Elizabeth (Issie) Karan

**FDA Regulation of Off-Label Promotion of Pharmaceuticals through the False Claims Act: Is There a Better Way?**

The Food and Drug Administration (FDA) has a broad mandate to protect public health by ensuring the safety and efficacy of foods, drugs, and cosmetics.\(^1\) In doing so, the FDA may scrutinize pharmaceutical manufacturers to ensure compliance with the Food, Drug, and Cosmetics Act (FDCA) and the Food and Drug Administration Modernization Act (FDAMA). Enforcement actions often lead to high profile cases and, in many instances, high dollar amount settlements. For example, Pfizer recently settled with the US government for $430 Million dollars on behalf of its Parke-Davis unit. Parke-Davis was accused of aggressively promoting the drug Neurotonin for indications not on its label. Neurotonin was approved by the FDA as a treatment for seizures associated with epilepsy.\(^2\) Parke-Davis allegedly developed an illegal marketing campaign to spur use of Neurotonin for pain and psychiatric disorders.\(^3\) Disclosure documents revealed that Parke-Davis marketing managers were knowingly promoting Neurotonin for uses the drug had no scientific medical basis for treating.\(^4\) During the course of the

\(^1\) 21 U.S.C. § 393 (b).


\(^3\) *Id.*

\(^4\) “I want you out there every day selling Neurotonin…We need to be holding their hand and whispering in their ear…Neurotonin for pain, Neurotonin for monotherapy, Neurotonin for bipolar, Neurotonin for everything.” Disclosure information by Relator David Franklin at 11, pursuant to 31 U.S.C. §3730b (2) (quoting John Ford, a Parke-Davis marketing manager), *available at* http://dida.library.ucsf.edu/pdf/rab00a10.
settlement, the government announced its intention to pursue off-label promotion violations as separate, actionable violations of the FDCA and False Claims Act (FCA).\(^5\)

The regulation of off-label promotion of pharmaceuticals is complex. The Parke-Davis, Neurotonin story presents a bleak picture of drug manufacturers. However, off-label promotion often occurs against the backdrop of extensive off-label prescribing of drugs based on scientifically valid support—a practice the FDA encourages. Additionally, enforcement of prohibitions on off-label promotion under the FCA is problematic. Courts interpret requirements for off-label promotion claims under the FCA differently. FCA claims for off-label promotion also move slowly making for an inefficient regulatory enforcement mechanism. Additionally, off-label promotion claims payout less damages when compared to other health care fraud claims which makes private citizens less likely to bring suit under the FCA. Regulation of drug marketing also creates tension with the First Amendment by restricting truthful, scientific speech. These aspects of the regulatory system for off-label promotion claims make enforcing the FDCA under the FCA problematic.

The FDA can improve the US system for regulating pharmaceutical advertising. The British model for regulating drug marketing provides insight into how the FDA should proceed. If the FDA clarifies regulation, collaborates with the drug industry, and expedites dispute resolution, regulation of off-label promotion would become more consistent and efficient. The FDA should also reevaluate if the FCA is the appropriate enforcement mechanism for off-label promotion claims.

Summary of the Issue

Drug companies have extensive rules governing marketing of their products. Drug manufacturers may only promote products for uses indicated on the product’s label. Physicians may prescribe drugs in any manner their medical judgment deems appropriate. The FDA cannot interfere with physician practices. However, the FDA can, and does, tightly regulate a product’s label and the manner in which drugs are promoted.

Physicians may choose to prescribe a drug for an indication unapproved by the FDA. Experts estimate that as many as twenty percent of all prescriptions written in physicians’ offices were for uses not indicated on their label. Off-label prescribing often occurs in the contexts of oncology and pediatrics. These settings demand innovative treatments or present vulnerable

