

ARTICLE

THE SHORT-SIGHTED VALUE OF INEFFICIENCY: WHY WE SHOULD MIND THE GAP IN THE REIMBURSEMENT OF OUTPATIENT PRESCRIPTION DRUGS

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ABSTRACT

As indicated by recent multi-million dollar settlements between the federal government and several major pharmaceutical companies, the current federal healthcare system is improperly paying claims through Medicaid and Medicare for off-label use of prescription drugs. These widespread improper payments are due, at least in part, to an information gap in the current billing system for the recently expanded Medicare and Medicaid programs, which, if fixed, could reduce or eliminate improper payments for off-label prescriptions. The solution includes incorporating patient diagnosis information into the billing system for Medicare and Medicaid prescription drug benefit programs, which would allow for real-time review of prescription drug claims for eligibility instead of the delayed audit currently used occurring weeks (or months and years) after payment has been made. In addition, linking diagnosis codes directly to prescription information would provide more robust data to better inform comparative effectiveness research, drug safety monitoring, and insurance coverage decisions. Doing so, however, will likely eliminate one of the critical legal theories under the False Claims Act on which the fraud

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enforcement community has relied upon for recouping billions of dollars from pharmaceutical companies for their off-label promotion of drugs. Even so, maintaining the information gap in the current billing system, while potentially valuable as an enforcement mechanism, is short-sighted and unnecessarily risky for both fiscal stability and the overall public health.

INTRODUCTION

Recent settlement agreements between the federal government and major pharmaceutical companies, totaling over \$2 billion recovered,² illustrate a significant problem in the current federal healthcare system: the improper payment of claims for outpatient prescription drugs that are ineligible for reimbursement due to off-label use. “Off-label” describes the use of a drug for a disease or condition that is not included in the product labeling, which is specifically approved by the U.S. Food and Drug Administration (FDA), for an otherwise FDA-

² See, e.g., Press Release, U.S. Dep’t of Justice, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox® (Sept. 1, 2010) [hereinafter Dep’t of Justice Allegran Press Release], available at <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>; Press Release, U.S. Dep’t of Justice, Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009) [hereinafter Dep’t of Justice Eli Lilly Press Release], available at <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html>; Settlement Agreement, U.S. Dep’t of Justice, Pfizer Settlement (2009) [Pfizer Settlement Agreement], available at <http://www.justice.gov/> (search “Pfizer Settlement”; then follow “Pfizer Settlement Agreement” hyperlink); Gardiner Harris, *Pfizer Pays \$2.3 Billion to Settle Marketing Case*, N.Y. TIMES, Sept. 3, 2009, at B4; see also *AstraZeneca Third Quarter 2009 Financial Results for Investors*, available at <http://www.astrazeneca.com/Investors/Financial-results/2009-Financial-results> (select the “Third quarter” tab and follow the “Figures” hyperlink) (last visited Apr. 15, 2011) (providing information regarding the \$520 million settlement with the DOJ to resolve a probe of its marketing practices for Seroquel).

Prior to 2009, the DOJ settled additional False Claims Act violations with Intermune for \$36.9 million for the unlawful promotion of Actimmune, with Schering for \$255 million for the off-label promotion of Temodar and Intron A, and with Serono for \$567 million for the unlawful promotion of Serostim. See Press Release, U.S. Dep’t of Justice, Biopharmaceutical Firm Intermune to Pay U.S. over \$ 36 Million for Illegal Promotion and Marketing of Drug Actimmune (Oct. 26, 2006), available at http://www.usdoj.gov/opa/pr/2006/October/06_civ_728.html; Press Release, U.S. Dep’t of Justice, Michael J. Sullivan, U.S. Attorney Dist. of Mass., Schering to Pay \$ 435 Million for the Improper Marketing of Drugs and Medicaid Fraud (Aug. 29, 2006), available at <http://www.justice.gov/> (search “Schering” & “Improper Marketing”; then follow “Press Release” hyperlink); Press Release, U.S. Dep’t of Justice, Serono to Pay \$ 704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), available at http://www.justice.gov/opa/pr/2005/October/05_civ_545.html.

approved prescription drug.³ As explained in Section I.A, the problem is not the improper reimbursement of off-label prescriptions generally, but rather the improper payment of ineligible claims due to medically inappropriate off-label use. Off-label use of prescription drugs is perfectly legal and occasionally reflects the recognized standard of care for a disease or condition. The Medicare and Medicaid outpatient prescription drug programs accommodate the legal off-label use of prescription drugs and cover some, but certainly not all, off-label uses.⁴ Whether an outpatient prescription drug is eligible for reimbursement under Medicare or Medicaid largely depends on *why* the drug was prescribed.

The current billing systems for Medicare Part D and Medicaid, described in Section I.B, do not require pharmacists submitting claims for outpatient prescription drugs to provide any information regarding the use of the drug beyond the drug name and amount dispensed. By contrast, reimbursement of physician services and inpatient prescription drugs under Medicare Parts A and B or Medicaid requires physicians to submit diagnosis codes (also known as ICD codes).⁵ While the data collected for Medicare and Medicaid reimbursement allows the Government to audit outpatient prescription drug claims after payment to determine whether prescriptions were properly reim-

³ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-96-212, PRESCRIPTION DRUGS: IMPLICATIONS OF DRUG LABELING AND OFF-LABEL USE 1-2 (1996) (providing background information about the off-label system).

⁴ The federal healthcare system includes insurance coverage under Medicare, Medicaid, the Federal Employee Health Benefit Program (insurance for federal government employees), CHAMPUS/TRICARE (insurance for active military personnel, civilian employees, and their families), and the Veterans' Administration, as well as, some smaller insurance programs. While each program has its own legal and regulatory framework, Medicare and Medicaid comprise the vast majority of federal healthcare spending and enforcement efforts, which is why this article is limited to these programs. See 42 U.S.C. §§ 1395-1395ccc (2006) (Medicare); 42 U.S.C. §§ 1396-1396v (2006) (Medicaid); 5 U.S.C. §§ 8901-8914 (2006) (Federal Employee Health Benefit Program).

⁵ "ICD" is the abbreviation for the International Classification of Diseases created by the World Health Organization. WORLD HEALTH ORG., INTERNATIONAL CLASSIFICATION OF DISEASES AND HEALTH RELATED PROBLEMS (10th rev. 2d. 2004), available at <http://www.who.int/classifications/icd/en/> (last visited Apr. 15, 2011). The ICD is currently in its tenth revision (ICD-10-CM), although it will not be fully implemented into federal healthcare billing until October 1, 2013. See Press Release, U.S. Dep't of Health and Human Services, HHS Issues Final ICD-10 Code Sets and Updated Electronic Transaction Standards Rules (Jan. 15, 2009), available at <http://www.hhs.gov/news/press/2009pres/01/20090115f.html>. Until that time, Medicare and Medicaid billing will use the diagnosis codes from the ninth revision (ICD-9). See HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS, 74 Fed. Reg. 3328-01 (Jan. 16, 2009) (to be codified at 45 C.F.R. pt. 162).

bursed, it is unable to flag suspect claims before payment, resulting in millions—if not billions—of dollars lost in improperly paid claims.

As explained in Section II.A, the staggering level of fraud and waste within the federal healthcare system has prompted Congress to devote significant financial resources to detect and recoup improper payments. As a result, there are thousands of federal and state employees and contractors charged with protecting the integrity of the federal health care system, by identifying ineligible claims through post-payment audits and pursuing the recoupment of improper payments. However, the information gap that facilitates the improper payment of claims in the first place also permits the federal government to use private counsel to represent whistleblowers under the False Claims Act. This allows the Government to focus on pursuing large, publicly traded pharmaceutical companies instead of individual physicians and pharmacists as discussed in Section II.B. Section II.C argues that instead of devoting its resources to enforcement efforts, the Government should focus on fixing the gaps in the current billing system in order to prevent the payment of ineligible, false, or fraudulent claims.

In anticipation of the significant efforts to overhaul the current federal healthcare system in the coming months and years,⁶ this Article proposes a straightforward regulatory fix that could potentially prevent billions of dollars in health care fraud and waste due to inappropriate off-label promotion of prescription drugs by pharmaceutical companies. Specifically, the Centers for Medicare and Medicaid Services (CMS) should require diagnosis codes on claims submitted for federal reimbursement of outpatient prescription drugs under the Medicare Part D and Medicaid programs, both of which were expanded under the most recent landmark health-overhaul legislation.⁷ The advantages of extending the requirement of a diagnosis code to Medicaid and Medicare Part D, as set out in Section III, are necessary to protect federal fiscal stability and patient safety, even if such a change would potentially eliminate one of the Government's current fraud enforcement mechanisms.

⁶ See *Combating Health Care Fraud and Abuse: Hearing Before the H. Appropriations Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies*, 111th Cong. 3 (2010) (statement of William Corr, Dep. Sec'y, U.S. Dep't of Health & Human Servs.) [hereinafter Corr] ("We [the Department of Health & Human Services] need to take on the tough job of overhauling the claims processing system, and with the commitment of the President and the help of the Congress, we intend to do just that.").

⁷ See Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

I. THE PROBLEM WITH THE MEDICARE AND MEDICAID BILLING SYSTEMS

The current billing systems for Medicare and Medicaid are woefully inadequate for the prevention and detection of mistakes and fraud. Nearly half of the improper payments made by the federal government as a whole can be attributed to the Medicare and Medicaid programs.⁸ It makes sense then that significantly reducing improper payment of funds will reduce federal health care costs.⁹ For instance, outpatient prescription drug reimbursement was recently identified as a major cause for increased federal health care spending. Thus, reducing these improper payments should be a priority, especially in light of the recent expansion of both Medicare Part D and Medicaid.¹⁰

⁸ “[The Department of Health and Human Services] reported improper payment estimates for Medicare and Medicaid totaling about \$36 billion for fiscal year 2008....This represents about 50 percent of the total \$72 billion in reported improper payments.” U.S. GOV’T. ACCOUNTABILITY OFFICE, GAO-09-628T, IMPROPER PAYMENTS: PROGRESS MADE BUT CHALLENGES REMAIN IN ESTIMATING AND REDUCING IMPROPER PAYMENTS 10 (2009) [hereinafter IMPROPER PAYMENTS]. However, the 2008 figure did not include an estimate for improper payments under Medicare Prescription Drug Benefit (Part D) and only indicated the federal share. *Id.* at n.12.

⁹ “Speaking at the Center for Business Intelligence’s Annual Strategic Medicare Policy Summit in Washington, Bruce Steinwald, an independent consultant and former director of health care at the Government Accountability Office, said there are a number of solutions to address the [current unsustainable Medicare spending trends].” *Medicare: Medicare Spending Unsustainable, Yet Can Still Be Controlled, Expert Says*, BNA HEALTH CARE DAILY REP., Feb. 16, 2010, at 1. Steinwald indicated that the “simplest solution...[was] to reduce waste, fraud, and abuse.” *Id.* See also Corr, *supra* note 6, at 7 (noting one estimate on prepayment edits and claims auditing indicates a 14-to-1 return on the investment to prevent health care fraud).

¹⁰ “While there are a number of reasons for the rise in health care costs over the past few decades, it is clear that prescription drugs are one of the main drivers of this increase.” *Oversight Challenges in the Medicare Prescription Drug Program: Hearing Before S. Subcomm. on Fed. Fin. Mgmt., Gov’t Info., Fed. Servs., & Int’l Sec., S. Comm. on Homeland Sec. & Governmental Affairs*, 111th Cong. (2010) (statement of Sen. Thomas R. Carper) [hereinafter Carper]. The Office of Inspector General for the Department of Health and Human Services (OIG-HHS)—responsible for protecting HHS programs against fraud, waste, and abuse—identified oversight of the Medicare Part D prescription drug benefit as its top management and performance challenge for fiscal year 2007 due to the complex structure and the cost of the program. See U.S. DEP’T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2007 AGENCY FIN. REPORT, MGMT. ISSUE 1: OVERSIGHT OF MEDICARE PLAN D 2-3 (2007), available at http://www.oig.hhs.gov/publications/challenges/files/TM_Challenges07.pdf. More recently, the Government Accounting Office identified the Medicare Part D prescription drug benefit as a program that is at high risk for being susceptible for making improper payments. IMPROPER PAYMENTS, *supra* note 8, at 13.

A. Federal Reimbursement of Outpatient Prescription Drugs

Currently, both Medicaid and Medicare offer outpatient prescription drug coverage, but each covers separate patient populations and has different claims processing systems.¹¹ Medicaid is a joint federal-state program that finances medical services and outpatient prescription drugs for qualifying low-income adults and children.¹² “Medicaid programs are jointly funded by Federal and State governments but solely administered by States pursuant to Federal statutes, regulations, and policies.”¹³ Further, CMS is responsible for overseeing the administration of the state Medicaid programs to ensure that the “State-submitted expenditures for Federal reimbursement are appropriate.”¹⁴ In 2006, “Medicaid covered over 57 million beneficiaries at a cost of over \$308 billion,” with the federal government contributing over \$174 billion.¹⁵ In 2007, Medicaid spent approximately \$15 billion on outpatient prescription drugs.¹⁶

Medicare is a program that provides health care assistance to elderly and disabled patients.¹⁷ Parts A and B have historically reimbursed use of prescription drugs in hospitals, skilled nursing facilities, and outpatient dialysis and oncology clinics, but did not cover outpatient prescription drugs.¹⁸ Federal reimbursement of most outpatient

¹¹ While Medicare and Medicaid target separate and distinct patient populations, there is a pool of patients who are eligible for both Medicare and Medicaid. These patients are known as “dual eligible beneficiaries.” MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONG.: NEW APPROACHES IN MEDICARE 71-72 (2004), available at http://www.medpac.gov/publications/congressional_reports/June_04_ch3.pdf.

¹² U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-118R, MEDICAID OUTPATIENT PRESCRIPTION DRUGS: SECOND QUARTER 2008 FEDERAL UPPER LIMITS FOR REIMBURSEMENT COMPARED WITH AVERAGE RETAIL PHARMACY ACQUISITION COSTS 1 (2009) [hereinafter, MEDICAID OUTPATIENT PRESCRIPTION DRUGS]. “Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include one for each of the 50 states; the District of Columbia; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands.” *Id.* at n. 1.

¹³ U.S. DEP’T OF HEALTH & HUMAN SERVS., OEI-04-07-00240, MEMORANDUM REPORT: MSIS DATA USEFULNESS FOR DETECTING FRAUD, WASTE, AND ABUSE 2 (2009) [hereinafter MEMORANDUM REPORT: MSIS DATA], available at <http://oig.hhs.gov/oei/reports/oei-04-07-00240.pdf>.

¹⁴ *Id.*

¹⁵ *Id.* (footnote omitted).

¹⁶ MEDICAID OUTPATIENT PRESCRIPTION DRUGS, *supra* note 12, at 1.

¹⁷ IMPROPER PAYMENTS, *supra* note 8, at 11 (“As HHS’s largest program, [Medicare] represented nearly \$400 billion or almost 60 percent of HHS’s outlays for fiscal year 2008.”).

