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Insurers Pursue Follow-On Civil Cases Against Pharmaceutical Companies Charged With Violations of the False Claims Act

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Over the past decade, the U.S. government has ramped up efforts to identify and combat fraud in the healthcare industry. Between January 2009 and the end of 2015, it collected more than $16.5 billion in damages, fines and settlement payments from the pharmaceutical, medical device and provider industries. The government's primary tool has been False Claims Act ("FCA") cases brought both by the government itself and *qui tam* cases brought by whistleblowers, also known as relators. The FCA creates liability for any person who knowingly submits or causes another to submit a false claim to the government or knowingly makes a false record or statement in order to get a false claim paid by the government. The falsity of claims under the FCA can both be express (*e.g.*, misrepresenting the service provided), or implied (*e.g.*, the express representations contain misleading half-truths or critical omissions).

Health and other insurers have long utilized follow-on litigation to recover monies they have expended due to health care fraud as third party payors ("TPPs") but have had to find appropriate alternatives to FCA claims, which may only be brought by or on behalf of the government. One category of health care fraud that has resulted in large government recoveries and consequently is an attractive target for TPPs has been fraudulent marketing claims against pharmaceutical companies.

For example, in three of the larger fraudulent marketing cases of the past decade, the U.S. Department of Justice recovered $1.415 billion from Eli Lilly, $520 million from AstraZeneca and $435 million from Schering-Plough for their illegal promotion of various drugs. Yet TPPs' follow-on actions based on nearly identical facts—albeit different legal theories—resulted in dismissals. Historically, courts have held that the TPPs' cases failed due to lack of causation, namely the absence of a sufficient nexus between the misconduct alleged and the resulting harm to the payors themselves. Recent cases, however, call this case law into serious question. This article lays out the challenges faced by TPPs and predicts that follow-on litigation by TPPs is likely to increase, not diminish, in the future.

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The views expressed are personal to the authors.

Explosion of Health Care Fraud Cases under the False Claims Act

The FCA was first enacted in 1863 to fight wide-ranging fraud by war profiteers against the federal government during the Civil War. In 1986, Congress substantially amended the FCA to allow the government to seek treble damages and revised the *qui tam* provisions to increase incentives for whistleblowers to report fraud. Since those amendments were enacted, the U.S. government has recovered approximately $50 billion dollars under the FCA.

Today, the majority of FCA recoveries are related to health care fraud. Of the $3.5 billion the government

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collected in connection with FCA claims during fiscal year 2015, more than half ($1.9 billion) came from the health care industry. As the health care market has thrived in recent years, so too have fraud recoveries. In just the past seven years alone, the government obtained more than half of all healthcare fraud recoveries since the FCA was amended.

According to the DOJ, the largest health care fraud recoveries in recent years have been associated with fraudulent marketing claims. The two most common theories asserted by the government are: (1) fraudulent off-label marketing and (2) marketing in violation of the Anti-Kickback Statute (''AKS''). One of the government's theories underlying the off-label marketing cases is that by promoting off-label uses that are not FDA approved, pharmaceutical manufacturers cause pharmacies to seek reimbursement for Medicare and Medicaid payments for ineffective and unnecessary treatments. With respect to the AKS, the Patient Protection and Affordable Care Act of 2010 amended the language of the AKS to provide that ''a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].'' 42 U.S.C. § 1320a-7b(g).

The government's prosecutions in fraudulent health care marketing have resulted in more than 30 settlements since 2004, ranging from multi-million to billion-plus dollar recoveries. In the last four years alone, the government has negotiated billion-dollar-plus settlements from Johnson & Johnson ($1.1 billion for claims relating to illegal marketing of drugs Risperdal, Invegas, and Natrecor), Abbott Laboratories ($1.5 billion from claims relating to illegal marketing of Depakote); and GlaxoSmithKline ($1.5 billion for claims relating to Paxil, Wellbrutrin, Advair, Lamictal, and Zofran).

