Testimony of
Thomas M. Greene
Managing Partner
Greene LLP

Before the
House Energy & Commerce Subcommittee on Health

Hearing on
Fostering Innovation to Fight Waste,
Fraud, and Abuse in Health Care

February 27, 2013

GREENE LLP
One Liberty Square, Suite 1200 | Boston, MA 02109 | p: 617.261.0040

TABLE OF CONTENTS

"*This bill is reported for the purpose of ferreting out and punishing these enormous frauds upon our Government; and, for one, my sympathies are with the Government, and not with the men who are committing these frauds…I trust that the Senate will pass this bill, or some bill that will put fraudulent contractors in a position where they may be punished for their frauds.*"

–Senator Henry Wilson of Massachusetts, 1863, in reference to the False Claims Act[1]

INTRODUCTION

Thank you Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee for inviting me to testify on innovations to fight health care waste, fraud and abuse. My name is Thomas M. Greene, Managing Partner of Greene LLP, a law firm that specializes in pharmaceutical litigation and in False Claims Act litigation on behalf of relators.[2]

Since 1992, Greene LLP attorneys have represented relators in a variety of False Claims Act cases, in the pharmaceutical, health care, defense, and import industries, as well as other industries. In a seminal lawsuit against Parke-Davis and Pfizer filed in 1996, we established for the first time that off-label promotion of prescription drugs was fraud that could result in liability to the government under the False Claims Act. To find out more about us please visit www.falseclaimsactattorney.com or www.greenellp.com.

I am here to offer my expertise in the area of health care fraud litigation, particularly pharmaceutical fraud litigation, in which I have represented

[1] 33 Cong. Globe 956 (1863).

[2] Special thanks to Michael Tabb, Partner, and Ryan P. Morrison and Sarah E. Godfrey, Associates, all of Greene LLP, who assisted me in the preparation of this testimony.

whistleblowers on behalf of the government as well as third-party payors, including large health insurance plans, Taft-Hartley funds, and self-insured employers.

Fraud in the health care system is rampant. Government health care programs include Medicare, Medicaid, TRICARE, and the Veterans Administration. Together, these programs account for approximately 40%-45% of all health care spending; consequently, government programs are frequent targets of fraud. Health care fraud comes from a wide spectrum of sources. Large-scale pharmaceutical fraud engaged in by large international corporations can be felt by the vast majority of payors; but physician practice groups, dental practices, and small hospital organizations also contribute to rampant instances of fraud.

I do not mean to imply that most pharmaceutical and health care organizations engage in fraud. Most hospitals and physicians are honest in their business dealings with government agencies and private payors. The challenge that remains for this country is in having adequate deterrence measures in place to stop fraud before it starts, as well as in identifying dishonest pharmaceutical practices or health care providers early, before they cause much harm.

SUMMARY

In Part I of this statement, I address current efforts to address health care fraud through the False Claims Act, which has become one of the government's most potent tools to deter and redress fraud. I recommend that Congress ensure that counsel for relators have ready access to CMS data, which is critical to the pursuit of *qui tam* cases. I recommend that the pleading standard for False Claims Act cases be adjusted, to allow more meritorious cases to go forward. And I recommend that more be done to encourage states to enact their own False Claims Acts.

In Part II, I focus on the effect of fraudulent pharmaceutical marketing on both government health care programs and private payors, and I make five recommendations. First and most importantly, marketing fraud can be prevented outright by requiring pharmaceutical companies to register all clinical trials in their early stages. This increased transparency would give peer reviewers, the police of the medical literature, the ability to do their jobs. Second, fraudulent pharmaceutical marketing could be deterred by giving private payors a right of action, because currently they are left to use ill-fitting options, like RICO, or patchworks of state laws. Third, it could be deterred by threatening the forfeiture of Hatch-Waxman Act patent extensions for particular drugs, which are granted, in part, for cooperation with the FDA approval process. Fourth, pharmaceutical marketing fraud could also be deterred by making sure that pharmaceutical executives have some skin in the game personally.

Finally, restrictions on the reimbursement of off-label drugs should be used as a model for restricting reimbursement for off-label medical devices.

PART I: HEALTH CARE FRAUD AND THE FALSE CLAIMS ACT

Next week, we celebrate the 150th anniversary of the False Claims Act, which was originally passed during the Civil War. The law had fallen into disuse, however, until Senator Grassley and former Representative Berman drafted amendments which were signed into law by President Reagan in 1986. The amendments breathed new life into the law, and today the False Claims Act stands as the government's primary weapon to combat health care fraud of all stripes.

Under the False Claims Act, companies or individuals may be liable to the government for treble damages if they submit or cause to be submitted false claims to the government – or if they make false statements material to the submission of false claims.[3] Private citizens may initiate cases under the *qui tam* provision of the statute.[4] Following the federal example, a majority of states have also enacted False Claims Acts, although some are directed only at health care.[5]

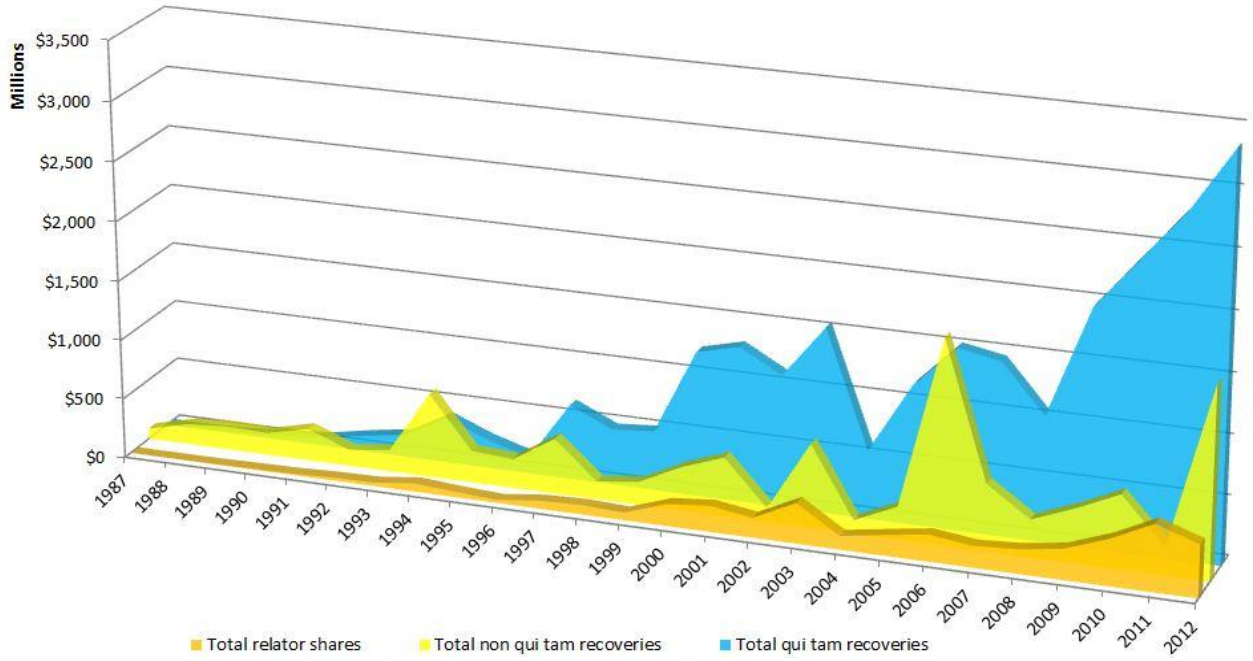
[3] 31 U.S.C. §3729.