¹⁸ *Id.* The Medicare Program is comprised of Parts A—D. The Medicare Fee-for-Service (FFS) represents the largest share of Medicare payments and includes

prescription drugs was limited to Medicaid claims prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which created Medicare Part D, an outpatient prescription drug benefit program that went into effect on January 1, 2006.¹⁹ In its first year, Part D provided federally subsidized prescription drug coverage to nearly 28 million beneficiaries at a cost of \$47.4 billion, nearly 12 percent of total Medicare spending.²⁰ In 2007, the total spending for Part D rose to \$54.4 billion.²¹ As of February 2010, 27.6 million beneficiaries were enrolled in Part D plans.²²

While both government attorneys and reporters have broadly stated that insurers do not reimburse prescriptions for off-label uses, the reimbursement framework is significantly more nuanced.²³ For purposes of Medicaid and Medicare Part D, a drug is eligible for reimbursement only if it is used for a “medically accepted indication.”²⁴ This includes any specific indication listed on the drug’s label-

Hospital Insurance (Medicare Part A) and Supplementary Medical Insurance (Medicare Part B). Medicare FFS “covers an array of items and services including hospital, skilled nursing and home health care; physician services; ambulance services; and medical equipment and supplies.” *Id.* Medicare Advantage (Medicare Part C) is designed to provide private healthcare coverage for beneficiaries who choose this as an alternative to Medicare FFS. *Id.* For purposes of this Article, the only relevant part dealing with reimbursement of outpatient prescription drugs is the Medicare Prescription Drug Benefit (Medicare Part D).

¹⁹ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-1074R, MEDICARE PART D PRESCRIPTION DRUG COVERAGE: FEDERAL OVERSIGHT OF REPORTED PRICE CONCESSIONS DATA 1 (2008) [hereinafter MEDICARE PART D PRESCRIPTION DRUG COVERAGE] (citing Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152).

²⁰ *Id.*

²¹ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-529T, MEDICARE PART D: SPENDING, BENEFICIARY OUT-OF-POCKET COSTS, AND EFFORTS TO OBTAIN PRICE CONCESSIONS FOR CERTAIN HIGH-COST 6 (2010), available at <http://www.gao.gov/new.items/d10529t.pdf>.

²² *Id.* at 1.

²³ See Kathleen M. Boozang & Simone Handler-Hutchinson, “Monitoring” Corporate Corruption: DOJ’s Use of Deferred Prosecution Agreements in Health Care, 35 AM. J. L. & MED. 89, 98 (2009) (“Drug and device reimbursement regulations are some of the most complicated regulations that exist.”); see also Joshua Cohen, Andrew Wilson & Laura Faden, *Off-Label Use Reimbursement*, 64 FOOD DRUG L. J. 391, 394 (2009) (Payment for off-label use is “murkier” because “off-label uses are usually not included on plan formularies, though some drugs are placed on prior authorization schedules owing to their off-label use ‘potential.’ Second, there is no premarketing approval evidence on off-label use safety and efficacy, and post-marketing evidence is often limited. This does not imply, however, that off-label uses are not reimbursed. They are usually reimbursed, albeit conditionally.”).

²⁴ See 42 U.S.C.A. § 1396r-8(k)(2) (West 2010) (defining “covered outpatient drug” for Medicaid); 42 C.F.R. § 423.100 (2010) (defining Medicare “Part D drug” by referring to Medicaid statute definition of “medically accepted indication”); see also Cohen et al., *supra* note 23, at 393 (“Of particular concern to policymakers

ling, as approved by the FDA (also known as an “on-label” use), any use which is supported by peer-reviewed medical literature,²⁵ or any use supported by one or more citations found in recognized drug compendia, including the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System.²⁶ The uses supported by peer-reviewed medical literature or compendia citations include, both on-label uses as well as, uses that are not included on the FDA-approved labeling for a drug (“off-label” uses).²⁷

The Food, Drug and Cosmetic Act (FDCA) provides the legal framework for the development, approval, and marketing of prescription drugs.²⁸ However, it does not control a physician’s prescribing habits or the practice of medicine.²⁹ Further, while off-label *promotion* of prescription drugs may be illegal under the FDCA, off-label *use* of prescription drugs is legal,³⁰ widespread,³¹ and, in many cases,

(regulators and payers) is the lack of supporting data for numerous off-label uses. Evidently, 15 percent of all off-label uses lack scientific evidence of any kind, while fewer than 30 percent of off-label practices are supported by strong clinical evidence.”).

²⁵ 42 U.S.C.A. § 1396r–8(g)(1)(B)(ii) (West 2010).

²⁶ 42 U.S.C.A. § 1396r–8(g)(1)(B)(i) (West 2010).

²⁷ 42 U.S.C.A. § 1395x(t)(2)(B) (West 2010). *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE BENEFIT POLICY MANUAL, PUB. NO. 100-02, ch. 15 §50.4.2, <https://www.cms.gov/manuals/Downloads/bp102c15.pdf> (last visited Apr. 15, 2011) (“An unlabeled use of a drug is a use that is not included as an indication on the drug’s label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.”); Cohen et al., *supra* note 23, at 392 (“Scientific findings that support off-label uses are first highlighted in medical professional meetings, drug compendia, peer-reviewed literature, and the general media.”) (footnote omitted).

²⁸ *See* 21 U.S.C. §§ 301-399a (2006).

²⁹ Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations of Off-Label Promotion Prosecutions*, 64 FOOD & DRUG L. J. 441, 444 (2009) (“Indeed, the Federal Food Drug and Cosmetic Act (FDCA) forbids the regulation of off-label use saying, ‘Nothing in this Act shall be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship.’”) (citing 21 U.S.C. §396).

³⁰ *See* 21 U.S.C. §396 (explaining how the FDCA does not limit the practice of medicine); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY ON GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES [hereinafter REPRINT PRACTICES], [available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm) (“Once a drug

considered the standard of care.³² Off-label use of prescription drugs “covers the range from experimental to standard therapy and even state-of-the-art treatment. In some instances, off-label use represents first-line treatment, in others second- and third-line therapy, and still others last resort therapy.”³³

The FDA has historically recognized the value of off-label use. For example, in 1982, FDA said:

Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in the approved labeling. Such “unapproved” or, more precisely, “unlabeled” uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been ex-

or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product’s approved labeling....”) (last updated Jan. 2009); Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 69 (2008) (noting that the FDCA does not limit the authority of medical practitioner to prescribe off-label prescription drug use).

³¹ See Hua Chen et al., *Off-Label Use of Antidepressant, Anticonvulsant, and Antipsychotic Medications Among Georgia Medicaid Enrollees in 2001*, 67 J. CLINICAL PSYCHIATRY 972 (2006) (concluding off-label use of antidepressant and antipsychotic medications is highly prevalent among Georgia Medicaid beneficiaries); Johnson, *supra* note 30, at 61 (“Some estimates . . . indicate that over half of the prescription medications provided to patients in the United States may be prescribed for a purpose, in a higher or lower dose, over a longer period of time, or for a population (such as children) different from that for which the drug has been approved.”) (footnote omitted).

³² See, e.g., *Wash. Legal Found. v. Friedman*, 13 F.Supp.2d 51, 56-57 (D.D.C. 1998) (describing the advantages and disadvantages of off-label use and acknowledging that it is part of the practice of medicine); see also REPRINT PRACTICES, *supra* note 30 (“These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals’ receipt of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical products that are truthful and not misleading.”); Jeffrey L. Blumer, *Off-Label Use of Drugs in Children*, 104 PEDIATRICS 598, 600 (1999) (“The prescribing of drugs for off-label use is entirely proper. The decision regarding how to use a drug must be made based on what is good medicine and what is best for the patient, regardless of conforming to labeling.”); Johnson, *supra* note 30, at 68 (“[O]ff-label use often becomes the customary standard of care in particular circumstances, with the result that doctors are at risk for malpractice liability for failure to prescribe an approved drug for an off-label use.”).

³³ Cohen et al., *supra* note 23, at 392 (citing Thomas Laetz & George Silberman, *Reimbursement Policies Constrain the Practice of Oncology*, 266 JAMA 2996, 2996-99 (1991)).

tensively reported in medical literature....Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations....³⁴

More recently, FDA has confirmed this position, recognizing that “the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products.”³⁵ This is especially true for diseases and patient populations in which clinical trials are particularly difficult because the specific disease is rare (making statistical significance in a clinical trial impossible),³⁶ the costs of the clinical trials are unlikely to be recouped even if the drug is approved by the FDA,³⁷ or the patient population is difficult to enroll and study.³⁸

While doctors can prescribe drugs for off-label uses, the FDCA restricts how pharmaceutical companies promote their products. Many government attorneys discussing off-label promotion investigations broadly state that it is illegal for a drug company to promote their products for off-label uses.³⁹ However, “promotion,” off-label or oth-

³⁴ *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4, 5 (1982).

³⁵ REPRINT PRACTICES, *supra* note 30.

³⁶ See Cohen et al., *supra* note 23, at 394 (“Some off-label uses may even represent then only therapeutic option available to patients.”); Gentry, *supra* note 29, at 442 (“[R]are diseases may never have an on-label drug use. Most diseases afflicting fewer than 200,000 Americans are ‘totally without’ FDA-labeled treatment. Some ‘90 percent of [patients] must rely on off-label uses’ to have any treatment at all.”) (citing Abbey S. Meyers, Pres., National Org. for Rare Diseases, Inc., Prepared Testimony before Subcomm. on Human Res. and Intergovernmental Relations of the House Comm. On Gov’t Reform and Oversight (Sept. 12, 1996)).

³⁷ See Cohen et al., *supra* note 23, at 392 (“Many off-label uses may never get approved, even if supported scientifically, if the sponsor decides that the cost and risk of seeking a supplemental approval outweigh the economic benefit to the sponsor of obtaining the approval.”).

³⁸ Two such patient populations are children and pregnant women. Gentry, *supra* note 29, at 441-42 (“It has been reported that 80 percent of all medications prescribed for children had FDA-required disclaimers about the use in children because of the paucity of pediatric research. Some patient populations may never have on-label drugs available to them. As one pharmaceutical executive asked, ‘Who in his right mind would work on a product that would be used by pregnant women?’”) (footnotes omitted).

³⁹ See, e.g., *Enforcement of the Criminal Laws Against Medicare and Medicaid Fraud: Hearing Before Subcomm. on Crime, Terrorism and Homeland Sec. of the H. Comm. on the Judiciary*, 111th Cong. 13 (2010) (statement of D. Mark Collins, Ass’t Att’y Gen., Dir., Neb. Medicaid Fraud Control Unit & Pres., Nat’l Ass’n of Medicaid Fraud Control Units) [hereinafter Collins], available at <http://judiciary.house.gov/hearings/pdf/Collins100304.pdf> (“[F]ederal law prohibits a manufacturer from promoting a drug for uses not approved by the FDA.”); *Allega-*

erwise, is not defined in the FDCA.⁴⁰ Instead, the FDCA prohibits off-label promotion indirectly. For example, violations may be triggered through the introduction of an unapproved “new drug” or a “misbranded” drug into interstate commerce.⁴¹

Before selling a prescription drug in interstate commerce, pharmaceutical companies are required to submit new drug applications (NDA) to the FDA for approval.⁴² When the FDA reviews and approves an NDA, the approval is specific to the disease or condition

tions of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the H. Comm. on Oversight and Government Reform, 110th Cong. 6 (2007) (statement of Lewis Morris, Chief Counsel, Office of Inspector Gen., Dep’t of Health and Human Servs.), available at <http://oig.hhs.gov/testimony/docs/2007/020907tmy.pdf> (“While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.”).

⁴⁰ Indeed, the strongest authority the federal government could provide for a definition of “promotional labeling” in recent litigation was a draft “Guidance for Industry,” which provides non-binding recommendations for drug and device manufacturers. Defendants’ Memorandum of Points and Authorities in Support of Motion to Dismiss or for Summary Judgment at 6, *Allergan, Inc. v. United States* (D.D.C. Jan. 11, 2010) (No. 09-cv-01879), 2010 WL 110193 (citation omitted). The draft guidance states that “[p]romotional labeling is generally any labeling other than the FDA-approved labeling,” and provides no statutory or regulatory authority for this definition. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: “HELP-SEEKING” AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS (2004) [hereinafter GUIDANCE FOR INDUSTRY], available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070068.pdf>.

⁴¹ See e.g., 21 U.S.C.A. § 331(a)-(c) (Supp. 2010) (misbranding violations); 21 U.S.C. § 331(d) (2006) (violation for “introduction or delivery for introduction into interstate commerce of any article in violation” of 21 U.S.C. § 355, the “new drug” application process).

The misbranding and new drug violations deal with “advertising” and “labeling,” both terms linked more directly to the promotion of a drug. “Advertising,” while referenced extensively in the FDCA is not defined by the statute. “Labeling,” however, is defined in 21 U.S.C. § 321(m) (2006) as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” Both terms are further clarified in the accompanying regulations. See 21 C.F.R. § 202.1(k)(l) (2010) (“Advertisements” include “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.” Additionally, “labeling” includes “[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the ‘Physicians Desk Reference’) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor.”).

⁴² 21 U.S.C.A. § 355 (Supp. 2010) (new drug application requirements).

(identified as the “indication,” on the FDA-approved prescribing information) for which the manufacturer conducted the required pre-market clinical trials.⁴³ For purposes of the FDCA, previously approved prescription drugs may still be considered “new” if the manufacturer promotes the drug for an unapproved use.⁴⁴ An approved drug is considered “misbranded” if “its labeling is false or misleading in any particular,” or potentially if it lacks “adequate directions for use.”⁴⁵ Off-label promotion may include false or misleading informa-

⁴³ *Id.* at § 355(b)(1) (2006).

⁴⁴ For the broader purposes of the FDCA, a “new drug” means a drug that “is not drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof,” or a drug that “as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.” 21 U.S.C. § 321(p) (2006). Promotion for an unapproved use for an otherwise approved drug may not render a drug “new” if the use has been extensively studied and recognized by treating physicians as the standard of care. What is not clear under the current law is whether a company’s mere knowledge of widespread off-label use is sufficient to render an approved drug “new.” See Gentry, *supra* note 29, at 443 n.13 (citing Jonathan S. Kahan, *Extra-Label Use: An Open Secret*, MED. DEVICE & DIAGNOSTIC INDUSTRY, Apr. 1990, at 47, 48-49 (“What are companies to do when they learn that, *contrary to their wishes*, their own device is being used for an extra-label indication? Companies may fear FDA regulatory sanctions . . . if their device becomes widely used for extra-label purposes.”) (emphasis added)).

⁴⁵ 21 U.S.C. § 352(a) (2006) (false or misleading label); 21 U.S.C. § 352(f) (2006) (directions for use). The FDCA and supporting regulations suggest that prescription drugs are technically exempt from needing “adequate directions for use.” See 21 U.S.C. § 353(b) (2006) (exemptions from labeling and prescription requirements); 21 C.F.R. § 201.100 (2010) (labeling exemptions from adequate directions for use). Even so, federal prosecutors still include misbranding due to lack of adequate directions for use in their summary of violations triggered by off-label promotion. See Government’s Memorandum for Entry of Plea and Sentencing at 2 United States v. Cephalon, Inc., No. 2:08-cr-00598 (E.D. Pa. Oct. 10, 2008), available at <http://www.justice.gov/civil/oclcases/Cases/Cephalon/Cephalon%20sentencing%20memorandum.PDF>.

The need to clarify “adequate directions for use” regulations and policies for prescription drugs was at issue in *Allergan, Inc. v. United States*. See *Complaint Allergan, Inc. v. United States*, (D.D.C. Oct. 1, 2009) (No. 09-cv-01879), 2009 WL 3187592 (Allergan filed a complaint seeking a determination of whether a discussion of safety concerns associated with off-label use would violate FDCA, in part, because product would not have adequate directions for the off-label use). Cross-motions for summary judgment were recently pending until Allergan agreed to stay the proceedings as part of their \$600 million criminal and civil settlement for alleged off-label promotion of their product, Botox. See Dep’t of Justice Allegran Press Release, *supra* note 2; Press Release, Allergan, Inc., Allergan Resolves United States Government Investigation of Past Sales and Marketing Practices Relating to Certain Therapeutic Uses of BOTOX® (Sept. 1, 2010), available at <http://agn.client.shareholder.com/rele>

tion or uses for which the FDA-approved prescribing information does not provide adequate directions for the off-label use.

