbrand its product by presenting information about safety and efficacy without corresponding information about side effects and contraindications.⁸⁴ Indeed, the vast majority of violations identified by the FDA in letters to pharmaceutical companies stem from inadequate presentation (i.e., omission or minimization) of risk information.⁸⁵

Misbranding of an approved drug may also occur when an approved drug is promoted for off-label uses.⁸⁶ Under those circumstances, the drug is not only a “new drug” but is also misbranded because no FDA-approved labeling for the new use exists and thus the labeling cannot bear adequate directions for use⁸⁷ as required. The FDA often couples misbranding charges with “new drug” charges when it asserts regulatory authority over unlawful promotion of a prescription drug.⁸⁸

II. ENFORCEMENT APPROACHES TO FD&C ACT VIOLATIONS

Whether a company is making an on-label or off-label claim for an approved drug, it faces potential prosecution for unlawful promotion if the FDA believes the claim violates the misbranding or new drug provisions of the FD&C Act. Enforcement options currently available include those provided by the FD&C Act and the False Claims Act. The FD&C Act enforcement options range from purely administrative remedies to the use of seizure, injunction, and civil and criminal penalties.⁸⁹ The FDA may act independently with regard to FD&C Act administrative options, which in the context of promotional violations are generally limited to the use of informal (i.e., “untitled”)⁹⁰ and formal (i.e., “warning”)

83. 21 U.S.C. § 321(n).

[I]n determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, *but also the extent to which the labeling or advertising fails to reveal* facts with respect to consequences which may result from the use of the article

Id. (emphasis added).

84. *Id.* The absence of a true statement of information corresponds to the manufacturer’s failure to present information that is fairly balanced. 21 C.F.R. § 202.1(e)(5)(ii).

85. See Thomas Abrams, U.S. Food & Drug Admin., FDA Update on Advertising and Promotion of Prescription Drugs 8 (Feb. 22, 2006), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm095984.ppt>.

86. 21 C.F.R. § 202.1(e)(4)(i)(a).

87. 21 U.S.C. § 352(f).

88. See, e.g., *id.* § 331(a), (d) (prohibiting interstate sale of misbranded drugs and unapproved new drugs in the same section).

89. See sources cited *supra* notes 32–33.

90. OFFICE OF REGULATORY AFFAIRS, *supra* note 10, at 4-25 to -26. “An Untitled Letter cites violations that do not meet the threshold of regulatory significance for a Warning Letter.” *Id.* at 4-25.

letters.⁹¹ These letters notify manufacturers of materials that the FDA considers to be unlawful and may request or require specific corrective action to disseminate accurate and complete information to any audience that received a misleading message.⁹² Where the FDA seeks more than an administrative remedy, the agency must refer the case to the DOJ's Office of Consumer Litigation (OCL) (although DOJ may initiate a case under the FD&C Act without a referral from FDA).⁹³ The FD&C Act referral process varies, depending on the nature of the case, but often includes multiple state and federal government agencies and offices.⁹⁴

When the False Claims Act is the vehicle for prosecuting pharmaceutical promotion violations, the enforcement option is civil fraud penalties.⁹⁵ As with the FD&C Act, the DOJ also has direct authority over False Claims Act litigation, which allows DOJ to initiate a False Claims Act prosecution on its own and also provides an avenue for the FDA to bring such cases.⁹⁶ Typically, however, False Claims Act litigation is initiated by private citizens acting on behalf of the government through the filing of a *qui tam* suit,⁹⁷ bypassing the FDA.

Among the incentives for private parties to expose fraud against the government is the False Claims Act provision that awards *qui tam* plaintiffs a

91. *Id.* at 4-1 to -3.

92. *See, e.g.*, Letter from Thomas W. Abrams to Brian A. Markison, *supra* note 36; Letter from Lisa M. Hubbard to Dennis Ahern, *supra* note 36.

93. The Assistant Attorney General for the Civil Division of the Department of Justice must approve any criminal prosecution and any civil penalty or injunctive proceeding brought under the FD&C Act. *See* 28 C.F.R. § 0.45(j) (2008). The Department of Justice sends civil and criminal cases to the Office of Consumer Litigation "pursuant to longstanding DOJ policy." *See* Office of Consumer Litig., The Federal Food, Drug, and Cosmetic Act (FDCA), <http://www.usdoj.gov/civil/ocl/monograph/fdca.htm> (last visited Nov. 8, 2009).

94. Office of Consumer Litig., *supra* note 93; *see, e.g.*, Press Release, Dep't of Justice, Medicis Pharmaceutical to Pay U.S. \$9.8 Million to Resolve False Claims Allegations (May 8, 2007), *available at* http://www.usdoj.gov/opa/pr/2007/May/07_civ_336.html (stating that the FDA's Office of Criminal Investigations and the Kansas Attorney General's Office investigated the case); Press Release, Michael J. Sullivan, U.S. Attorney Dist. of Mass., Schering to Pay \$435 Million for the Improper Marketing of Drugs and Medicaid Fraud (Aug. 29, 2006), *available at* <http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Schering-Plough/press%20release.pdf> (stating that the investigation was conducted by FDA's Regional Office of Criminal Investigations, HHS's OIG, The Department of Defense's Criminal Investigation Services, and the U.S. Office of Veterans Affairs, and that the New York and Washington State Attorneys General also assisted in the investigation).

95. 31 U.S.C.A. § 3729(a) (West Supp. 2008).

96. 28 C.F.R. § 0.45(d).

97. Press Release, Dep't of Justice, More than \$1 Billion Recovered by Justice Department in Fraud and False Claims in Fiscal Year 2008 (Nov. 10, 2008), *available at* <http://www.usdoj.gov/opa/pr/2008/November/08-civ-992.html> (stating that almost 78% of False Claims Act recoveries in 2008 were "associated with suits initiated by private citizens . . . under the False Claims Act's *qui tam* provisions"). *Qui tam* is a short version of the full Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which translates as "who as well for the king as for himself sues in this matter." BLACK'S LAW DICTIONARY 1282 (8th ed. 2004).

percentage of any successful prosecution or settlement.⁹⁸ Use of the False Claims Act to combat fraud against the government dates back to the Civil War, when the statute was used primarily in the context of supply contracts connected to the government's war efforts.⁹⁹ In modern times, expansion of the False Claims Act to address health care fraud has encompassed a variety of unlawful activities ranging from billing for services never rendered to reimbursement issues based on drug company practices regarding Average Wholesale Prices.¹⁰⁰ The use of the False Claims Act to punish unlawful promotion under the FD&C Act is the most recent attempt to use the False Claims Act as a regulatory tool against pharmaceutical companies. Although False Claims Act complaints against unlawful promotion are rooted in FD&C Act violations, for which adequate enforcement provisions already exist,¹⁰¹ the potential for greater civil fines under the False Claims Act and its attraction of qui tam plaintiffs are among the features that distinguish the False Claims Act from enforcement under the FD&C Act and likely account for much of its appeal to government prosecutors.

In addition to the enforcement options provided under the FD&C Act and False Claims Act, fraudulent scheme theories punished under either of these Acts also raise the specter of exclusion from participation in federal health care programs pursuant to the Social Security Act.¹⁰² Under the exclusionary regime administered by the HHS's Office of the Inspector General, an individual or entity convicted of a felony related to health care fraud (or for other enumerated crimes) is prohibited from participating in federal health care programs (mandatory exclusion) for a minimum of five years.¹⁰³ Permissive exclusion may be imposed for various other prohibited activities, including conviction of a misdemeanor related to health care fraud, which carries a minimum exclusionary period of three years.¹⁰⁴ The threat of exclusion from Medicare, Medicaid, and all other health care

98. 31 U.S.C. § 3730(d) (2006).

99. Edward P. Lansdale, Note, *Used as Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 NEW ENG. L. REV. 159, 168 (2006). For a detailed history of the False Claims Act and its evolution in the health care context, see *id.* at 168–71.

100. *Id.* at 177.

101. See sources cited *supra* note 32–33.

102. See 42 U.S.C. § 1320a-7(a)(3) (2006). Also included within the Social Security Act and sometimes associated with prosecutions for unlawful promotion are sections 1128A (the Civil Monetary Penalties Law), *id.* § 1320a-7a, and 1128B (the Anti-Kickback Statute), *id.* § 1320a-7b. This Article does not address the use of those sections in the context of unlawful promotion cases. For a detailed discussion of the interplay between the Anti-Kickback Statute and the False Claims Act, see Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claim Actions*, 51 VAND. L. REV. 1003, 1017–22 (1998).