Given the success of the government's FCA litigation involving off-label promotion, it is likely to continue its aggressive approach. Nevertheless, two developing trends in the legal landscape may complicate such lawsuits. The first is heightened constitutional protection of speech constituting off-label promotion, in particular the Second Circuit Court of Appeals' 2012 decision in *United States v. Caronia*, which held that a sales representative's promotion of off-label uses for a drug, which was *not* misleading or untruthful, is protected speech under the First Amendment. 703 F.3d 149 (2nd Cir. 2012). The second is the Supreme Court's June 2016 decision in *United States ex rel. Escobar v. Universal Health Services*, which emphasized that implied certification claims under the FCA must involve material misrepresentations. 136 S.Ct. 1989. Specifically, the Supreme Court rejected the materiality standard previously announced by several courts that ''any statutory, regulatory or contractual violation is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation.'' Instead, it adopted a narrower view of materiality, namely that a violation is material only if the government would *in fact* refuse to pay the claim if it knew of the violation. *Id*. at 2003-04. This standard for materiality may be problematic for the government's off-label promotion cases because the government often pays for off-label prescriptions, which medical providers may properly write in their sound medical discretion.

Given the government's continuing interest in off-label promotion cases and the vast potential recoveries at issue in such cases, we are unlikely to see a significant decline in FCA fraudulent marketing cases going forward. Moreover, with respect to follow-on litigation brought by TPPs, any decrease in opportunities for follow-on litigation would likely be counterbalanced by increased potential for success in TPP lawsuits brought about by the *Neurontin* decision discussed below.

Increased Follow-on Litigation by Third Party Payors

Health insurers and other TPPs have a growing incentive to pursue follow-on claims. Although insurers and other TPPs have established business relationships with potential defendants, they are facing increased pressure from shareholders to reduce costs, ferret out fraud and abuse, and recover overpayments paid out for costly drugs, devices and procedures. The primary benefit of these follow-on claims is that the government has already done significant legwork in collecting information through civil investigatory demands, discovery in litigation, and/or criminal investigations. The primary challenge for TPPs is that pharmaceutical companies often settle rather than litigate FCA cases brought by the government, and therefore TPPs will need to prove both liability and damages in their own follow-on cases.

For TPPs that have pursued follow-on cases, they have concentrated on matters involving high-volume/value drugs, devices and procedures since such cases come with the largest upside to justify the costs of all-out litigation with large pharmaceutical companies. The relatively undeveloped state of the law, however, creates uncertainties for both sides in such litigation. Some insurers have also availed themselves of the victim restitution process set up as a part of some FCA settlements obtained by the government.

Theories of Liability Asserted by Third Party Payors

Because TPPs do not have a private right of action under the FCA, they have tried other avenues to recover damages for amounts paid on fraudulently marketed pharmaceuticals. These include a variety of causes of action, including Racketeer Influenced and Corrupt Organizations Act (''RICO''), unfair competition, fraud and unjust enrichment claims. Of all the claims, the type most aggressively pursued—likely because of treble damage provisions—are claims under RICO. RICO claims require proof of, among other things, an ''enterprise'' through which defendants' racketeering activity is conducted.

Private follow-on actions are simply more difficult to prosecute than government- or relator-initiated litigation under the FCA given the government's vast array of resources, and the attendant negative publicity associated with being charged with defrauding the government. The most significant additional hurdle is that the government's damages in fraudulent marketing cases under the FCA are presumed whereas a private litigant is entitled to no such presumption under any of the available causes of action. If the government shows that such a claim is false, it can recover the full amount of the false claim, along with a fine between $5,500 and $11,000 per claim regardless of whether the government actually suffered damage as a result of the claim. Private TPPs, on the other hand, must show that their payment of a fraudulently induced claim actually *caused* the TPP to suffer damages. In other words, TPPs

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must establish a sufficient link between the drug companies' alleged misconduct and the damages incurred by the TPP. Historically, this task has proven to be challenging for TPPs in cases involving fraudulent pharmaceutical marketing.