Historically, the FDA has been involved with relatively little enforcement of off-label promotion.⁴⁶ This reflects, in part, the FDA's position that not all off-label promotion is illegal under the FDCA.⁴⁷ The FDA's current guidance on the distribution of off-label information allows pharmaceutical companies to distribute peer-reviewed medical journal reprints on off-label uses provided they are "distributed separately from information that is promotional in nature."⁴⁸ Therefore, while a sales representative may deliver a reprint to a doctor, it "should not be physically attached to any promotional material the sales representative uses or delivers during the office visit and

asedetail.cfm?ReleaseID=503974 ("To resolve the criminal and civil investigation, Allergan was required by the Government to dismiss Allergan's First Amendment lawsuit pending in Washington, D.C., in which Allergan sought a ruling that it could proactively share truthful scientific and medical information with the medical community to assist physicians in evaluating the risks and benefits if they choose to use BOTOX® off-label to treat certain forms of spasticity. Allergan is disappointed that the court was not afforded an opportunity to hear and rule on these important First Amendment issues, as Allergan believes that physicians, patients, manufacturers, payers, and ultimately the quality of evidence-based medicine itself would have benefited from a ruling clarifying the law.").

⁴⁶ See generally U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-835, FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES (2008), available at <http://www.gao.gov/new.items/d08835.pdf>. See also Katherine A. Helm, *Protecting Public Health from Outside the Physician's Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 177 (2007) (noting the lack of FDA enforcement of misbranding violations historically).

⁴⁷ Originally, the Food and Drug Administration Modernization Act of 1997 (FDAMA) specified that types of off-label promotion were legal provided certain statutory and regulatory requirements were met. See 21 U.S.C. § 360aaa (repealed 2006). Further, both the FDA and the federal government traditionally did not pursue the regulation of off-label use. See, e.g., *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("[N]either Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers. A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."); Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 FOOD & DRUG L.J. 653, 657 (2006) (discussing the FDA's complex stance on the promotion of off-label use). However, the provisions of FDAMA sunsetted in 2006. Pub. L. No. 105-115, § 401(e), 111 Stat. 2296, 2364 (1997). Currently, the FDA Guidance for Industry provides the FDA's position on the distribution of off-label information. See REPRINT PRACTICES, *supra* note 30. To the extent that promotional activities may extend beyond "labeling" or "advertising," the statute is silent on the propriety of the activities. See 21 U.S.C. §§ 301-399a (2006).

⁴⁸ REPRINT PRACTICES, *supra* note 30.

should not be the subject of discussion between the sales representative and the physician during the sales visit.”⁴⁹

As this language suggests, the line between permissible and impermissible off-label promotion may be crossed by something as simple as a misplaced staple or an errant sales representative comment.⁵⁰ Further, there is also some question as to whether a sales representative’s discussion of safety concerns associated with known off-label uses could render an approved drug “new.”⁵¹

B. Current Difficulties in Identifying Ineligible Claims for Reimbursement Due to Off-Label Use

Current systemic hurdles make both real-time detection and post-payment identification of specific ineligible claims due to medically inappropriate off-label use difficult.⁵² Because the Medicare Part D and Medicaid billing systems do not currently require diagnosis codes on claims submitted for reimbursement of outpatient prescription drugs,⁵³ it is impossible to identify false claims based on the submitted claims information alone.⁵⁴ In order to identify an ineligible claim due to off-label use, the Government must match a patient’s treatment history (based on claims submitted for the prescribing physician’s services) to a claim for reimbursement for an outpatient prescription drug, and show that the patient’s diagnosis is not a medically accepted indication for the particular drug.⁵⁵

⁴⁹ *Id.*

⁵⁰ See Cohen et al., *supra* note 23, at 401 (“There is a fine line, however, between informing and promoting or marketing.”).

⁵¹ See Complaint Allergan, Inc. v. United States, (D.D.C. Oct. 1, 2009) (No. 09-cv-01879), 2009 WL 3187592 (Allergan sought a determination of whether the discussion of safety concerns associated with off-label use would violate FDCA). However, the complaint was dismissed as part of a plea agreement in a separate case. See also discussion, *supra* note 45.

⁵² Cohen et al., *supra* note 23, at 398 (“15 percent of respondents commented that the difficulty of detecting off-label use prevented them from instituting ‘effective’ off-label use policies, such as denials of coverage or reimbursement restrictions.”).

⁵³ See MEDICARE PART D PRESCRIPTION DRUG CLAIM FORM, available at http://www.anthem.com/ca/member/f0/s0/t0/pw_a116572.pdf (last visited Apr. 15, 2011).

⁵⁴ Cohen et al., *supra* note 23, at 394 (“That a different set of circumstances surrounds off-label reimbursement presupposes the payer’s ability to detect off-label uses, which is not necessarily the case. As most pharmaceuticals do not require prior authorization, it is hard to know whether they are being prescribed off-label.”).

⁵⁵ See United States *ex rel.* Franklin v. Parke-Davis, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, *10-11 (D. Mass. Aug. 22, 2003) (“But the Relator has provided analysis linking patients’ treatment histories to Neurontin prescriptions that

Physicians submit claims to Medicare and Medicaid to receive payment for the services they provide to their federally-insured patients. In order to receive payment physicians must include information specific to the level of service provided and an ICD-9-CM diagnosis code that allows the payor to evaluate whether the service provided was medically necessary and appropriate.⁵⁶ By contrast, retail pharmacists are not required to provide such information when seeking reimbursement from Medicare and Medicaid for outpatient prescription drugs.⁵⁷ When retail pharmacists receive outpatient prescriptions from patients or physicians, the patients' diagnoses are not typically provided on the prescription. Retail pharmacists only need a patient's diagnosis for reimbursement purposes when the drug is covered under Medicare Part B.⁵⁸ Otherwise, pharmacists are able to submit claims for reimbursement without any diagnosis information.⁵⁹

generated reimbursement claims; Relator contends this analysis demonstrates that many reimbursement claims must have been for off-label, non-compendium indications, given the patients' treatment histories. Parke-Davis has submitted expert testimony contesting the reliability of comparing data from pharmacy claim forms with diagnosis data from patient medical-services claim forms. Relator's expert evidence suffices to survive summary judgment."); Cohen et al., *supra* note 23, at 394-5 ("[P]ayer drug utilization reviews can link diagnosis with hospital-assigned ICD-9-CM codes.") (footnote omitted). Thus, this cross-referencing of data will only identify claims that are not eligible for reimbursement because of the off-label use of the drug, not claims "tainted" by violations of anti-kickback, self-referral, or misbranding statutes.

⁵⁶ See, e.g., *United States ex rel. Sikkenga v. Regence Bluecross Blue-shield*, 472 F.3d 702, 708 fn.8 (10th Cir. 2006) ("ICD-9-CM codes refers to the International Classification of Diseases, Ninth Revision, Clinical Modification codes, a coding system used to describe the diagnosis or medical condition for which medical services are rendered when Medicare claims are submitted to Medicare carriers.").

⁵⁷ See MEDICAID OUTPATIENT PRESCRIPTION DRUGS, *supra* note 12.

⁵⁸ See MEDICARE CLAIMS PROCESSING MANUAL, Chapter 7, Section 7 (explaining exceptions to general Part B coverage rule, including self-administered oral versions of covered injectable cancer drugs, that self-administered drugs furnished to outpatients for therapeutic purposes are not covered by Medicare unless those drugs must be put directly into an item of durable medical equipment or a prosthetic device), available at <http://www.cms.hhs.gov/manuals/downloads/clm104c07.pdf> (last visited Apr. 15, 2011); *Id.* at Chapter 17, Section 80.1.3 ("A cancer diagnosis code must be reported when billing for [oral cancer drugs using] these HCPCS [Healthcare Common Procedure Coding System] codes. If there is no cancer diagnosis the claim is denied."); MEDICARE BENEFIT POLICY MANUAL, Chapter 15, Section 50, available at <http://www.cms.hhs.gov/Manuals/downloads/bp102c15.pdf> (last visited Apr. 15, 2011).

⁵⁹ *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *10 ("Parke-Davis also raises a factual argument about why Relator cannot show a false claim: Parke-Davis points out that the Medicaid reimbursement claim forms for prescription drugs do not require the claimant to list the indication for which the drug is being prescribed.").

Due to the current patchwork of contracted private insurers responsible for administering Medicare Parts A, B, D, and Medicaid, the claims submitted for a physician's services are processed and paid by different entities⁶⁰ than the claims submitted by retail pharmacists for reimbursement of outpatient prescription drugs.⁶¹ At best, for any individual patient these entities may be two parts of the same umbrella corporation.⁶² At worst, linking the data between claims for physician services and outpatient prescription drug reimbursement requires coordination between competing insurance companies.⁶³ Either way, identification of ineligible claims due to medically inappropriate off-

⁶⁰ Entities that administer Medicare Part A are called "intermediaries" and entities that administer Medicare Part B physician service benefits are called "carriers." In addition, carriers that deal with Part B reimbursement of durable medical equipment may be separate from those administering physician service benefits. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS., CENTERS FOR MEDICARE & MEDICAID SERVS., MEDICARE FEE-FOR-SERVICES CLAIMS CONTRACT DIRECTORY (2010) [hereinafter CMS CONTRACT DIRECTORY], available at http://www.cms.hhs.gov/contractinggeneralinformation/downloads/02_icdirectory.pdf (indicating the number of companies involved in Part A and Part B reimbursement).

⁶¹ The federal government does not directly administer the Medicare Part D prescription drug benefit. Part D sponsors—entities that enter into contracts with Medicare—administer the benefit and compete for beneficiary enrollment. Part D sponsors are typically private health plans or insurers. In addition to their Medicare business, Part D sponsors typically offer drug coverage in the private insurance market. *See* MEDICARE PART D PRESCRIPTION DRUG COVERAGE, *supra* note 19. As a condition of payment, all Part D sponsors must submit data and information necessary for CMS to carry out payment provisions. 42 U.S.C. § 1395w-115(c)(1)(C) & (d)(2) (2006); 42 C.F.R. § 423.322 (2010). Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the prescription drug event (PDE) record to CMS. The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans and otherwise administer the Part D benefit. In April 2006, CMS issued a guidance document on how CMS anticipated implement the statutory payment mechanisms by collecting a limited subset of data elements on 100 percent of prescription drug "claims" or events. U.S. DEP'T OF HEALTH AND HUMAN SERVS., CENTERS FOR MEDICARE & MEDICAID SERVS., PRESCRIPTION DRUG EVENT DATA GUIDANCE, INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA, § i, Background, available at <http://www.cms.hhs.gov/DrugCoverageClaimsData/Downloads/PDEGuidance.pdf> (last updated Apr. 27, 2006). Payment of PDE claims does not require submission of diagnosis codes. *Id.*

⁶² For example, Blue Cross and Blue Shield of Alabama provide both Medicare Part A and Part B coverage for beneficiaries in Alabama. *See* CMS CONTRACT DIRECTORY, *supra* note 60, at 12.

⁶³ Even with full cooperation between entities, 26 states are still submitting Medicaid data to CMS in hard copy format, not electronic. MEMORANDUM REPORT: MSIS DATA, *supra* note 13, at 2.

label prescriptions requires side-by-side evaluation of multiple decentralized data sets maintained by private contractors.⁶⁴

II. THE STATUS QUO

The False Claims Act (FCA) is central to the current federal health care fraud enforcement efforts, but these efforts only provide short-sighted financial benefit and do not fix the underlying systemic problem.⁶⁵ The statute allows the federal government to mobilize thousands of non-governmental employees in its enforcement efforts through a very generous whistleblower provision. In addition, the information gap in the current billing system allows the federal government to consolidate its efforts to recoup mistaken payments for ineligible off-label claims by prosecuting pharmaceutical companies who promoted their products for off-label uses rather than the individual physicians or retail pharmacists who wrote and filled the prescriptions. Even so, the government's enforcement efforts under the FCA do not address the underlying problem of improper payments of ineligible Medicare and Medicaid claims for outpatient prescription drugs.

⁶⁴ See *Oversight Challenges in the Medicare Prescription Drug Program: Hearing Before the S. Subcomm. on Fed. Fin. Mgmt., Gov't Info., Fed. Servs., and Int'l Sec. of the S. Comm. on Homeland Sec. and Governmental Affairs*, 111th Cong. 4 (2010) (statement of Robert A. Vito, Dep't of Health and Human Servs., Office of Inspector Gen., Reg'l Inspector Gen. for Evaluation and Inspections) [hereinafter Vito] ("One barrier to conducting data analysis was that CMS and its contractors lacked a centralized data repository that would enable proactive data monitoring.")

⁶⁵ *Combating Health Care Fraud: Hearing Before the H. Subcomm. on Labor, Health & Human Servs., Educ. & Related Agencies of the H. Comm. Appropriations*, 111th Cong. 8 (2010) (statement of Gary Grindler, Acting Deputy Att'y Gen., U.S. Dep't of Justice) [hereinafter Grindler] ("The primary enforcement tool possessed by the Department of Justice to pursue civil remedies in health care fraud matters is the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733."). In addition to the FCA, the Deficit Reduction Act of 2005 provided an incentive for many states to adopt statutes that allow parallel actions in the state court for Medicaid claims because of the joint federal-state funding and administration of the Medicaid program. Pub. L. No. 109-171, § 6031, 120 Stat. 4 (2006). The Deficit Reduction Act allows states to retain an extra 10 percent of recovered Medicaid funds, which otherwise would be returned to the federal government, if the state has a false claims statute "at least as effective as" the federal FCA. 42 U.S.C. § 1396h(b)(2) (2006).

A. The False Claims Act Provides Significant Financial Incentives for Governmental and Private Enforcement of Fraud

Congress originally enacted the FCA as a Civil War-era statute to combat fraud on the government.⁶⁶ The FCA imposes liability on any person who either “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,”⁶⁷ or any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim” paid or approved by the Government.⁶⁸ Each FCA violation carries a per-claim penalty of \$5,000 to \$10,000, plus treble damages.⁶⁹ In 1986, Congress added a whistleblower provision to the FCA that provides private citizens, known as *qui tam* relators, the opportunity to bring a FCA action on behalf of the Government in exchange for 15-30% of any eventual verdict or settlement.⁷⁰ Since the *qui tam* provision was added in 1986, relators involved in health care fraud cases (and presumably relators’ counsel) have received nearly \$1.8 billion as a result of their FCA allegations.⁷¹

Qui tam complaints are filed *in camera*, under seal, and are not served on the defendant until a court orders service.⁷² In addition to the complaint, the *qui tam* relator also provides the government with a “written disclosure of substantially all material evidence and information” the relator possesses.⁷³ Based upon the information in the complaint and written disclosure (and subsequent investigation of the relator’s allegations), the government may elect to intervene and take over

⁶⁶ See Act of March 2, 1863, ch. 67, 12 Stat. 696-98 (1863) (The original False Claims Act was passed in 1863 and included both criminal and civil penalties.); Rev. Stat. §§ 3490-94, 5438 (1875) (separately codifying the criminal and civil penalties). Currently, the civil provisions are located at 31 U.S.C. §§ 3729-3733 (2006) and the criminal provisions are now found, for the most part, at 18 U.S.C. §§ 286, 287, 1001, 1002 (2006). See also Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1, 44-45 (2002).