6 See PETER HUTT, RICHARD MERRILL & LEWIS GROSSMAN, FOOD AND DRUG LAW 532–555 (3rd ed. 2009)
7 See id. at 545.
8 Physicians will often prescribe products for (1) a use not indicated by a product’s label; (2) a population not included in a product’s label; or (3) dosages different from that on the label. See Ralph Hall & Elizabeth Sobotka, Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review Under Greater New Orleans, 62 FOOD & DRUG LAW J. 1, 6 (2010).
11 See Am. Soc’y of Clinical Oncology, Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications, 24 J. CLINICAL ONCOLOGY 3206, 3206 (2006). Off-label prescribing is necessary in the oncology field which demands rapid innovation in a slow-moving regulatory framework. It has been
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sub-populations for treatment which are inappropriate for clinical trials. Off-label prescriptions are so common that the military encourages off-label prescriptions by purchasing drugs and providing them specifically for an off-label use.13 Moreover, the Centers for Medicare and Medicaid Services authorize government reimbursement of products for off-label uses.14 Although off-label prescription is common practice, drug manufactures may be held liable for promotion of products for off-label uses under the FDCA and the FCA.

The FDA simultaneously encourages off-label prescriptions and restricts off-label promotion. Since the 1980’s the FDA has encouraged and expanded access to investigational drugs.15 The FDA recently proposed rules which would further expand access to investigational drugs.16 The FDA stated that one purpose of the proposed rule is to increase awareness of possible access to unapproved drugs.17 This purpose is tied to an overall FDA goal of improving estimated as high as 50 to 80 percent of patients will receive off-label therapies. Radley, supra note 10, at 1023.

12 See Alicia Bizzano et al., Off-Label Prescribing to Children in the United States Outpatient Setting, 9 ACAD. PEDIATRICS 81 (2009). Off-label treatment is essential in pediatrics since it would be unethical to test drugs on children.

13 Osborn, supra note 2, at 304.


15 See Abigail Alliance v. von Eschenbach, 445 F.3d 470, 484 (D.C. Cir. 2006) (finding that patients had a substantive due process right to unapproved therapies).

16 Proposed Rule, Expanded Access to Investigational Drugs for Treatment Uses, 71 Fed. Reg. 75,

17 See Hall & Sobotka, supra note 8, at 38.
The prohibition on off-label promotion of drugs creates difficulties for drug company executives and their counsel. Specifically, how should drug companies apply broad mandates to daily activities which require interactions with physicians? For example, may pharmaceutical sales representatives present information to all physicians or only physicians whose patients suffer from an on-label condition? May a pharmaceutical company discuss the mechanisms of an active compound with physicians if it is not indicated on the product’s label? May a drug company provide information on reimbursement for off-label uses to physicians or their staff? May a company hire a physician consultant without being seen as improperly influencing prescribing practices and what form would that relationship have to take? These are only a small portion of the legal problems attorneys in this field must grapple with. Although the broad strokes of the legal framework for acceptable drug promotions are defined, specific instruction from the FDA is lacking.

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18 See id.
19 See id.
20 See Osborn, supra note 2, at 319 for examples.
21 See id.
22 See id.
23 See id.
24 See id.
Off-label promotion is prohibited by the FDCA, enforced through the FCA and often defended under the First Amendment. These instruments define the legal framework surrounding off-label promotion claims. In addition, each instrument brings a unique set of difficulties. This paper examines the role of the FDCA, the FCA, and the First Amendment in off-label promotion claims. It also examines the British model for regulating pharmaceutical marketing for insight into how to improve the US system. Finally, this paper suggests regulating off-label drug promotions, without the FCA, in a transparent, collaborative, and efficient manner.

**FDCA**

The FDCA grants the FDA authority to regulate labeling and advertising of pharmaceutical products. The term “labeling” has a broad definition. Statutorily labeling means all labels and other written, printed, or graphic matters upon any of a product’s containers or wrappers or accompanying the product.\(^{25}\) This definition, however, has been interpreted expansively. Labeling no longer requires that materials physically accompany a product.\(^{26}\) Labeling must only supplement or explain a product.\(^{27}\) The FDA has stated that brochures, booklets, file cards, movies all may be considered part of a product’s labeling.\(^{28}\) Therefore, advertising of pharmaceutical products is part of a product’s label\(^ {29}\) and includes advertisements in journals, magazines, newspapers, and broadcast media.\(^ {30}\)

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\(^{27}\) Id.