103. 42 U.S.C. § 1320a-7(a)(3); 42 C.F.R. § 1001.102(a) (2008) (detailing the five-year time limit for mandatory exclusions).

104. 42 U.S.C. § 1320a-7(b)(1)(A); 42 C.F.R. § 1001.201(a)–(b)(1). Detailed requirements related to the imposition of permissive exclusion are set forth in implementing regulations. See 42 C.F.R. §§

programs is serious and has been characterized as a corporate “death sentence” for pharmaceutical companies.¹⁰⁵ Indeed, the risk of losing millions of customers covered under these programs explains many companies’ willingness to settle rather than litigate issues related to off-label promotion.¹⁰⁶ Thus, the threat of exclusion is a powerful enforcement option for punishing unlawful promotion.

Unlawful promotion that negatively impacts the public health should be punished, but not necessarily through the creative enforcement options currently employed by the DOJ. Because there is a long history of punishing pharmaceutical companies for the unlawful promotion of drugs under the FD&C Act, the procedures, application, and understanding of the impact associated with those enforcement options are well-established. In contrast, the DOJ’s efforts to employ the False Claims Act and to incorporate the threat of exclusion from federal programs against pharmaceutical companies for unlawful promotion are less than a decade old.¹⁰⁷ To date, most scholars commenting on the use of the False Claims Act against companies that unlawfully promote their approved prescription drugs have focused primarily on prosecution of truthful, off-label promotion.¹⁰⁸ Applying the False Claims Act to prosecute truthful claims about a drug has been criticized as raising free speech issues under the First Amendment,¹⁰⁹ but of greater concern is DOJ’s current enforcement approach generally and whether the False Claims Act is an appropriate enforcement vehicle under any circumstance.¹¹⁰

1001.201–.951; *see also* Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act, 62 Fed. Reg. 67,392 (Dec. 24, 1997).

105. Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests: Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 241 & n.27 (2006).

106. *Id.*; *see also* Robert Ullmann, *Unhealthy Justice*, PHARMACEUTICAL EXECUTIVE, May 2005, at 194. Mr. Ullmann describes the DOJ as beating large settlement payments from companies under threat of exclusion, basing his view on the creative efforts by DOJ to avoid application of the government’s exclusion authority. *Id.* For example, Mr. Ullmann notes that the guilty plea for Warner-Lambert’s promotion of Neurontin was for activity “through at least August 20, 1996”—one day prior to the August 21, 1996 effective date of the exclusion statute. *Id.*; Gardiner Harris, *Pfizer to Pay \$430 Million over Promoting Drug to Doctors*, N.Y. TIMES, May 14, 2004, at C1.

107. *See* Hall & Berlin, *supra* note 52, at 661–63.

108. *See, e.g.*, Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN. ST. L. REV. 41, 48–50 (2005); Hall & Berlin, *supra* note 52, at 1; *but see* Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 320–25 (2007).

109. *See* Wash. Legal Found. v. Henney, 56 F. Supp. 2d 81, 84, 87 (D.D.C. 1999). The focus on truthful off-label promotion in this context is similar to the Washington Legal Foundation’s litigation efforts to prevent FDA from prohibiting the dissemination of truthful information on the grounds that it violates the right to free speech under the First Amendment. *See id.*

110. *See* Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 201–06 (2001). Concerns about the application of the False Claims Act to the health care industry are not new; Professor Joan Krause provides a detailed analysis of the fiscal harm associated with damages imposed under the False Claims Act and criticizes the lack of judicial guidance associated with negotiated settlement agreements. *Id.*

A. *Using the False Claims Act to Punish Unlawful Drug Promotion*

The DOJ's recent prosecution of Medicis Pharmaceutical Company (Medicis) under the False Claims Act illustrates use of the Act to enforce FD&C Act violations related to unlawful promotion. Medicis manufactures Loprox, a topical anti-fungal approved by the FDA as a prescription drug to treat certain skin infections in humans over the age of ten.¹¹¹ The professional package insert for Loprox indicates that individuals using the drug should avoid covering the treatment area with air-tight wrappings or dressings.¹¹² In 2001, despite the age and use restrictions specified by the FDA as part of Loprox's approval, Medicis began aggressively marketing Loprox to pediatricians, training its sales force to solicit, market, and promote Loprox for the off-label use of diaper rash (and various other skin related infections) in patients under the age of ten.¹¹³

According to sales representatives employed by Medicis, in national and regional meetings held through April 2004, Medicis trained its sales force to use marketing brochures, graphics, photographs, and scripted sales pitches to encourage pediatricians to prescribe Loprox for diaper rash and other skin infections in babies and toddlers.¹¹⁴ In a complaint alleging violations of the False Claims Act, four Medicis employees acting as *qui tam* plaintiffs (also called *relators*) described examples of Medicis' management purposely misleading its sales representatives and doctors in its attempt to gain a share of the pediatric market.¹¹⁵ Among other things, the plaintiffs alleged that Medicis (1) instructed the sales force on how to defuse and deflect objections from health care practitioners about the off-label use of Loprox by making false and misleading statements about data and studies on the safety and efficacy of using Loprox to treat infants;¹¹⁶ (2) provided a colorful marketing brochure on the off-label pediatric use of Loprox that was designated "For presentation purposes only. Not to be left with physicians" for use as a visual sales aid;¹¹⁷ (3) otherwise trained the sales force to refuse to leave

Many of the concerns she raised in 2001 regarding DOJ's use of the False Claims Act against billing and other more traditional health care fraud practices apply to DOJ's expansion of the statute to unlawful promotion of drugs by pharmaceutical companies. See discussion *infra* Part III.

111. Press Release, Dep't of Justice, *supra* note 94.

112. First Amended Complaint at 8, United States *ex rel.* Mulqueen. v. Medicis Pharmaceutical Corp., No. 04-02389-KHV-GR (D. Kan. Apr. 5, 2007).

113. *Id.* at 8–9. Prior to the Fall of 2001, Medicis' products were marketed primarily to dermatologists, podiatrists, and general internists treating adults with dermatological conditions. *Id.* at 6. This new marketing scheme coincided with Medicis' merger with Ascent Pediatrics, Inc., a company focused on marketing pediatric pharmaceuticals. *Id.*

114. *Id.* at 17–18.

115. *Id.* at 4, 10–11. According to the Medicis employees, the company targeted pediatricians because of the high percentage of Medicaid patients eligible for prescription drug reimbursement seen by such doctors. *Id.* at 10.

116. *Id.* at 11, 19.

117. *Id.* at 17.

any written marketing materials on the off-label use of Loprox with pediatricians to avoid detection of their activities by the FDA;¹¹⁸ and (4) misrepresented to the sales force that Loprox was FDA approved for pediatric use and that there was a Japanese study supporting the successful use of Loprox for diaper rash.¹¹⁹

Assuming the truth of the allegations in the complaint against Medicis, the company's off-label promotion of Loprox misbranded the drug under the FD&C Act because it included false and misleading statements about the drug and made claims about the use of Loprox for which no adequate (i.e., FDA approved) directions existed.¹²⁰ Medicis' promotional scheme for Loprox also violated the new drug provisions of the FD&C Act by ascribing intended uses for the product that were not part of its approved NDA.¹²¹ Although the government could have prosecuted Medicis under the FD&C Act, the False Claims Act became the enforcement vehicle when Medicis' sales representatives decided to file a qui tam suit against the company.

As the plaintiffs did here, under the qui tam provisions of the False Claims Act, private parties can file an action on behalf of the United States¹²² and receive a portion of any prosecution or settlement that the government achieves against the defendants.¹²³ One of the advantages to the government of using the False Claims Act is that the private plaintiffs do much of the critical preliminary work. As former or current employees, they have access to information and experience that allows them to identify internal company efforts to encourage unlawful promotion of a prescription drug, providing key investigative information about how to establish liability under the False Claims Act. The government then has the opportunity to sort through the myriad cases filed by qui tam plaintiffs and select only the claims most likely to succeed.

As required under the False Claims Act, the four Medicis plaintiffs served the U.S. Attorney General and the U.S. Attorney for the District of Kansas with a complaint setting forth the alleged misconduct of their employer.¹²⁴ The complaint, filed in August 2004, was kept under seal while the government investigated the allegations.¹²⁵ False Claims Act complaints are kept under seal for at least sixty days while the government decides whether to intervene and proceed with the action or to decline, in which case the private plaintiffs may proceed on their

118. *Id.* at 20–21.

119. *Id.* at 19–20.

120. See 21 U.S.C. § 352(f), (n) (2006), amended by Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 940, 942 (2007).

121. *Id.*

122. See 31 U.S.C. § 3730(b), (d) (2006) (describing the qui tam process).

123. *Id.* § 3730(d).