[4] 31 U.S.C. §3730(b).

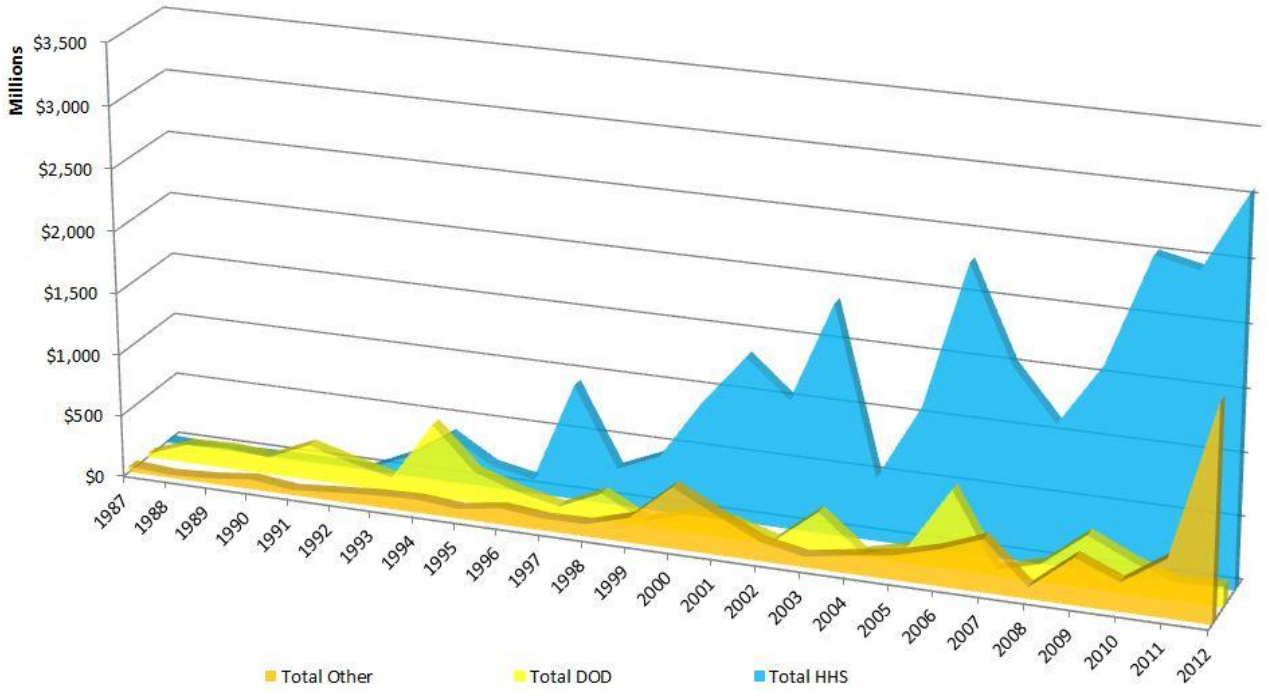
[5] Thirty-three states currently have False Claims Acts, as well as the District of Columbia, but several of these state statutes do not contain *qui tam* provisions, and several only relate to health care.

RECOVERIES

Since 1986, $35.19 billion has been recovered through the False Claims Act for the government. The key to the False Claims Act's very significant success has been through the *qui tam* provision. In fact, the vast majority of False Claims Act recoveries come from whistleblower-initiated cases:



Of the $35.19 billion that has been recovered through the False Claims Act since 1986 through the end of fiscal year 2012, the vast majority — $24.07 billion — has come from HHS expenditures, and represents money recovered from health care fraud:



The vast majority of HHS False Claims Act recoveries, in turn, have come from pharmaceutical fraud, with over $20 billion in recoveries.[6] Of the remainder, over $3 billion has come from False Claims Act cases against hospitals,[7] and over $1 billion has come from laboratories.[8]

The above figures tell only part of the story of the False Claims Act's success in combating fraud, because they only represent the civil portions of federal False Claims Act recoveries. In addition to the $35.19 billion recovered between the 1986 amendments and the end of fiscal year 2012, approximately $7 billion has been recovered in the criminal counterparts of False Claims Act cases. Moreover, approximately $6 billion has been recovered during the same time frame on behalf of states through Medicaid related cases.

The number of meritorious *qui tam* cases under the False Claims Act continues to rise on a yearly basis. Between 1986 and the end of fiscal year 2012, 8,489 *qui tam* cases were filed, and 4,424 government-initiated cases were filed. In the last several years, *qui tam* cases outnumber government-initiated cases about five to one; although the

---

[6] These recoveries have continued to increase after the end of fiscal year 2012, and now total over $23 billion. More recoveries are impending, as Johnson & Johnson has publicly stated that they have reserved $2.2 billion for the pending Risperdal case, and Pfizer has reserved $500 million for the pending Rapamune case.

[7] The most significant hospital settlements include $900 million against Tenet, $731.4 million against HCA, $631 million also against HCA, $325 million against HealthSouth, $324.2 million against National Medical Enterprises, $265 million against St. Barnabas Hospitals, $76.5 million against Staten Island Community Hospital, $72 million against Beth Israel Hospital, $62.55 million against Tenet Healthcare, and $54 million also against Tenet Healthcare.