\(^{29}\) See Wasserstein, supra note 25, at 2.

The FDA does not approve a product generally but approves a specific use of a product. The approval process for an “indication” of a drug often takes extensive research. A new drug indication requires pharmacology and toxicology information, bench testing, animal studies, clinical testing in humans, and submission of a New Drug Application. During this process, the drug is being tested for one specific indication. An approved label will include usages, appropriate patient populations, warnings, dosages, and other drug data. The FDA will approve a drug if it is shown to be safe and effective according to uses proscribed on its label.

The FDCA states that a drug or device is misbranded if “its labeling is false or misleading in any particular.” The FDCA also prohibits distributing misbranded product. Therefore, the indication on a product’s label defines permissible speech. A manufacturer may only promote a product for a use indicated on its label. This effectively creates a prohibition on advertising or discussing uses for a product not indicated on its label.

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31 See Hall & Sobotka, supra note 8, at 4.

32 Id.

33 Rogaine was originally tested as a treatment for high blood pressure but began new clinical trials when one of its major side effects was hair growth. Food and Drug Law Lecture by Professor Ralph Hall, Oct. 26, 2010. This led to the creation of a topical treatment for male-pattern baldness. MEDICINE.NET.COM, Minoxidil, Rogaine, http://www.medicinenet.com/minoxidil/article.htm.

34 Hall & Sobotka, supra note 8, at 4.

35 The final submission of a New Drug Application will include the approved drug labeling. Id.


38 Hall & Sobotka, supra note 8, at 6.

39 Id.
The FDA regulates speech based on its content and the identity of the speaker—not its truthfulness. Therefore, any dissemination of information regarding a product’s off-label uses by a manufacturer, even truthful information, is prohibited. By contrast, a speaker who is unaffiliated with the manufacturer may discuss any off-label uses. This means that a physician medical officer of a manufacturer could give the same presentation as a private physician, and it would still be illegal.

The FDA’s actor-and content-based approach often creates confusion. Drug companies are allowed to discuss off-label uses with investors and investigators of clinical trials but not doctors generally. This presumes that physician investors and physician investigators may simply wear “two coats.” Given that speech is restricted by both its content and the speaker, many drug companies struggle to discern what is and is not acceptable promotion.

The FDCA prohibits off-label promotion of pharmaceuticals. It has its own enforcement provisions. However the FDA often utilizes other federal statutes to impose liability for off-label drug promotion. In the context of off-label promotion claims, the FCA is a common method for enforcement.

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40 See id at 8.
41 See id.
42 Id. at 9.
43 Id. at 9.
44 Id.
46 See HUTT, MERRIL & GROSSMAN, supra note 6, at 550.
47 See id. at 555.
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**False Claims Act**

The FCA lets private citizens\(^\text{48}\) or the U.S. Attorney General bring suit on behalf of the government for fraud.\(^\text{49}\) The FCA imposes triple damage liability on a party who knowingly submits false records to the federal government for payment, such as through Medicare and Medicaid receipts.\(^\text{50}\) The FCA also makes it illegal to make a false statement which leads another party to make a false claim which is subsequently paid or approved by the federal government.\(^\text{51}\)

The FCA has a lengthy history in US law. The FCA dates back to the Civil War.\(^\text{52}\) President Lincoln promoted the passage of the FCA to curb fraud by private contractors.\(^\text{53}\) At the time, contractors were reaping large profits due to increased spending by the government on military procurement.\(^\text{54}\) Since then, the FCA has undergone several transformations but remained true to its purpose of preventing fraud against the government.\(^\text{55}\)

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\(^{48}\) These private individuals are referred to as relators or “whistleblowers” and are often employees of the company committing fraud. 78 AM. JUR. 3d Proof of Facts §357 (2010).


\(^{50}\) Sally Wang, *False Claims Act: The Right for Off-Label Marketing?*, JOURNAL OF LAW, MEDICINE & ETHICS, Fall 2010, at 708.


\(^{52}\) See 78 AM. JUR. 3d Proof of Facts §357 (2010).

\(^{53}\) See id.