124. See *id.* § 3730(b)(2); First Amended Complaint, *supra* note 112, at 62.

125. See 31 U.S.C. § 3730(b)(2)–(4); First Amended Complaint, *supra* note 112, at 62.

own.¹²⁶ In fact, the investigation of a *qui tam* case usually takes much longer than sixty days and courts are generally liberal in granting requests to keep claims under seal beyond the required sixty days.¹²⁷ Not until March 2006 did the government finalize its election to proceed with the case against Medicis and assume primary responsibility for the prosecution, with the Medicis employees retaining the right to continue as parties, subject to certain limitations.¹²⁸

Consistent with prior False Claims Act prosecutions for the unlawful promotion of prescription drugs, the charges filed against Medicis were based on the company's violations of the FD&C Act.¹²⁹ There are two prevailing theories for prosecuting FD&C Act violations under the False Claims Act. First, "any person" is liable to the United States "who knowingly presents, or causes to be presented . . . [to the government] . . . a false or fraudulent claim for payment or approval."¹³⁰ Second, "any person who knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government" is liable under the statute.¹³¹ In the most general sense, the use of the False Claims Act against unlawful drug promotion by a pharmaceutical company is premised on the DOJ's assumption that the drug company's unlawful marketing is the *but for* cause of the physician's decision to prescribe the drug and request federal health care program reimbursement.¹³² That a

126. 31 U.S.C. § 3730 (b)(2)–(4).

127. *See id.* § 3730 (b)(3) (allowing a court to extend the time a complaint remains sealed for "good cause shown"); Kimberly A. Lucia, *United States v. Baylor University Medical Center: Impact of FRCP 15(c)(2) on the False Claims Act's Seal Provision*, 42 U.C. DAVIS L. REV. 255, 265 n.71, 276 n.163, 278 n.186 (2008) (discussing courts routine nature in granting extensions and situations where an extension was denied); Letter from Laurie E. Ekstrand, Dir., Homeland Sec. & Justice, Gov't Accountability Office, to F. James Sensenbrenner, Jr., Chairman, Comm. on the Judiciary, House of Representatives 24, 30 (Jan. 31, 2006), available at <http://gao.gov/new.items/d06320r.pdf> (calculating the median time for governmental False Claims Act investigations between 1987 and 2005 as 38 months).

128. Settlement Agreement Between the United States and Medicis (on file with author).

129. First Amended Complaint, *supra* note 112, at 4. The government's settlement with TAP Pharmaceuticals was among the earliest intimations that the False Claims Act could be used to punish unlawful promotional activity. *See* Press Release, Dep't of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), available at <http://www.usdoj.gov/opa/pr/2001/October/513civ.htm>.

130. 31 U.S.C. § 3729(a)(1).

131. *Id.* § 3729(a)(2). A third avenue of liability based on conspiracy is not addressed in this Article. *See id.* § 3729(a)(3).

132. *See, e.g., United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158, 1163 (N.D. Ill. 2007) (asserting in action under the False Claims Act that "many doctor's would not have prescribed Lovenox but for defendant's fraudulent statements"); *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449, at *23 (E.D. Mo. 2006) (requiring a plaintiff to plead that "but for Defendant's allegedly fraudulent misrepresentations, the doctors would not have made claims to Medicare for off-label uses" for a False Claims Act violation). In general, Medicaid and Medicare reimburse pharmacies only for prescription drugs that are "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10)(A) (2006). Drugs that are FDA approved meet that definition, unless they are prescribed for an indication that is not "medically accepted." *See id.* § 1396-

company lacks any direct involvement in the actual preparation or submission of the request for reimbursement under Medicaid or Medicare is irrelevant under the DOJ's theory if there is sufficient circumstantial evidence to suggest that the company acted in a way that induced the false claim(s) to be submitted.¹³³ The expansiveness of this view was acknowledged by a federal District Court in *United States ex rel. Franklin v. Parke-Davis*. The Court nonetheless agreed with the basic premise that Parke-Davis' unlawful promotion caused doctors to submit claims that were not eligible for reimbursement by Medicaid: "Thus, the alleged [False Claims Act] violation arises—not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses *induced by Defendant's fraudulent conduct.*"¹³⁴

The causation and inducement theories acknowledged in *Parke-Davis* were applied by the government in its case against Medicis. Working with the four Medicis plaintiffs, the DOJ traced the marketing history for Loprox as it expanded from its FDA-approved dermatological uses in patients over the age of ten to a patient population that included babies and toddlers and focused on pediatric practices.¹³⁵ According to the government:

Notwithstanding Medicis' knowledge that off-label prescriptions of Loprox and Loprox TS were not medically accepted uses eligible for Medicaid reimbursement,¹³⁶ Medicis knowingly and intentionally took steps to increase the number of off-label Loprox and Loprox TS prescriptions submitted to Medicaid. But for Medicis' promotion of off-label uses, most of the ineligible claims for payment of Loprox and Loprox TS prescriptions would never have been filed because they were not in compliance with Medicaid and other government statutes and regulations.¹³⁷

In the final settlement agreement with Medicis, the government reiterated that because the company promoted uses of Loprox that were not "medically accepted indications" under Medicaid, Medicis caused false and/or fraudulent claims to be submitted to the government from November 2001 through April 2004.¹³⁸ Under

8(k)(2)–(3). A medically accepted indication means any FDA approved use or use that is "supported by" a citation in certain statutorily or agency recognized compendia. *Id.* § 1396r-8(k)(6).

133. See Greene, *supra* note 108, at 63; *but see* Hall & Berlin, *supra* note 52, at 665–70 (arguing that the lack of direct involvement from manufacturers should prove fatal to False Claims Act claims).

134. 147 F. Supp. 2d 39, 52 (D. Mass. 2001) (emphasis added).

135. First Amended Complaint, *supra* note 112, at 6–9.

136. Drugs not used for a medically accepted use are not eligible for Medicaid reimbursement. 42 U.S.C. § 1396r-8 (k)(3).

137. First Amended Complaint, *supra* note 112, at 25.

138. Press Release, Nat'l Ass'n of Medicaid Fraud Control Units, The National Association of Medicaid Fraud Control Units Announces \$9.8 Million Settlement with Medicis (Dec. 2007), available at <http://www.namfcu.net/press/the-national-association-of-medicare-fraud-control-units-namfcu-announces-9-8-million-settlement-with-medicis/>.

the False Claims Act, the penalty for each false claim submitted to the government includes a civil fine of between \$5,500 and \$11,000 plus punitive damages up to three times the amount of the false claim submitted to the government.¹³⁹ Denying the allegations presented by the government but in the absence of any form of adjudication under the FD&C Act by an Article III court, Medicis entered into a civil settlement agreement under which it entered into a corporate integrity agreement with the HHS's Office of Inspector General and paid \$9.8 million to the government, over one million of which was paid by the DOJ to the original qui tam plaintiffs.¹⁴⁰

Similar uses of the False Claims Act in unlawful promotion cases have enriched the government by substantially higher amounts, all without going to trial. In 2005, Serono settled False Claims Act charges related to its off-label promotion of the prescription drug Serostim for \$567 million.¹⁴¹ Intermune paid \$36.9 million under the False Claims Act in its 2006 settlement agreement for unlawful promotion of the prescription drug Actimmune.¹⁴² Also in 2006, Schering paid \$255 million under the False Claims Act to settle charges of off-label promotion of the prescription drugs Temodar and Intron A.¹⁴³ In combination with settlements from other companies referenced above, since 2004 pharmaceutical companies facing the threat of prosecution under the False Claims Act for unlawful promotion have paid over \$1 billion to avoid higher penalties and the possibility of exclusion from federal programs if found liable in court.¹⁴⁴

139. See 31 U.S.C. § 3729 (a)(7) (2006). These civil fine amounts reflect the adjustments for inflation made by regulation. 28 C.F.R. § 85.3(a)(9) (2008).

140. See Press Release, Nat'l Ass'n of Medicaid Fraud Control Units, *supra* note 138; Press Release, U.S. Dep't of Justice, *supra* note 94.

141. Press Release, U.S. Dep't of Justice, Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), available at http://www.justice.gov/opa/pr/2005/October/05_civ_545.html (attributing \$567 million of the settlement amount to False Claims Act claims and \$136.9 million to violations of the FD&C Act).

142. Press Release, U.S. Dep't of Justice, Biopharmaceutical Firm Intermune to Pay U.S. over \$36 Million for Illegal Promotion and Marketing of Drug Actimmune (Oct. 26, 2006), available at http://www.usdoj.gov/opa/pr/2006/October/06_civ_728.html.