[8] The most significant laboratory settlements include $385 million against Fresenius Medical Care of North America, $325 million against SmithKline Beecham Clinical Labs, $241 million against Quest Diagnostics, $182 million against Laboratory Corporation of America, $100 million against National Health Labs, and $83.7 million against Damon Clinical Laboratories.

number of government-initiated cases has remained somewhat static,[9] more and more *qui tam* cases have been filed.[10]

These trends favor *qui tam* cases even more significantly in HHS cases, with 4,775 *qui tam* and 752 government-initiated cases filed between 1986 and the end of fiscal year 2012. After reaching a peak in 2008, the number of government-initiated False Claims Act cases involving HHS has tailed off in the last five years,[11] while the corresponding number of *qui tam* cases has almost doubled in the same time frame.[12]

RECENT AMENDMENTS

In 2009, the Fraud Enforcement and Recovery Act (FERA) passed with overwhelming bipartisan support.[13] According to the Senate Committee Report, the impetus for the bill was to combat the types of fraud that caused the financial crisis in 2008 – mortgage fraud, securities fraud, and financial institution fraud – and to protect against fraud in the programs Congress created to counter the consequences of the financial collapse, i.e. the federal stimulus package.[14] The Senate Committee report for FERA, however, has no references to health care fraud or Medicare – surprising omissions since the largest settlements under the False Claims Act then, as now, were in connection with claims of Medicare and Medicaid fraud. Moreover, FERA's changes to

[9] Total government-initiated cases: 162 in 2008, 132 in 2009, 140 in 2010, 124 in 2011, and 135 in 2012.

[10] Total *qui tam* cases: 379 in 2008, 433 in 2009, 575 in 2010, 638 in 2011, and 647 in 2012.

[11] Total government-initiated HHS cases: 60 in 2008, 34 in 2009, 42 in 2010, 37 in 2011, and 24 in 2012.

[12] Total *qui tam* HHS cases: 231 in 2008, 278 in 2009, 383 in 2010, 417 in 2011, and 412 in 2012.

[13] The Senate vote was 92-4. The House vote was only slightly less lopsided, 367-59.

[14] S. Rep. No. 111-10 at 3.

the False Claims Act principally concerned amendments of 31 U.S.C. § 3729, the statute that defines the elements of a False Claims Act violation, and § 3733, the statute concerning civil investigative demands. FERA left largely untouched the statute that sets forth the procedural and jurisdictional requirements for bringing a *qui tam* claim under the False Claims Act, 31 U.S.C. § 3730.[15]

Congress turned its attention to these matters in 2010 with the Patient Protection and Affordable Care Act[16] and the Health Care and Education Affordability Reconciliation Act[17] (collectively, PPACA). PPACA affected False Claims Act practice significantly with three important amendments: (1) the complete revision of the public disclosure bar; (2) new provisions in the Social Security Act that concern the recovery of overpayments made by the government to Medicare and Medicaid providers; and (3) amendments to the Anti-Kickback Statute that expressly state that claims for payment that result from kickbacks are "false claims" under the False Claims Act.

RECOMMENDATIONS

The FERA and PPACA amendments to the False Claims Act recalibrated a machine that has accomplished great results in combating health care fraud. The recently-recalibrated False Claims Act is not broken and does not need to be fixed, as it appears that the government is getting much, if not all, of the dollars wasted by health

[15] FERA made minor changes to § 3730(h), the subsection of the statute that creates a private right of action for persons who have been retaliated against due to their attempts to enforce the provisions of the False Claims Act. But FERA did not make any changes to the requirements for actions brought by the United States or relators to hold defendants liable for violations of § 3729.

[16] Pub. L 111-148 (March 23, 2010).

[17] Pub. L 111-152 (March 25, 2011).

care fraud. There are, however, several new innovations which would better position relators and the attorneys who represent them to play their important role in eradicating the effects of significant health care fraud.

1. Make Government Data Available to Relators' Counsel Acting on Behalf of the Government

The first and most important step that Congress could take to make the False Claims Act a more potent health care fraud fighting tool would be to make government data available to relators' counsel. Claims data, such as Medicare claims data in the possession of CMS, is critical to many aspects of False Claims Act prosecution. Not only does this data evidence how much money was lost due to fraudulent conduct, but the data proves how widespread the illegal activity was. It is also often necessary to establish the element of causation as proof that the defendant's conduct really did harm the United States.

Failure to obtain this data impacts False Claims Act cases in several ways. Most obvious, is that without reliable, rigorous claims data analysis, the United States may not be able to collect the full amount it lost due to the fraud, or the full amount it is entitled to recover. But even more importantly, without this data, some cases may not be able to be prosecuted at all. When a False Claims Act case is litigated, many District Courts require specific allegations describing the presentation of actual false or fraudulent claims to the United States. A relator's detailed knowledge of the fraudulent scheme and how the defendant knowingly implemented it may not be sufficient unless the relator can also recite information about the claims that Medicare or other

government health care programs paid as a result of the fraud. Often this cannot be done without access to claims data before a case is unsealed.

Even where the relator is able to meet the specificity requirements for pleading fraud without claims data access, lack of access to this data can severely limit the scope of the litigation and deprive the United States of the recovery it is otherwise entitled to receive. In the Neurontin litigation, for example, my client, Dr. Franklin, could provide specific information about the fraudulent scheme during the relatively short time he was employed by Parke-Davis—but the scheme continued long after he left. Because he did not possess any details regarding the off-label marketing that occurred after he left, or the extent of off-label marketing outside of his region, the Magistrate in the case limited discovery to conduct that occurred within a 13 month window—when, in fact, the scheme went on for more than 4 years—and which occurred in Parke-Davis' Northeast Region—even though the off-label promotion scheme was national. Ultimately the District Court permitted us to discover conduct during a four year period, but retained the geographical limitation. Access to claims data would have allowed us to demonstrate to the court the full scope of the fraudulent conduct.

CMS does allow some access to claims data to academic researchers. But such access is limited to research projects that either have the potential to improve the quality of life for Medicare beneficiaries or improve the administration of the Medicare program. Neither of these categories encompass efforts to obtain recompense for defrauding the program. It seems misguided that academics who may (or may not) be

able to produce pragmatic information that could assist the program or its beneficiaries may peruse this data, but forensic researchers, who have consistently saved the program hundreds of millions of dollars, cannot.