\(^{55}\) In 1943, Congress amended the FCA and significantly restricted the relator’s role under the FCA by preventing them from bringing claims based on evidence that was already known by the government. See 78 AMJUR 3d 357. However, in 1986, Congress passed another wave of amendments which were
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In the context of off-label promotion, a company may be held liable under the FDCA and the FCA if the company markets a product for an unapproved use.\(^{56}\) It is legal for physicians to prescribe products for uses not indicated on the product’s label\(^{57}\) and it is legal for providers to submit claims to the federal government for products prescribed off-label.\(^{58}\) However, it is illegal for companies to encourage physicians and prescribers to engage in these activities.\(^{59}\) This prohibition holds regardless of the truthfulness of the drug company’s speech.\(^{60}\) A determination of off-label promotion is made based on the label in effect at the time of the speech.\(^{61}\) Therefore, a drug company may still be liable for off-label promotion of a drug if the FDA subsequently approves a product’s use and amends the label.

Courts have applied the FCA to off-label promotion claims in different manners. The Eleventh Circuit has created a significant barrier for whistleblowers that bring suit under the FCA against a company for off-label promotion.\(^{62}\) In *Hopper v. Solvay Pharmaceuticals*, the Court determined that, in the context of FCA claims, a complaint is deficient, under the


\(^{56}\) *See Osborn, supra* note 2, at 312.

\(^{57}\) The FDA cannot influence physician’s practice of medicine. 21 U.S.C. §396.

\(^{58}\) *See Osborn, supra* note 2, at 310–311.

\(^{59}\) *See id.*

\(^{60}\) One court has held that the FCA does not require both a false statement and a false claim. U.S. *ex rel Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001). Practically, this means that a drug company may be liable under the FCA regardless of the truthfulness of their statements or promotions.

\(^{61}\) *See Osborn, supra* note 2, at 310–311.

\(^{62}\) *See Wang, supra* note 50, at 708.
heightened pleading standard of Federal Rules of Civil Procedure 9(b), if it cannot make specific factual allegations that identify physicians, pharmacists, or health programs involved in the off-label promotion.\textsuperscript{63} In addition, the Eleventh Circuit requires that relators have personal knowledge of payments or show that false claims were paid.\textsuperscript{64} In June 2010, the Supreme Court denied \textit{Hopper} certiorari.\textsuperscript{65} At the same time, the First Circuit interpreted the FCA in favor of relators. In \textit{United states ex rel Duxbury v. Ortho Biotech Products}, the court held that the FCA only required relators to voluntarily provide information to the government before filing their claim.\textsuperscript{66} In their opinion, the First Circuit noted that there are circuit splits and a general lack of uniformity among jurisdictions with regard to the requirements of off-label promotion claims under the FCA.\textsuperscript{67} The \textit{Duxbury} case was denied certiorari the same day as \textit{Hopper}.\textsuperscript{68} The lack of consistency in the requirements of off-label promotion claims under the FCA extends beyond the First and Eleventh Circuits. Relators bringing off-label promotion claims under the FCA face much more restrictive rules in the Ninth, Sixth, and DC Circuits than the Fourth Circuit where rules are viewed as more permissive.\textsuperscript{69} 

\textsuperscript{63} Hopper v. Solvay Pharmaceuticals, Inc., 588 F.3d 1318, 1325 (11th Cir. 2009).

\textsuperscript{64} Id. at 1326.

\textsuperscript{65} \textsuperscript{66} Hopper v. Solvay Pharmaceuticals, Inc., 130 S.Ct. 3465 \textit{cert. denied} (2010).

\textsuperscript{66} United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 26 (1st Cir. 2009)

\textsuperscript{67} \textit{Id.}


\textsuperscript{69} See Wang, supra note 50, at 710.
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FCA proceedings move at a notoriously slow pace.70 According to Taxpayers Against Fraud, the federal government has a backlog of 180 pending lawsuits—all alleging false claims about drugs by pharmaceutical companies.71 This slow pace and backlog of FCA claims are problematic for both sides of enforcement efforts. First, it discourages whistleblowers from bringing potential claims.72 Second, it creates uncertainty for drug companies. There are more questions than answers in the context of drug marketing—especially given the differing applications of the FCA to off-label drug promotion.73 Additionally, the slow pace of prosecution renders fines effectively hypothetical for drug companies.74 Both the government and the pharmaceutical industry would benefit from quicker resolution of lawsuits involving FCA off-label drug promotion claims.

