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

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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 Justice Department (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 ten to hundreds of millions of dollars. In part, companies settle these cases 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 participate in federal health care programs. Even more disturbing, these settlements allow DOJ to circumvent judicial review of its enforcement approach, preventing any type of accountability for its legal theories or 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 prosecuting 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 settlements in lieu of developing a more coherent and responsible enforcement strategy.
TABLE OF CONTENTS

INTRODUCTION

I. Restrictions on Drug Promotion Under the FD&C Act.
   B. Promotion that “Misbrands” A Drug.

II. Enforcement Approaches to FD&C Act Violations.
   A. Using the False Claims Act to Prosecute Unlawful Drug Promotion.
   B. Using the FD&C Act to Prosecute Unlawful Drug Promotion.

III. Punishing Promotion that Violates the FD&C Act: Why DOJ’s Current Enforcement Approach is the Wrong Rx.
   A. 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.
   B. Use of the FCA to Punish Unlawful Promotion Marginalizes FDA’s Expertise.
   C. Marginalizing FDA’s Enforcement Role Undercuts the Public Health Goals of the FD&C Act.
   D. Relying on the FCA to Punish Unlawful Promotion Relies on a Questionable Theory of Causation and Should not be Used in Lieu of the FD&C Act.
   E. 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.

CONCLUSION
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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 dollars,² including more than $7 billion dollars spent on promotion targeting prescribing physicians and other health care professionals and another $4.2 billion attributable to direct-to-consumer advertising.³ Other estimates calculate promotional expenditures at more than twice that amount.⁴ 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 prevention for serious diseases and health conditions,⁵ the pharmaceutical industry is entrusted with obligations far beyond those of whitening teeth, preventing wrinkles, and stopping odor. We expect public health and safety to come first and demand that companies

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² Estimates based on those provided by Intercontinental Marketing Services (IMS), one of the primary authorities on pharmaceutical promotional expenditures. Approximately $18.4 billion (in retail value) of that amount was devoted to promotional free samples distributed to patients through physicians. IMS Health, Total U.S. Promotional Spend by Type, 2006 (Mar. 8, 2007); available at http://imshealth.com/ims/portal/front/articleC/0,2777,6599_80402580_81493254,00.html.


⁵ For example, more than 26 million Americans have been prescribed the statin drug Lipitor, used to lower LDL cholesterol and fight the plaque that contribute to heart disease. See http://www.lipitor.com/about-lipitor/clinical-trials.jsp?setShowOn=.about-lipitor/clinical-trials.jsp&setShowHighlightOn=.about-lipitor/clinical-trials.jsp last visited July 28, 2008.
promote prescription drugs within the parameters established under the Federal Food, Drug, and Cosmetic Act (FD&C Act).\textsuperscript{6} When the limits on promotion are exceeded, we rely on the government to step in and ensure compliance. But how compliance is achieved matters, 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, its use of the False Claims Act to prosecute violations of the FD&C Act, and its reliance on negotiated settlements to circumvent judicial review of its new enforcement procedures deserve careful scrutiny.

The United States Food and Drug Administration (FDA) is the federal agency authorized under the FD&C Act to regulate the promotion of prescription drugs.\textsuperscript{7} Consistent with its mission to protect and promote the public health, FDA exercises that 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.”\textsuperscript{8} The “labeling and promotional information” referenced by FDA, and on which this article focuses, falls into two categories: (1) promotional labeling and (2) advertising.\textsuperscript{9}

\textsuperscript{6} 21 U.S.C.A. §§ 321-397 (West 1999 & Supp. 2008). 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.


\textsuperscript{8} Division of Drug Marketing, Advertising and Communication (DDMAC) Mission Statement, http://www.fda.gov/cder/ddmac/ DDMAC is responsible for promotion and advertising of drugs. The Office of Compliance for Biological Quality (OCBQ) handles the same issues for biological products.

\textsuperscript{9} 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 Form FDA 2253 “Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use.”
No formal definition of promotional labeling exists, although the term is generally understood to refer to everything except FDA-approved labeling.\textsuperscript{10} FDA-approved labeling for prescription drugs includes professional labeling (i.e., the full prescribing information that accompanies every prescription drug)\textsuperscript{11} and consumer-oriented labeling (i.e., “Medication Guides,” which are required by FDA to ensure the safe and effective use of certain prescription drugs).\textsuperscript{12} As the catch-all for everything except FDA-approved labeling, promotional labeling covers most of the labeling information to which consumers and healthcare professionals are exposed. 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.”\textsuperscript{13} For prescription drugs, which are articles under the FD&C Act,\textsuperscript{14} 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.\textsuperscript{15} The form and manner of information encompassed under this view includes all variety of printed, audio, or visual matter.\textsuperscript{16}

Promotional materials that do not qualify as labeling are regulated as advertising by FDA. Although neither “advertisement” nor “advertising” is defined in the FD&C Act, section 352(n) and implementing regulations evidence the broad nature and scope of information

\textsuperscript{10} See discussion supra ___; and FDA’s Draft Guidance for Industry on Help-seeking and Other Disease Awareness Communications by or on Behalf of Drug or Device Firms (DDMAC Jan. 23, 2004) at 5.

\textsuperscript{11} The requirements for professional labeling are set forth by regulation. 21 C.F.R. § 201.57 (2007). 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 and may be required (as it is for oral contraceptives, 21 C.F.R. § 310.501) or voluntary.

\textsuperscript{12} 21 C.F.R. Part 208 (2007).

\textsuperscript{13} 21 U.S.C.A. § 321(m).

\textsuperscript{14} See 21 U.S.C.A. § 321(g)(1).

\textsuperscript{15} See Kordel v. United States, 335 U.S. 345 (1948).

\textsuperscript{16} 21 C.F.R. § 202.1(l)(2).
regulated as advertising.\textsuperscript{17} 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.”\textsuperscript{18} 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.”\textsuperscript{19} Thus, in combination with its authority over promotional labeling, FDA’s regulatory oversight of prescription drug marketing extends to practically every type of material and media imaginable.\textsuperscript{20}

Given the enormous range of materials regulated as promotional labeling and advertising, FDA depends heavily on voluntary compliance by pharmaceutical companies to market products according to the requirements of the FD&C Act. 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.\textsuperscript{21} A small percentage of promotional materials are pre-approved by FDA.\textsuperscript{22} Companies submit all other promotional materials for prescription drugs to FDA at the time of first use.\textsuperscript{23} Additionally, FDA engages in regular, but limited, surveillance to assess compliance with its promotional standards for prescription drugs and pursues enforcement

\textsuperscript{17} 21 U.S.C.A. § 352(n); 21 C.F.R. § 202.1. 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).