⁶⁷ 31 U.S.C.A. § 3729(a)(1) (West 2010).

⁶⁸ *Id.* § 3729(a)(2).

⁶⁹ *Id.* § 3729(a).

⁷⁰ *Id.* § 3730; see also Collins, *supra* note 39, at 12 (“In addition, twenty-five states currently have state false claims statutes with *qui tam* provisions, and an increasing number of relators are filing their cases with the states as well as the federal government. This development has fostered a significant increase in state/federal investigative partnerships.”).

⁷¹ See U.S. DEP’T OF JUSTICE, FRAUD STATISTICS – HEALTH AND HUMAN SERVS., CIVIL DIVISION, OCT. 1, 1987 – SEPT. 30, 2009, 2 (2010), <http://www.justice.gov/civil/frauds/fcastats.pdf>.

⁷² 31 U.S.C. § 3730(b)(2).

⁷³ *Id.* § 3730(b)(2).

prosecution of the case or decline to intervene.⁷⁴ If the government chooses to formally intervene, it notifies the court, which in turn orders the complaint to be unsealed and served on the defendant.⁷⁵

If the government declines to intervene, the complaint is unsealed and the relator is still able to prosecute the case on behalf of the government, but without the aid of the government's considerable resources.⁷⁶ *Qui tam* relators, often current or former employees of de-

⁷⁴ *Id.* §§ 3730(b)(2), 3730(c).

⁷⁵ See U.S. DEP'T OF JUSTICE, FALSE CLAIMS ACT CASES: GOVERNMENT INTERVENTION IN QUI TAM (WHISTLEBLOWER) SUITS, <http://www.justice.gov/usao/pae/Documents/fcprocess2.pdf> (last visited Apr. 15, 2011). According to the U.S. Attorney's Office for the Eastern District of Pennsylvania, "[t]here are no statistics reported on the length of time the average qui tam case remains under seal. In [that] District, most intervened or settled cases are under seal for at least two years (with, of course, periodic reports to the supervising judge concerning the progress of the case, and the justification of the need for additional time)." *Id.*

⁷⁶ See 31 U.S.C. § 3730(c)(3) (2006). See also Pamela H. Bucy, *Private Justice and the Constitution*, 69 TENN. L. REV. 939, 944-45 & n.35 (2002) ("Historically, relators who proceed on their own after the DOJ has declined to intervene [as a plaintiff] have enjoyed little success. Their cases are dismissed more often and their recoveries are substantially less. For example, the aggregate amount paid to relators from ... October 1, 1986 through ... September 30, 2000, as the relators' statutory share when the government intervened was \$576 million. The aggregate amount to relators during this same time period when the government did not intervene was \$35.3 million. Also, only 2.1% (12 out of 570) of qui tam FCA cases in which the government has intervened have been dismissed, whereas 71.1% (1357 out of 1907) of qui tam FCA cases in which the government has not intervened have been dismissed.") (citing letter from the U.S. Dep't of Justice to Pamela H. Bucy, FOIA Request 145-FOI-6072 (Oct. 20, 2001) (on file with Tennessee Law Review)). "The litigational advantages to private plaintiffs of obtaining DOJ intervention are so substantial that the acknowledged goal of any experienced relators' attorney is to obtain the government's intervention. As one experienced relator's counsel explained: 'When evaluating a case and during the beginning stages of representing a whistleblower never forget your initial mission: persuade the government to pursue the case.'" Pamela H. Bucy, *Moral Messengers: Delegating Prosecutorial Power*, 59 SMU L. REV. 321, 328 n.42 (2006) (citing Mitchell Kreindler, *So You Wanna Be a Whistleblower's Lawyer?*, Address before the ABA National Institute, THE CIVIL FALSE CLAIMS ACT AND QUI TAM ENFORCEMENT 5 (Nov. 28, 2001)).

A large part of the reason why relators seek U.S. Department of Justice ("DOJ") intervention is the resources that the DOJ can bring to a case. One such resource is the work that DOJ attorneys and agents perform with the relevant agency to obtain government records pertaining to the alleged false claims. For example, in the healthcare field, DOJ and HHS attorneys and agents work with private insurers who contract with the Government to service Medicare and Medicaid claims, thereby obtaining billing data, longitudinal comparisons, and other helpful interpretations of billing regulations and history that would be available to private parties only through subpoenas or Freedom of Information Act requests, if at all. See generally ROBERT FABRIKANT, PAUL E. KALB, MARK D. HOPSON & PAMELA H. BUCY, HEALTH CARE FRAUD, ENFORCEMENT AND COMPLIANCE ch. 6 (2001) (discussing the investigation of healthcare fraud cases).

endant pharmaceutical companies, have been especially prominent in the development and pursuit of the current legal theory supporting enforcement of off-label promotion through the FCA.⁷⁷ Indeed, the landmark case establishing potential FCA liability for off-label promotion was filed and principally litigated by a relator alleging off-label promotion of the prescription drug, Neurontin.⁷⁸

In addition, the DOJ is authorized by the Health Insurance Portability and Accountability Act ("HIPAA") to issue subpoenas "[i]n any investigation of—(i)(I) a Federal health care offense." 18 U.S.C. § 3486 (2006). HIPAA subpoenas may require the production of tangible things but not oral testimony. The FCA authorizes the DOJ to seek civil investigative demands ("CID"), which are standard civil investigative tools (interrogatories, documents subpoenas, and depositions) before a suit is filed. 31 U.S.C. § 3733 (2006). Moreover, most federal agencies have authority to issue "Inspector General Subpoenas" to investigate, among other things, fraud by government contractors upon that agency. 5 U.S.C. app. § 6(a) (2006). These subpoenas are quite versatile because they are not subject to the Federal Rules of Civil Procedure (thus no showing of relevance is required) nor to the secrecy requirements of the grand jury. *See, e.g.*, *FTC v. Atl. Richfield Co.*, 567 F.2d 96, 104-05 & n.19 (D.C. Cir. 1977).

Also, in instances where it appears that criminal violations may have occurred, the DOJ can commence a criminal investigation and employ investigative tools, such as grants of immunity under 18 U.S.C. § 6002 (2006) and the grand jury, which has broad topical and jurisdictional reach. *See United States v. R. Enter., Inc.*, 498 U.S. 292, 297-98 (1991) (explaining the importance and duties of a grand jury). Upon a "strong showing of particularized need for grand jury materials," information gathered during a criminal grand jury investigation may be disclosed to government attorneys and their assistants who are investigating FCA violations. *See United States v. Sells Eng'g*, 463 U.S. 418, 443 (1983).

⁷⁷ For example, in January 2009, Eli Lilly resolved four *qui tam* actions as part of a settlement for alleged off-label promotion of Zyprexa, including: *United States ex rel. Rudolf v. Eli Lilly and Co.*, Civ. Action No. 03-943 (E.D. Pa.); *United States ex rel. Faltaous v. Eli Lilly and Co.*, Civ. Action No. 06-2909 (E.D. Pa.); *United States ex rel. Woodward v. Jerusalem*, Civ. Action No. 06-5526 (E.D. Pa.); and *United States ex rel. Vicente v. Eli Lilly and Co.*, Civ. Action No. 07-1791 (E.D. Pa.). The four relators received nearly \$78.9 million from the federal share of the settlement amount. *See* U.S. Dep't of Justice Eli Lilly Press Release, *supra* note 2, at 3.

Similarly, the government's FCA allegations against Forest Laboratories for off-label promotion of Celexa and Lexapro were *qui tam* cases that settled in 2010 for an undisclosed amount. *See United States ex rel. Gobble v. Forest Labs. Inc.*, 729 F. Supp. 2d 446, 448 (D. Mass. 2010); *In re Celexa and Lexapro Mktg. and Sales Litig.*, No. MDL 09-02067-NM, 2010 WL 4644429 (D. Mass. Nov. 10, 2010).

⁷⁸ The government declined to intervene in this FCA action alleging off-label promotion of prescription drugs manufactured by Parke-Davis, Neurontin and Accupril, and kickbacks to prescribing physicians. *See United States ex rel. Franklin v. Parke-Davis (Parke-Davis I)*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001). The relator, David Franklin, Ph.D., was a former Parke-David employee who pursued the case without the government's assistance after the complaint was unsealed. *United States ex rel. Franklin v. Parke-Davis (Parke-Davis II)*, No. Civ.A. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *20 (D. Mass. Aug. 22, 2003) ("But while the Govern-

B. The Information Gap Allows False Claims Act Prosecution of Pharmaceutical Companies for Off-Label Promotion

As explained above in Section I.B, the gap between a physician's diagnosis of a patient and a pharmacist's submission of a claim for federal reimbursement of an outpatient prescription drug facilitates the widespread improper payment of ineligible claims. This gap also facilitates the government's use of the FCA to recoup these wrongful payments from pharmaceutical companies, rather than the physician who wrote the prescription or the pharmacists who actually submitted the claims.

In settlement agreements with pharmaceutical companies, the government has alleged that the pharmaceutical companies' off-label promotion of their prescription drugs caused the submission of false claims for payment in violation of the False Claims Act.⁷⁹ While at first glance this broad-sweeping statement may seem relatively straightforward, the causal chain between a pharmaceutical company and a false claim for payment of its product must include a prescribing physician, a federally-insured patient, and the pharmacist who fills the prescription and submits the claim for reimbursement (see Figure 1, below).⁸⁰ A FCA violation based upon off-label promotion of a prescription drug does not arise from the pharmaceutical companies' unlawful marketing activity itself,⁸¹ but rather from the submission of

ment's brief was persuasive on several points, the Government is (still) not a party to this suit, and the Court declines to use the Government's brief to revive Relator's claim.").

⁷⁹ See, e.g., Pfizer Settlement Agreement, *supra* note 2, at 3 (summarizing allegations by the United States against Pfizer).

⁸⁰ See generally Hall & Berlin, *supra* note 47, at 658 ("Adding to the complexity for manufacturers is that they generally do not know whether a specific patient is receiving an off-label product. They also generally do not know whether that patient is a private pay or public pay patient, or the substance of any particular reimbursement claim. However, the manufacturer may well know, from any number of sources, that the product is being used off-label by some number of patients even if the manufacturer could not identify the specific patients or their claims.").

⁸¹ Illegal off-label promotion may be criminally prosecuted under the FDCA and the government can seek equitable disgorgement. See 21 U.S.C. § 332(a) (2006) ("The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown[,] to restrain [certain] violations of the [FDCA, including new drug and misbranding violations]."); *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1058 (10th Cir. 2006) ("Section 332(a) of the FDCA invokes the equity jurisdiction of courts using the same statutory language the Supreme Court construed in *Mitchell* to authorize all traditional equitable remedies. Disgorgement is a traditional equitable remedy. Moreover, because the present action was brought by the government to protect the public health and safety, courts' equitable jurisdiction under the statute 'assume[s] an even broader and more flexible character.' Thus, disgorgement is available under the FDCA unless (1) there is a clear

a claim that is ineligible for reimbursement under the federal health care system.⁸²

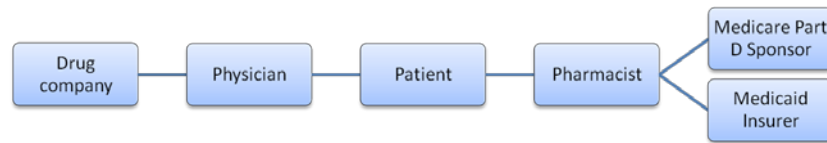


Figure 1. Actors in the chain of causation for submission of false claim due to off-label promotion.

Theoretically, a pharmaceutical company's statements about medically inappropriate off-label uses, whether false or truthful, are made "knowingly,"⁸³ and "ineluctably result in false Medicaid claims."⁸⁴ This assumes that a physician would not write a prescription for an

legislative command or necessary and inescapable inference prohibiting disgorgement or (2) disgorgement is inconsistent with the purposes of the FDCA.") (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) (other citations omitted); Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx*, 12 J. HEALTH CARE L. & POL'Y 119, 156 (2009) ("In lieu of the DOJ's current approach to unlawful promotion by pharmaceutical manufacturers, such activity should be prosecuted solely under the FD&C Act, which is the statutory scheme established by Congress. Any DOJ concerns that the remedies available under the False Claims Act are uniquely suited to motivate companies to comply with FD&C Act promotional restrictions are misplaced. Combining the penalty provisions in the FD&C Act with the doctrine of equitable disgorgement is sufficient to punish promotional activities that violate the FD&C Act and provide a preferable long-term approach to the continued use of the legally questionable theory of causation asserted by the DOJ in claims prosecuted under the False Claims Act.").

⁸² See, e.g., *Parke-Davis I*, 147 F. Supp. 2d at 52 ("Thus, the alleged FCA violation arises—not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct.").

⁸³ Under the FCA, "'knowingly' and 'knowing' 'mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.'" See 31 U.S.C.A. § 3729(b)(1) (West 2010). It requires "no proof of specific intent to defraud." *Id.* Pharmaceutical companies closely track the reimbursement status of their products under federal and state health insurance programs, making it very likely that any statements generated from company information about an off-label use that is not eligible for reimbursement were indeed made "knowingly."

⁸⁴ *United States ex rel. Franklin v. Parke-Davis (Parke-Davis II)*, No. Civ.A. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *14 (D. Mass. Aug. 22, 2003) ("While it is now clear that Relator's theory of the case is not limited to a 'scheme of fraud,' the Court holds that Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct (including non-fraudulent promotion of off-label Neurontin uses) would ineluctably result in false Medicaid claims.").

off-label use that is not eligible for federal reimbursement but for a drug company's off-label promotion of that product.⁸⁵ Setting aside the question of actual causation between the alleged off-label promotion and the filing of a false claim (a factual question that allowed the Neurontin litigation to survive summary judgment),⁸⁶ the information gap prevents either the prescribing physician or the submitting pharmacist, both state-licensed professionals capable of exercising professional judgment, from being considered an independent actor sufficient to break the causal chain between the pharmaceutical company's

⁸⁵ See Girard, *supra* note 81, at 140-141 (“[T]he use of the False Claims Act against unlawful drug promotion is premised on the DOJ’s assumption that the drug company’s unlawful marketing is the *but for* cause of the physician’s decision to prescribe the drug and request federal health care program reimbursement.”) (footnote omitted).

⁸⁶ See *Parke-Davis II*, 2003 U.S. Dist. LEXIS 15754, at *12-13 (“Whether Parke-Davis’s conduct was a substantial factor in causing the presentation of false Medicaid claims is a question of fact. Relator has produced enough evidence on this score to create at least a genuine issue of material fact.”).

In terms of actual causation, the circulation of peer-reviewed medical journal articles, recognized by the FDA as truthful and not misleading, may have very little impact on prescribing habits. For example, in considering physician decision-making, there is a “universal skepticism” among practicing physicians regarding the usefulness of the scientific literature. See Johnson, *supra* note 30, at 75. Moreover, this notion comes from the idea that “doctors ‘have a deep skepticism about clinical trials, from a belief that clinical experience, rather than the scientific evidence should govern clinical practice.’” *Id.* at 74 (quoting Rebecca K. Schwartz et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 Soc. Sci. & Med. 577, 581 (1989)). This “[h]igh valuation of experience over studies” translates into a notion that some “doctors do not regard FDA approval as a necessary indicator of effectiveness (e.g., when they prescribe for an unapproved use) and perhaps even safety (e.g., when they prescribe at unapproved dosages or durations or for significantly distinct populations on which the drug has not been tested).” *Id.* at 73, 74. Similarly, standard continuing medical education (CME) and promotional speaker programs use a standard lecture format, which has shown minimal impact on improving clinical care. See *id.* at 77-8.