Relators have less incentive to bring FCA claims for off-label promotion than other FCA health care fraud claims. Off-label promotion under FCA is essentially “small potatoes” compared to FCA claims related to other forms of health care fraud.75 The FCA has been highly effective at generating health care fraud claims.76 However, off-label promotion cases are only a small portion of the funds generated by health care fraud claims generally. For example, in the

70 One author referred to the pace of FCA claims as “glacial.” Art Levine, Medifraud Amok, The American Prospect, Volume 18, Number 9: September 26, 2007.

71 Id.

72 Seventy percent of whistleblower-submitted cases ultimately are rejected by prosecutors. Id.

73 See Osborn, supra note 2, at 316.

74 See Levine, supra note 70.

75 See Wang, supra note 50, 710–711.

76 Health care fraud claims have generated $14.3 billion between 1986 and 2008. Id.
Miami area alone, a multi-agency team reduced medical billing fraud by $2 billion dollars.\textsuperscript{77} Over the same period for the entire country, off-label marketing suits only totaled $3 billion dollars.\textsuperscript{78} As a result, an off-label marketing claim under the FCA generates a fraction of the damages as a FCA claim for kickbacks or fraudulent billing.\textsuperscript{79} Therefore, relators have less monetary incentive to bring off-label promotion claims.

The FCA provides the federal government with a means to prosecute parties who submit false claims to the government or cause another to submit false claims to the government. The FCA has a long history in US law of protecting the federal government from fraud. The FCA allows the government or private citizens to prosecute drug companies who market a drug for a use not indicated on the product’s label. FCA claims do not depend on the marketing to be false or for drug companies to submit claims to the federal government. The FCA is not without its flaws. Courts have interpreted the FCA, in the context of off-label promotion claims, in different manners. FCA claims also move forward rather slowly and comprise a small portion of the overall FCA claims related to health care fraud. Although the FCA has a rich history in the US legal framework, its application in the context of off-label drug promotion has been thorny.

**The First Amendment**

In the context of off-label promotion, drug companies often challenge the constitutionality of FDA restrictions on speech. It is possible for two parties to give an identical speech, to an identical audience, using identical publicly available information, and for one person to be found guilty of felony violation of the FDCA and liable under the FCA for off-label promotion of a

\textsuperscript{77} Id.

\textsuperscript{78} Id.

\textsuperscript{79} See id.
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drug. 80 As one would expect, the unequal treatment of the speakers creates tension with the First Amendment. The FDA has, at times, attempted to characterize off-label promotion efforts as conduct rather than speech. 81 However, courts have firmly rebuffed this position. 82 Challenges to the constitutionality of restrictions on off-label speech require a two-fold analysis. First, what type of speech are drug companies are engaging in? 83 Second, assuming the speech is commercial, has the FDA satisfied the constitutional requirements set forth in Central Hudson and its progeny? 84

Commercial speech is afforded less protection than non-commercial speech under the First Amendment. 85 Therefore if off-label speech by drug companies was considered scientific speech, rather than commercial speech, the FDA’s ability to restrict it would be severely limited since restrictions would violate the First Amendment. 86 The Supreme Court has not created a definitive rule for determining whether speech is scientific or commercial. 87 Lower courts generally look to the motivation of the speech. 88

80 See 31 U.S.C. §3729; Hall & Sobotka, supra note 8, at 1; Wang, supra note 50, at 710.


82 See id. (“[T]he court is hard pressed to believe that the agency is seriously contending…that ‘promotion’ is entitled to no First Amendment protection.”)