\textsuperscript{20} Although internet information falls under FDA’s regulatory authority, FDA has equivocated on its precise legal status, suggesting that it may be labeling or advertising depending on the circumstances. Among the policies and guidance currently under development FDA’s Center for Drugs Division of Drug Marketing, Advertising and Communication includes how advertising and promotion of FDA-regulated products will be regulated on the Internet. See http://www.fda.gov/cder/handbook/pol_guid.htm. \textsuperscript{21} See, e.g., 21 C.F.R. § 202.1; Guidance for Industry: Consumer-Directed Broadcast Advertisements (August 1999).

\textsuperscript{22} Pre-approval of promotional materials is required for drugs approved under FDA’s accelerated approval process. 21 C.F.R. § 314.550.

\textsuperscript{23} 21 C.F.R. § 314.81(b)(3)(i); see also supra note 9.
actions as necessary. But despite 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, whether by design, by mistake, by employment of unscrupulous sales representatives, or by other means, companies continue to push the outer limits of the law with regard to promotional activities.

Until fairly recently, FDA has exercised almost exclusive regulatory and enforcement authority over pharmaceutical companies’ promotional activities related to prescription drugs. In its role as primary watchdog, FDA has at its disposal a variety of methods for punishing unlawful promotion under the FD&C Act, including administrative, civil, and criminal penalties for unlawful promotion; however, FDA’s use of these punishment options has been rare. Rather, FDA typically attempts to achieve compliance from companies through less formal means, often relying on “untitled” 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 their products. But the agency’s enforcement approach

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24 See supra note 8 re: the transmittal form, which is used by FDA as a source of information as to what companies are disseminating and publishing.
25 Some of the more recent willingness to stretch 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 FDA-approved products. See Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), appeal dismissed, 202 F.3d 331 (D.C. Cir. 2000).
26 FDA’s reticence to exercise its enforcement authority may be partly attributable to the lack of resources at the agency’s disposal. Although consent decrees in the early 1990s requiring FDA pre-approval of all advertising and labeling included provisions to cover some of the agency’s oversight costs, the dearth of similar enforcement activity that followed suggests that the administrative and financial burdens imposed by oversight programs may have been too much for FDA to bear on a widespread scale. See, e.g., Consent Decree entered with Kabi Pharmacia, Inc. (D.C.N.J. August 1993).
27 According to FDA’s website, “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.” http://www.fda.gov/cder/handbook/pruntlet.htm
28 Warning letters are reserved for activity FDA perceives as raising more serious health concerns and require that companies take corrective action, which often includes sending “Dear Doctor” letters to physicians.
has not been perceived as terribly successful in stopping or preventing unlawful marketing practices, and critics have complained that companies operate on the premise that the benefits of questionable promotional tactics outweigh the risk that FDA will take action or that the consequences of any action will be significant.  

In part, that perception and critique are probably fueled by 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.

FDA’s enforcement restraint has undoubtedly contributed to the United States Department of Justice’s (DOJ’s) emergence as a more strident crusader against FD&C Act violations arising from the promotion of off-label uses. Bypassing FDA’s traditionally narrower emphasis on individual claims and activities, DOJ has indicated 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. In 1999, for example, DOJ brought the first ever criminal prosecution against a drug company (Genentech, Inc.) for violating FDA's rules against promoting a drug for unapproved uses.  

Faced with DOJ’s misbranding charges pointing to discernible “patterns” of off-label promotion, Genentech paid $50 million dollars 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 short for reasons other than the lack of adequate growth hormone, children with a

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rare form of juvenile obesity, and for burn patients. More recently, DOJ’s continued focus on the overall impact of companies’ promotional marketing schemes rather than on individual labeling and advertising claims was evident in its 2004 settlement with Warner-Lambert following the decision in United States ex. rel. Franklin v. Parke-Davis, Division of Warner Lambert Co. (Parke-Davis). DOJ based its charges against Warner-Lambert on a compilation of 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. As part of its guilty plea Warner-Lambert agreed to pay a $240 million dollar criminal fine for violating the FD&C Act and an additional $190 million dollars to settle civil liabilities under the False Claims Act.

DOJ’s increased enforcement role and interest in punishing violations of the FD&C Act have precipitated several major changes in its approach to unlawful promotion by pharmaceutical companies. First, 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. Second, 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 promoting their products for off-label uses cause false requests for reimbursements to be filed with Medicare, Medicaid, and other federal health care programs. Third, by negotiating settlements under the FD&C and the False Claims Acts, DOJ has avoided judicial review of its enforcement theories and

31 Id.
procedures, fueling the likelihood that its significantly altered approach to unlawful drug promotion will continue unchecked.

For the reasons described below, this article criticizes the manner in which DOJ has expanded its prosecution options 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, 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. Indeed, within the last five years DOJ has managed to negotiate criminal and civil settlements with individual pharmaceutical companies ranging from just under ten, to hundreds of millions of dollars. 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 DOJ because of the potential costs associated with the exclusion regime administered by the U.S. Department of Health and Human Services, under which companies risk losing the right to participate in any federal health care program. Yet, there are genuine concerns

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35 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 gauging crooks. See, e.g., Gottlieb, Stop the War on Drugs, Wall Street Journal (December 17, 2007) (“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.”). Mr. Gottlieb is a Former Deputy Commissioner for Medical and Scientific Affairs.


37 42 U.S.C. § 1320a-7 (2007). “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). Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.” http://www.oig.hhs.gov/fraud/cias.html (last visited on 5/27/08).
raised by DOJ’s focus on punishment, its application of the False Claims Act (FCA) to unlawful promotion cases, and its readiness to negotiate settlements that stretch remedies available under the FCA and the FD&C Act.

First, to the extent DOJ’s enforcement approach to unlawful promotion reaps large monetary recoveries, DOJ prosecutors are likely to continue focusing on the rewards of punishment without regard to the benefits associated with FDA’s more traditional aims of correction and compliance. But such a shift is problematic in the context of pharmaceutical labeling and advertising, where FDA’s long-standing reliance on industry self-regulation achieved through fair and reasonable compliance efforts legitimately serve the public health and are consistent with the goals of the FD&C Act and agency resources. Punitive remedies in the form of large monetary fines and criminal penalties ought not to be imposed without careful consideration of their impact on those goals. Thus, DOJ should be mindful to respect the benefits of FDA’s enforcement approach and expertise in a way that promotes the public health by ensuring that FDA’s role in assessing the legitimacy of promotional claims under the FD&C Act is not too diminished.