Privacy and confidentiality concerns, including preservation of the sealed status of *qui tam* actions, would have to be addressed. But CMS' Limited Data Set program, which provides beneficiary level data but with patient identifiers removed, demonstrates that CMS can process and disclose claims data in such a way that protects patient privacy. Data Use Agreements similar to those employed when access is granted to Limited Data Sets can be used, with small modifications that take into account the forensic nature of the work and the fact that the data will be used in court proceedings to combat fraud and abuse. Alternatively, since all such disclosures would take place in existing federal court proceedings, protective orders or other court orders can define permissible access to relators and their counsel, but place binding restrictions on unauthorized disclosure. Violation of such orders would be subject to the federal courts' contempt powers.

Expanding the access of relators and their counsel to claims data will allow significantly more review of relevant data with almost no additional cost to the United States. Under the False Claims Act, a significant share of any amount recovered in *qui tam* cases will be paid to a relator. It makes sense to permit the relator and his counsel to earn their recovery by doing work that will either speed the process or increase the amount of the recovery. Although some who file False Claims Act cases are content to

let U.S. Attorneys or the Department of Justice do all of the work after a case has been brought, the best attorneys in this field want to do whatever they can to help the government prove the alleged fraud. Changes to CMS rules relating to the disclosure of claims data should be made so the federal government can harness this talent without any concomitant cost to the United States.

2. Clarify the Pleading Standard Required for False Claims Act Cases

The procedural filing requirements of Federal Rule of Civil Procedure 9(b) have severely limited the ability of relators and their counsel to file suit under the False Claims Act. Rule 9(b) subjects False Claims Act cases to an unusually high pleading threshold, meaning that unless certain facts are pleaded with sufficient detail, the claim will fail before it is considered on the merits. But Rule 9(b) is generally applied to common law fraud claims, and because the term "knowingly" is defined in the False Claims Act as including "deliberate ignorance" and "reckless disregard," claims under the False Claims Act can be uncomfortable fits with 9(b).

Rule 9(b) requires that complaints alleging fraud "state with particularity the circumstances constituting fraud."[18] False Claims Act claims, however, often involve complex fraud schemes where relators have in depth knowledge of the scheme, but limited access and authority to acquire certain details. A relator, for example, may have detailed knowledge of a fraudulent scheme within their employer company, in addition to details regarding how the employer company knowingly implemented it. The relator's claim may fail under Rule 9(b), however, if he could not also provide detailed

[18] Fed. R. Civ. P. 9(b).

information about specific claims submitted to the government program that was defrauded.

Recognizing the difficulty of applying the Rule 9(b) standard to False Claims Act cases, some courts have relaxed the application of the Rule 9(b) standard to allow complaints that allege the schemes themselves with enough particularity to create a strong inference of the existence of false claims.[19] This application of Rule 9(b) should be encouraged, but courts have sometimes struggled to apply the standard in that manner. This uncertainty is not just a division within the Circuits; it raises disputes within individual Courts of Appeal. Just two weeks ago, a majority of a Ninth Circuit panel decided that a more relaxed standard should apply, but made its ruling over a rigorous dissent.[20]

The relator in that case, an Admissions Representative at a for-profit university, was able to allege his first-hand experience of how a scheme to defraud the United States of financial aid funds unfolded, as well as detail about how he learned of the fraud. He was not, however, able to point to specific false claims. The majority ruled that, in line with the court's previous Ebeid decision, the relator had met his 9(b) burden and that it was sufficient to allege "particular details of a scheme to submit false claims

[19] See e.g. United States ex rel. Duxbury v. Ortho Biotech Products, 579 F.3d 13, 30 (1st Cir. 2009)(ruling that the relator had sufficiently conformed his complaint to Rule 9(b) by alleging that free packages of a drug were made available to health care providers who submitted claims to Medicare, *despite not identifying specific false claims*); United States ex rel. Walker v. R&F Properties of Lake County, Inc., 433 F.3d 1349 (11th Cir. 2005)(court found that relator included enough evidence in complaint to explain why relator credibly believed defendant had submitted false claims despite not specifically identifying those claims). These cases, however, represent a very small minority and are not enough for firms to risk diverting resources to putting forth a pleading substandard of Rule 9(b).

[20] United States ex rel. Jajdelski v. Kaplan, Inc., ---Fed. Appx. ---- 2013 WL 520418 (not published) (9th Cir. Feb. 13, 2013), available at http://falseclaimsactattorney.com/jajdelski.

paired with reliable indicia that lead to a strong inference that claims were actually submitted."[21] The dissent disagreed, however, that the relator's complaint could survive under Ebeid without providing "a representative false claim for *any* allegation."[22]

The lack of uniformity regarding the applicability of the higher Rule 9(b) pleading standards to False Claims Act cases is problematic for relators and their counsel. Some potential cases, despite high similarity to other cases that have survived Rule 9(b) challenges, are dismissed. This has caused some attorneys within the practice area to pass on cases with strong evidence of fraud but no evidence of representative false claims. Congress should relax the requirements of Rule 9(b) with respect to False Claims Act cases, or clarify that Rule 9(b) particularity should only apply to fraudulent schemes, rather than false claims themselves. If Congress does so, more False Claims Act cases will be pursued, more cases will be successful, and the government will recover more of the losses suffered by health care or other frauds.

3. Encourage More States to Enact False Claims Acts

As a consequent of the Deficit Reduction Act of 2005, states are eligible to get an additional 20%-35% in moneys recovered under the False Claims Act (attributed to Medicaid funds) if they have enacted their own False Claims Acts that are at least as robust as the federal version. Thirty-three states have a False Claims Act of some

[21] Jajdelski at *4-5, quoting Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998–99 (9th Cir. 2010), in turn quoting United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009).

[22] Jajdelski dissent at *3 (emphasis in original).

fashion, but several of these do not contain *qui tam* provisions, and several more only extend to health care claims.

The federal government has an interest in doing more to encourage more states to enact False Claims Acts, because more whistleblowers will follow. Whistleblowers' share of the state portion of national health care False Claims Act cases will increase if there are more state False Claims Acts. Increasing shares in this way will incentivize more whistleblowers without costing the federal government a dime.

PART II: FIGHTING PHARMACEUTICAL MARKETING FRAUD

Pharmaceutical marketing fraud impacts government health care programs, but it also defrauds private payors, and, through increased premiums, the public at large. This means that many taxpayers pay the price for marketing fraud twice – once, by footing the bill for Medicare and Medicaid, and a second time through the payment of increased premiums for their own insurance. The fact that the lion's share of False Claims Act recoveries come from the fraudulent marketing of drugs is some indication that the practice leads to a great measure of waste, fraud and abuse—deserving of special attention by Congress.