For example, in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (''*Zyprexa*''), a case typical of its time period, the Second Circuit examined causation issues in connection with TPPs' RICO claim against Eli Lilly based on Lilly's allegedly fraudulent misrepresentations to physicians regarding the safety and efficacy of its drug Zyprexa. The Second Circuit reversed a federal district court's decision to certify a class of TPPs and vacated the district court's denial of Lilly's motion for summary judgment after finding that the alleged misrepresentations by Lilly and ultimate injury to the TPPs were too attenuated given the independent actions of ''third and even fourth parties,'' including physicians and pharmacy benefit managers. 620 F.3d at 134. The court emphasized the role of physicians as decision-makers, noting that there were other sources of information that factored into a physician's prescribing decision other than the allegedly fraudulent information received from Lilly, such as the patient's diagnosis, the patient's current medications, and the physician's own experience with Zyprexa. In short, the court in *Zyprexa*—along with numerous courts in similar cases—held that TPPs could not use generalized proof to show that their payments for prescriptions were the result of fraud because an individual inquiry regarding the facts and circumstances surrounding each prescription was necessary to determine if there was a direct relationship between the fraudulent marketing directed at the physician and the physician's decision to prescribe the drug.

The First Circuit Court of Appeals did not follow this line of cases when it ruled, in *In re Neurontin Marketing & Sales Practices Litigation*, that Kaiser Foundation Health Plan, Inc. and certain of its affiliates could recover damages from Pfizer for its fraudulent marketing of the drug Neurontin. 712 F.3d 21 (1st Cir. 2013).) The *Neurontin* case was initially filed in 2004 as the government was nearing an agreement with Pfizer to resolve civil liabilities, including FCA claims, as well as criminal charges relating to Pfizer's fraudulent promotion of Neurontin for $430 million.

At issue in *Neurontin* were Pfizer's fraudulent marketing campaign targeting both doctors and TPPs. With respect to the TPPs, the court held that the marketing plan was designed to influence Kaiser's formulary decisions. *Id.* at 28. For example, Pfizer developed a strategy of ''develop[ing] relationships with [decision-makers affiliated with Kaiser] *who are not considered whistle blowers*.'' *Id.* Pfizer also employed Kaiser-affiliated physicians to serve on speakers' bureaus and to publish misleading articles about Neurontin. As a result of these activities, the district court found that '' 'Kaiser relied on Pfizer's misrepresentations and omissions during the development of drug monographs in both June and September 1999'. . . and that Pfizer's misrepresentations 'directly affected decisions about Neurontin's placement on formulary without restrictions[.]' '' *Id.* at 29. On appeal, the First Circuit affirmed the jury and lower court's finding that the prescribing of Neurontin had in fact been causally affected by Pfizer's fraudulent marketing, despite the fact that no physician testified that he or she prescribed Neurontin because of the fraudulent marketing. *Id.* Instead, the primary evidence on this point was the expert testimony of Dr. Meredith Rosenthal, a Ph.D. in health economics and professor of public health at Harvard. *Id.* at 29-30.

Dr. Rosenthal used ''aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug'' and found a causal connection between the fraudulent marketing and the prescriptions written for off-label indications. *Id.* Through regression analysis, Dr. Rosenthal opined as to which portion of the prescriptions written for Neurontin were caused by Pfizer's fraudulent marketing scheme. *Id.* Rosenthal also testified that this method was the ''best way to estimate the number of prescriptions and the share of prescriptions that were affected by the alleged misconduct.'' *Id.* at 30. Although Pfizer argued that doctor-by-doctor evidence would be more reliable, Rosenthal dismissed such evidence because of its ''well-recognized unreliability.'' *Id.* According to Rosenthal, ''self-reporting from physicians about patterns of practice that may be controversial shows both conscious reluctance and unconscious bias, which lead them to deny being influenced.'' *Id.*

Since the *Neurontin* decision, numerous third party payors have attempted to emulate Kaiser's strategy.