83 See Hall & Sobotka, supra note 8, at 10.

84 Id.


86 See Hall & Sobotka, supra note 8, at 13.

87 The Supreme Court denied certiorari to cases which would give them the opportunity to define a concrete rule. Kasky v. Nike Inc., 45 P.3d 243 (Cal. 2001), cert. granted, Nike, Inc. v. Kasky, 537 U.S. 1099 (2003), cert dismissed as improvidently granted, 539 U.S. 654 (2002).
There are two arguments for classifying off-label promotion as commercial speech. First, in the past, the Supreme Court and lower courts have treated off-label speech as commercial speech. Second, most off-label promotion has an economic motive. This element is not entirely determinative since speech may have multiple motivations. In determining primary motivations, courts will examine whether the speech is an advertisement, whether the speech refers to a specific product, and whether the speaker has an economic motivation. When speech has mixed motivations, the higher level of First Amendment protection should apply. However, the linkage of off-label promotion to economic incentives sways most courts.

Drug manufacturers argue that not all off-label speech is commercial speech and should, therefore, be protected as scientific information. This argument gains traction in the context of new clinical trials and information disseminated for patient safety. Such examples demonstrate mixed motivations for off-label speech and would likely be afforded higher First Amendment protection.

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88 Timothy Schmidt & Ralph Hall, Central Hudson 2.0: FDA Regulation of Commercial Speech in Social Media, in USING SOCIAL MEDIA IN FDA-REGULATED INDUSTRIES 105 (2010).

89 See e.g., Thompson v. Western States, 535 U.S. 357, 366 (2002); Washington Legal Foundation, 13 F.Supp.2d at 65.


91 In re Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 793 (3d Cir. 1993).


93 See Hall & Sobotka, supra note 8, at 14.

94 Id.

95 Id.
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*Central Hudson* governs permissible restrictions of commercial speech. The four prongs of *Central Hudson* are that: (1) speech must be truthful and not misleading; (2) the government must have a legitimate interest in restricting speech; (3) the restriction on speech must further the government interest; and (4) the restriction must be the least burdensome method for achieving the government’s objective. Off-label speech restrictions are challenged under all four prongs of *Central Hudson*.

US regulation of off-label promotion is difficult and overly complicated. This alone would not warrant concern; however, restrictions on off-label speech create tension with the First Amendment. Additionally, prosecution of off-label promotion moves slowly and courts inconsistently apply the FCA to off-label promotion claims. Furthermore, these problems occur against a backdrop in which the FDA simultaneously encourages off-label prescriptions and prohibits off-label promotion by drug manufacturers. With these difficulties in mind, the British Model of regulation of off-label speech provides insight into how to improve the US system.

**The British Model**

The British Model for regulating prescription drugs relies heavily on self-regulation, efficient dispute resolution, and extensive guidance materials. This system embraces longstanding British traditions of flexibility and privatized self-regulation. The drug marketing

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97 *Id.; see generally* Schmidt & Hall, *supra* note 88, at 106–08 (describing the four prongs of the *Central Hudson* test).


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complaint resolution in Britain is expeditious. This provides pharmaceutical manufacturers with guidance on permissible marketing practices and transparency in government regulation. These characteristics of the British system provide important lessons for improving the US model.

The current British system came into being under the Medicines Act of 1968.100 The Medicines Act created a regulatory agency, the Medicines and Healthcare Regulatory Agency (MHRA), to ensure safe pharmaceuticals and protect public safety.101 In contrast to the FDA, the MHRA does not assume responsibility for routine oversight of pharmaceutical advertising and promotion.102 Instead the MHRA focuses on matters which pose serious risk to public health and facilitates control of drug advertising and promotion by a semi-autonomous association of British pharmaceutical companies.103

The British system is led by a self-regulating body associated with the British pharmaceutical trade association.104 The MHRA works closely with the professional trade association to develop a code of ethics for pharmaceutical practices.105 Companies themselves regulate business practices and limit inappropriate commercial activities.106 Enforcement activities rely heavily on an informal system of encouragement and shaming. However, when a company engages in illegal activities, complaints may be brought by competitors, former employees, physicians, patients, and the MHRA.