143. Press Release, Michael J. Sullivan, U.S. Attorney Dist. of Mass., *supra* note 94.

144. See Press Release, Dep't of Justice, *supra* note 97 (accounting for more than \$1 billion collected from False Claims Act settlements with pharmaceutical companies for the fiscal year of 2008 alone). For more information on settlements paid by pharmaceutical companies, see Taxpayers Against Fraud, FY 2007 False Claims Acts Settlements, <http://www.taf.org/total2007.htm> (last visited Nov. 20, 2009); Taxpayers Against Fraud, FY 2006 False Claims Acts Settlements, <http://www.taf.org/total2006.htm> (last visited Nov. 20, 2009); Taxpayers Against Fraud, FY 2005 False Claims Acts Settlements, <http://www.taf.org/total2005.htm> (last visited Nov. 20, 2009); Taxpayers Against Fraud, FY 2004 False Claims Acts Settlements, <http://www.taf.org/total2004.htm> (last visited Nov. 20, 2009).

B. Using the FD&C Act to Punish Unlawful Drug Promotion

The DOJ's use of the False Claims Act as a punishment vehicle for unlawful promotion has not replaced liability under the FD&C Act, which continues to be a strong enforcement tool. The primary misbranding charges filed against the Purdue Frederick Company (Purdue) in May 2007 were based on FD&C Act enforcement options.¹⁴⁵ Purdue manufactures OxyContin, an opium-type analgesic derived from the chemical oxycodone.¹⁴⁶ OxyContin, a prescription drug, was approved by the FDA in 1995 for the management of moderate to high pain associated with injuries, bursitis, dislocations, fractures, neuralgia, arthritis, lower back pain, and pain associated with cancer.¹⁴⁷ Although approved as a controlled release painkiller, the NDA for OxyContin did not claim superiority over immediate release oxycodone or other pain medications.¹⁴⁸ Also, the NDA did not reference any clinical studies showing that OxyContin was safer or more effective than other pain medications.¹⁴⁹ Nevertheless, from the time of its approval through June 2001, Purdue sales representatives were instructed to promote OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.¹⁵⁰ During this time, sales of OxyContin generated approximately \$2.8 billion in revenue.¹⁵¹ During the same period, the annual number of prescriptions for OxyContin increased from approximately 300,000 to 7.1 million.¹⁵² Following a four year investigation by federal and state law enforcement groups working in cooperation, the U.S. Attorney's Office for the Western District

145. Plea Agreement at 1, 12, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (No. 1:07CR00029), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Plea-Agreement-Purdue.pdf> (in which Purdue pleaded guilty to violation of the FD&C Act, 21 U.S.C §§ 331(a), 333(a)(2) (2006)). Although violations of the False Claims Act were also alleged, Purdue's response to those charges represented only a small portion of the negotiated settlement and were not at all the focus of the government's prosecution (only \$160 million of the \$634 million settlement was for False Claims Act violations). Press Release, U.S. Attorney's Office W. Dist. of Va., *supra* note 50.

146. U.S. GEN. ACCOUNTING OFFICE, *PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM* 1, 8 (2003), available at <http://www.gao.gov/new.items/d04110.pdf>.

147. *Id.* at 1; U.S. Drug Enforcement Admin., *OxyContin Description/Overview*, <http://www.usdoj.gov/dea/concern/oxycontin.html> (last visited Nov. 20, 2009). OxyContin is listed as a Schedule II drug by the Drug Enforcement Administration and has an abuse liability similar to morphine. *Id.*

148. Agreed Statement of Facts at 4, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (No. 1:07CR00029), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Exhibit-B.pdf>.

149. *Id.*

150. *Id.* at 5–6.

151. *Id.* at 2.

152. U.S. GEN. ACCOUNTING OFFICE, *supra* note 146, at 31 tbl.2.

of Virginia filed misbranding charges against Purdue, alleging that the company's promotion of OxyContin was false and misleading under the FD&C Act.¹⁵³

The crux of the government's case against Purdue focused on three specific activities that the government alleged constituted misbranding. First, the government alleged that Purdue trained its sales representatives to falsely promote OxyContin as less addictive and less subject to abuse than other pain relief medications.¹⁵⁴ Based on graphs that exaggerated the stability of blood levels associated with OxyContin's controlled release formula, Purdue sales representatives told health care providers that OxyContin had less euphoric effect and less abuse potential than immediate release alternatives.¹⁵⁵

Second, based on an article published in a medical journal in March 2000, the government alleged that Purdue promoted OxyContin as less likely to cause withdrawal symptoms even when the product was discontinued abruptly.¹⁵⁶ The article, which was drafted by Purdue, made positive claims about the withdrawal effects of OxyContin despite Purdue's receipt of contrary analysis and awareness of reports of adverse experiences related to withdrawal symptoms in a number of patients.¹⁵⁷ For more than one year, Purdue relied on and distributed over ten thousand reprints of the article to promote and market OxyContin as having fewer withdrawal concerns than supported by Purdue's own data.¹⁵⁸

Third, the government alleged that Purdue misbranded OxyContin by actively misrepresenting the general statement: "Delayed absorption, as provided by OxyContin tablets . . . is believed to reduce the abuse liability of a drug."¹⁵⁹ The government claimed that Purdue supervisors and employees falsely cited this statement, which was part of the FDA-approved package insert for OxyContin, as evidence that the drug, among other things, caused less euphoria, had less addiction

153. Press Release, U.S. Attorney's Office W. Dist. of Va., *supra* note 50; Laurence Hammack, *Maker of OxyContin Toughens Its Tablets*, ROANOKE TIMES (Virginia), May 2, 2008, at A1 (detailing the timeline of the Purdue investigation from 2002 until the guilty plea in 2007). Other government entities involved in the case against Purdue included the FDA's Office of Criminal Investigations, the Internal Revenue Service's Criminal Investigation Division, the Department of Health and Human Services' Office of Inspector General, the Department of Labor's Office of Inspector General, Defense Criminal Investigative Service, and Virginia and West Virginia State Police. See Press Release, U.S. Attorney's Office W. Dist. of Va., *supra* note 50.

154. Agreed Statement of Facts, *supra* note 148, at 5–6.

155. See *id.* at 6–9. These graphical data and statements had been specifically rejected by the FDA's Division of Drug Marketing, Advertising, and Communication. *Id.* at 6–7.

156. *Id.* at 11–13.

157. *Id.* at 10–12.

158. *Id.* at 12–13.

159. *Id.* at 13–14.

and abuse potential, and was less likely to be diverted than immediate-release pain medications of a similar nature.¹⁶⁰

Consistent with its approach of examining the collective impact of marketing activities, the DOJ argued that Purdue engaged in an extensively orchestrated scheme to disseminate false and misleading information about its approved drug to physicians and other health care professionals in violation of the misbranding provisions of the FD&C Act.¹⁶¹ In May 2007, Purdue entered an agreement with the United States, pleading guilty to felony misbranding of OxyContin with intent to defraud and mislead under sections 331(a) and 333(a)(2) of the FD&C Act and agreed to pay more than \$600 million.¹⁶² Of the Purdue settlement amount, which far exceeded the criminal penalty recoverable solely under the penalty provisions of the FD&C Act,¹⁶³ \$276 million was forfeited to the United States;¹⁶⁴ \$160 million was allocated to federal and state government agencies to resolve claims under the False Claims Act, at common law, and in equity for government healthcare programs;¹⁶⁵ and \$130 million was designated to resolving private civil claims.¹⁶⁶ Additional amounts were paid to the Virginia Attorney General's Medicaid Fraud Control Unit and to the Virginia Prescription Monitoring program.¹⁶⁷ Although the government could have applied its theory of "inducement" under the False Claims Act to Purdue's violations of the FD&C Act, the bulk of the monetary penalties

160. *Id.* For example, despite its own study suggesting otherwise, Purdue incorrectly represented that it was more difficult to extract the oxycodone from an OxyContin tablet for intravenous abuse than from similar drugs. *Id.* at 5–6.

161. Information at 5–6, 14, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (No. 1:07CR00029), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Exhibit-F.pdf>; U.S. GEN. ACCOUNTING OFFICE, *supra* note 146, at 16.

