

Enforcing Integrity

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INTRODUCTION

In 2010, the pharmaceutical industry was crowned “the biggest defrauder of the federal government,” as it surpassed the defense industry in False Claims Act¹ recoveries for the first time in history.² This dubious distinction is largely due to the illegal promotional activities of pharmaceutical manufacturers, such as distributing information on unapproved uses of their drugs and paying kickbacks to doctors to

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1. 18 U.S.C. § 287 (2006).

2. SAMMY ALMASHAT, CHARLES PRESTON, TIMOTHY WATERMAN & SIDNEY WOLF, PUBLIC CITIZEN, RAPIDLY INCREASING CRIMINAL AND CIVIL MONETARY PENALTIES AGAINST THE PHARMACEUTICAL INDUSTRY: 1991 TO 2010, at 12 (2010), <http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf>. One of the authors of the report, Sidney Wolfe, MD, is a member of the U.S. Food and Drug Administration’s Drug Safety and Risk Management Advisory Committee. See *Drug Safety and Risk Management Advisory Committee Roster*, U.S. FOOD AND DRUG ADMIN. (Sept. 29, 2011), <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm094892.htm>.

induce them to prescribe those drugs.³ The large recoveries are due in part to the fact that the government has put the marketing practices of large pharmaceutical companies, like Pfizer, under a microscope. The government spends years investigating and building cases against pharmaceutical manufacturers that engage in illegal promotional activities to market their drugs but does not prosecute them. Instead, the government enters into Corporate Integrity Agreements (CIAs) with pharmaceutical giants. By entering into these civil administrative settlements, the pharmaceutical manufacturers are able to avoid the collateral consequences of criminal conviction. Importantly, if a pharmaceutical manufacturer enters into a CIA, the manufacturer will not be excluded from participation in federal health care programs, such as Medicare and Medicaid,⁴ as they would upon conviction in most cases. Medicare and Medicaid are significant sources of revenue for pharmaceutical manufacturers. In return for remaining eligible for Medicare and Medicaid reimbursements, the manufacturer pays the government a large fine and agrees to structural changes that are designed to prevent future marketing violations.

The CIA seems like a reasonable solution to the problem of illegal promotional activities because it employs a cooperative approach to compliance, but its use has not led to demonstrable reductions in health care fraud. In part, this is because the government has entered into multiple CIAs with some manufacturers, like Pfizer, rather than seeking exclusion of those manufacturers that violate existing CIAs. Thus, the message to manufacturers is that, as long as they are willing to pay large fines and enact more compliance measures, the government will not exclude them from Medicare and Medicaid, no matter how egregious the violation. While the settlement amounts are often eye-popping—Pfizer settled for \$2.3 billion⁵—the reality is that these settlements are a small portion of overall profits. Nevertheless, the government touts these settlements in the media as proof that they are tough on health care fraud and abuse.⁶

3. ALMASHAT ET AL., *supra* note 2, at 18 (“From 1991 through 2005, unlawful promotion constituted only 16 percent of all [health care fraud] violations, comprising only \$516 million in financial penalties. Over the past five years (2006–2010), unlawful promotion came to comprise over half (53 percent) of all violations, totaling at least \$3.3 billion in financial penalties, a six-fold increase in financial penalties for this violation compared with the previous fifteen years. In comparison, total financial penalties for all violations increased just three-fold over this same time period.”).

4. This Article uses Medicare and Medicaid as short hand for all federal health care programs. A federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the U.S. government or a state health care program. 42 U.S.C. § 1320a-7b(f). The most significant federal health care programs are Medicare, Medicaid, Tricare, and the Veterans programs.

5. See Press Release, U.S. Dep’t of Health & Human Servs., Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (Sept. 2, 2009), available at <http://www.hhs.gov/news/press/2009pres/09/20090902a.html>.

6. See Press Release, U.S. Dep’t of Justice, Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), available at http://www.justice.gov/opa/pr/2007/September/07_civ_782.html; Press Release, U.S. Dep’t of Justice, Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label

The ultimate question is why is the government complicit in schemes to thwart the statutory remedy of exclusion? Unfortunately, the alternative—exclusion of the manufacturer from participation in Medicare and Medicaid—has devastating consequences that spill over to innocent patients, employees, and stockholders. Not only does the impact of the exclusion hit innocent third parties, but its imposition on the manufacturer substantially outweighs the harm the manufacturer inflicts through its improper marketing practices. The penalty for improperly marketing one drug is blanket exclusion, or exclusion of all drugs produced by that manufacturer, from Medicare and Medicaid. It is the government's unwillingness to harm innocent third parties and its reluctance to impose a disproportionate penalty on drug manufacturers that leads them to CIAs. Thus, the real problem is not that the government uses CIAs—it is that the government does not have penalties of increasing severity to impose in place of exclusion. If the choice is simply between a CIA and exclusion, the government will choose the CIA each time to spare innocent third parties.