Second, applying the FCA to unlawful promotion cases raises significant legal questions. DOJ’s position that unlawful promotional activity by pharmaceutical companies “induces” physicians to write prescriptions that result in the filing of false claims for reimbursement under the FCA relies on an unreasonable theory of causation. Given that the penalty provisions in the FD&C Act in conjunction with the doctrine of equitable disgorgement provide sufficient means to punish unlawful promotional activity, relying on the questionable theory of causation required under the FCA to prosecute those cases is

38 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 United States v. Lane Labs-USA, Inc., 427 F.3d 219 (3d Cir. 2005); United States v. Rx Depot, Inc., 438 F.3d 1052 (10th Cir. 2006); United States v. Universal Management Services, Inc., 191 F.3d 750 (6th Cir. 1999).
unnecessary. In lieu of using the FCA, DOJ should prosecute such activity solely under the FD&C Act, which is the statutory scheme established by Congress specifically for that purpose and which is more than adequate to punish unlawful promotion by pharmaceutical companies.

Third, even if the shift from compliance to punishment is warranted, and even if the use of the FCA against unlawful promotional claims is legitimate, to date, DOJ’s enforcement approach under both the FCA and the FD&C Act has culminated in negotiated settlements with individual companies. The amounts of these settlements are sizeable, 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, it is unclear whether the significant legal and policy decisions related to DOJ’s interpretation and application of the FD&C Act and FCA are valid. Thus, at the very least, if the government is going to continue to employ the FCA in these types of cases, it must be careful to exercise its prosecutorial discretion with vigilance and resist the temptation to impose 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 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, DOJ’s “recovery” of what it views as companies’ “ill-gotten gains” may enrich the United States Treasury --but 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). The success of an NDA application depends, in part, on the drug sponsor’s ability to prove that the drug is safe and effective for its intended use(s). The intended use of an approved drug is carefully circumscribed and must be properly reflected in the labeling that accompanies the drug, which is also subject to FDA approval. 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 towards health care professionals (including physicians and pharmacy benefit managers), consumers, or both. While the majority of companies’ promotional labeling and advertising efforts fall within the regulatory parameters set by 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

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39 21 U.S.C. § 355(a). “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.

40 21 U.S.C. § 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)(describing the proposed text of labeling that must be submitted as part of the application to market a new drug).

41 21 U.S.C. § 355(b)(1)(F) (requiring submission of labeling specimens for the drug as part of the NDA); see also 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. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.100(c)(1). See Draft Guidance supra note (cited above)
FD&C Act: that a company has introduced a new drug into interstate commerce, or misbranded a drug.

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

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

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

42 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 as well to biologics, 42 U.S.C. § 262(a)(2000 & Supp. V 2005), and any reference to drugs in this article should be read to include biological products as well.
43 21 U.S.C. § 331(a) (prohibiting the introduction or delivery for introduction into interstate commerce that is misbranded); 21 U.S.C. §.352(a) (defining a drug as misbranded if its labeling is false or misleading) and 352(f)(1) (defining a drug as misbranded where its labeling lacks adequate directions for use).
44 See 21 U.S.C. § 321(p)
47 Id.
approved drugs.\textsuperscript{48} 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.\textsuperscript{49} And allowing some exchange of scientific and educational information is also consistent with physicians’ prescribing authority.\textsuperscript{50} Because regardless of whether 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.\textsuperscript{51} Indeed, the opportunity to increase sales by marketing off-label uses to physicians provides much of the impetus for unlawful promotion by pharmaceutical companies that may result in a “new drug” charge.

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. 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

\textsuperscript{48} 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. \textit{See} 21 C.F.R. § 201.128.

\textsuperscript{49} Michael Soares, \textit{“Off Label” Indications for Oncology Drug Use and Drug Compendia: History and Current Status}, 1 J. of Oncology Practice 102, 104 (September 2005) (noting also that off-label uses are even more prevalent in the pediatric population).

\textsuperscript{50} 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. \textit{See}, e.g., FDA’s Information Sheet for Institutional Review Boards and Clinical Investigators, \textit{Off-Label and Investigational Use of Marketed Drugs, Biologics, and Medical Devices} available at \url{http://www.fda.gov/oc/ohrt/irbs/offlabel.html} (“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 \textit{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).”).

\textsuperscript{51} \textit{Id.}
such information is scientifically valid and not presented in a promotional manner.\textsuperscript{52} Thus, all of these limited exceptions to 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\textsuperscript{53}

The types of unlawful promotion that may result in new drug charges under the FD&C Act are often combined with certain of the FD&C Act’s misbranding prohibitions. When a pharmaceutical company labels a drug in a way that is false or misleading,\textsuperscript{54} 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,\textsuperscript{55} or suggests uses for a drug for which no adequate directions are provided,\textsuperscript{56} 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 FDA in conjunction with the drug’s NDA; a manufacturer may promote its prescription drug only for those claims relating to the intended uses for which the drug has been approved (i.e., “on-

\textsuperscript{52} There are a number of methods by which a company, its employees, or agents may disseminate information about off-label uses of an approved drug. The exchange of scientific information in a non-promotional context is permitted by regulation. 21 C.F.R. § 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 FDA Guidance, supra note 48. An informal policy of allowing companies to respond to unsolicited requests from healthcare personnel for information about off-label uses also exists. \textit{Id}. at 64091. 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 FDA’s Draft 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” 73 F.R. 9342 (February 20, 2008); see also \textit{Washington Legal Foundation 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 section 401(e) of the Food and Drug Modernization Act of 1997, 21 U.S.C. §§ 360aaa et. seq. expired pursuant to sunset provisions in September 2006.

\textsuperscript{53} While there are many other ways to misbrand a product, means that are not related to the promotional labeling or advertising for a product are not included in this discussion. \textsuperscript{54} 21 U.S.C. § 352(a).
\textsuperscript{55} \textit{Id}. at § 352(n).
\textsuperscript{56} \textit{Id.} at§ 352(f)(1); see \textit{infra} note 58 and accompanying text.
label” uses). Promotional claims relating to on-label uses violate the FD&C Act prohibitions on misbranding when they are “false or misleading.” 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 FDA for approval of the drug actually supports. In addition to affirmative statements that are false or misleading, misbranding also encompasses what a company fails to say about its product. Thus, for example, a manufacturer may misbrand its product by presenting information about safety and efficacy without corresponding information about side effects and contraindications. Indeed, the vast majority of violations identified by FDA in letters to pharmaceutical companies stem from inadequate presentation (i.e., omission or minimization) of risk information.

Misbranding of an approved drug may also occur when an approved drug is promoted for off-label uses. 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 use as required. FDA often couples misbranding charges with new drug charges when it asserts regulatory authority over unlawful promotion of a prescription drug.