OFF-LABEL PROMOTION REGULATIONS

The Food, Drug and Cosmetics Act (FDCA) prohibited off-label promotion of drugs, and gave the FDA authority to regulate labeling and advertising of pharmaceutical products. The Food and Drug Administration Modernization Act (FDAMA) softened some of these rules; it is now possible for pharmaceutical companies to disseminate reprints of medical journal articles (or medical reference publications) that tout off-label uses of their products.

When a pharmaceutical company submits a New Drug Application for a new product, the drug's safety and efficacy is tested through Level One scientific evidence: double-blind, randomized, placebo-controlled clinical trials. The labeling for the drug that results from the New Drug Application process specifies usages, appropriate patient populations, warnings, and dosages. FDA approval is specifically for use of the

drug in accord with the label proposed by the company and accepted by the FDA. In approving the drug and labeling, the FDA is saying that, when the drug is used in accord with the label, the drug is both safe and effective.

As defined by statute, however, "labeling" is not simply the package insert included with the drug when it is distributed or sold. In addition to all labels, "labeling" also includes other written, printed, or graphic matters upon any of the product's containers or wrappers or accompanying a product.[23] The Supreme Court has ruled that material need not physically accompany a product in order to be considered "labeling."[24] The FDA has promulgated regulations in the Code of Federal Regulations that clarifies that brochures, file cards, movies, and booklets may all be "labeling" under some circumstances.[25] Advertisements may also be considered "labeling."[26]

Under the Food, Drug and Cosmetics Act, a drug or device is considered "misbranded" if "its labeling is false or misleading in any particular."[27] And drug manufacturers are prohibited from distributing "misbranded" products.[28] In effect, manufacturers are prohibited from selling drugs or devices for which they have falsely advertised.

---

[23] 21 U.S.C. §321(m).

[24] Kordel v. U.S., 335 U.S. 345, 346-48, 350 (1948).

[25] 21 C.F.R. §202.1(l)(2).

[26] 21 C.F.R. §202.1(l)(1).

[27] 21 U.S.C. §352.

[28] 21 U.S.C. §331.

FDAMA, however, created an exception to the general prohibition on off-label marketing. In response to an unsolicited request, manufacturers may provide doctors with publications on off-label uses of a drug. Nonetheless, the right to distribute these publications is narrowly defined by regulation.[29] Manufacturers may disseminate unabridged[30] reprints of peer-reviewed articles – but not letters to the editor, abstracts, Phase 1 trials for healthy people, or observations of four or fewer people. Manufacturers may also disseminate unabridged sections of reference publications.

This FDAMA-created reprint exception is further limited with several very important limitations. Dissemination of reprints touting uses that have not been approved by the FDA:

- Must not be false or misleading;
- Must not pose a significant risk to public health;
- Cannot be derived from research of another manufacturer, without that manufacturer's permission; and
- Cannot be disseminated with information that is promotional in nature.

To illustrate what was meant by "false or misleading" and to otherwise explain this reprint safe harbor, the FDA published a "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

[29] 21 C.F.R. § 99.101.

[30] For purposes of 21 C.F.R. § 99.101, "unabridged" means a reprint or copy that "retains the same appearance, form, format, content, or configuration as the original article or publication."

Cleared Medical Devices."[31] The Guidance explains and expands on reprint and promotion regulations in the Code of Federal Regulations.

A couple of the FDA's illustrations are particularly helpful. It would be false or misleading if a distributed journal article or reference test was "characterized as definitive or representative of the weight of credible evidence derived from adequate and well-controlled clinical investigations if it is inconsistent with that weight of credible evidence or a significant number of other studies contradict the article or reference text's conclusions." Similarly, it would be false or misleading to tout or even to "discuss a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate and well-controlled."

Of course, physicians are free to prescribe FDA-approved drugs off label, whenever they deem it appropriate. There are a variety of circumstances when off-label prescriptions are appropriate; sometimes they work. That does not mean, however, that the government will actually pay for it. Medicare and Medicaid are not authorized to pay for off-label drugs except in very narrow circumstances. The programs can only pay for "covered outpatient drugs,"[32] and can only do so for "medically accepted indications"—uses that are either (1) approved by the FDA, or (2) used as supported by reference in one of three medical compendia specified by statute.[33]

---

[31] Accessible at http://www.fda.gov/oc/op/goodreprint.html.

[32] 42 U.S.C. § 1396r-8(k)(2).

[33] 42 U.S.C. § 1396r-8(k)(6) (Medicaid); 42 U.S.C. § 1395w-102(e)(4) (Medicare).

When prescriptions have been induced by fraudulent marketing of particular drugs, that fraud is paid for by the government as well as by private payors, despite it being legal for physicians to write such prescriptions. While efforts to recoup the government's losses through the False Claims Act have been very successful, private payors have had very little success.

OFF-LABEL PROMOTION AND THE FALSE CLAIMS ACT

In 1996, I filed what I believe to be the first False Claims Act complaint to allege that off-label promotion by pharmaceutical companies caused the submission of actionable false claims on the government. The case alleged that Parke-Davis, a division of Warner Lambert that was acquired by Pfizer, marketed the epilepsy drug Neurontin for a wide variety of off-label indications despite a lack of scientific support. When this case was eventually settled in 2004 for a combined $430 million in civil fines and criminal penalties, it was the first off-label promotion settlement under the False Claims Act. It was not the last.

Since the settlement of the Neurontin case, almost $15 billion dollars – almost half of all False Claims Act recoveries – have been recovered through the nearly thirty cases to employ this once-novel theory. These cases have all been settled within the last eight years, and include a $704 million settlement with Serono relating to the marketing of Serostim; $435 million with Schering-Plough for Intron A and Temodar (included resolution of other claims); $36.9 million with InterMune for Actimmune; $10.5 million with Cell Therapeutics for Trisenox; $9.8 million with Medicis Pharma for Loprox; $20

million with Orphan Medical and Jazz Pharmaceuticals for Xyrem; $519 million with Bristol-Myers Squibb and Otsuka American for Abilify (included resolution of other claims); $425 million with Cephalon for Actiq, Gabitril and Provigil; $1.415 billion with Eli Lilly for Zyprexa; $2.3 billion with Pfizer for Bextra, Geodon and Lyrica; $42.5 million with Alpharma for Kadian; $520 million with AstraZeneca for Seroquel; $81.51 million with Ortho-McNeil-Janssen for Topamax; $72.5 million with Novartis for TOBI; $600 million for Allergan for Botox; $420 million with Novartis for Trileptal (included resolution of other claims); $313 million with Forest Laboratories for Levothroid, Celexa and Lexapro (included resolution of other claims); $214.5 million with Elan and Eisai for Zonegran; $41 million with Kos Pharmaceuticals for Advicor and Niaspan; $34 million with UCB for Keppra; $25 million with Novo Nordisk for Novoseven; $14.5 million with Pfizer for Detrol; $158 million with Johnson & Johnson for Risperdal (Texas only, with other marketing allegations yet to be resolved); $950 million with Merck for Vioxx; $1.5 billion with Abbott Laboratories for Depakote; and $3 billion with GlaxoSmithKline for Wellbutrin, Paxil, Avandia, Zofran, Imitrex, Lamictal, Lotronex, Floven, Valtrex, and Advair.