Ultimately, using the False Claims Act for “unlawful promotion cases raises significant legal questions. The DOJ’s position that unlawful promotional activity by pharmaceutical companies ‘induces’ physicians to write prescriptions, resulting in the filing of false claims for reimbursement relies on a questionable theory of causation. Given that the penalty provisions in the FD&C Act, in conjunction with the doctrine of equitable disgorgement, provide sufficient means to punish unlawful promotional activity, reliance on the questionable theory of causation required to prosecute cases under the False Claims Act is unnecessary. Instead of using the False Claims Act, the DOJ should address unlawful promotional activity solely under the FD&C Act, which is the statutory scheme established by Congress specifically for that purpose and provides adequate remedies and punishment.” Girard, *supra* note 81, at 129 (citations omitted).

illegal off-label promotion and the submission of a false claim.⁸⁷ As a result, the government can consolidate its efforts to recoup funds from pharmaceutical companies, with their relatively deep pockets and corporate stability, instead of seeking recoupment from the more numerous prescribing physicians and retail pharmacists.⁸⁸

To be clear, though, these claims are not necessarily “false” or “fraudulent” in the traditional sense in that all the information provided on the claim is accurate. The false claims related to off-label

⁸⁷ See, e.g., *Parke-Davis I*, 147 F.Supp.2d at 52-53 (“Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that—as a matter of law—Relator’s allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.”) (citations omitted).

Mistaken payment of ineligible claims due to off-label promotion becomes significantly less foreseeable where retail pharmacists are able to review a prescription in light of a patient diagnosis and an automated billing system can easily flag ineligible claims due to off-label use. See, e.g., *Parke-Davis II*, 2003 U.S. Dist. LEXIS 15754, at *9 (“If the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a state exercised its discretion to cover such prescriptions, then an off-label Neurontin prescription in that state would not be a false claim. On the other hand, if the Medicaid statute does *not* give states the discretion to cover off-label, non-compendium prescriptions, *but a state misconstrued the statute and authorized coverage of such prescriptions*, an FCA action against Parke-Davis in that state would likely fail, as it would be difficult to establish Parke-Davis’s scienter.”) (emphasis added).

⁸⁸ The corporate stability of publicly-traded pharmaceutical companies is incredibly important for purposes of recouping funds. Smaller, closely held corporations are often used as shell companies in health care fraud schemes and recoupment of improper payments is particularly difficult once the funds received from CMS have left the shell company. See *Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid: Hearing before H. Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies of H. Comm. of Appropriations*, 111th Cong. 2 (2010) (statement of Omar Perez, Special Agent, OIG, Dep’t Health & Human Servs.) [hereinafter Perez] (“Once CMS paid the claims and deposited money into the company’s bank account, it was withdrawn within days using multiple check cashers. The idea was to deplete the account so that once Medicare discovered the fraudulent billing, which could take 6 months to 1 year, there would be no money in the account.”) These fraud schemes “were executed within a matter of months. After billing Medicare for millions of dollars, companies would change ownership, bill Medicare again for millions of dollars, close and simply take over another company and repeat the process in another location. By the time traditional investigative referral methods came to fruition, criminals had absconded with millions of tax payer dollars.”).

promotion of prescription drugs are predominantly claims that are not eligible for federal reimbursement because the prescribed drug is being used for a disease or condition that is not considered a medically appropriate indication.⁸⁹ The falsity of these claims arises out of the specific disease or condition that the doctor is trying to treat with the prescription and whether the prescribed use is covered under Medicare or Medicaid.⁹⁰

More often than not, *qui tam* relators have first-hand, insider knowledge of the defendant companies' sales and marketing practices and allege company communications with doctors about off-label use of prescription drugs in violation of the FDCA. The relators are often limited, however, in their first-hand knowledge of any specific prescriptions or claims for reimbursement and often assume that off-label promotion has caused the submission of false claims. Even so, if reimbursement claims for off-label prescriptions are considered false, and they have been caused by the pharmaceutical companies' sales and marketing efforts, then each off-label prescription submitted for federal reimbursement exposes the companies to a penalty of \$5,000 to \$10,000 per claim and the threat of treble damages.⁹¹

⁸⁹ See, e.g., *Parke-Davis I*, 147 F.Supp.2d at 53 (specifically noting that the fact that the prescriptions at issue were for off-label use was material to whether a false claim was submitted to the government).

⁹⁰ In the Neurontin litigation, Parke-Davis did not "dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA." *Parke-Davis I*, 147 F.Supp.2d at 51. However, it is unlikely that a similar assertion (i.e., that an ineligible off-label prescription submitted for reimbursement by Medicare Part D is a false claim) would be conceded because unlike Medicaid, Medicare is not inherently a "payer of last resort." See *Ark. Dep't Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 291 (2006). This scheme "means that all other available resources must be used before Medicaid pays for the medical care of an individual enrolled in a Medicaid program." *Caremark, Inc. v. Goetz*, 480 F.3d 779, 783 (6th Cir. 2007).

While both Medicare and Medicaid provide coverage for outpatient prescription drugs, when both programs offer coverage, federal law requires that Medicare, not Medicaid, must bear the cost. See *Conn. Dep't of Soc. Servs. v. Leavitt*, 428 F.3d 138, 141-142 (2d Cir. 2005) (recognizing that 42 U.S.C. § 1396a(a)(25) requires Medicaid to offer coverage when both programs apply). However, there are situations when Medicare does not cover a particular off-label use that is covered under Medicaid. Thus, health care providers may knowingly submit ineligible (and, per the DOJ's legal theory, "false") claims for off-label use when a patient carries both Medicare Part D and Medicaid coverage and proper coverage under Medicaid requires a denial letter from Medicare.

⁹¹ See S. REP. NO. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274 ("Each separate bill, voucher or other 'false payment demand' constitutes a separate claim for which a forfeiture shall be imposed, and this is true although many such claims may be submitted to the Government at one time. For example, a doctor who completes separate Medicare claims for each patient treated will be liable

In addition to the financial penalties, a defendant faces potential exclusion from Medicare and Medicaid.⁹² “Exclusion” in the context of a health care fraud investigation, including a FCA action for off-label promotion, means that the defendant company is no longer able to participate in the federal health care system—no payment will be made by any federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity.⁹³ Because “the federal government is the single largest payor of health care services [in the United States], exclusion, known as the ‘death penalty’ to health care providers, is the most feared result of [FCA] prosecutions.”⁹⁴ Furthermore, the loss of Medicare reimbursement can cause a provider to enter bankruptcy and thus, can drive a provider to bankruptcy, fear of exclusion often drives these

for a forfeiture for each [form]...even though several such forms may be submitted to the fiscal intermediary at one time.”) (citation omitted); *see also* United States *ex rel.* Tyson v. Amerigroup Ill., Inc., 488 F.Supp.2d 719, 740-742 (N.D. Ill. 2007) (discussing each separate claim form and the corresponding liability); Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control Qui Tam Litigation Under the Civil False Claims Act*, 76 U. CIN. L. REV. 1233, 1248 (2008) (“[P]otential recoveries and settlements can spiral quickly into tens or hundreds of millions of dollars, surpassing or even dwarfing the damages award.”).

⁹² See 42 U.S.C. § 1320a-7(a) (2006) (mandatory exclusion); 42 U.S.C. § 1320a-7(b)(7) (2006) (permissive exclusion for fraud and kickbacks). However, the future application of these penalties is somewhat in question because of the new health care legislation. See The Patient Protection and Affordable Care Act, Pub.L. No. 111-148, 124 Stat. 119 (2010), amended by the Health Care and Education Reconciliation Act of 2010, Pub.L. No. 111-152, 124 Stat. 1029 (2010). The constitutionality of the new health care legislation is currently in dispute. Compare Florida *ex rel.* Bondi v. U.S. Dept. of Health and Human Servs., No. 3:10-cv-91-RV/EMT, 2011 WL 285683, at *40 (N.D.Fla. Jan. 30, 2011) (holding “individual mandate” unconstitutional and all amended provisions of the existing health care laws unconstitutional as not severable), with Thomas More Law Center v. Obama, 720 F.Supp.2d 882, 893-94 (E.D.Mich. 2010) (“individual mandate” held constitutional) and Liberty Univ., Inc. v. Geithner, No. 6:10-cv-00015-nkm, 2010 WL 4860299, at *14 (W.D.Va. Nov. 30, 2010) (“individual mandate” held constitutional).

⁹³ See generally *Exclusions Program*, OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://oig.hhs.gov/fraud/exclusions.asp> (last visited Apr. 15, 2011) (background information on the exclusions program); Stephanie L. Trunk, Note, *Sounding the Death Toll for Health Care Providers: How the Civil False Claims Act Has a Punitive Effect and Why the Act Warrants Reform of its Damages and Penalties Provision*, 71 GEO. WASH. L. REV. 159, 161 (2003) (“Providers who are found to have submitted false claims or settle false claims may also be subject to exclusion from the Medicare program under Title IX of the Social Security Act.”).

⁹⁴ Trunk, *supra* note 93, at 161; *see also* Rich, *supra* note 91, at 1252 (stating that “[e]xclusion or debarment can be the equivalent of the death penalty in the health care industry, where much of a provider’s business typically is dependent on Medicare reimbursement.”).

entities to settle FCA allegations, often before a *qui tam* complaint is even unsealed, rather than challenge the legal theories or factual allegations.⁹⁵

Because recently, however, there has been a suggestion that the unique status major pharmaceutical companies enjoy a unique status as providers of have by providing patent-protected drugs perceived as essential to consumers' health, there is the suggestion that this places certain constraints on prosecutors' ability to leverage exclusion as a possibility of FCA prosecution.⁹⁶ Given the widespread hardship exclusion of a major pharmaceutical company would have on the beneficiaries of the federal health care system, it is not clear whether the threat of exclusion will drive future settlement negotiations in off-label promotion cases as much as it has in the past.⁹⁷

In addition to the false claims for ineligible off-label prescription reimbursements, traditional FCA off-label promotion cases often include allegations of illegal marketing schemes that include kickbacks and self-referrals.⁹⁸ These allegations utilize additional provisions of the reimbursement framework that try to minimize the influence of financial incentives on physicians' prescribing habits. While anti-kickback and self-referral violations deal broadly with potentially problematic financial arrangements involving healthcare providers, the typical allegations seen in this context are specific to the financial relationships between pharmaceutical companies and physicians.⁹⁹

⁹⁵ Trunk, *supra* note 93, at 161; *see also* Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 456 (1998) (discussing the aggressive enforcement of the FCA and its effect on *qui tam* actions).

⁹⁶ Boozang, *supra* note 23, at 89-90 & n.6 (noting that there is more at stake in the health care context because federal prosecutors are aware of the importance these companies have in society, causing some "[m]ajor pharmaceutical companies epitomize the 'too big to fail' situation.").

⁹⁷ *See* Medicare & Medicaid Services, Civil Money Penalties, Assessments, Exclusions, 42 C.F.R. § 402.308 (2008) (providing CMS the ability to request a waiver of exclusion where it "negatively affects Medicare beneficiaries...because the excluded person is the sole community physician or sole source of essential specialized services in the Medicare community.").

⁹⁸ Hall & Berlin, *supra* note 47, at 659 (exploring recent cases involving illegal marketing schemes).

⁹⁹ *See, e.g.,* United States *ex rel.* Franklin v. Parke-Davis (*Parke-Davis I*), 147 F. Supp. 2d 39, 53-54 (D. Mass. 2001) ("Relator contends that Parke-Davis violated the antikickback provision by, *inter alia*: paying doctors for inconsequential drug 'studies'; paying doctors for minimal participation as 'consultants' or 'preceptors' or for participating in a 'speakers bureau'; giving doctors cash payments for small record-keeping tasks, such as allowing Parke-Davis access to information about the doctors' patients who were receiving Neurontin; and giving gifts such as travel and Olympics tickets to doctors prescribing large amounts of Parke-Davis drugs.").

These relationships may arise out of company-sponsored speaker training and speaker programs or company-sponsored advisory boards where physicians are brought in as consultants.¹⁰⁰ The goal of the statutes is to ensure that a physician's professional judgment remain focused solely on her patient's best interests and is free from undue influence by companies with financial interests in specific services or products.¹⁰¹

Use of the FCA to enforce the anti-kickback and self-referral statutes assumes that a reimbursement claim induced by an improper payment to the prescribing physician is a false claim. Assuming that the factual information provided on the face of the claim form is accurate, the claim may still be considered "false" in one of two ways: (1) it is submitted for a service or prescription which is ineligible for reimbursement as a result of an improper payment, or (2) it is tarnished, or "tainted," by the fact that the health care provider violated a separate underlying statute or regulation, including conditions of payment or participation in the Medicare and Medicaid programs.¹⁰² While a violation of the anti-kickback statute is not a *per se* violation of the FCA,¹⁰³ anti-kickback and self-referral violations may still be

¹⁰⁰ Prior to January 2009, it was standard practice in the pharmaceutical industry to provide gifts to healthcare providers, such as pens, prescription pads, textbooks, bags, umbrellas, or free lunches for a physician's office staff, which, if excessive, potentially ran afoul of the anti-kickback statute. However, gifts no longer play the prominent role they once did because of widespread adoption of the Code on Interactions with Healthcare Professionals by the Pharmaceutical Research and Manufacturers of America (PhRMA). See PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2008), available at http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf (effective Jan. 1, 2009).

Federal prosecutors agree that the era of flagrant remuneration in exchange for prescriptions is effectively over. See Mary Anne Pazanowski, *Government Attorneys Discuss Trends in Fraud Enforcement for Drugs, Devices*, BNA'S HEALTH CARE FRAUD REP., Feb. 10, 2010, at 4 ("The 'paying for prescriptions' era is over.... The trends now seem to involve paying physicians for their knowledge and using science to market products.").

¹⁰¹ See OFFICE OF INSPECTOR GEN., OFFICE OF PUB. AFFAIRS, FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS: FACT SHEET (Nov. 1999), available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>.

¹⁰² See Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 533 (2001).

¹⁰³ See, e.g., *Parke-Davis I*, 147 F.Supp.2d at 54. But see, *United States ex rel. Franklin v. Parke-Davis (Parke-Davis II)*, No. Civ.A. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *19-20 (D. Mass. Aug. 22, 2003) ("The Court agrees with the government that recent caselaw supports implied-certification FCA claims in the healthcare context, including kickback-based claims. But while the Government's brief was persuasive on several points, the Government is (still) not a party to this

considered in determining causation under the first theory¹⁰⁴ and potentially trigger parallel criminal investigations.

Under the criminal provisions of the anti-kickback statute, anyone who pays or receives a kickback to influence a healthcare provider's prescribing habits can be found guilty of a felony and "fined not more than \$25,000 or imprisoned for not more than five years, or both."¹⁰⁵ In addition, an anti-kickback violation can lead to exclusion from the federal health care program, and a civil fine of \$50,000.¹⁰⁶ Similarly, a self-referral violation can result in civil penalties including denial of federal payment for any services or products implicated by the problematic financial arrangement, refund of any payment received, a \$15,000 per service civil monetary penalty or the imposition of a \$100,000 civil monetary penalty for any arrangement considered to be a circumvention scheme.¹⁰⁷

C. The Information Gap's "Value" is not Worth the Price to the Federal Health Care System

There is limited value in the inefficiency created by the information gap for patients, physicians, pharmaceutical companies, pharmacists, and those charged with protecting the integrity of the federal healthcare system. This value, though, is short-sighted and has come at the cost of the federal health care system as a whole.