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57 21 U.S.C. § 352(a) (“A drug shall be deemed misbranded if its labeling is false or misleading in any particular).
58 See 21 C.F.R. § 202.1(e). Claims of this type, which are made in the context of the approved uses for a drug violate FDA’s regulatory requirement that advertisements include a “true statement of information.” 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.
59 "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in 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 material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.” 21 U.S.C. § 321(n).
60 21 U.S.C. § 352(n). In which case 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).
II. Enforcement Approaches to FD&C Act Violations.

Whether a company is making an on-label or off-label claim for an approved drug, if FDA believes the claim violates the misbranding or new drug provisions of the FD&C Act, the company faces potential prosecution for unlawful promotion. 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. 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” letters and formal, i.e., “warning” letters. These letters put companies on notice regarding materials that 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. Where FDA seeks more than an administrative remedy, however, the agency must refer such cases to the Department of Justice (DOJ), Office of Consumer Litigation (OCL) (although DOJ may initiate a case under the FD&C Act without a referral from FDA). 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.

63 21 U.S.C. § 332(a) (injunction); § 333(a)(1) and (2) (misdemeanor and felony criminal provisions); § 333(g) (civil penalties for false and misleading direct-to-consumer ads); § 333(f)(4) (civil monetary penalties for misbranding); and § 334(a)(1) (seizure).
65 Id. at Chapter 4-1 available at http://www.fda.gov/ora/compliance_ref/rpm/chapter4/ch4-1.html.
67 See 28 C.F.R. § 0.45(j) (FDA may also refer cases directly to the U.S. Attorneys Office in the district in which the case will be brought for filing, concurrently notifying OCL). The Assistant Attorney General for the Civil Division must approve any criminal prosecution and any civil penalty or injunctive proceeding brought under the FD&C Act.
When the FCA is the vehicle for prosecuting pharmaceutical promotion that violates the FD&C Act, the enforcement option is for civil fraud penalties. As with the FD&C Act, DOJ also has direct authority over FCA litigation, which allows DOJ to initiate an FCA prosecution on its own and also provides an avenue for FDA to bring such cases. Typically, however, the route to FCA litigation bypasses FDA and is initiated by private citizens acting on behalf of the government or qui tam. Among the incentives for private parties to expose fraud against the government is the FCA provision that awards qui tam plaintiffs a percentage of any successful prosecution or settlement. Use of the FCA to combat fraud against the government dates back to the Civil War, when it was used primarily in the context of supply contracts connected to the government’s war efforts. In modern times, expansion of the FCA to address healthcare related fraud has encompassed a variety of unlawful activities ranging from billing for services never rendered to more complicated reimbursement issues based on companies’ practices regarding Average Wholesale Prices. The use of the FCA to punish unlawful promotion under the FD&C Act is the most recent attempt to use the FCA as a regulatory tool against pharmaceutical companies. Although FCA complaints against unlawful promotion are rooted in FD&C Act violations, for which adequate enforcement provisions already exist, the potential for greater civil fines under the FCA and its attraction of qui tam plaintiffs are among the features that distinguish the FCA from enforcement under the FD&C Act and likely account for much of its appeal to government prosecutors.

69 21 C.F.R. § 0.45(d).
70 “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 thing as for himself sues in this matter. Black’s Law Dictionary (8th ed. 2004).
72 For a detailed history of the FCA and its evolution in the health care context see Edward Landsdale Note Used as Directed? How Prosecutors are Expanding the False Claims Act to Police Pharmaceutical Off-label Marketing 41 New. Eng. L. Rev. 159, 168-81.
73 See id. at 177-78.
In addition to the enforcement options provided under the FD&C Act and FCA, unlawful promotion violations under either of these Acts also raise the specter of exclusion from participation in federal health care programs pursuant to the Social Security Act.\(^\text{74}\) Under the exclusionary regime administered by the Health and Human Services Office of 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.\(^\text{75}\) 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.\(^\text{76}\) The threat of exclusion from Medicare, Medicaid, and all other healthcare programs is a serious one and has been characterized as a corporate “death sentence” for pharmaceutical companies facing prosecution for unlawful promotion.\(^\text{77}\) 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.\(^\text{78}\) Thus, the threat of exclusion is a powerful enforcement option for punishing unlawful promotion.

\(^{74}\) 42 U.S.C. § 1320a-7 (2000 & Supp. V 2005). Also included within the Social Security Act and sometimes associated with prosecutions for unlawful promotion are section 1128A (the Civil Monetary Penalties Law), 42 U.S.C. § 1320a-7a, and section 1128B (the Anti-Kickback Statute), 42 U.S.C. § 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 FCA 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 (1998).

\(^{75}\) Id. § 1320a-7(a)(3). Detailed requirements related to the imposition of mandatory exclusion are set forth in implementing regulations. See 42 C.F.R. Part 1001 Subpart B.

\(^{76}\) Id. § 1320a-7(b)(1)(A). Detailed requirements related to the imposition of permissive exclusion are set forth in implementing regulations. See 42 C.F.R. Part 1001 Subpart C; see also Notice from the Office of Inspector General, Health and Human Services, Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act, 62 F.R. 67,392 (December 24, 1997). Authority to exert permissive exclusion is extremely broad, extending to any “prohibited” activity for any minimum period. § 1320a-7(b)(1)(7).


\(^{78}\) Id.; see also Robert Ullmann, Unhealthy Justice: The Medicare exclusion statute is a lose-lose for pharma companies—and distorts the criminal justice system, PharmExec.com (May 1, 2005) available at http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=162043 Mr. Ullmann describes DOJ as beating large settlement payments from companies under threat of exclusion, basing his view on what present as
Unlawful promotion that negatively impacts the public health should be punished—but not necessarily through the creative enforcement options currently employed by 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, DOJ’s efforts to employ the FCA and to incorporate the threat of exclusion from federal programs against pharmaceutical companies for unlawful promotion are less than a decade old. To date, most scholars commenting on the use of the FCA against companies that unlawfully promote their approved prescription drugs have focused primarily on FCA prosecution of truthful, off-label promotion. Applying the FCA to prosecute truthful claims about a drug has been criticized as raising free speech issues under the First Amendment, but of greater concern is DOJ’s current enforcement approach generally and whether the FCA is an appropriate enforcement vehicle under any circumstance.