More off-label settlements are in the pipeline, with Johnson & Johnson reserving $2.2 billion for the remainder of the Risperdal marketing allegations, and Pfizer reserving $500 million for the expected settlement of allegations that it marketed Rapamune off label.

Pharmaceutical marketing fraud is staggeringly significant, as this line of False Claims Act cases shows. We can take two lessons from this string of settlements. First: the False Claims Act has been a very effective tool in recovering payments for false claims caused by off-label marketing practices. Second: off-label marketing has been a pervasive and frequent component of pharmaceutical business plans, with most major pharmaceutical companies resorting to it, sometimes multiple times.

FRAUDULENT OFF-LABEL PROMOTION AND PRIVATE PAYORS

In very stark contrast to the overwhelming success of the federal False Claims Act and state False Claims Acts, however, very few private payors have succeeded in using litigation to recoup losses caused by pharmaceutical marketing fraud. Once again, Neurontin has been a trailblazer. On behalf of Kaiser Foundation Health Plan and the network of Kaiser plans, which together are the largest non-profit health care insurer in the country, my team successfully proved in a five week trial in 2010 that Pfizer's marketing activities with Neurontin were racketeering activity. The jury returned a $47 million verdict under RICO which was trebled to $142 million. The court, acting as finder of fact, also entered a judgment of $102 million under the California Unfair Competition Law. In so doing, the court accepted our evidence that 99.4% of prescriptions of Neurontin for bipolar disorder were induced by fraud, as were 70% of neuropathic pain prescriptions, 27.9% of migraine prescriptions, and 37.5% of prescriptions written for Neurontin for over 1800 mg per day (the FDA-approved dose).

But RICO may not be the answer to the question of how to get recoveries for pharmaceutical fraud on behalf of private payors. Pharmaceutical companies are getting smarter. With Neurontin, Parke-Davis engaged a medical marketing firm and an advertising agency to help with its off-label promotion efforts. These two relationships formed RICO enterprises, setting the stage for RICO liability – but fraudulent marketing schemes can be just as fraudulent without enterprises. The shadow of fraud remains real, because if a pharmaceutical company does not engage an outside firm to write articles touting off-label use, it can still do so in house.

I would not go so far as to say that the Neurontin RICO case on behalf of Kaiser is a harbinger of things to come; it may be safer to assume that Neurontin is a special case, and that private payors will still have trouble recouping their losses suffered as a result of pharmaceutical marketing fraud. We know from the series of False Claims Act promotion cases that the fraud is likely there – but because pharmaceutical companies have almost never been liable for their fraud to private payors, there is no sufficient deterrent in place to stop pharmaceutical companies from fraudulently promoting their drugs off label.

RECOMMENDATIONS

The government has an array of current tools to combat pharmaceutical marketing fraud. The FDA can issue warning letters to pharmaceutical companies. In addition, FDA and HHS OIG have administrative remedies available, such as suspension and debarment; criminal fines may also be assessed. Theoretically, the

Department of Justice could employ the Park Doctrine to charge company executives with FDCA misdemeanors. And the government can also initiate False Claims Act cases. Private litigants can also help to detect or deter health care fraud; as discussed above, *qui tam* False Claims Act cases have also been very successful in recouping losses due to pharmaceutical marketing fraud. But all of these tools have been available for some time, and pharmaceutical marketing fraud is still rampant. I propose five possible solutions that could, in some combination, deter most fraudulent pharmaceutical marketing before it starts.

1. Require Registration of Clinical Trials

Many off-label marketing frauds can be stopped before they start by requiring pharmaceutical companies to register all clinical trials, pre-identifying primary endpoints. This would work to prevent fraud because the most damaging marketing frauds occur when pharmaceutical companies engage in "publication bias," which is manipulating medical literature to make it seem to the medical community that a drug is more effective than it really is. If all clinical trials are registered before commenced, then the marketing arms of pharmaceutical companies cannot make them disappear after the fact, and they will remain available to the medical community.

In the Neurontin RICO case, Dr. Kay Dickersin, a professor at the Johns Hopkins University Bloomberg School of Public Health's Center for Clinical Trials, testified that Parke-Davis and Pfizer engaged in significant publication bias. One type, "selective

outcome reporting," also sometimes referred to as "moving the goalposts," is worthy of particular note here.

In designing a trial protocol, an investigator defines one primary outcome to be studied in the trial, but also defines several secondary outcomes, measures in which she is interested but that are not as important as the primary outcome. With "selective outcome reporting," if the results of the study are negative for the primary outcome, but positive for one of the secondary outcomes, the investigator might publish an article that describes a previously-defined secondary outcome as the primary outcome studied. As Judge Saris determined in her Findings of Fact and Conclusions of Law in the Kaiser Neurontin case, "[t]his 'selective outcome reporting' is viewed as problematic within the scientific community."[34] And this is no surprise; given several defined secondary outcomes, chance might dictate that there will be positive results for at least one of the secondary outcomes, which often involve small subpopulations within the larger study. Scientists should not "cherry-pick" outcomes that support their other interests, whether academic or financial, because it increases the likelihood that the results are not accurate if they are chosen after the study has been completed. Peer reviewers police medical literature, and they will be better able to do their job and prevent "selective outcome reporting" if possibly conflicting trials can be located, and if primary outcomes have been pre-identified through the registration process I recommend.

[34] Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg and Sales Practices Litig.), 2011 WL 3852254 (D. Mass. Aug. 31, 2011); available at http://www.greenellp.com/wp-content/uploads/2011/04/Findings-of-Facts-and-Conclusions-of-Law-Saris-11.3.10.pdf

It is extremely difficult for a doctor to realize that the authors of a journal article have tainted their findings through "selective outcome reporting." Only pharmaceutical companies have the access to the frontline clinical trial data from their own studies; the only version of these trials that is available to the medical community at large is what is published in medical journals. If the results have already been perverted, then the damage cannot be undone without the aid of litigation discovery.