Since *Neurontin*, numerous TPPs have attempted to emulate Kaiser's strategy. However, their attempts to replicate the analysis of Dr. Rosenthal, including by Dr. Rosenthal herself, have met with mixed results. For example, In *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015), a case involving allegedly fraudulent marketing of the drug Ketek, the Second Circuit rejected Dr. Rosenthal's analysis of the marketing's effect on Ketek noting that it was overly simplistic and lacked any regression analysis of the type she had performed in *Neurontin*.

Likewise, in *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, No. CV 13-13113-NMG (D. Mass. June 2, 2016), the court found Dr. Rosenthal's analysis insufficient but for a different reason. Whereas in *Neurontin* Dr. Rosenthal's regression analysis measured the impact of fraudulent, off-label promotion on the quantity of off-label prescriptions, in *Celexa* her analysis claimed a causal effect between *all* promotions and *all* sales of prescriptions. The court found that the use of relationship between total promotions and total prescribing was not a ''reasonable proxy'' for the relationship between off-label promotions and off-label prescribing and thus constituted a ''fundamental flaw'' in Dr. Rosenthal's approach. Accordingly, because the TPPs in *Celexa* primarily relied on the flawed Rosenthal report as class-wide proof of causation, the court rejected class certification on that basis.

Other courts have narrowed the holding in *Neurontin* to apply only to cases where defendants made direct misrepresentations to TPPs. *See In re Testosterone Replacement Therapy Products Liab. Lit. Coordinated*

Pretrial Proceedings, No. 14 C 1748 (N.D. Ill. Aug. 2, 2016) (''*In re. TRT*'') (''whether a TPP [can] satisfy RICO's proximate cause element largely depend[s] on whether the drug manufacturer's alleged fraudulent marketing included the communication of misrepresentations directly to the TPP''); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs. & AbbVie Inc.*, No. 13 C 5865 (N.D. Ill. June 29, 2016) (''The Court finds the distinguishing characteristic to be whether the drug manufacturer directly made misrepresentations to the TPP because otherwise intervening factors—such as a physician's independent medical judgment or a patient's decision-making—interrupt the chain of causation[.]'').

Although these cases are distinguishable from *Neurontin*, they arguably are at odds with two related decisions issued by the First Circuit on the same day as *Neurontin*: *In re Neurontin Mktg. & Sales Practices Lit.*, 712 F.3d 51 (1st Cir. 2013) (''*Aetna*'') and *In re Neurontin Mktg. & Sales Practices Lit.*, 712 F.3d 60 (1st Cir. 2013) (''*Harden*''). These cases are based on very similar facts and reach the same general conclusions as *Neurontin*, largely by incorporating the analysis of *Neurontin* by reference. However, unlike *Neurontin*, the TPPs in these cases did not allege that they directly relied on Pfizer's misrepresentations. Nevertheless, the First Circuit held in *Aetna* and *Harden* that, even in the absence of direct reliance, the plaintiff TPPs were allowed to proceed with their claims based on indirect misrepresentations Pfizer made to physicians.

The case law regarding how and under what circumstances TPPs can recover from pharmaceutical companies for fraudulent marketing continues to evolve. Nevertheless, in the wake of the *Neurontin* decision, the possibility of success and promise of substantial recoveries should be sufficient motivation to spur increased litigation by TPPs. Even in Circuits where courts require direct misrepresentations, TPPs should be able to state viable claims where statements by pharmaceutical representatives caused the drug in question to be placed on formulary as the court found recently in the *In re TRT* case.

Going forward, health insurers and other TPPs will certainly be following developments in the government's FCA efforts closely. Pharmaceutical companies would be wise to plan for the likely contingency of follow-on litigation based on alleged FCA violations and explore ways to leverage their business relationships and the law to avoid or reduce the costs of follow-on litigation by insurers and other payors.

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