While this Article focuses primarily on limiting federal reimbursement to treatments that are supported by clinical evidence of safety and efficacy, the practice of medicine is inherently personal and experienced by most on an individual patient or individual practitioner level. A prescription drug that works for many patients will not work for all patients. Historically, much of our health care policy has been discussed and decided in terms of individual autonomy and privacy, for patients and practitioners alike. For example, the body of law supporting the need for a patient's informed consent before undergoing

suit, and the Court declines to use the Government's brief to revive Relator's claim.") (citations omitted). Thus, it still is not clear whether improper kickbacks and self-referral arrangements between physicians and pharmaceutical companies will trigger liability under an implied certification theory on claims submitted by otherwise uninvolved retail pharmacists.

¹⁰⁴ See, e.g., *Parke-Davis II*, 2003 U.S. Dist. LEXIS 15754 at *20 ("Evidence of kickbacks is relevant, however, to Relator's more clear-cut claim under § 3729(a)(1): Parke-Davis 'caused to be presented' claims for reimbursement for off-label prescriptions that were ineligible for coverage under Medicaid.").

¹⁰⁵ 42 U.S.C. § 1320a-7b(b) (2006).

¹⁰⁶ § 1320a-7a(a).

¹⁰⁷ 42 U.S.C. § 1395nn(g) (2006).

medical procedures¹⁰⁸ and the patient privacy provisions in HIPAA,¹⁰⁹ rests on the understanding that patients should be able to choose what happens to their bodies and personal information. In order to be effective, a comprehensive health care system should strive to protect this autonomy and privacy, but not at the expense of facilitating rampant fraud and improper payments.¹¹⁰

The federal government's current efforts to recoup mispaid funds, though well-intended, are an insufficient and inefficient afterthought for a fundamentally broken billing system. Nevertheless, these efforts have provided real value in terms of employment and purpose for many Americans. Many a federal employee and contractor is specifically "charged with protecting the integrity of the [Medicare Part D prescription drug program]" and Medicaid programs.¹¹¹ This group includes legislators,¹¹² CMS,¹¹³ the Office of Inspector General for the Department of Health and Human Services (OIG),¹¹⁴ Medicare Part D

¹⁰⁸ See, e.g., *Moore v. Regents of the Univ. of California*, 793 P.2d 479, 483-84 (Cal. 1990) (recognizing that a patient's consent to treatment must be an informed consent); *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 78 (N.J. 2002) (stating that the informed consent requirement balances a "patient's need for sufficient information with the doctor's perception of the appropriate amount of information to impart for an informed decision").

¹⁰⁹ See Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, § 1177, 110 Stat. 1936, 2029 (1996) (discussing penalties for the wrongful disclosure of individually identifiable health information); see also HIPAA Privacy Rule, 45 C.F.R. § 164 (2010) (Subparts A & E).

¹¹⁰ See Cohen et al., *supra* note 23, at 394 ("Reimbursement restrictions on such uses could therefore negatively impact both physicians' clinical autonomy and health outcomes. Nevertheless, given that resources are finite, off-label use reimbursement implies an opportunity cost: the more off-label uses payers reimburse, the fewer resources they may have for on-label uses.").

¹¹¹ Vito, *supra* note 64, at 1.

¹¹² See *Combating Health Care Fraud and Abuse: Hearing Before the H. Appropriations Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies*, 111th Cong. 1 (2010) (statement of Rep. David R. Obey, Chairman, H. Appropriations Subcomm. On Labor, Health & Human Servs., and Educ.) ("Congress has an obligation to meet the needs of people who qualify for programs covered by this appropriation bill. In doing that, we also have an obligation to try to assure that taxpayers' funds are used effectively—and not wasted or lost to fraud.").

¹¹³ See Vito, *supra* note 64, at 3 (noting that as the program administrator, CMS is required to perform financial audits of the contracted Part D plan sponsors and may "conduct a number other types of audits of plan sponsors, including bid audits, program audits, benefit integrity audits, and compliance plan audits").

¹¹⁴ "OIG is comprised of more than 1,500 professionals who perform comprehensive health care oversight and enforcement activities, including:

- Office of Investigations: conducts criminal, civil, and administrative investigations of health care fraud, which result in convictions, civil and administrative actions, and monetary recoveries;

plan sponsors,¹¹⁵ and program integrity contractors.¹¹⁶ In addition to these parties, the U.S. Department of Justice, state attorneys general, whistleblowers, private counsel for whistleblowers, and defense counsel for pharmaceutical companies rely, at least in part, on federal health care fraud enforcement efforts for their livelihoods.¹¹⁷

- Offices of Audit Services: conducts and oversees audits of Medicare and Medicaid payments and operations; identifies improper payments and program vulnerabilities; and recommends audit disallowances and program improvements;

- Office of Evaluation and Inspections: conducts evaluations of the Medicare and Medicaid programs to identify program integrity vulnerabilities and make recommendations to prevent fraud, waste, and abuse and to promote economy, efficiency, and effectiveness; and

- Office of Counsel to the Inspector General: represents OIG in all civil and administrative fraud and abuse cases, and in connection with these cases, negotiates and monitors corporate integrity agreements; provides guidance to the health care industry to promote compliance; and provides legal support to OIG operations.”

Vito, supra note 64, at 1-2. In the five years that Medicare Part D has been in effect, OIG has generated over 30 reports on the program and anticipates at least 25 more. *See id.* at 12-14. Needless to say, these reports represent a significant investment of human and financial resources toward oversight of Part D.

¹¹⁵ *See id.* at 3. (“Within the Medicare program, the responsibility for ensuring integrity in the Part D program is shared between Part D plan sponsors, program integrity contractors, and CMS. The plan sponsors serve as the first line of defense against fraud in the Part D program and CMS requires that plan sponsors have compliance plans in place to protect the integrity of the program. CMS requires plan sponsors to include certain elements in their compliance plans. These elements include the designation of a compliance officer, the establishment of effective compliance training for employees and contractors, and the establishment of procedures for effective internal monitoring and auditing. CMS also requires compliance plans to have measures to detect, correct, and prevent fraud, waste, and abuse.”).

¹¹⁶ *See id.* (CMS also “contracts with Medicare Drug Integrity Contractors (MEDICs) to perform integrity functions such as identifying and investigating potential fraud, waste, and abuse in the Part D program.” MEDICs are responsible for auditing plan sponsors’ compliance plans and identifying fraud through data analysis.).

¹¹⁷ *See Combating Health Care Fraud and Abuse: Hearing Before the H. Appropriations Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies*, 111th Cong. 1 (2010) (statement of Timothy J. Menke, Dep. Inspector Gen. for Investigations, Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.) [hereinafter Menke] (“OIG is not alone in the fight to combat fraud and protect the integrity of Federal health care programs. We work closely with the Department of Justice (DOJ), our Federal, State, and local law enforcement partners, and our colleagues at the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration. Additionally, commercial and private insurance entities and trade associations, such as the National Health Care Anti-Fraud Association (NHCAA), are also involved in the identification and prevention of health care fraud.”).

While not specific to a FCA action for health care fraud, the example provided by Pamela Bucy in her article, *Private Justice*, is equally representative of the resources often devoted to FCA actions for off-label promotion. Bucy, *supra* note

While some are likely motivated by altruistic intentions, it seems more than likely that they, like the infamous twentieth-century bank robber Willie Sutton, also do what they do “[b]ecause that’s where the money is.”¹¹⁸ To quote Senator Thomas R. Carper, Chairman of the Senate Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, “[t]here is a lot of money in Medicare, and that attracts a lot of criminal activi-

66, at 58-59 (“Recent examples demonstrate the formidable legal and investigative resources the FCA brings to the public regulatory efforts. In one *qui tam* FCA case, six law firms devoted forty lawyers (twenty full time equivalents) to the case, and incurred \$1 million in fees and expenses per month while the case was being intensively litigated. In another recent *qui tam* FCA case, where there were 125 defense attorneys, fifteen relators’ attorneys, plus DOJ attorneys, the federal courthouse was not large enough to accommodate the group for docket calls. The defendant, Shell Oil Company, produced 7,000 banker boxes of records. One of the relators’ counsel took responsibility for handling all documents in the case. Doing so required 5,000 square feet of warehouse space (with the record boxes stacked seven feet high). This relator’s counsel organized the records so that plaintiffs could respond to any defense request for identification of any record pertaining to any particular claim within thirty days by production of a CD containing the requested records. This case was settled with a recovery to the U.S. Treasury of \$400 million and a relator’s share of \$64 million.”) (footnotes omitted).

¹¹⁸ Carper, *supra* note 10, at 2. See also Pamela H. Bucy, *Game Theory and the Civil False Claims Act: Iterated Games and Close-knit Groups*, 35 *LOY. U. CHI. L.J.* 1021, 1034 (2004) (“Assistant U.S. Attorneys vie for meritorious FCA *qui tam* cases because the greater FCA recoveries that an office can garner, the more resources and recognition within the DOJ that office obtains. In addition, individual attorneys within the DOJ advance their careers, inside the DOJ and beyond, by handling high profile, large-dollar FCA cases.”); Joan H. Krause, “*Promises to Keep*”: *Health Care Providers and the Civil False Claims Act*, 23 *CARDOZO L. REV.* 1363, 1412 (2002) (describing the personal agendas of some U.S. Attorneys); Matthew, *supra* note 102, at 582 (“[T]he presence of financial incentives offers an explanation for the reason the government is pursuing increasingly aggressive and arguably questionable theories of recovery against health care providers in anti-kickback and self-referral cases.”); Dayna Bowen Matthew, *The Moral Hazard Problem With Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 *U. MICH. J.L. REFORM* 281, 300 n.69 (2007) (“The Government does bear some minimal monitoring costs. Some argument can also be made that the more the Government entertains frivolous suits, the more it signals a willingness to participate in specious litigation, thus inviting an increase in the number of cases that it has to monitor but would not pursue.”); Rich, *supra* note 91, at 1260 (“[T]he costs of dismissing the suit include any harm caused by permitting the defendant’s conduct to continue and the detriment to the government and the individual prosecutor of foregoing the possible benefits of a favorable outcome. These potential benefits include the majority of any settlement or judgment obtained that is returned to the government fisc, the specific portion of the proceeds that becomes available to the DOJ for future FCA investigations, and the political benefits to an individual prosecutor of a successful recovery.”) (footnotes omitted).

ty.”¹¹⁹ In turn, a lot of criminal activity attracts a lot of attention from legislators, regulators, lawyers, auditors, accountants, compliance officers, and reporters, provided the funding is available to pay for all of these professionals’ services (see Figure 2, below).¹²⁰

¹¹⁹ Carper, *supra* note 10, at 2; *see also* Menke, *supra* note 117, at 4 (“Health care fraud is attractive to organized crime because: (1) the penalties are lower than those for other organized-crime-related offenses (e.g., offenses related to illegal drugs); (2) there are low barriers to entry (e.g., a criminal can obtain a supplier number, gather some beneficiary numbers and bill the program); (3) schemes are easily replicated; and (4) there is the perception of the low risk of detection.”).

¹²⁰ *Compare Indigent Representation: A Growing National Crisis: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Sec. of the Comm. on the Judiciary*, 111th Cong. 1 (2009) (statement of Rep. Robert C. Scott, Chairman, Subcomm. on Crime, Terrorism, and Homeland Sec. of the Comm. on the Judiciary) (“Researchers have estimated that between 80 and 90 percent of all state criminal defendants rely on indigent defense systems for counsel.”), *and* Eric Holder, Attorney Gen., Addressing the Dep’t of Justice Nat’l Symposium on Indigent Defense: Looking Back, Looking Forward, 2000–2010 (Feb. 18, 2010) (transcript available at <http://www.justice.gov/ag/speeches/2010/ag-speech-100218.html>) (“As we all know, public defender programs are too many times under-funded. Too often, defenders carry huge caseloads that make it difficult, if not impossible, for them to fulfill their legal and ethical responsibilities to their clients. Lawyers buried under these caseloads often can’t interview their clients properly, file appropriate motions, conduct fact investigations, or spare the time needed to ask and apply for additional grant funding.”), with *Combating Health Care Fraud and Abuse: Hearing Before H. Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies of the H. Comm. on Appropriations*, 111th Cong. 1 (2010) (statement of Daniel Levinson, Inspector Gen., U.S. Dep’t of Health & Human Servs.) [hereinafter Levinson] (“[T]he President’s Budget for FY 2011 requests approximately \$272 million in Medicare and Medicaid integrity funding for OIG, a net increase of \$40 million....OIG’s funding is used to hire and support investigators, auditors, evaluators, attorneys, and management and support staff to carry out our mission and functions.”).

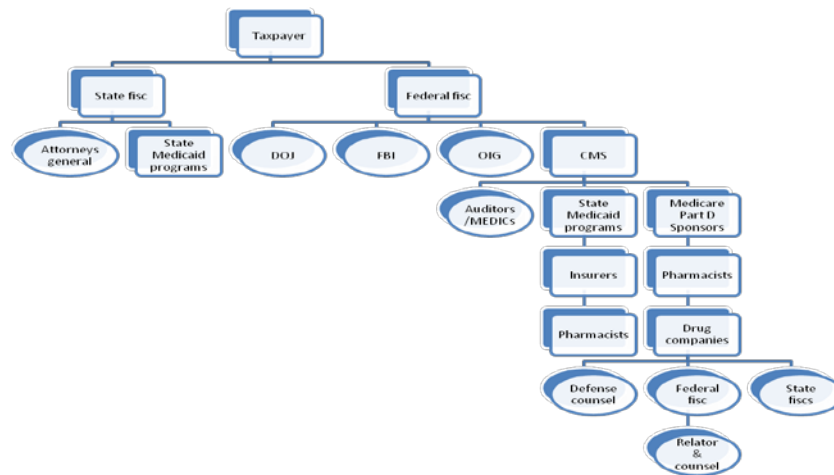


Figure 2. Flow of money from taxpayers to parties who rely, at least in part, on federal health care fraud enforcement efforts for their livelihoods. Parties represented in rectangles are necessary for the delivery of Medicare and Medicaid program benefits. Parties represented in ovals only get involved in efforts to recoup improper payments.

Luckily for those invested in health care fraud enforcement efforts, legislation geared towards enforcement is easier to get through Congress than legislation to overhaul the federal healthcare system. As an example, on May 20, 2009, barely three and a half months after it was first introduced to the Senate on February 5, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009 (“FERA”), which significantly expanded whistleblowers’ ability to bring FCA actions.¹²¹ By contrast, Congressional attempts to reform the national healthcare system were in process for well over a year, accompanied by acrimonious political partisanship and subsequent challenges from individual states. The complexity of the national healthcare system, including the parameters of coverage and reimbursement rates, is arguably ill-suited to the nature of the Congress-

¹²¹ Congress considered the FERA as “an Act to improve enforcement of mortgage fraud, securities and commodities fraud, financial institution fraud, and other frauds related to Federal assistance and relief programs, for the recovery of funds lost to these frauds, and for other purposes.” Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617. As it pertained specifically to the False Claims Act, the FERA amendments were meant to “clarif[y]...the False Claims Act to reflect the original intent of the law.” *Id.* The amendments passed under FERA were preceded by “[o]ther amendments [that] made FCA cases easier to prove overall, thereby improving all plaintiffs’ chances of success. These amendments included relaxing the *mens rea* requirement...and clarifying that the preponderance burden of proof, rather than a clear and convincing burden of proof, applies to FCA cases.” Bucy, *supra* note 66, at 46-47.

sional process. As a result, the historical revision and amendment of the Social Security Act has resulted in piecemeal health care legislation that ignores the underlying systemic inefficiencies.