My team provided Dr. Dickersin with the true clinical trial data for Pfizer's Neurontin studies, after we obtained it through litigation. Once she compared the true results with what was published, she found an astonishing discrepancy. The resulting article that she co-authored, entitled "Outcome Reporting in Industry-Sponsored Trials of Gabapentin for Off-Label Use," was published in the New England Medical Journal in 2009.[35] The article provides true insight into the dangers we risk when we allow pharmaceutical companies to bypass FDA oversight by marketing their drugs off label through the FDAMA-mandated reprints safe harbor.

Dr. Dickersin and others have advocated for the mandatory registration of clinical trials before they are initiated or completed; if this practice were followed without exception, pharmaceutical companies would not be able to engage in "selective outcome reporting," because the existence of other trials would be ascertainable by researchers, and because primary outcomes would be publicly and permanently

[35] S. Swaroop Vedula, M.D., M.P.H., Lisa Bero, Ph.D., Roberta W. Scherer, Ph.D., and Kay Dickersin, Ph.D., N Engl J Med 2009; 361:1963-1971. Available at http://www.nejm.org/doi/full/10.1056/NEJMsa0906126?siteid=nejm&keytype=ref&ijkey=fSALtumKaUpyI&&

identified. Making such pre-disclosures of clinical trials mandatory would go a very long way toward safeguarding the evidence base on which evidence-based medicine is so firmly grounded.

2. Create a Private Right of Action

Once harm is caused by pharmaceutical marketing fraud, it is possible that the government will be able to recover through the False Claims Act—but there is currently little that a private payor can do to recoup their own losses. Without a right of action against pharmaceutical companies for even the most egregious of frauds, it is the public that eventually foots the bill through the increase of insurance premiums.

Kaiser is a special case in part because it has a high rate of physician prescribing compliance with its formularies, and it takes an active role in policing its own formulary. Most private payors do not employ their own doctors, however, and most use pharmacy benefit managers (PBMs) to manage prescription access. While RICO may be an available remedy some of the time for an insurer like Kaiser, that law is often less available as an avenue for recovery for smaller plans. State unfair competition or consumer fraud statutes are also imperfect solutions, because the smallest of private payors will only ever recover their losses with class actions, and amalgamations of state claims between payors have been unpopular with judges.

To solve these problems, legislation could be introduced which provides a private right of action for private payors against pharmaceutical companies. A new federal statute covering pharmaceutical fraud could enable class actions for private

payors. Treble damages (as with RICO) would probably not be necessary, but double damages would be advisable, and an attorneys' fees provision would be essential.

In addition to saving the public money by preventing private payors from passing on their increased, fraud-induced costs in the form of increased premiums, a private right of action for private payors would go a long way toward deterring pharmaceutical marketing fraud. At the moment, the government pays for approximately 40% of prescription drugs, and because most False Claims Act cases settle, defendants have taken a discount from the full treble damages that they may otherwise have been required to repay to the government. This means that pharmaceutical companies essentially pay back exactly what they take from the government, but only that amount – leaving the other 60% of what they have obtained from fraud in pharmaceutical companies' coffers. When their worst case scenario is paying back less than half of what fraud would afford them, it is no wonder that pharmaceutical companies opt to engage in fraudulent marketing. If private payors had a private right of action, however, pharmaceutical companies may be liable for one hundred cents on each dollar of ill-gotten gains, or perhaps slightly more; we might finally have a sufficient deterrent in place against fraudulent pharmaceutical marketing.

3. Revoke Hatch-Waxman Patent Extensions for Fraudulently Marketed Drugs

If zeroing in on companies' concern for their own bottom lines is the key to deterring pharmaceutical companies from fraudulent promotion, there may be no better way than taking back a special accommodation that the government has already given

them. The Drug Price Competition and Patent Term Restoration Act, often referred to as the Hatch-Waxman Act, provides patent term extensions to pharmaceutical companies. In general terms, the idea is that because the FDA approval process can be quite lengthy, some portion of that time should be restored to the pharmaceutical companies that originally patented drugs.

The Hatch-Waxman Act provided that a pioneer drug could receive an extension of patent life, equal to one-half of the time of the investigational new drug period, which runs from the time human clinical trials begin to the time the New Drug Application is submitted. In addition to getting this one-half credit for the investigational new drug period, the entire time that the FDA takes to review a New Drug Application is also credited toward an extension of the life of the patent.

The Hatch-Waxman patent extensions are predicated on FDA approval; the extensions are given in direct correlation with the steps a pharmaceutical company must take before a drug can hit the market. When a pharmaceutical company markets a drug off label, however, it has bypassed the FDA in its role as efficacy watchdog.

I propose that when pharmaceutical companies engage in illegal or fraudulent marketing, as the result of a business plan, they should forfeit their Hatch-Waxman Act patent extensions. Pharmaceutical companies would be very likely to think twice before devising and enacting a fraudulent, illegal, off-label marketing scheme if they risked losing years of profits at the end of a drug's patent life. This practice should not decrease companies' incentives to invest in research and development, because the

forfeiture of patent life extensions would only happen if the company engages in fraud. This practice would, however, deter pharmaceutical companies from engaging in fraudulent marketing with the drugs that they have already researched and developed, stopping the problem before it starts.

To avoid giving companies an incentive to delay a forfeiture process through litigation, the procedure for revoking patent life extensions should be entrusted to an administrative agency, preferably the FDA. Pharmaceutical companies would be given an opportunity for hearing, at which time they might present evidence that off-label promotion was not the result of an overarching scheme. The public wins, regardless of the outcome of individual hearings; if companies engage in fraudulent promotion, the public will enjoy the cost savings of cheaper, generic drugs, and if the threat of such hearings prevents companies from engaging in fraudulent promotion in the first place, so much the better.

4. Enhance Criminal Liability and Exclusion Measures for Executives

I believe a fourth possible solution to the problem of rampant, fraudulent off-label promotion could be to force company executives to get some skin in the game. The basis for doing so is already in place, particularly for executives who remain at companies accused of health care fraud, by way of criminal prosecutions and exclusion or debarment from doing business with federal health care programs.