A. Using the False Claims Act to Prosecute Unlawful Drug Promotion.

DOJ’s recent prosecution of Medicis Pharmaceutical Company (Medicis) under the FCA illustrates use of that Act to enforce FD&C Act violations related to unlawful promotion. Medicis manufactures Loprox, a topical anti-fungal approved by FDA as a prescription drug to treat certain skin infections in humans over the age of ten years old. The professional package insert for Loprox indicates that individuals using the drug should avoid covering the treatment

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79 Creative efforts by DOJ to avoid application of the government’s exclusion authority. 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. See, e.g., Ralph Hall & Robert 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 (2006). While the authors refer briefly to the misapplication of the FCA to unlawful promotion generally, their primary focus is on truthful, off-label promotion.

80 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 supra note __
area with air-tight wrappings or dressings. In 2001, despite the age and use restrictions 
specified by 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.\textsuperscript{81}

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.\textsuperscript{82} In a complaint 
alleging violations of the FCA, four Medicis employees acting as qui tam plaintiffs (also called 
“relators” under the FCA) described examples of Medicis’ management purposely misleading 
its sales representatives and doctors in its attempt to gain a share of the pediatric market.\textsuperscript{83} 
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;\textsuperscript{84} 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;\textsuperscript{85} 3) otherwise trained the sales force to refuse to 
leave any written marketing materials on the off-label use of Loprox with pediatricians to

\textsuperscript{81} \textit{United States ex. rel. Mulqueen et. al. v. Medicis Pharmaceutical Corp.}, No. 04-02389, (D. Kan. April 
5, 2007) First Am. Compl. at ¶ 28. Prior to the Fall of 2001, Medicis’ products were marketed primarily to 
dermatologists, podiatrists, and general internists treating adults with dermatological conditions. \textit{Id.} at ¶ 11. This 
new marketing scheme coincided with Medicis’ merger with Ascent Pediatrics, Inc., a company focused on 
marketing pediatric pharmaceuticals.

\textsuperscript{82} \textit{Id.} at ¶¶ 65-68.

\textsuperscript{83} 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. \textit{Id.} at ¶ 39.

\textsuperscript{84} \textit{Id.} at ¶¶ 40 and 70.

\textsuperscript{85} \textit{Id.} at ¶ 67.
avoid detection of their activities by FDA;\textsuperscript{86} 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.\textsuperscript{87}

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.\textsuperscript{88} 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.\textsuperscript{89} Although the government could have prosecuted Medicis under the FD&C Act, the FCA became the enforcement vehicle when Medicis sales representatives decided to file an FCA complaint against the company.

As the plaintiff’s did here, under the qui tam provisions of the FCA, private parties can file an action on behalf of the United States\textsuperscript{90} and receive a portion of any prosecution or settlement that the government achieves against the defendants.\textsuperscript{91} One of the advantages to the government of using the FCA 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 that provides key investigative information about how to establish liability under the FCA. The government then has the opportunity to sort through the myriad of cases filed by qui tam plaintiffs and select only the most likely to succeed.

\textsuperscript{86} Id. at ¶ 77.
\textsuperscript{87} Id. at ¶¶ 71-72 and 75.
\textsuperscript{88} Infra. pages
\textsuperscript{89} Infra. pages
\textsuperscript{90} 31 U.S.C. § 3730(b).
\textsuperscript{91} Id. § 3730(d).
As required under the FCA, the four Medicis plaintiffs served the U.S. Attorney General and the U.S. Attorney General for the District of Kansas with a complaint setting forth the alleged misconduct of their employer, Medicis. The complaint, filed in August 2004, was kept under seal while the government investigated the allegations. FCA 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 with the action on their own. In fact, however, the investigation of a qui tam case usually takes much longer than sixty days and courts are generally liberal in granting requests to extend the time under which complaints are kept under seal. 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.

Consistent with prior FCA 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. There are two prevailing theories for prosecuting FD&C Act violations under the FCA. 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.” Second, liability under subsection (a)(2) exists for “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

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92 See id. § 3730(b)(2).
93 See id. § 3730(b)(3).
94 Id. § 3730 (b)(2) – (4).
95 See id. § 3730 (c).
96 The government’s settlement with TAP Pharmaceuticals was among the earliest intimations that the FCA could be used to punish unlawful promotional activity. See DOJ Press Release, 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.
approved by the Government.”

In the most general sense, the use of the FCA against unlawful drug promotion by a pharmaceutical company is premised on DOJ’s assumption that the drug company’s unlawful marketing, is the “but for” cause of the physician’s decision to prescribe that drug and the consequent request for reimbursement. That a company lacks any direct involvement in the actual preparation or submission of the request for reimbursement under Medicaid or Medicare is irrelevant under 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.

The expansiveness of this view was acknowledged by the court in United States ex. rel. Franklin v. Parke-Davis, which 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 FCA 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.”

The causation and inducement theories established in Parke-Davis were applied by the government in its case against Medicis. Working with the four Medicis plaintiffs, 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. 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, 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 would not have been submitted.

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98 Id. at § (a)(2). A third avenue of liability based on conspiracy is not addressed in this article. See 3729(a)(3).
99 Stephanie Greene, False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products, 110 Penn St. L. Rev. 41, 65 (2005); Hall & Berlin supra note __ at 658.
100 147 F. Supp. 2d at 53 (emphasis added).
101 Drugs not used for a medically accepted use are not eligible for Medicaid reimbursement. 42 U.S.C. § 1396r-8.
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.\textsuperscript{102}

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 September 2005.\textsuperscript{103} Under the FCA, the penalty for each false claim submitted to the government includes a civil fine of between $5,500 to $11,000 dollars and the potential for punitive damages up to three times the amount of the false claim submitted to the government.\textsuperscript{104} Denying the allegations presented by the government but in the absence of any form of adjudication under the FD&C Act by either FDA or an Article III court, Medicis entered into a civil settlement agreement under which it entered a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General and paid $9.8 million dollars to the government, over a million of which was paid to the original quit tam plaintiffs.\textsuperscript{105}

Similar uses of the FCA in unlawful promotion cases have enriched the government by substantially higher amounts, all without going to trial. In 2005, for example, Serono settled FCA charges related to its off-label promotion of its prescription drug Serostim for $567 million dollars. Intermune paid $36.9 million dollars in FCA penalties under its 2006 settlement agreement for unlawful promotion of its prescription drug Actimmune. Also in 2006 Schering paid $255 million dollars in civil penalties under the FCA to settle charges of off-label promotion of its prescription drugs Temodar and Intron A. In combination with

\textsuperscript{102} \textit{Supra} note 81 at ¶ 97.
\textsuperscript{104} 31 U.S.C. § 3729 (a)(7). These civil fine amounts reflect the adjustments for inflation made by regulation. 28 C.F.R. § 85.3(a)(9).
\textsuperscript{105} \textit{Supra} note 103 at 4.
settlements from other companies referenced above, since 2004 pharmaceutical companies facing the threat of prosecution under the FCA for unlawful promotion have paid over a billion dollars to avoid higher penalties and the possibility of exclusion from federal programs if found liable in court.