100 Id. at 343.


102 See Osborn, supra note 2, at 343.

103 Id.

104 See id. at 346.

105 Id. at 347–48.

106 Id.
The complaint system in Britain is efficient. It moves rapidly and does not involve extensive discovery.\textsuperscript{107} Complaints are common.\textsuperscript{108} Complaints are decided quickly.\textsuperscript{109} Additionally, complaints are appealable and allow full participation of the parties. This process enables drug company compliance by providing a high level of clarity regarding acceptable promotional activities and transparency in the decision-making process.

The British system also gives companies extensive guidance on acceptable promotion and advertising conduct. The MHRA publishes a “Blue Guide” that establishes clear rules on complicated regulatory matters.\textsuperscript{110} For example, the Blue Guide attempts to define the line between scientific exchange of information and promotion.\textsuperscript{111} It also states specifically what gifts pharmaceutical companies can give to physicians.\textsuperscript{112} Additionally, the MHRA routinely engages pharmaceutical professionals in discussions of the challenges facing the regulatory system.\textsuperscript{113}

The British system for drug regulation provides insight into how to improve the US system. It is unrealistic to suggest that the US adopt a system of self-regulation since it is not a part of its regulatory tradition.\textsuperscript{114} However, the FDA should consider key aspects of the British system. Specifically, the FDA should clarify regulations, actively engage with industry, and create quicker regulatory processes.

\begin{itemize}
\item \textsuperscript{107} See id. at 350.
\item \textsuperscript{108} More than one-hundred complaints are brought annually. Id. at 345.
\item \textsuperscript{109} Complaints are generally decided within months if not weeks. Id.
\item \textsuperscript{110} Id. at 344–45.
\item \textsuperscript{111} See id.
\item \textsuperscript{112} See id.
\item \textsuperscript{113} See id.
\item \textsuperscript{114} See id. at 353.
\end{itemize}
The FDA should provide more guidance to drug companies in a user friendly format. There are many regulatory areas where the FDA’s position is ambiguous. For example, in the context of off-label promotion, drug companies struggle with consulting agreements, sponsorship of continuing medical education, internet and electronic media postings, and sales representatives’ promotional messages.\textsuperscript{115} If the FDA clarified its position on these matters, compliance would improve and unnecessary enforcement action would be reduced.

The FDA should engage in discussions with industry when creating policies. If the FDA initially asks industry leaders how they approach ambiguous areas of off-label promotion, industry leaders are more likely to comply with subsequent policies. A collaborative clarification process is valuable because both parties benefit from the process. Industry benefits because it gains certainty in the regulatory structure.\textsuperscript{116} The FDA benefits because it gains compliance and efficiency in the regulatory system.

The FDA must resolve disputes quicker. If the FDA could resolve off-label promotion suits faster, companies would have more understanding of what is acceptable advertising activity. Similarly, if the FDA could amend labels more quickly, fewer companies would be tempted to violate off-label promotion restrictions. With regard to efficient complaint resolution, the FDA must consider whether the FCA is a valid enforcement mechanism for off-label promotion claims. An enforcement route, which compels fast resolution of disputes, may not include the FCA.

\textsuperscript{115} See id.

\textsuperscript{116} Id.
Conclusion

The FDA is given broad power to protect public safety and ensure pharmaceutical safety. The FDA has interpreted this mandate to require restrictions on off-label promotion of drugs. While FDA concerns regarding off-label promotion of drugs are valid, they contradict FDA policies encouraging access to experimental drug trials and information on experimental uses of drugs. Additionally, restrictions on off-label promotion generate tension with the First Amendment when they restrict valid, scientific speech. These concerns are made all the more prescient when enforcement of restrictions on off-label promotion is accomplished through the FCA. Courts interpret the FCA requirements for off-label promotion claims in conflicting manners. FCA claims also move very slowly. Given these concerns, it may be time for the FDA to enforce the prohibition of off-label drug promotion without the FCA. Without the FCA, regulation of off-label drug promotion could become more efficient, more transparent, and more predictable. The British system for regulating drug advertising provides a useful example of how the US system can move forward. If the FDA can clarify its position on off-label drug promotion, actively engage industry leaders in forming that position, and resolve regulatory disputes more efficiently, all parties will benefit.