162. Plea Agreement, *supra* note 145, at 1, 3–7. The Plea Agreement was accepted by the District Court two months later. *U.S. v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 570, 576–77 (W.D. Va. 2007). The plea agreement also applied to three of Purdue's top executives, who pleaded guilty to misdemeanor charges of misbranding in their capacities as responsible corporate officers and agreed to pay a total of \$34.5 million in fines. Barry Meier, *Narcotic Maker Guilty of Deceit over Marketing*, N.Y. TIMES, May 11, 2007, at A1. Although it is beyond the scope of this Article, the fines paid by the Purdue executives are particularly troubling to the extent they suggest an increased willingness by the DOJ to extract individual liability as part of settlement negotiations in these types of cases. Formal litigation efforts against corporate executives in this manner have largely failed, with ten of eleven executives acquitted in the case against TAP executives and all four of the Serono executives acquitted. See David L. Douglass, *Financial Relationships in the Health Care Industry: A Look at Lessons Gained from Recent Cases and Settlements*, HEALTH LAW., Aug. 2006, at 6; Bruce Jaspén, *TAP's Bill for Lupron Grows; \$150 Million Deal Covers Civil Suits*, CHI. TRIBUNE, Nov. 30, 2004, at C1; Ross Kerber, *Jury Acquits 4 in Serono Kickback Case; Verdict Delivers Blow to US Probe of Drug Industry*, BOSTON GLOBE, May 4, 2007, at C1.

163. See Plea Agreement, *supra* note 145, at 3 (stating that the statutory maximum fine was \$500,000).

164. *Id.* at 5.

165. *Id.* at 4–5.

166. *Id.* at 5.

167. *Id.* at 4.

imposed on Purdue under the plea agreement were based on FD&C Act violations, with the government relying on the equitable principle of disgorgement to justify the large civil penalties imposed.¹⁶⁸ Theoretically, the *blockbuster* success of OxyContin justified the government's large recovery.

Other prosecutions for unlawful promotion that have relied primarily on the FD&C Act rather than the False Claims Act include a 2007 case against Pharmacia & Upjohn Company, LLC (a subsidiary of Pfizer, Inc.) and a 2005 case against Eli Lilly and Company. Pharmacia entered a deferred prosecution agreement and paid a \$15 million fine for promoting Genotropin, a human growth hormone drug, for off-label anti-aging, cosmetic, and athletic performance enhancement uses.¹⁶⁹ Eli Lilly entered a civil consent decree and paid \$36 million for off-label promotion of Evista, a prescription drug for osteoporosis.¹⁷⁰ The government alleged that Eli Lilly sales representatives were trained to promote Evista for the prevention and reduction in risk of breast cancer and cardiovascular disease.¹⁷¹ In both cases the government was able to successfully negotiate settlement agreements for unlawful promotion and to recover substantial monetary penalties under the FD&C Act without resorting to use of the False Claims Act.¹⁷²

III. PUNISHING PROMOTION THAT VIOLATES THE FD&C ACT: WHY THE DOJ'S CURRENT ENFORCEMENT APPROACH IS THE WRONG RX

Punishing pharmaceutical companies that unlawfully promote their products to deter future violations of the FD&C Act is consistent with the goals of promoting and protecting the public health. False and misleading claims, whether

168. See, e.g., *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1053–54, 161 (10th Cir. 2006) (explaining how the “disgorgement” justifies large civil penalties by deterring future violations that put “public health and safety at risk”); *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 222, 225, 229, 234 (3d Cir. 2005) (holding “disgorgement” was a proper basis for civil fines and citing multiple jurisdictions concurring with the “disgorgement” theory).

169. Press Release, U.S. Attorney's Office Dist. of Mass., Dep't of Justice, Pfizer Subsidiary Agrees to Plead Guilty for Offering Kickback and Pay \$19.68 Million Criminal Fine; Second Subsidiary Agrees to Pay Additional \$15 Million Penalty to Resolve Allegations of Illegal Promotion of Human Growth Hormone (Apr. 2, 2007), available at <http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Apr2007/Pharmacia-Information-Settlement.html>.

170. Press Release, Dep't of Justice, Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion (Dec. 21, 2005), available at http://www.usdoj.gov/opa/pr/2005/December/05_civ_685.html.

171. *Id.*

172. Michele L. Adelman & Catherine N. Caruga, *A Low Dose Prescription: Criminal Prosecution of Off-Label Promotion*, BOSTON B. J., Nov.–Dec. 2007, at 17, 18–19, available at http://www.foleyhoag.com/~media/Files/Publications/Generic/2007-11-12-BBJ-Legal-Analysis-Adelman_Karuga.ashx; Press Release, Dep't of Justice, *supra* note 169; but see *Pfizer Unit Pleads Guilty, Prosecutors Praise the Corporate Criminal, Not the Whistleblower*, CORP. CRIME REP., Apr. 3, 2007, at 15, available at <http://www.corporatecrimereporter.com/pfizer040307.htm> (detailing a private False Claims Act suit against Pharmacia that may have “triggered” the federal investigation, however, the government did not join).

about on-label or off-label uses, increase the potential for unnecessary and dangerous risks to patients and undermine the FDA's mission of assuring that approved drugs are safe and effective for their intended uses. But punishment alone, even if financially successful, needs to be measured against the FDA's more traditional procedures for advancing correction and compliance. Evidence that financial punishment is actually deterring unlawful promotion under the FD&C Act should be required before we assume that the DOJ's approach to enforcement is promoting and protecting the public health. Granting the DOJ unfettered authority to adopt enforcement approaches that may not be as effective as the FDA's correction and compliance efforts is a mistake and inconsistent with the purposes of the FD&C Act. Nor should we tolerate the DOJ's novel use of the False Claims Act to enforce the FD&C Act without seriously testing the theory of causation upon which it relies. Even if the DOJ's current enforcement approach to and use of the False Claims Act are the most effective means of punishing and preventing unlawful promotion under the FD&C Act, such means ought not to be adopted as *de rigueur* without first surviving genuine judicial or congressional scrutiny. The risk of exclusion from participation in federal health care programs should not fuel the DOJ's ability to circumvent judicial review of its enforcement procedures; nor should negotiated monetary fines, the amounts of which in some cases suggest overreaching on the part of prosecutors, continue unchecked.

A. The DOJ's Current Enforcement Approach Subordinates the Traditional Public Health Goals of Correction and Compliance Under the FD&C Act to the Recovery of Large Fines

The DOJ's financial success in prosecuting unlawful promotion by pharmaceutical companies over the past decade has occurred independent of the FDA's more traditional focus on achieving timely correction and compliance of individual labeling and advertising materials.¹⁷³ While it may be impossible to know the extent to which the DOJ's prosecutorial decisions are influenced by the potential for large monetary rewards, a company's ability and willingness to negotiate a large settlement likely bears some weight and may even be more relevant than the seriousness of the underlying promotional violation or the need to correct the violation expeditiously.¹⁷⁴ Successful use of the False Claims Act as a

173. See generally Richard C. Ausness, "There's Danger Here, Cherie!": Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses, 73 BROOK. L. REV. 1253, 1259-64 (2008) (describing the DOJ's investigation and litigation in multiple cases as opposed to the FDA's accusations and warnings).

174. Qui tam litigation can continue for years before a settlement or court decision is reached. See, e.g., United States *ex rel.* Barnak v. Sutter Corp., No. 95 CV 7637(KTD), 2002 U.S. Dist. LEXIS 10446, at *2-3 (S.D.N.Y. 2003) (finding against a qui tam plaintiff after an investigation and litigation that lasted approximately seven years); United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (denying a motion to dismiss a qui tam action in part almost five years after the

punishment for FD&C Act violations, as measured by the hundreds of millions of dollars recovered through settlement agreements, undoubtedly contributes to the DOJ's evaluation of the financial incentives inherent in any proposed qui tam case. Also contributing to the DOJ's increased focus on the recovery of large fines rather than on the FD&C Act's twin purposes of promoting and protecting the public health (achieved by the FDA through correction and compliance) is the absence of any FDA role in the initial evaluation of unlawful promotion cases brought under the False Claims Act. According to a recent government report, although FDA entities within the agency are ultimately involved in the DOJ prosecutions of unlawful promotion under the False Claims Act, at least during 2003 through 2007, the FDA did not initiate any of the DOJ enforcement actions taken against pharmaceutical manufacturers for unlawful promotion.¹⁷⁵

Most False Claims Act cases involving unlawful promotion are initiated by qui tam plaintiffs who file notice of claims directly with the DOJ.¹⁷⁶ The ability of qui tam plaintiffs to bypass preliminary review by FDA regulators experienced in the area of drug labeling and advertising reduces the FDA's gate keeping role in the initial evaluation of whether the promotion in question is actually unlawful. A diminished role for FDA experts, who are specifically charged with implementing the public health goals of the FD&C Act, appears to have contributed to the shift in emphasis from correction and compliance to punishment, a shift that is not likely to change in light of the DOJ's success in recovering substantial monetary fines for unlawful promotion.