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

DOJ’s use of the FCA as a punishment vehicle for unlawful promotion has not replaced liability under the FD&C Act, which continues to be a strong enforcement tool. Indeed, the primary misbranding charges filed by FDA against the Purdue Frederick Company (Purdue) in May 2007, were based on FD&C Act enforcement options.\(^{106}\) Purdue manufactures OxyContin, an opium-type analgesic derived from the chemical oxycodone. Oxycontin, a prescription drug, was approved by 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.\(^{107}\) Although approved as a controlled release painkiller, the NDA for OxyContin did not claim superiority over immediate release oxycodone or other pain medications.\(^{108}\) Nor did the NDA reference any clinical studies showing that OxyContin was any safer or more effective than other pain medications.\(^{109}\) 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.\(^ {110}\)

\(^{106}\) Although violations of the FCA 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.

\(^{107}\) OxyContin is listed as a Schedule II drug by the Drug Enforcement Administration and has an abuse liability similar to morphine.


\(^{109}\) *Id.*

\(^{110}\) *Id.* at ¶ 20.
generated approximately $2.8 billion dollars in revenue.\textsuperscript{111} During that same period, the annual number of prescriptions for OxyContin increased from approximately 300,000 to nearly 6 million.\textsuperscript{112} 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 of Virginia filed misbranding charges against Purdue, alleging that the company’s promotion of OxyContin was false and misleading under the FD&C Act.\textsuperscript{113}

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.\textsuperscript{114} 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.\textsuperscript{115}

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.\textsuperscript{116} 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 in a number of

\begin{itemize}
\item \textsuperscript{111} \textit{Id.} at ¶ 6.
\item \textsuperscript{113} Other government entities involved in the case against Purdue included 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. DOJ News Release (May 10, 2007).
\item \textsuperscript{114} Supra note 108 at ¶ 20.
\item \textsuperscript{115} These graphical data and statements had been specifically rejected by FDA’s Division of Drug Marketing, Advertising, and Communication (DDMAC). \textit{Supra} note 108 at ¶¶ 21-26.
\item \textsuperscript{116} \textit{Supra} note 108 at ¶¶ 31-38.
\end{itemize}
patients related to withdrawal symptoms.\textsuperscript{117} For more than a year, Purdue relied on and distributed over ten thousand reprints of the article to promote and market OxyContin as having fewer withdrawal concerns than was actually supported by Purdue’s own data.\textsuperscript{118}

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.” The government claimed that certain 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 and abuse potential, and was less likely to be diverted than immediate-release pain medications of a similar nature.\textsuperscript{119}

Consistent with its approach of examining the collective impact of marketing activities, 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. In May 2007, faced with the results of the government’s investigation, 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 agreeing to the payment of more than six hundred million dollars by the company.\textsuperscript{120} Of the Purdue settlement amount, 

\footnotesize{\textsuperscript{117}Id. at ¶¶ 30-38.  
\textsuperscript{118}Id. at ¶¶ 34-38.  
\textsuperscript{119}Id. at ¶¶ 39-43. 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.  
\textsuperscript{120}The Plea Agreement was accepted by the district court two months later. United States v. Purdue Frederick Co., 495 F. Supp. 2d 569 (W.D. Va. 2007). The plea agreement also applied to three of Purdue’s top executives, who pled guilty to misdemeanor charges of misbranding in their capacities as responsible corporate officers and agreed to pay a total of $34.5 million dollars in fines. 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 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}
which far exceeded the criminal penalty that could have been recovered solely under the penalty provisions of the FD&C Act, $276 million dollars were forfeited to the United States, $160 million dollars were allocated to federal and state government agencies to resolve claims under the FCA for government healthcare programs and $130 million dollars were designated to resolving private civil claims. Additional amounts were paid to the Virginia Attorney General's Medicaid Fraud Control Unit and to the Virginia Prescription Monitoring program. Although the government’s theory of “inducement” under the FCA could have been applied to Purdue’s violations of the FD&C Act, the bulk of the monetary penalties 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. The “blockbuster” success of OxyContin theoretically justified the government’s large recovery.

Other prosecutions for unlawful promotion within the last few years that have relied primarily on the FD&C Act rather than the FCA 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 delayed prosecution agreement and paid a $15 million dollar fine for promoting Genotropin, its human growth hormone drug, for off-label anti-aging, cosmetic and athletic performance enhancement uses. Eli Lilly entered a civil consent decree and paid $36 million dollars for off-label promotion of Evista, a prescription drug for osteoporosis. The government alleged that Lilly sales representatives were trained to promote Evista for the prevention and reduction in risk of breast cancer and cardiovascular disease. In both of these cases the government was able to successfully force settlement agreements for acquitted in the case against TAP executives and all four of the Serono executives acquitted. Add cites for these cases.

See, e.g., United States v. Rx Depot, Inc., 438 F.23d 1052 (10th Cir. 2006); United States v. Lane Labs-USA Inc., 427 F.3d 219, 223-36 (3d Cir. 2005).
unlawful promotion and to recover substantial monetary penalties under the FD&C Act, without resorting to use of the FCA.

III. Punishing Promotion that Violates the FD&C Act: Why 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 about on-label or off-label uses, increase the potential for unnecessary and dangerous risks to patients and undermine FDA’s mission of assuring that approved drugs are safe and effective for their intended uses. But punishment alone, even if financially successful, should still be measured against FDA’s more traditional procedures for advancing correction and compliance and some evidence in that regard should be required before we abandon FDA’s more traditional focus on encouraging correction and compliance in drug labeling and advertising in a way that promotes and protects the public health. It is a mistake to grant DOJ unfettered authority to adopt enforcement approaches that may not as effectively ensure the protection and promotion of the public health. Nor should we tolerate DOJ’s novel use of the FCA to enforce the FD&C Act without seriously testing the theory of causation upon which it relies. Even if DOJ’s current enforcement approach and use of the FCA 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 some genuine judicial or congressional scrutiny. The risk of exclusion from participation in federal health care programs should not fuel DOJ’s ability to circumvent judicial review of its enforcement procedures. Allowing DOJ to negotiate monetary fines, the amounts of which in some cases suggest overreaching on the part of prosecutors, should not continue unchecked. Thus, rather than tolerating DOJ’s ability to extract whatever pharmaceutical companies can
afford to pay when faced with charges of unlawful promotion, we should require that DOJ exercise its enforcement authority under the FD&C Act in a reasonably thoughtful and fair manner.