The Supreme Court held in United States v. Park that prosecutions for misdemeanor violations of the FDCA do not require that a defendant intended that a

violation occur; in fact, in certain circumstances, an executive's *failure to act* could be considered the basis of an FDCA misdemeanor violation.[36] In March 2010, the FDA stated publicly that it intended to increase the number of FDCA misdemeanor cases it refers to federal prosecutors.[37] Congress should determine whether the FDA has, in fact, increased the number of FDCA misdemeanor cases it has referred.

More action can be taken to spur HHS OIG to initiate exclusion or debarment proceedings, as well. Some criminal offenses trigger mandatory exclusions from participation in any federal health care program, including program-related crimes, crimes related to patient abuse, felony convictions relating to controlled substances, and felony convictions relating to health care fraud.[38] Other health care fraud events trigger only permissive exclusion, however, including claims for excessive charges or unnecessary services, as well as fraud, kickbacks, or other prohibited activities.[39] Because HHS OIG exclusions can be appealed, and may even be overturned if courts consider the exclusion decision arbitrary and capricious,[40] there is no reason to tiptoe

---

[36] United States v. Park, 421 U.S. 658, 666 (1975) ("the government establishes a prima facie case [of an FDCA misdemeanor violation] when it introduces evidence sufficient to warrant a finding by the trier of facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so…The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link [to sustain a conviction]").

[37] Letter, FDA Commissioner Margaret Hamburg to Sen. Grassley, March 4, 2010, available at: http://www.grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf

[38] 42 U.S.C. § 1320a-7(a).

[39] 42 U.S.C. § 1320a-7(b)(6)–(7).

[40] Three senior officials of the Purdue Frederick Company were prosecuted in 2007 in connection with the company's marketing of Oxycontin, pleading guilty to FDCA misbranding charges, solely as responsible corporate officers under Park. After HHS OIG notified the three officials that they would then be excluded from participation in federal health care programs, the officials appealed. The District Court for

around false health care claims and health care fraud. More of these events should be changed from triggering permissive exclusion power to mandatory exclusion power, or at the very least, HHS OIG should be urged to ramp up use of its permissive exclusion power.

Furthermore, it is frequently the case that by the time a fraudulent off-label scheme has been devised, put into effect, discovered, and eventually litigated, the executives who played a central role in that scheme have moved on to other positions. Sometimes these other positions are at other companies, posing a difficulty for criminal actions that might otherwise have been brought against such executives. HHS OIG is sometimes handcuffed when the executives responsible are no longer working for a defendant company, meaning that persons who devised schemes to engage in health care fraud can move on in their careers without significant consequence.

It is time to make sure that there *is* a consequence. It is my understanding that a couple of years ago, Representative Herger and former Representative Stark proposed closing this loophole, to make sure that executives who devised health care fraud schemes could be barred from companies that do business with government health care programs. I believe it is time to revive such a proposal.

---

the District of the District of Columbia upheld the exclusion, but the District of Columbia Circuit reversed and remanded, holding that while the convictions in questions fit under the HHS permissive exclusion power, the twelve year exclusion issued by HHS was "arbitrary and capricious" because the Secretary failed to provide a reasoned explanation for departing from agency precedent. See Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010); Friedman v. Sebelius, 686 F.3d 813 (D.C. Cir. 2012).

5. Restrict Reimbursement for Off-Label Medical Devices

In addition to deterring fraudulent off-label promotion of drugs, off-label marketing fraud in the medical device industry should be addressed by Congress. Abuse of the FDA's 510(k) process as a vehicle for getting poorly designed or inadequately tested medical devices to the market without adequate efficacy or safety review is well documented. Sometimes, unscrupulous manufacturers only claim that their device is substantially similar to an existing device so that once premarket clearance has been granted, the manufacturer can promote the new device for a novel indication that has never been proven to be safe or effective. Specialized stents are the poster boy for this type of abuse, with some manufacturers selling 80% or more of those devices for uses which were never proven to be effective or safe for the device they are marketing (or sometimes even for the predicate devices whose prior approval was the basis of their market clearance). When the vast majority of a device's sales have been generated by an unapproved use, there are often grounds to suspect that the reason the manufacturer has not sought to expand the device's approved indication is because the manufacturer knows the device would not pass the FDA's tests for safety and efficacy.

In these cases, where only the manufacturer knows that the device is not likely safe or effective for its off-label use, the United States should not encourage such inappropriate usage by continuing to pay for the device. The same rules that protect the taxpayers from paying for most unproven uses of drugs should be expanded to medical devices. The Medicare and Medicaid statutes should both be amended to restrict reimbursements for "covered medical devices" in the same way drug

reimbursement is limited to "covered outpatient drugs." Analogs to 42 U.S.C. § 1396r-8(k)(6) and 42 U.S.C. § 1395w-102(e)(4) should be enacted that would only permit payment for medical devices that were used for indications approved by the FDA or specific uses that were explicitly approved in recognized medical references. Deprived of government reimbursement, the incentive for device manufacturers to play games with the 510(k) process will be significantly reduced.

Although restricting government reimbursement of off-label medical devices will not directly assist private insurers in combating device fraud, it is likely to lead insurers to institute their own payment restrictions in the future. Although insurers are theoretically more nimble in their ability to prohibit reimbursement of unproven treatments, in reality, private insurers are loath to tell physicians how to practice medicine. Neither patients nor physicians appreciate insurers defining what treatment is acceptable, as they assume that insurers only institute such restrictions to increase the insurers' profits. Time and again, however, private insurers have followed Medicare's lead in implementing strategies that reduce waste and fraud. Once the government has made it clear to the industry that it considers certain practices abusive, insurers have the confidence to act. Restricting reimbursement of off-label device usage to those circumstances where independent, recognized authorities agree that medical evidence supports the unapproved usage, is a step private payors will feel comfortable taking after the federal government has led the way on this issue.

CONCLUSION

After the recalibrations of 2009 and 2010, the False Claims Act is a finely-tuned machine for recovering money lost to health care fraud and abuse. It is an excellent tool for redressing harm against the government after it has already occurred, but could be made better if Congress did more to encourage more state False Claims Acts, if it relaxed the pleading standard courts have applied, and, most importantly, if it gave relators' counsel ready access to claims data from CMS. With respect to pharmaceutical marketing fraud, further steps should be taken to stop the fraud before it starts. This can be done by making sure that private payors can recover damages from pharmaceutical companies. Fraudulent marketing can also be deterred without resort to litigation, either by requiring the reporting of clinical trials, by making sure that companies risk revocation of Hatch-Waxman patent life extensions in certain circumstances, or by making sure that company executives have skin in the game.