Now, regardless of whether it is focusing on enforcement options under the False Claims Act (as it did in the Medicis case) or the FD&C Act (as it did in the Purdue case), the DOJ appears committed to achieving deterrence through financial penalties.¹⁷⁷ However, the advantages associated with focusing on correction and

initial filing); Anna Mae Walsh Burke, *Qui Tam: Blowing the Whistle for Uncle Sam*, 21 NOVA L. REV. 869, 882 (1997).

175. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 19.

176. Matthew, *supra* note 108, at 284, 308–19; *see also* Press Release, Dep't of Justice, *supra* note 97.

177. Since constructing its theory of False Claims Act liability, the DOJ has resorted to a mix and match approach to the prosecution of unlawful promotion by pharmaceutical companies. Alleging specific violations of the FD&C Act, the DOJ then decides whether to seek penalties under the False Claims Act, the FD&C Act, or some combination thereof. For example, the 2006 Schering settlement on Temodar included approximately \$180 million of criminal penalties and \$255 million in FD&C Act and False Claims Act civil penalties. Press Release, Michael J. Sullivan, U.S. Attorney Dist. of Mass., *supra* note 94, at 1–2. The 2005 case against Eli Lilly for Evista promotion was settled solely under the FD&C Act for \$36 million. Press Release, Dep't of Justice, *supra* note 169. More recently, Bristol-Myers Squibb settled False Claims Act allegations that included charges of off-label promotion of its drug Abilify for more than \$515 million (the company faced civil but not criminal charges by DOJ). Press Release, Dep't of Justice, Bristol-Myers to Pay More than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), available at http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html.

compliance should not be cast aside without careful consideration of the impact on the FD&C Act's primary goal of promoting and protecting the public health.

B. Use of the False Claims Act to Punish Unlawful Promotion Marginalizes the FDA's Expertise in a Way that Undercuts the Public Health Goals of the FD&C Act

The DOJ's implementation of its False Claims Act theory of liability heralded a dramatic change in the government's approach to unlawful promotional activity by pharmaceutical companies. Prior to the suggestion in *United States ex rel. Franklin v. Parke-Davis* that the False Claims Act might be a valid enforcement tool against unlawful drug promotion,¹⁷⁸ concerns about drug labeling and advertising were generally handled within the FDA by its Division of Drug Marketing, Advertising, and Communications (DDMAC), which is responsible for prescription drugs,¹⁷⁹ and by the Office of Compliance and Biologics Quality (OCBQ), which monitors promotional activities for biological products.¹⁸⁰ Consistent with the intent of the FD&C Act to promote and protect the public health, DDMAC and OCBQ strive to ensure that promotional labeling and advertising information is not false, lacking in fair balance (i.e., between the drug's risks and benefits), or otherwise misleading.¹⁸¹

Enforcement activity undertaken by FDA regulators tends to be flexible and is usually initiated by a regulatory compliance (untitled or warning) letter that objects to specific claims made in promotional labeling or advertising and provides an opportunity for the company to communicate and negotiate with the FDA about appropriate marketing messages.¹⁸² In most cases, companies comply with the agency's directives regarding allegedly unlawful promotional activity, or respond

178. See *Parke-Davis*, 147 F. Supp. 2d at 50–53.

179. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L. J. 423, 429–30 (2002).

180. Suzanne M. Sensabaugh, *A Primer on CBER's Regulatory Review Structure and Process*, 32 DRUG INFO. J. 1011, 1016–17 (1998).

181. See Mark E. Boulding, *The Statutory Basis for FDA Regulation of Scientific and Educational Information*, 4 J. PHARMACY & L. 123, 123, 128, 131 (1995); Sensabaugh, *supra* note 180, at 1017; Div. of Drug Mktg., Adver., & Comm'ns, U.S. Food & Drug Admin., Description, <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm> (last visited Nov. 20, 2009).

182. DEP'T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 22, at 53–54. The Center for Drug Evaluation and Research maintains a database of untitled and warning letters sent out to companies since 1997. Ctr. for Drug Evaluation & Research, U.S. Dep't of Health & Human Servs., Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773> (follow hyperlinks to choose a specific year) (last visited Nov. 20, 2009). The FDA also maintains a searchable database of warning letters sent by the District Offices of individual states. Food & Drug Admin., U.S. Dep't of Health & Human Servs., Warning Letters, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (last visited Nov. 20, 2009).

to the objections raised and reach some mutually agreeable resolution with DDMAC or OCBQ.¹⁸³ Only if the parties are unable to agree is further action sought through the FDA's Office of Chief Counsel or the DOJ's Office of Consumer Litigation.¹⁸⁴ Under those circumstances, civil and criminal enforcement actions under the FD&C Act may include, among other options, injunction proceedings, negotiated consent decrees, and seizures.¹⁸⁵ Rarely do cases escalate to those formal levels; overall, the FDA's enforcement efforts focus on achieving correction and compliance, not punishment.¹⁸⁶

In contrast, when the False Claims Act is the primary vehicle for punishing companies that violate the FD&C Act, *qui tam* plaintiffs commonly initiate enforcement, not FDA regulatory personnel with expertise in the area of unlawful drug promotion.¹⁸⁷ Consequently, because the DOJ is the lead agency on False Claims Act cases aimed at unlawful drug promotion, initial prosecutorial discretion is transferred from the FDA—the agency specifically designated by Congress to promote and protect the public health—to an entity whose primary focus is high profile criminal enforcement of health care fraud and whose expertise in the area of drug labeling and advertising is limited.¹⁸⁸ When the FDA is less involved in decisions of whether and to what extent to prosecute unlawful promotional activity, there is inevitably a significant loss of expertise in evaluating the legal status of information and its public health benefits in accordance with the FD&C Act.

Consistent with its congressionally mandated mission to protect the public health, when the FDA considers the substantive content and impact of promotional labeling and advertising, its primary goal is to ensure that information is not false

183. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 19 (stating the “drug companies have generally complied with . . . directives as suggested in [warning and untitled] letters” from DDMAC).

184. See Mary Olson, *Substitution in Regulatory Agencies: FDA Enforcement Alternatives*, 12 J. L. ECON. & ORG. 376, 385 (1996) (describing the great cost associated with litigation and the “[thirteen] levels of hierarchical approval” before seizures or injunctions are sent to the Office of the Chief Counsel). Multiple types of litigation are open to the FDA. See sources cited *supra* notes 32–33.

185. See sources cited *supra* notes 32–33; Press Release, U.S. Food & Drug Admin., Cardinal Health 303, Inc. Signs Amended Consent Decree with FDA (Feb. 19, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149530.htm>.

186. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 6 (comparing the FDA's issuance of warning letters to the DOJ's enforcement actions, which resulted in settlements); Arthur K. Yellin, *FDA Prescription Drug Enforcement Policies and Techniques*, 42 FOOD DRUG COSM. L.J. 552, 556, 558 (1987).

187. See Press Release, Dep't of Justice, *supra* note 97 (stating that almost 78% of False Claims Act recoveries were “associated with suits initiated by private citizens”).

188. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 6; Zalesky, *supra* note 105, at 247–48. The Attorney General's role as the lawyer for the United States allows that once a lawsuit is filed, even if by a *qui tam* relator, the Attorney General and DOJ wield exclusive authority to decide how to proceed in a given matter, with or without the consent of FDA. Although the 2008 GAO Report indicates that FDA regulators are involved in the resolution of DOJ's enforcement actions, the extent of that role is not discussed. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 6.

or misleading.¹⁸⁹ The FDA's regulatory expertise enables the agency to balance that goal against the benefits of encouraging the free exchange of scientific information, which is not unlawful and upon which many health care providers and patients rely.¹⁹⁰ For example, determinations about the extent to which information about off-label uses should be allowed under the rules for scientific and educational information¹⁹¹ and where dissemination of information amounts to unlawful promotion are complicated and have long been debated among the FDA, Congress, health care professionals, industry, consumers, and other groups.¹⁹² Even as the DOJ continues to sift through its pipeline of potential False Claims Act cases, many of which focus on the promotion of off-label uses and promotional schemes alleged to include the distribution of misbranded drugs,¹⁹³ the FDA has been working on a guidance document on the dissemination of information on off-label uses that would expand the ability of pharmaceutical companies to provide health care practitioners with medical journal studies of unapproved uses for drugs.¹⁹⁴ As

189. See U.S. DEP'T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 11, at 7; U.S. Food & Drug Admin., What We Do, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Nov. 20, 2009). In contrast, under the DOJ's False Claims Act theory, it may be that even truthful off-label marketing may give rise to a "false" claim. See Lansdale, *supra* note 99, at 161 (commenting on Judge Saris' decision in *United States ex rel. Franklin v. Parke-Davis*).