A. 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.

DOJ’s financial successes from prosecuting unlawful promotion by pharmaceutical companies over the past decade have not relied on FDA’s more traditional focus on achieving timely correction and compliance of individual labeling and advertising materials. It is unclear the extent to which DOJ’s prosecutorial decisions are influenced by the potential for large monetary rewards. But it is likely that a company’s ability and willingness to negotiate a large settlement bears some weight and may even be more relevant than the seriousness of the underlying promotional violation at issue, or the need to correct the violation expeditiously. Successful employment of the FCA as a punishment for FD&C Act violations likely has encouraged DOJ’s consideration of financial incentives. Compounding the drift away from the traditional notions of safety and efficacy under the FD&C Act is FDA’s reduced role in the evaluation of unlawful promotion cases brought under the FCA.

Most FCA cases involving unlawful promotion are initiated by qui tam plaintiffs who file notice of claims directly with DOJ. The ability of qui tam plaintiffs to bypass preliminary review by FDA regulators experienced in the area of drug labeling and advertising reduces the likelihood that FDA can provide any significant gate keeping role in the initial evaluation of whether promotion 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 soon in light of DOJ’s success in recovering substantial monetary
fines for unlawful promotion. Now, regardless of whether it is focusing on enforcement options under the FCA (as it did in the Medicis case) or the FD&C Act (as it did in the Purdue case), DOJ appears most interested in achieving deterrence through financial penalties. But the advantages associated with focusing on correction and 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 FCA to Punish Unlawful Promotion Marginalizes FDA’s Expertise.

DOJ’s implementation of its FCA 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 Davis123 that the FCA might be a valid enforcement tool against unlawful drug promotion, concerns about drug labeling and advertising were generally handled within FDA by its Division of Drug Marketing, Advertising, and Communications (DDMAC), which is responsible for prescription drugs, and by the Office of Compliance and Biologics Quality (OCBQ), which monitors promotional activities for biological products. 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., as between the drug’s risks and benefits), or otherwise misleading.

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 being made in promotional labeling or advertising and provides an opportunity for the

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122 Since constructing its theory of FCA liability, 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, DOJ then decides whether to seek penalties under the FCA, the FD&C Act, or some combination of these: For example, the 2006 Schering settlement on Temodar included approximately $180 million in FD&C Act penalties and $255 million in FCA penalties. The 2005 case against Eli Lily for Evista promotion was settled solely under the FD&C Act for $36 million.

company to communicate and negotiate with FDA about appropriate marketing messages. In most cases, companies respond to the objections raised and reach some mutually agreeable resolution with DDMAC or OCBQ. Only if the parties are unable to agree, is further action sought through FDA’s Office of Chief Counsel or the Office of Consumer Litigation of the Department of Justice. Under those circumstances, civil and criminal enforcement under the FD&C Act include, among other options, injunction proceedings, negotiated consent decrees, and seizures. Rarely, however, do cases escalate to those formal levels; overall, FDA’s enforcement efforts focus on achieving compliance, not punishment. And regardless of the option chosen, when FDA initiates an enforcement activity it is undertaken by, or with the express guidance of, regulators with expertise in the promotion of prescription drugs and pharmaceutical marketing practices generally.

In contrast, when the FCA is the primary vehicle for punishing companies that violate the FD&C Act, qui tam plaintiffs more commonly initiate enforcement—not FDA regulatory personnel with expertise in the area of unlawful drug promotion. Consequently, because DOJ is the lead agency on FCA cases aimed at unlawful drug promotion, prosecutorial discretion is transferred from 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 healthcare fraud and whose expertise in the area of drug labeling and advertising is limited.\(^{124}\) 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

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pharmaceutical companies,\textsuperscript{125} it is the large financial rewards that garner primary attention and thus appear to be the primary focus of DOJ’s enforcement efforts.\textsuperscript{126}

C. Marginalizing FDA’s Enforcement Role Undercuts the Public Health Goals of the FD&C Act.

When FDA is less involved in decisions of whether to prosecute unlawful promotional activity, there is 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 FDA considers the substantive content and impact of promotional labeling and advertising, its primary goal is to ensure that information is not false or misleading.\textsuperscript{127} 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.\textsuperscript{128} For example, determinations about the extent to which information about off-label uses should be allowed under the rules for scientific and educational information\textsuperscript{129} and where dissemination of information amounts to unlawful promotion are complicated and have long been debated among FDA, congress, health care professionals, industry, consumers, and other

\textsuperscript{125} Correction and compliance goals are achieved by requiring that companies alter and monitor their sales and marketing schemes. Strict parameters are encompassed in separate Corporate Integrity Agreements, when the enforcement vehicle is the FCA, or in Consent Decrees under the FD&C Act.


\textsuperscript{127} In contrast, under DOJ’s FCA theory, even truthful off-label marketing may give rise to a “false” claim. See Edward P. Landsdale, Used as Directed? How prosecutors are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing, 41 New Eng. L. Rev. 159, 161 (Fall 2006) (commenting on Judge Saris decision in United State sex. rel. Franklin v. Parke-Davis).

\textsuperscript{128} “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.” Guidance for Industry, Industry-Supported Scientific and Educational Activities, (November 1997). The treatment of cancer, pediatric, and rare “orphan” diseases often depend on access to off-label information.

\textsuperscript{129} See id.
groups. Indeed, even as DOJ continues to sift through its pipeline of potential FCA cases, many of which focus on the promotion of off-label uses, 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.\textsuperscript{130}

DOJ’s reliance on the FCA to punish unlawful promotional activity does not grant adequate deference to FDA’s expertise in this area. It is unrealistic to think that government prosecutors can be relied upon to ensure that use of the FCA does not usurp 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 DOJ’s inclination to value FDA’s interpretation of the FD&C Act. Emboldened by its successful use of the FCA in the \textit{Parke-Davis} case, DOJ has successfully shifted the traditional focus of the government’s approach to addressing unlawful drug promotion from achieving correction and compliance with the FD&C Act, to punishing pharmaceutical companies financially. As evidenced by the press releases issued by DOJ in conjunction with its negotiated settlement agreements, all of which tout the large fines being recovered, the impact of such punishment on companies’ actual behavior has assumed a position of secondary importance.\textsuperscript{131}

\textsuperscript{130} FDA Draft Guidance Document “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” (February 2008).