In addition, the costs and benefits of enforcement are quantifiable while the value of deterrence and prevention remains abstract because it requires weighing the costs of compliance efforts against “what might have been.”¹²² Through FCA enforcement actions, the federal government pursued and received “\$1.12 billion in recoveries from health care fraud, waste, and abuse,” during 2008 alone.¹²³ According to one estimate, the federal government recovers \$15 for every \$1 invested in FCA investigations and prosecutions in the health care arena.¹²⁴ This estimate suggests that the FCA is a particularly efficient and effective means of recouping improperly paid funds, especially when compared to the \$6 to \$1 average return-on-investment reported by the Office of Inspector General for the Department of Health and Human Services for the Healthcare Fraud and Abuse Control Account or the \$4 to \$1 return on investment reported by the Department of Justice.¹²⁵ The increased efficiency of the FCA is due, at least in part, to the government’s ability to tap into the private law enforcement ranks of *qui tam* relators and relators’ counsel, and the insider information they receive because of the financial incentive provided by the FCA.¹²⁶ Unfortunately, as a result of the financial incentives of the

¹²² Vito, *supra* note 64, at 2 (“In FY 2009, OIG investigations resulted in \$4 billion in settlements and court-ordered fines, penalties, and restitution, and in 671 criminal actions. OIG audits results in almost \$500 million in receivables through recommended disallowances. OIG also produced equally important but less quantifiable gains in deterrence and prevention of fraud, waste, and abuse.”).

¹²³ Dinh Nguyen, *Renewed Scrutiny of the Pharmaceutical and Medical Device Industries and Research Institutions in 2010*, BNA MEDICAL RES. LAW & POL’Y REP., Feb. 17, 2010, at 3.

¹²⁴ *False Claim Act Statistics*, TAXPAYERS AGAINST FRAUD EDUCATION FUND, <http://www.taf.org/statistics.htm> (last visited Apr. 15, 2011) (The Taxpayers Against Fraud Education Fund (TAF) is a nonprofit public interest organization dedicated to combating fraud against the Federal Government through the promotion and use of the federal False Claims Act and its *qui tam* provisions).

¹²⁵ Levinson, *supra* note 120, at 6 (reporting the OIG figures); *Enforcement of the Criminal Laws Against Medicare and Medicaid Fraud: Hearing before H. Subcomm. on Crime, Terrorism, and Homeland Sec. of the H. Comm. on the Judiciary*, 111th Cong. 1 (2010) (statement of Greg Andres, Acting Deputy Ass’t Att’y Gen., U.S. Department of Justice) [hereinafter Andres] (reporting the DOJ figures).

¹²⁶ See Sharon Finegan, *The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law*, 111 PENN ST. L. REV. 625, 653 (2007) (“[T]he use of *qui tam* suits in civil actions under the FCA has created an enforcement mechanism greater in resources and potential prosecutors than any governmental criminal enforcement body. Thus, the FCA has a greater enforcement power than that available in most criminal actions.”).

FCA, whistleblowers and lawyers (both in private practice and working for the government) are more likely to find real value in filing *ex post* lawsuits as compared to *ex ante* internal compliance reporting or other systemic changes.¹²⁷ The resulting multi-million or billion dollar cases against pharmaceutical companies may be considered headline-worthy, but still only skim the surface of the fraud, abuse, and waste in the federal health care system.¹²⁸

If CMS decides to require diagnosis codes on claims for reimbursement of outpatient prescription drugs the opportunity to collect from pharmaceutical companies under the False Claims Act may decrease¹²⁹ and liability for specific false claims that make it through the

¹²⁷ Pursuant to the many Corporate Integrity Agreements currently in place between pharmaceutical companies and the OIG, the companies have implemented extensive internal compliance departments and reporting systems. See OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENTS DOCUMENT LIST, http://oig.hhs.gov/fraud/cia/cia_list.asp (last visited Apr. 15, 2011). These compliance programs (as well as those voluntarily adopted by companies who have not entered a Corporate Integrity Agreement) usually require a designated compliance officer to educate and train all company officers, directors, employees, contractors, and agents on critical laws and regulations including the anti-kickback, self-referral, misbranding, and FCA whistleblower statutes, and regularly report to the company's board of directors, CEO or president, about ongoing compliance efforts and internal investigations, including the nature of any investigation, its results, and any remedial or disciplinary action taken. See Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057, 62,064 (Oct. 3, 2002).

¹²⁸ In the 13 years since the Health Care Fraud and Abuse Control Program has been in effect, it has returned \$15 billion to the federal government. Grindler, *supra* note 65, at 3-4. The largest single criminal and civil settlement for health care fraud to date is \$2.3 billion. See Pfizer Settlement Agreement, *supra* note 2. While these numbers represent significant efforts by the federal government's law enforcement programs, they amount to only 3% or less than 0.5% of the annual Medicare spending, respectively. See *The Enforcement of Criminal Laws Against Medicare and Medicaid Fraud: Hearing Before H. Subcomm. on Crime, Terrorism and Homeland Sec. of H. Comm. on the Judiciary*, 111th Cong. 6 (2010) (statement of James Frogue, Vice President, Center for Health Transformation) [hereinafter Frogue] (stating that "[o]ne percent of annual Medicare spending is \$5 billion.").

¹²⁹ See Grindler, *supra* note 65, at 11-12 ("At the end of FY 2009, the USAOs reported that there were several dozen pharmaceutical, as well as, other complex health care fraud investigations pending—with potential significant recoveries—and following the landmark settlements of the last year, a large number of additional *qui tams* have been filed in the first few months of FY 2010. These cases not only represent potential recoveries in the billions of dollars, but the opportunity to change the current corporate culture that is so harmful to the financial health of the federal, state and private health care programs. This funding for attorney and support personnel, as well as, for litigation expenses including, the creation of databases to house billions of documents, expert analysis of Medicare and Medicaid data, and medical consultants to unravel the sophisticated fraud schemes is essential to the successful resolution of these important cases. In addition to supporting the investigation and

real-time review of the prescriptions will fall more squarely on individual prescribers and pharmacists instead of larger corporations.¹³⁰ Of course, assuming an effective real-time review of prescriptions, any improper payments for medically inappropriate off-label use will be those payments that went forward due to a coding error on the part of the insurer's review algorithm (in which case these payments should be easily identified in a post-payment audit of the drugs and diagnosis codes), or those deliberately miscoded by physicians and pharmacists in order to treat their patients. While the ethical question of whether miscoding should be prosecuted when done in the interest of patient health remains, deliberate miscoding does render the information submitted in the claim inconsistent with the actual purpose for a prescription, rendering the claim "false" for purposes of the FCA.

If the information gap is fixed, one of the critical legal theories that have driven *qui tam* actions for the past decade may no longer be available to relators' counsel or the government. Even so, the criminal and civil remedies provided by the FDCA, the anti-kickback, and the self-referral statutes remain available, in addition to a veritable laundry list of other criminal provisions.¹³¹

litigation of pending cases, this funding would provide the AUSAs with the opportunity to pro-actively pursue the large dollar frauds, i.e., pharmaceutical and medical device fraud. Combining the knowledge and experience gained from numerous investigations with sophisticated data analysis, the AUSAs, with their colleagues in the Civil Division, could identify high dollar, over utilized, and inappropriately promoted drugs, procedures, and other services.”)

¹³⁰ See Andres, *supra* note 125, at 6 (“The primary enforcement tool possessed by the Department of Justice to pursue civil remedies in health care fraud matters is the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733.”); Frogue, *supra* note 128, at 6 (“Many of the attorneys and investigators I have spoken with off the record say that prosecutions focus almost exclusively on very large cases where convictions are a virtual slam dunk. The message criminals hear is that they should just not get too greedy. So long as their theft remains in the tens of thousands of dollars, they need not fear prosecution. Those smaller activities multiplied across the country thousands of times likely add up to far more dollars than the marquee indictments, prosecutions and convictions.”).

The financial stability of a publicly-traded company also makes collection of any eventual verdict or settlement easier than the smaller, more transient companies seen in many of the fraudulent billing schemes prosecuted by the DOJ and OIG. Perez, *supra* note 88, at 2 (Once CMS paid the claims and deposited “money into the company’s bank account, it was withdrawn within days using multiple check cashers. The idea was to deplete the account so that once Medicare discovered the fraudulent billing, which could take 6 months to 1 year, there would be no money in the account.”).

¹³¹ Andres, *supra* note 125, at 7 (“[T]he Civil Division, as a part of our health care fraud enforcement efforts, investigates and pursues False Claims Act matters that are predicated on claims that doctors and others were paid kickbacks or other illegal remuneration to induce referrals of Medicare or Medicaid patients in

III. THE BETTER SOLUTION

Despite the “value” of the inefficiency created by the information gap in the Medicare and Medicaid billing systems, this gap should be eliminated by requiring diagnosis codes on all claims for reimbursement of outpatient prescription drugs. Eliminating the systemic disconnect between a physician’s diagnosis of a patient and a pharmacist’s submission of a claim for an outpatient prescription drug has the potential to both reduce federal health care spending and improve public safety.¹³²

A. Protection of the Public Fisc

The amount of taxpayer money tied up in the federal health care system for the reimbursement of outpatient prescription drugs is staggering, as is the amount of money wasted due to health care fraud.¹³³ In its current iteration, oversight by CMS, plan sponsors, and benefit integrity contractors has been limited and “the program is vulnerable to fraud, waste, and abuse.”¹³⁴ In particular, CMS needs to improve its

violation of the Physician Self-Referral laws, commonly referred to as the ‘Stark’ laws, the Anti-kickback Statute, and the civil monetary penalties statute. These statutes have been extremely important in protecting the integrity of our health care system and have proven useful in going after fraudsters.”); *see Menke, supra* note 117, at 4-5 (stating that current criminal statutes available for prosecuting fraud include the Health Care Fraud statute (18 U.S.C. § 1347), Criminal Forfeiture statute (18 U.S.C. § 982), Conspiracy to Commit Health Care Fraud (18 U.S.C. § 1349), Conspiracy (18 U.S.C. § 371) charged in combination with False, Fictitious, or Fraudulent Claims (18 U.S.C. § 287), Laundering of Monetary Instruments (18 U.S.C. § 1956), Criminal Penalties for Acts Involving Federal Health Care Programs (42 U.S.C. § 1320a-7b(b)), and Aggravated Identity Theft (18 U.S.C. § 1028A)).

¹³² On occasion, the prescription of drugs for off-label use can result in both harm to patients as well as the public fisc. *See, e.g., Collins, supra* note 39, at 6 (“Two Washington state providers, one a physician, maintained a medical practice where they treated patients for pain management. They were indicted for unlawfully billing several governmental health care benefit programs and prescribing Methadone, Oxycontin and Oxycodone for improper purposes, resulting in at least one death. The physician was sentenced to nine months in prison and ordered to pay restitution and fees.”).

¹³³ *See Perez, supra* note 88, at 1 (describing how in one investigation OIG uncovered a scheme involving over \$200 million in fraudulent billing to Medicare over two years); Vito, *supra* note 64, at 1 (“With approximately \$50 billion at risk in the [Medicare Part D drug] program each year, it is important that all of us who have programmatic and oversight responsibilities work collaboratively to ensure that program vulnerabilities are identified and resolved.”).

¹³⁴ Vito, *supra* note 64, at 1; *see also Carper, supra* note 10, at 2 (“Unfortunately, Health and Human Services has not been able to determine the level [of waste and fraud] for the prescription drug program, so the amount wasted in Medicare Part D is still largely unknown.”).

oversight of Part D payments for outpatient prescription drugs.¹³⁵ Despite the government's goal of addressing fraud "as early as [it] can in the process,"¹³⁶ CMS and its contractors lack a centralized data repository for proactive data monitoring.¹³⁷ As a result, there has been no significant Part D data analysis conducted by CMS or its contractors to specifically detect or prevent fraud and abuse because the contractors encountered significant delays in receiving access to the necessary data.¹³⁸

Even if the contractors charged with auditing the Part D data were granted full access to the underlying claims and data, an audit is inherently reactive and only as good as the data being audited.¹³⁹ At present, the Part D data provides no information about patient diagnoses.¹⁴⁰ The diagnosis data necessary for evaluating eligibility of outpatient prescription drug claims is only available for Medicare Part A and Part B.¹⁴¹ While requiring diagnosis codes on reimbursement

¹³⁵ See Vito, *supra* note 64, at 7. The Medicaid statute already requires covered outpatient drug use reviews from the individual states in order to assure that prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results. See 42 U.S.C.A. § 1396r-8(g) (West 2010). These reviews are intended to generate information "to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care." *Id.*

¹³⁶ Vito, *supra* note 64, at 10.

¹³⁷ *Id.* at 4.

¹³⁸ *Id.* at 5 ("[Medicare Drug Integrity Contractors] did not receive access to [Part D prescription drug event] data until August 2007; nearly a year after their contracts began. Once they received access to PDE data, [the contractors] found that there were significant limitations in the data and important variables were not available or were stored incorrectly. In addition, two [contractors] were not given access to Part B data (physician services) until the fall of 2008 and the third [contractor] did not receive access to Part B data before its contract ended.").

¹³⁹ This is especially a concern for Medicaid data. See MEMORANDUM REPORT: MSIS DATA, *supra* note 13 (On August 26, 2009 OIG sent a letter to the CMS Director of State Operations essentially saying that the Medicaid's data collection is so poor OIG cannot accurately measure the extent of fraud in the Medicaid system.).

¹⁴⁰ See Perez, *supra* note 88, at 3 (explaining that the claims data currently used by the Medicare Strike Force Teams to identify fraudulent schemes includes: total amount paid; dates of service; referring/ordering physicians; beneficiaries; claim dates; types of procedures billed; place of service; provider banking information; and ownership status). While these are helpful data points for tracking outlier claims generally, they are specific to Medicare Parts A and B. The addition of linked prescription drug and diagnosis data could only strengthen their analytic tools.

¹⁴¹ Vito, *supra* note 64, at 4-5 ("[Medicare Drug Integrity Contractors] reported that they needed both [Part D prescription drug event] data and Part B data to effectively identify and investigate potential fraud and abuse incidents."). In addition, the contractors also "lack [the] authority to directly obtain information, such as pre-

claims for outpatient prescription drugs will not provide enough information to sniff out all fraud, abuse, or waste, it would potentially allow automated real-time evaluation of prescription drug claim eligibility, eliminate the need to cross-reference data from Part B claims, and provide information sufficient to flag potentially problematic prescribing patterns for further investigation.¹⁴²

The current health care fraud enforcement methods within the DOJ rely heavily on data mining.¹⁴³ The inclusion of diagnosis codes on Medicare Part D claims would allow for more targeted enforcement instead of the current nationwide investigations that are enormously inefficient and resource intensive. The Department of Health and Human Services anticipates spending \$15 million to \$20 million of its allocated federal funds to upgrade Medicare and Medicaid claims databases used by investigators to catch individuals committing health care fraud.¹⁴⁴ One of the upgrades that should be included in this effort is directly linking prescription drug claim data to diagnosis codes.

scription and medical records from pharmacies, pharmacy benefit managers, and physicians.” *Id.* at 5.

¹⁴² See Menke, *supra* note 117, at 6 (“Real-time access to data is critical to the success of the [Health Care Fraud Prevention and Enforcement Action Team] Strike Force initiative.”); Perez, *supra* note 88, at 3 (“Before Strike Force teams were initiated, the referrals we received contained billing data that was typically between 6 months and 1 year old. Today, the data we receive provides billing information that is only 2 to 3 weeks old. In South Florida, as elsewhere, criminals can receive several hundred thousand dollars in fraudulent payments within a matter of weeks. The ability to retrieve real-time data, meaning being able to access claims data within hours of the claims being submitted, would allow us to potentially obtain evidence immediately to substantiate fraudulent activity, thus stopping the payment of a significant amount of money and catching the criminals before they and the money disappear.”). See also Frogue, *supra* note 128, at 3-4 (providing example of how real-time data analysis allows credit card companies to flag problematic behavior and significantly reduce fraud in the system).