190. Guidance for Industry, Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093, 64,095 (Dec. 3, 1997).

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are nonpromotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny.

Id. The treatment of cancer, pediatric, and rare "orphan" diseases often depend on access to off-label information. Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescribing*, 5 INDEP. REV. 25, 26, 28 (2000).

191. See Joseph Leghorn et al., *The First Amendment and FDA Restrictions on Off-Label Uses: The Call for a New Approach*, 63 FOOD & DRUG L.J. 391, 396–403 (2008) (analyzing different types of dissemination by manufacturers, such as scientific, promotional, commercial and hybrid forms, and when such dissemination is allowed); James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANN. HEALTH L. 295, 309–15 (2003) (discussing the First Amendment right for companies to disseminate off-label uses for scientific and educational purposes).

192. O'Reilly & Dalal, *supra* note 191, at 306–07 (discussing such debates in multiple court cases). These regulatory "gray areas" are of just the sort identified by Krause as least appropriate for "punitive penalties . . . especially when the allegations are resolved by settlement." Krause, *supra* note 110, at 206–10, 213–14.

193. George S. Craft, Jr., *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 HOUS. J. HEALTH L. & POL'Y 103, 105–06, 127–28 (2007).

194. See Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of

suggested by Krause, clarifying these regulatory “gray areas” should be one of the first steps in ensuring that the DOJ’s application of the False Claims Act to unlawful promotional activity is accepted as a reasonable, fair, and coherent enforcement option.¹⁹⁵

The DOJ’s use of the False Claims Act to punish unlawful promotional activity requires no special deference to the FDA’s expertise. Furthermore, even to the extent the DOJ consults with the FDA on whether application of the False Claims Act is appropriate, the DOJ likely lacks sufficient motivation to consistently defer to the FDA’s judgment and expertise in matters of pharmaceutical promotion. The combined attraction of *qui tam* plaintiffs willing and able to assume responsibility for the initial investigation into companies’ promotional practices with the opportunity for large recoveries likely decreases the DOJ’s inclination to value the FDA’s interpretation of the FD&C Act. Rather, its successful use of the False Claims Act in *Parke-Davis* and other cases suggests that the DOJ will continue the shift from achieving correction and compliance with the FD&C Act to punishing pharmaceutical companies financially. As evidenced by the press releases touting settlements for unlawful promotion cases over the past few years, while correction and compliance are included in the concessions obtained from pharmaceutical companies,¹⁹⁶ the impact of such punishment on manufacturers’ actual behavior appears to have assumed a position of secondary importance with the large financial rewards garnering the vast amount of DOJ and media attention.¹⁹⁷

Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. 9342 (Feb. 20, 2008); U.S. FOOD & DRUG ADMIN., *supra* note 73, at 3.

195. Krause, *supra* note 110, at 213–14.

196. Greene, *supra* note 108, at 42–43 & n.9; Office of Inspector Gen., *supra* note 51. Settlement agreements calculate the amounts to be paid by companies facing prosecution for unlawful promotion. Correction and compliance goals are achieved by requiring that companies alter and monitor their sales and marketing schemes. To the extent False Claims Act prosecutions impact pharmaceutical behavior it is through separate Corporate Integrity Agreements. Greene, *supra* note 108, at 42.

The Office of Inspector General (OIG) often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG’s agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. . . . Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.

Office of Inspector Gen., *supra* note 51. When the enforcement vehicle is the FD&C Act, the same results are achieved by Consent Decree. *See Schering-Plough GMP Consent Decree Puts Drug Industry on Notice*, FOOD & DRUG LETTER, June 7, 2002, at 1, 1.

197. *See* Greene, *supra* note 108, at 42–43 & n.9 (noting how “corporate integrity agreements” are a part of off-label promotion settlements, yet citing several news headlines stressing the monetary portion of settlements); *see, e.g.*, Press Release, U.S. Dep’t of Justice, *supra* note 43; Press Release, Dep’t of Justice, *supra* note 97.

To the extent the DOJ remains committed to elevating punishment of unlawful promotional cases beyond available administrative remedies, DOJ prosecutors will continue to exercise significant discretionary authority and control over such cases. Based on financial incentives alone, in deciding whether particular cases warrant prosecution, the DOJ may be inclined to usurp and undervalue the FDA's goals of correction and compliance and to rely less on the agency's expertise in assessing the legitimacy of unlawful promotion claims under the FD&C Act. And as long as the DOJ's successful enrichment of the public coffers persists, it seems unlikely to consider abandoning the False Claims Act route to large monetary recoveries. If the goals of promoting and protecting the public health under the FD&C Act are truly paramount, the FDA should be afforded an early and substantive role in the decision of whether prosecution is warranted.

C. Use of the False Claims Act to Punish Unlawful Promotion Turns on a Questionable Theory of Causation and Should Not Be Used in Lieu of the FD&C Act

The DOJ's application of the False Claims Act to pharmaceutical companies that engage in promotional activity that violates the FD&C Act is founded on the premise that such activity "induces" physicians to file false claims.¹⁹⁸ The DOJ's reliance on this idea of inducement to support the causation required under the False Claims Act is fairly novel and has yet to survive serious judicial scrutiny.¹⁹⁹ Because to date the prosecution of unlawful promotion under the False Claims Act almost always resulted in negotiated settlements, pharmaceutical manufacturers lack the benefit of precedent and reliable information on which to base decisions about the legitimacy of the DOJ's use of the False Claims Act.²⁰⁰ While the False Claims Act has long been used to combat improper billing, inadequate services, and other traditional health care fraud by doctors, hospitals, and healthcare providers, its application to pharmaceutical companies in the context of drug promotion is relatively new.²⁰¹ The DOJ's use of the False Claims Act as a sword

198. United States *ex rel.* Franklin v. Parke-Davis, No. Civ.A. 96-11651PBS, 2003 U.S. Dist. LEXIS 15754, at *11-19 (D. Mass. Aug. 22, 2003) (stating that the relationship between off-label promotion and physician prescription practices may satisfy the causation prong of the False Claims Act); Greene, *supra* note 108, at 43-44.

199. Greene, *supra* note 108, at 64 ("The [*Parke-Davis*] court's conclusions about the viability of a False Claims Act claim based on off-label promotion undoubtedly contributed to the settlement of this case."). The denial of summary judgment in *Parke-Davis*, on which DOJ relies, merely held that the qui tam plaintiff had presented a viable theory and enough evidence of causation to avoid summary dismissal. 2003 U.S. Dist. LEXIS 15754, at *17-19. To date, no court has had an opportunity to consider the merits of the theory or ultimate liability after trial.

200. See Nicole Huberfeld, *Pharma on the Hot Seat*, 40 J. HEALTH L. 241, 243-45 (2007).

201. Paul E. Kalb, *Health Care Fraud and Abuse*, 282 JAMA 1163, 1164-65 (1999); see *Parke Davis*, 2003 U.S. Dist. LEXIS 15754 (analyzing whether to broaden False Claims Act claims to apply to pharmaceutical companies).

against pharmaceutical companies to induce settlement for unlawful promotion has been incredibly successful,²⁰² giving the DOJ little incentive to question its application of the False Claims Act to these promotion cases or to entertain doubt about its causation theory. Thus, unless forced to do so, the DOJ seems unlikely to abandon its aggressive prosecution of unlawful promotion, whether it is acting against off-label (unapproved) uses or on-label (approved) uses. Rather, the more likely scenario is that the DOJ will continue to expand application of and stretch remedies under the False Claims Act to unlawful promotion by pharmaceutical companies.

The willingness of companies to settle False Claims Act charges lends an unfair air of appropriateness to the DOJ's use of the False Claims Act in the context of promotional labeling and advertising. Under the provisions of the False Claims Act, liability is premised on specific claims filed for payment.²⁰³ Unlike other health care fraud situations, where actual claims are identified as false based on substantial factual information related to the claim,²⁰⁴ the DOJ's settlements of cases against promotional labeling and advertising generally allege wholesale violations tied to promotional schemes, without proof that each prescription for which a claim for reimbursement is filed with Medicare or Medicaid is a false claim.²⁰⁵ The one court that has considered the reasonableness of this type of broad sweeping approach to connecting companies' promotional activities and the filing of individual false claims dismissed the *qui tam* plaintiff's case as impossible to prove.²⁰⁶

The case against Purdue for its promotion of OxyContin illustrates how the DOJ's application of the False Claims Act to drug promotion that violates the FD&C Act portends the continued expansion of an unreasonable theory of causation designed primarily to maximize financial punishment. As noted previously, the DOJ's theory of False Claims Act liability starts with the premise that a pharmaceutical manufacturer's unlawful promotion of a prescription drug *induces* or *causes* a physician or other health care provider to file a false claim for reimbursement with Medicare or Medicaid.²⁰⁷ Because liability attaches to individual claims, theoretically, the government must separately examine each

202. See Greene, *supra* note 108, at 42 & n.9.

203. See 31 U.S.C. § 3729(a)(2) (2006).

204. See Kalb, *supra* note 201, at 1164–65.

205. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 24 tbl.3, 28 tbl.4 (listing FDA's narrow regulatory letters and the DOJ settlements and alleged actions based on broad marketing schemes). Scrutinized individually, some portion of the claims collectively designated as *false* by the DOJ would likely qualify for reimbursement under the provisions for compendia drugs, the practice of medicine, or some other legitimate basis.