\textsuperscript{131} Settlement agreements calculate the amounts to be paid by companies facing prosecution for unlawful promotion. Requirements that companies alter and monitor their sales and marketing schemes are encompassed in separate Corporate Integrity Agreements. From the OIG website: “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.” \url{http://www.oig.hhs.gov/fraud/cias.html} (last visited on 5/27/08).
To the extent 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 DOJ may be inclined to usurp and undervalue FDA’s goal of compliance in the areas of pharmaceutical advertising and labeling and to disregard the agency’s expertise in assessing the legitimacy of unlawful promotion claims under the FD&C Act. As long as DOJ’s successful enrichment of the public coffers persists, it seems unlikely to consider abandoning the FCA route to large monetary recoveries. But if the goals of promoting and protecting the public health under the FD&C Act are truly paramount, then DOJ ought to at least thoughtfully consider its enforcement approach and consider whether it needs to readjust its prosecutorial stance toward unlawful promotion to ensure those goals are being adequately addressed.

D. Relying on the FCA to Punish Unlawful Promotion Relies on a Questionable Theory of Causation and Should not be Used in Lieu of the FD&C Act.

DOJ’s application of the FCA 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 under the FCA. But DOJ’s reliance on this idea of inducement to support the causation required under the FCA is fairly novel and has yet to survive serious judicial scrutiny. Because the history of prosecution of unlawful promotion under the FCA consists almost solely of negotiated settlements, companies lack the benefit of precedent and reliable information on which to base decisions about the legitimacy of DOJ’s use of the FCA to punish unlawful promotion.132 While the FCA has long been used to combat improper billing, inadequate services, and other traditional healthcare fraud by doctors, hospitals, and

healthcare providers, its application to pharmaceutical companies in the context of promotion of healthcare products is relatively new. DOJ’s use of the FCA as a sword against pharmaceutical companies to induce settlement for unlawful promotion has been incredibly successful, giving DOJ little incentive to question its application of the FCA to these types of cases or to entertain doubt about its causation theory. Thus, unless forced to do so, 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 DOJ will continue to expand application of and stretch remedies under the FCA to unlawful promotion by pharmaceutical companies.

The willingness of companies to settle FCA charges lends an unfair air of appropriateness to DOJ’s use of the FCA in the context of promotional labeling and advertising. Under the provisions of the FCA, liability is premised on specific claims filed for payment. But unlike other health care fraud situations, where actual claims are identified as false based on substantial factual information related to the claim, 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. 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.

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133 Scrutinized individually, some portion of the claims collectively designated as “false” by DOJ would likely qualify for reimbursement under the provisions for compendia drugs, the practice of medicine, or some other legitimate basis.
The case against Purdue for its promotion of OxyContin illustrates particularly well how DOJ’s application of the FCA 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, DOJ’s theory of FCA liability starts with the premise that a pharmaceutical company’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. Because FCA liability attaches to individual claims, theoretically, the government must separately examine each 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. To prove that a claim was improperly paid, the government must establish that the prescription for which reimbursement was sought was not medically necessary.\(^{135}\) When the second prong of this proof is applied to individual prescriptions in the context of unlawful promotion of on-label uses, DOJ’s causation theory is particularly problematic.

In *Purdue* 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 then similar drugs for pain. But because the allegedly unlawful promotional claims were directly related to the approved uses of OxyContin, part of DOJ’s 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 it would have been a medically necessary drug for which the government was obligated to pay. Thus, even if Purdue was

\(^{135}\) See Medicare reimbursement statute 42 U.S.C. § 1395y(a)(1).
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 DOJ to
successfully circumvent any need to establish the legitimately false nature of reimbursement
requests on a claim by claim basis. Although the use of the FCA against Purdue was only a
limited part of the prosecution for unlawful promotion, its application in that context is
representative of the weakness of DOJ’s causation theory under the FCA.136

Thus far, 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 to
support the requisite “but for” causation necessary for an FCA violation. While such behavior
by pharmaceutical companies is reprehensible, forcing companies to pay ransom in amounts
that by their very size suggest abuse of prosecutorial discretion should not be tolerated. Given
the lack of probability that in these unlawful promotion cases DOJ can prove each alleged false
claim satisfies the requirements of the FCA, some more reasonable basis for justifying the
settlement numbers is required. At the very least, if DOJ is going to continue using the FCA in
this context, it should be exercising more prosecutorial discretion and policing the cases
brought by individuals.

Having pioneered this theory of causation under the FCA to punish unlawful
promotion, 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
Claims

136 The Supreme Court’s recent decision in Allison Engine Co. v. U.S. ex. rel. Sanders, 128 S. Ct. 2123
(2008) also suggests that 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
expressly intended the government to rely on the false statement as a condition of payment in order to establish
FCA liability. See Allison Engine, 128 S. Ct. at 2130.
Acts” modeled after the FCA. As a result of these new statutory options, we should anticipate that many more qui tam plaintiffs will seek to 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, then we will have private attorneys acting without the benefit of FDA expertise interpreting the FD&C Act. And when a state court adopts a qui tam plaintiff’s interpretation of the FD&C Act, precedent will be set (as compared to settlements which apply only to the parties involved). Merely declining to intervene in cases that it views as unwarranted is not enough to contain the probability of individual plaintiff suits and the misinterpretation of the FD&C Act that may result. Rather, DOJ should accept responsibility by intervening in cases that it does not support and requesting that such cases be dismissed.

In lieu of DOJ’s current approach to unlawful promotion by pharmaceutical companies, such activity should be prosecuted solely under the FD&C Act, which is the statutory scheme established by Congress specifically for that purpose. Any DOJ concerns that the remedies available under the FCA 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 provides a preferable long-term approach to the continued use of the legally questionable theory of causation necessitated by DOJ’s current reliance on the FCA.

E. 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.

DOJ has been able to sidestep judicial scrutiny of its interpretation and application of the FCA to unlawful promotion cases because of the potential for exclusion from participation
in federal programs faced by companies threatened with prosecution under the FCA.\textsuperscript{137}  

Exclusion under the Social Security Act, which threatens companies with the loss of the right to participate in federal health care programs, perpetuates companies’ willingness to settle with DOJ rather than risk imposition of such penalty. By holding companies hostage in this manner, 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 DOJ in prosecuting unlawful promotion cases to exercise vigilance 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 FCA 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 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, DOJ has succeeded in shifting the focus on labeling and promotion of pharmaceutical products from compliance to punishment. Because the FD&C Act has been shown to be just as

\textsuperscript{137} See 42 U.S.C. § 1320a-7(b)(7).
effective an enforcement tool as the FCA, serious consideration of the legal and practical concerns associated with relying on the FCA 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 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 pursuit of large monetary settlements that are negotiated without any judicial review of the underlying substantive legal issues.