¹⁴³ The DOJ is currently using data analysis techniques in an interagency Medicare Fraud Strike Force model in seven cities: Miami, Los Angeles, Detroit, Houston, Brooklyn, Tampa and Baton Rouge. See *Medicare Fraud Strike Force Expands Operations*, STOP MEDICARE FRAUD.GOV, <http://www.stopmedicarefraud.gov/heatsuccess/taskforces.html> (last visited Apr. 15, 2011). See also James Swann, *DOJ Prosecutor Details Enforcement Methods for Combatting Health Care Fraud*, 14 BNA HEALTH CARE FRAUD REP. 151, 184 (2010) (“The strike force model entails extensive data mining...[and requires] matching [Medicare] data from a metropolitan area with national data and then searching for anomalies.” By using this method, the DOJ “speeds up the process of getting defendants into the system to be prosecuted.”).

¹⁴⁴ Corr, *supra* note 6.

B. Improving Public Health

In addition to helping CMS, OIG, and DOJ in their efforts to fight health care fraud, the new data generated by including diagnosis codes on claims for reimbursement of outpatient prescription drugs could also be used to support current efforts by the FDA and pharmaceutical companies to monitor prescription drug post-marketing risks and minimize abuse, overdose, and inappropriate prescribing.

The past decade has been fraught with patient safety concerns related to the use and abuse of prescription drugs. One of the most widely-covered stories, that concerning the safety of the painkiller Vioxx (rofecoxib), arose out of cardiovascular safety concerns that could not have been detected from the clinical trials conducted for purposes of FDA-approval.¹⁴⁵ Following the voluntary recall of Vioxx, the Institute of Medicine (at FDA's request) undertook an extensive evaluation of the prescription drug safety system in place at the time and issued a list of recommendations for improving the system.¹⁴⁶ Many of the Institute of Medicine's recommendations were then incorporated into the Food and Drug Administration Amendments Act of 2007 (FDAAA),¹⁴⁷ including significant authority for FDA post-marketing risk assessment for prescription drugs.¹⁴⁸

The FDAAA requires the FDA to establish an active post-marketing risk identification system for the timely identification of potential risks associated with prescription drug use.¹⁴⁹ It also gave the FDA authority to require drug manufacturers to submit proposed

¹⁴⁵ Merck did not specifically test for the cardiovascular risks, raised by clinical studies completed after FDA approval. See Alex Berenson, Gardiner Harris, Barry Meier & Andrew Pollack, *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES, Nov. 14, 2004, available at <http://www.nytimes.com/2004/11/14/business/14merck.html>.

¹⁴⁶ COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 2 (2007) (“[T]he committee considered the drug safety system as the sum of all activities conducted by FDA and other stakeholders to monitor, evaluate, improve, and ensure drug safety.... Although much of the committee’s work was focused on drug review, safety surveillance, and related activities of CDER, the committee also reviewed some key aspects of the roles and considered the potential contributions of the pharmaceutical industry, the academic research enterprise, Congress, the health care delivery system, patients, and the public.”).

¹⁴⁷ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

¹⁴⁸ See Bruce M. Psaty & David Korn, *Congress Responds to IOM Drug Safety Report—In Full*, 298 JAMA 2185 (2007) (“The FDAAA gives the FDA the authority to require postmarketing studies to identify or assess potential serious risks.”).

¹⁴⁹ 21 U.S.C. § 355(k)(3) (2006) (Active postmarket risk identification).

Risk Evaluation and Mitigation Strategies (REMS) to ensure that the benefits of their drugs outweigh the risks to patients taking their drugs.¹⁵⁰ When evaluating the appropriateness of a REMS, the FDA is required to consider: the estimated size of the population likely to use the drug involved, the seriousness of the disease or condition that is to be treated with the drug, the expected benefit of the drug with respect to such disease or condition, the expected or actual duration of treatment with the drug, and the seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.¹⁵¹ This type of patient-specific and treatment-specific information is often difficult for drug companies to collect outside of their own sponsored clinical trials due to patient privacy statutes.¹⁵² Controlled clinical trials, however, are limited in their ability to predict drug efficacy and safety in actual medical practice due to the necessity to establish selection criteria for clinical trial subjects.¹⁵³

If diagnosis codes were required for federal reimbursement of outpatient prescription drugs, the data generated by Medicare Part D and Medicaid claims could provide much of this information and it would be indicative of drug use in actual medical practice. Indeed, Medicare Part D data is already available upon request to the FDA for research purposes, but does not include patient diagnosis data.¹⁵⁴ In-

¹⁵⁰ § 355-1 (Risk Evaluation and Mitigation Strategies).

¹⁵¹ § 355-1(a)(1) (factors considered in determining if a risk evaluation and mitigation strategy is necessary).

¹⁵² See 42 U.S.C. § 1320d-6(a) (2006) (covering the illegality of wrongfully disclosing individually identifiable health information); Hall & Berlin, *supra* note 47, at 656 (“The manufacturer rarely has any knowledge of, or involvement with, the specific patient and his or her therapy. Manufacturers cannot practice medicine and are rarely involved in actual treatment.”).

There are private sector companies, like Intercontinental Marketing Services (IMS) Health, that sell information about doctors’ prescribing habits, but they purchase supporting data primarily from pharmacies. See Jacob Goldstein, *Should Docs’ Prescribing Habits Be for Sale?*, WALL ST. J. HEALTH BLOG (Dec. 11, 2009, 8:51 AM), <http://blogs.wsj.com/health/2009/12/11/should-docs-prescribing-habits-be-for-sale> (“Companies like IMS buy the information from pharmacies, crunch it, and sell it to drug companies, which use it to guide the way they market drugs to individual doctors (the records identify doctors but not patients).”).

¹⁵³ See generally Norman Sharpe, *Clinical Trials and the Real World: Selection Bias and Generalisability of Trial Results*, 16 *CARDIOVASCULAR DRUGS & THERAPY* 75 (2002).

¹⁵⁴ See 42 U.S.C.A. § 1396r-8(g) (West 2010) (The Medicaid statute already requires covered outpatient drug use reviews from the individual states in order to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. Further, these reviews are intended to generate information to educate physicians and pharmacists “to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unneces-

creasing the amount of personalized health information in a single database hardly seems problematic in itself, but there may be concerns about the increased circulation of that information. Admittedly, the ethical, legal, and social concerns implicated by use of Medicare and Medicaid data for widespread human subject research, as defined and regulated by the Common Rule, 45 C.F.R. Part 46 (Protection of Human Subjects), are many but beyond the scope of this article.

Also, one of the “elements to assure safe use” associated with existing REMS is a proactive, real-time check at the dispensing pharmacy that patients are being treated solely for an on-label disease or condition.¹⁵⁵ While the administrative and logistical hurdles put in place for prescription drugs under REMS are not needed for most prescription drugs, requiring diagnosis codes for reimbursement of outpatient prescription drugs would provide retail pharmacists with patient-specific diagnosis information that would allow them to better monitor their patients’ medications for prescribing errors.¹⁵⁶

sary care.”); 42 C.F.R. § 423 (2010) (explaining that Medicare Part D data is already available upon request to the FDA for research purposes, but does not include patient diagnosis data).

¹⁵⁵ For example, *Onsolis* is a painkiller currently sold by MEDA Pharmaceuticals, Inc. According to the FDA-approved product labeling for *Onsolis*, “ONSOLIS is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” MEDA Pharm., Inc., *Onsolis Prescribing Information*, ONSOLIS.COM (July 2009), http://www.onsolisHCP.com/assets/downloads/onsolis_pi.pdf (emphasis in original). The *Onsolis* REMS requires, as one of its elements to assure safe use, that (1) physicians prescribing *Onsolis* “[e]nsure appropriate patient selection, including that the patient is opioid tolerant,” (2) patients prescribed *Onsolis* “complete and sign the Patient Enrollment Form,” which is in turn faxed by the prescribing physician to a centralized database maintained and monitored by the manufacturer, and (3) pharmacies dispensing *Onsolis* certify that all pharmacy staff dispensing *Onsolis* are trained on the REMS procedures, which include confirming that both the prescribing physician and patient are actively enrolled in the centralized database before dispensing the drug to the patient. *Questions and Answers about Onsolis (fentanyl buccal soluble film)*, U.S. FOOD & DRUG ADMIN. (July 16, 2009), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm172039.htm#BriefSummariesofREMSElements> (last visited Apr. 15, 2011).

¹⁵⁶ Medicare Part D already recognizes the value of pharmacist review and management of patient prescription medication by requiring all Part D sponsors to have quality assurance programs. See 42 C.F.R. § 423.153(c) (2010). The quality assurance program requires point-of-sale review of prescriptions for potential drug therapy problems due to therapeutic duplication, age or gender-related contraindications, over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse or misuse. § 423.153(c)(2). Retail pharmacists are currently limited in their reviews to diagnostic information gleaned from the patient and the prescription.

Improper prescribing not only puts the individual patient's safety at risk, but also greatly increases the likelihood of misuse and abuse of prescription drugs. Between 1994 and 2004, the population of the United States grew 12%, while at the same time the number of prescription drugs dispensed grew nearly 68%. The only thing that has outpaced this figure is the rate of abuse of those drugs, growing nearly 80%. In fact, more Americans abuse prescription drugs than the number who abuse cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined. In fact, one out of five teenagers in America has abused, or is abusing, prescription drugs. Aside from our financial responsibility, we have a social responsibility to ensure that our public health care system isn't used to further intensify and subsidize a public health crisis.¹⁵⁷

Despite the fact that federal prosecutors often tout their off-label promotion enforcement efforts as furthering patient safety, federal FCA litigation does little to change physicians' off-label prescribing habits.¹⁵⁸ Two significant initiatives are currently underway within the federal health care system to address the problem of improper prescribing: the adoption of electronic health records, which include electronic prescriptions,¹⁵⁹ and increased funding for comparative effectiveness research and "evidence-based" medical practice.¹⁶⁰ First,

¹⁵⁷ Carper, *supra* note 10, at 2.

¹⁵⁸ See Johnson, *supra* note 30, at 115-16 ("In 2002, 94% of Neurontin prescriptions were for off-label indications, up from 40% in 1995. Neurontin sales amounted to \$2.7 billion in 2003, of which nearly \$2.5 billion was for off-label uses....In August, 2004, two years into the state and federal governments' pursuit of the lawsuit and shortly after the attention-grabbing settlement, sales of Neurontin had actually increased by 32% over the same quarter the year before. Lehman Brothers estimated that the great bulk of those prescriptions of Neurontin—90% of sales, in fact—were still for off-label uses.").

¹⁵⁹ The American Recovery and Reinvestment Act provided financial incentives for health care providers to adopt electronic health records (EHR). See *CMS Proposes Definition of Meaningful Use of Certified Electronic Health Records (EHR) Technology*, CTRS. FOR MEDICARE AND MEDICAID SERVS., (Dec. 30, 2009), http://www.cms.hhs.gov/apps/media/fact_sheets.asp (last visited Apr. 15, 2011).

¹⁶⁰ See Nathaniel Wiexel, *Obama Budget Plan Includes \$286 Million In Funding for Medical Option Comparisons*, 18 HEALTH CARE POL'Y REPORT 168 (2010) ("President Obama's fiscal year 2011 budget blueprint includes \$286 million in the Agency for Healthcare Research and Quality (AHRQ) for research that compares the effectiveness of different medical options. The funding for comparative effectiveness research (CER) would build on the expansion of this research begun under the American Recovery and Reinvestment Act (ARRA, Pub. L. No. 111-5). According to budget documents, 'the dissemination of this research is expected to lead to higher quality, evidence-based medicine, arming patients and physicians with the best available information to allow them to choose the medical option that will work the best for them.'").

adoption of electronic health records makes inclusion of diagnosis on prescriptions easier for physicians because the diagnosis code necessary for patient records and physician reimbursement can be easily transmitted with any electronic prescription generated from the EHR system.¹⁶¹ Second, robust data on on- vs. off-label use of drugs and devices has been elusive, at best, and will be critical for any serious efforts to drive evidence-based medical practice.¹⁶² Medicare Part D and Medicaid outpatient prescription data, if linked to patient diagnosis, could provide much of the data needed to link off-label use of prescription drugs to health outcomes in order to inform physicians' prescribing habits and insurers' evaluation of medical services.¹⁶³

While the federal government and public opinion have put the blame for wrongful payment of outpatient prescription drug claims primarily on pharmaceutical companies' off-label promotion, the re-

In addition to the funds appropriated to the AHRQ, another \$400 million went to the National Institutes of Health (NIH) with the goal of "improv[ing] health outcomes by providing evidence to enhance medical decisions made by patients and their medical providers." DEP'T HEALTH & HUMAN SERVS., NATIONAL INSTITUTES OF HEALTH: COMPARATIVE EFFECTIVENESS RESEARCH 1, *available at* http://www.hhs.gov/recovery/reports/plans/nih_cer_plan.pdf (last visited Apr. 15, 2011). The NIH already recognizes that "[t]his research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness." *Id.* at 1. Thus, linking prescription information to diagnosis codes in a single database would help expand the current universe of data sources available for CER and allow for significantly more diverse patient populations than are currently observed in the majority of clinical studies.

¹⁶¹ See Corr, *supra* note 6, at 6-7 ("The development and implementation of Electronic Health Records (EHR) should also have a positive impact on reducing the error rate for Medicare [fee-for-service payments]. After EHRs are fully implemented there will be fewer errors for illegible or missing signatures. Further, documentation errors are the most frequent reason for claim denials. The expectation is that the EHR will contain all the documentation to support the claim.").

¹⁶² See generally Emily A. Largent et al., *Going Off-label Without Venturing Off-Course: Evidence and Ethical Off-label Prescribing*, 169 ARCH. INTERN. MED. 1745 (2009) (arguing that there should be more reflection and scrutiny of evidence on behalf of physicians before prescribing off-label uses).

¹⁶³ This data could be especially valuable given the current disparity between federal and private funding for post-marketing clinical trials and the concern that pharmaceutical company funds may improperly influence clinical researchers. See Johnson, *supra* note 30, at 85 ("In comparison to the approximately \$950 million of federal money devoted to all phases of clinical trials, pharmaceutical firms may be spending as much as \$8 to \$12 billion on post-marketing trials alone."); Harry P. Selker & Alastair J.J. Wood, *Industry Influence on Comparative-Effectiveness Research Funded through Health Care Reform*, 361 N. ENGL. J. MED. 2595 (2009) (arguing that commercial and political interests may "taint" comparative effectiveness research). See generally Bernard Lo, *Serving Two Masters—Conflicts of Interest in Academic Medicine*, 362 N. ENGL. J. MED. 669 (2010) (discussing the divergence in interests between pharmaceutical companies and academic health centers).

sponsibility of properly administering Medicare and Medicaid benefits falls also on those writing the checks for individual claims. The government has poured billions of dollars into targeted enforcement mechanisms and incentivized whistleblower actions to mobilize thousands of professionals in the fight against health care fraud. Even so, at their best, these efforts merely scratch the surface of the problem. Instead of dedicating even more resources to enforcement, there needs to be more attention paid to fixing the system on the front end. One small step in that direction would be to make patient diagnosis codes a part of the Medicare Part D and Medicaid system for reimbursing claims for outpatient prescription drugs.