206. United States *ex rel.* Hess v. Sanofi-Synthelabo Inc., No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449 (E.D. Mo. 2006).

207. Hall & Berlin, *supra* note 52, at 658.

request for reimbursement and determine that the request was caused by the pharmaceutical company's allegedly unlawful promotion *and* was a claim that the government should not have paid.²⁰⁸ To prove that a claim was improperly paid, the government must establish that the prescription for which reimbursement was sought *was not medically necessary*.²⁰⁹ When the second prong of the test is applied to individual prescriptions in the context of unlawful promotion of on-label uses, the DOJ's causation theory is particularly problematic.

In *Purdue*, the DOJ challenged the legitimacy of reimbursements for OxyContin prescriptions based on allegations that Purdue falsely motivated doctors to prescribe OxyContin by claiming, among other things, that OxyContin was less addictive than similar drugs for pain.²¹⁰ Because the allegedly unlawful promotional claims were directly related to the approved uses of OxyContin, part of the universe of false claims would have included prescriptions written for patients who legitimately needed to manage pain. For any prescription written under those circumstances, the government would not have been able to establish that the claim for reimbursement was false because the prescription was for a medically necessary drug for which the government was obligated to pay. Thus, even if Purdue was responsible for promoting misperceptions that encouraged doctors to prescribe OxyContin based partially on false and misleading information, many of the individual prescriptions for OxyContin likely qualified as medically necessary and were legitimately submitted for reimbursement. Avoiding judicial review of its enforcement approach allowed the DOJ to successfully circumvent any need to establish the false nature of reimbursement requests on a claim-by-claim basis. Although the use of the FD&C Act against Purdue was only a limited part of the prosecution for unlawful promotion, its application mirrors the weakness of the DOJ's causation theory under the False Claims Act.²¹¹

Thus far, the DOJ seems to be limiting its enforcement focus to cases where it can tie flagrant violation of promotional guidelines by companies to increased prescription patterns in support of the *but for* causation necessary for a False Claims Act violation.²¹² While such behavior by pharmaceutical manufacturers is reprehensible, Congress and the courts should not tolerate a practice of forcing

208. *Sanofi-Synthelabo Inc.*, 2006 U.S. Dist. LEXIS 22449 at *3–6.

209. 42 U.S.C. § 1395y(a)(1) (2006).

210. Agreed Statement of Facts, *supra* note 148, at 5.

211. See *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007). The Supreme Court's recent decision in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2130–31 (2008), also suggests that the DOJ's theory of inducement in unlawful promotion cases may be too broad to withstand judicial scrutiny. The Court's holding indicates that in addition to proving that a pharmaceutical company made a false statement to a prescribing physician about a drug, the government would need to prove that the company intended the false statement to cause the government to pay the claim in order to establish False Claims Act liability. *Id.* at 2130.

212. See Greene, *supra* note 108, at 63.

companies to pay amounts that by their very size call into question the exercise of prosecutorial discretion. Given the lack of probability that the DOJ could prove each alleged false claim in the unlawful promotion cases that satisfies the requirements of the False Claims Act, some reasonable basis for justifying the settlement numbers is required. At the very least, if the DOJ is going to continue using the False Claims Act in this manner, assurance that the FDA is involved in influencing prosecutorial discretion and policing the cases brought by individuals should be transparent.

Having pioneered this theory of causation under the False Claims Act to punish unlawful promotion, the DOJ bears some responsibility for its embracement by *qui tam* plaintiffs and state governments, especially now that numerous states are passing their own *State False Claims Acts* modeled after the federal False Claims Act.²¹³ As a result of these new statutory options, we should anticipate that many more *qui tam* plaintiffs will file suits in state courts. In state cases it is even less likely any uniform federal interpretation and application of the FD&C Act can be guaranteed. If we make it easier for whistleblowers to bring cases on their own, private attorneys will act without the benefit of the FDA's expertise in interpreting the FD&C Act. When a state court adopts a *qui tam* plaintiff's interpretation of the FD&C Act, precedent will be set (as compared to settlements that apply only to the parties involved). Merely declining to intervene in cases that it views as unwarranted is likely not enough to contain the individual plaintiff suits and the misinterpretation of the FD&C Act that may result.²¹⁴ Rather, the DOJ should accept responsibility by intervening in cases that it does not support and moving for dismissal.

In lieu of the DOJ's current approach to unlawful promotion by pharmaceutical manufacturers, such activity should be prosecuted solely under the FD&C Act, which is the statutory scheme established by Congress. Any DOJ concerns that the remedies available under the False Claims Act are uniquely suited to motivate companies to comply with FD&C Act promotional restrictions are misplaced. Combining the penalty provisions in the FD&C Act with the doctrine of equitable disgorgement is sufficient to punish promotional activities that violate the FD&C Act and provide a preferable long-term approach to the continued use of the legally questionable theory of causation asserted by the DOJ in claims prosecuted under the False Claims Act.

213. See, e.g., Florida False Claims Act, FLA. STAT. ANN. § 68.081–09 (LexisNexis Supp. 2009); New Jersey False Claims Act, N.J. STAT. ANN. § 2A:32C-1 to -17 (Supp. 2008); Delaware False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1201–09 (2005).

214. For example, certain aspects of the decision in *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.* could be read as inconsistent with prevailing FDA policy. No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449, at *1–3 (E.D. Mo. Jan. 23, 2006).

D. The DOJ's Reliance on Negotiated Settlements to Punish Unlawful Promotion Is Legally Coercive and also Undermines the Public Health Goals of the FD&C Act

The DOJ has been able to sidestep judicial scrutiny of its interpretation and application of the False Claims Act to unlawful promotion cases largely because of the potential for exclusion from participation in federal programs faced by companies threatened with prosecution.²¹⁵ Exclusion from reimbursement under the Social Security Act, which threatens manufacturers with the loss of the right to participate in federal health care programs, perpetuates manufacturers' willingness to settle with the DOJ rather than risk imposition of the penalty. By holding companies hostage, the DOJ further undermines confidence that its punitive goals are consistent with the public health purposes of the FD&C Act and confirms its message that companies are powerless to challenge the government's characterization of their promotional materials.

It is incumbent upon the DOJ to exercise discretion and resist the temptation to impose inappropriate and unsubstantiated monetary and other settlements. Similar restraint should be exercised when relying on the FD&C Act to punish unlawful promotion by pharmaceutical companies. Including secondary False Claims Act charges in order to threaten companies with debarment, and basing disgorgement calculations on theoretical rather than actual numbers, results in unsubstantiated and unfair monetary awards that will ultimately be passed on to consumers in the form of higher health care costs. If such a result is reached without a corresponding increase in correction and compliance in pharmaceutical labeling and advertising, the public health goals of the FD&C Act are reduced to a secondary role that diminishes confidence that the government can be relied upon to promote and protect the public health.

CONCLUSION

The government's success in recovering large financial settlements—exemplified by the Medicis, Purdue, and other recent cases—suggests that regardless of the enforcement vehicle, the DOJ has succeeded in shifting the focus on labeling and promotion of pharmaceutical products from correction and compliance to punishment. Because the FD&C Act may be just as effective an enforcement tool as the False Claims Act, serious consideration of the legal and practical concerns associated with relying on the False Claims Act to prosecute unlawful promotion under the FD&C Act is warranted. Legitimate debate about the nature of pharmaceutical labeling and advertising is a necessary part of ensuring that the FD&C Act's goals of promoting and protecting the public health are realized. Those goals are undermined when such conversations are avoided in the

215. See 42 U.S.C. § 1320a-7b(a) (2006) (allowing exclusion from participation in federal programs for False Claims Act violations).

pursuit of large monetary settlements that are negotiated without any judicial review of the underlying substantive legal issues.