Despite the government's compromise practice of using CIAs instead of the exclusion remedy, the government has been sharply criticized for targeting pharmaceutical manufacturers that are marketing their drugs by distributing truthful scientific and medical information on unapproved uses of the drugs.⁷ That criticism is not without merit. Unfortunately, however, that criticism clouds the discussion of the appropriate remedy when the pharmaceutical manufacturer has engaged in more egregious illegal marketing practices, such as misrepresenting the safety and efficacy of an approved drug for an unapproved use or the payment of kickbacks to health care providers. The problem lies in the fact that the government has employed a one-size-fits-all approach to illegal promotional practices, without regard to the seriousness of the offense or the culpability of the offender. Whether the marketing activities involve truthful or untruthful promotion, the remedy is a CIA. Whether the pharmaceutical manufacturer is a first time or fifth time offender of the marketing rules, the remedy is a CIA. With so much emphasis in the literature on the injustice of prohibiting truthful promotion, there has been a lack of

Promotion (Dec. 21, 2005), *available at* http://www.justice.gov/opa/pr/2005/December/05_civ_685.html; Press Release, U.S. Dep't of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), *available at* http://www.justice.gov/opa/pr/2008/February/08_civ_094.html.

7. See, e.g., Margaret Gilhooley, *Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses*, 47 SAN DIEGO L. REV. 845 (2010) (arguing that the Food and Drug Administration cannot lawfully restrict truthful off-label promotion when those claims are widely accepted and reimbursable under federal health care programs); 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 (2006) (arguing that the False Claims Act should not apply to truthful off-label promotional activities); Aaron S. Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225 (2011) (arguing for the development of a scaled regulation model based on biological principles); John E. Osborn, *Can I Tell You The Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information*, 10 YALE J. HEALTH POL'Y L. & ETHICS 299, 307 (2010) (arguing that "communicating truthful, non-misleading scientific and medical information supports sound medical practice and should not subject companies to civil or criminal liability").

concern with crafting the best remedy for pharmaceutical manufacturers that violate the law by blatantly misrepresenting the safety and efficacy of their drugs or providing illegal kickbacks. Thus, this Article fills an overlooked gap in the literature by critically examining the use of CIAs to resolve cases where pharmaceutical manufacturers engage in illegal and untruthful promotional activities.

This Article argues that neither the exclusion of manufacturers from Medicare and Medicaid nor the use of CIAs coupled with large fines is an effective deterrent for pharmaceutical manufacturers that repeatedly engage in illegal marketing activities to promote their drugs. This Article assesses the alternatives to exclusion and CIAs and evaluates whether they may be effective remedies for illegal promotional activities. Part II of this Article surveys the statutory and regulatory framework for pursuing illegal marketing activities and critically examines the marketing activities and motives of pharmaceutical manufacturers. Part III examines deterrence theory and uses Pfizer as a repeat offender case study to scrutinize the government's use of CIAs to settle cases involving untruthful promotional activities. It argues that CIAs fail to deter drug manufacturers from engaging in illegal promotional practices because the penalty imposed by and the cost of compliance with the CIA are significantly lower than the profits that a pharmaceutical company can obtain by illegally marketing its drugs. Further, the government's willingness to enter into multiple CIAs with repeat offenders of the marketing rules rather than exclude them from Medicare and Medicaid substantially diminishes the ability of CIAs to deter illegal promotional activities. Part IV argues that there are viable alternatives to be used in place of or in conjunction with CIAs, such as funding clinical trials, compulsory licensing, corporate officer liability, and targeted exclusion, that would be more effective deterrents for repeat offenders. Each of these remedies could be used to increase the severity of punishment when a one-time offender becomes a repeat offender. This Article concludes that these proposed measures would be more successful than CIAs at increasing compliance and enforcing integrity in drug promotion.

I. BACKGROUND

The Food and Drug Administration (FDA) regulates the introduction of prescription drugs into commerce.⁸ Manufacturers that wish to introduce a new

8. Congress established the FDA "to protect consumers from the dangers of fraudulent, impure, or mislabeled substances." STEPHEN J. CECCOLI, *PILL POLITICS: DRUGS AND THE FDA* 3 (2004). In 1938, Congress passed the Federal Food, Drug and Cosmetic Act (FDCA), which required drug manufacturers to demonstrate that a drug was safe for use before the manufacturer could sell the drug on the market. *Id.* In 1962, Congress passed the Kefauver-Harris Amendments, which required drug manufacturers to demonstrate efficacy as well as safety for each of a drug's intended uses. *Id.* at 77-78. Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, in 1984. *Id.* at 129-30. The Hatch-Waxman Act gave the FDA the power to accelerate approval for new drug applications for generic drugs, thereby reducing the cost of manufacturing and marketing generic drugs. *Id.* at 130. It also increased the patent term for brand-name drugs. *Id.* at 13. In 1987, Congress passed the Prescription Drug Marketing Act,

drug into the market must submit a New Drug Application (NDA) along with scientific evidence that demonstrates the drug's safety and efficacy for a specified purpose.⁹ In turn, the FDA either approves or rejects the particular drug for the applied-for use. The FDA considers both patient safety and the potential benefit from the proposed use when approving or rejecting an NDA. At bottom, the FDA must decide whether the new drug is sufficiently effective for the proposed use relative to the safety risks of the drug.¹⁰ "In other words, the approval standard is medical benefits versus medical risks."¹¹ In some cases, the NDA may seek approval for several uses, but the FDA rejects the drug as unsafe for all but one or two proposed uses.¹² Therefore, a drug may be declared "safe" for marketing for a

which prohibited counterfeit, misbranded, substandard, subpotent, ineffective, or expired drugs. FDA, REGULATORY INFORMATION, *available at* <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/default.htm>. Finally, in 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which explicitly permits doctors to prescribe drugs for off-label uses. 21 U.S.C. § 396. At the same time, however, the FDAMA prohibits drug manufacturers from promoting drugs for off-label uses unless the manufacturer resubmits the drug to the FDA for testing and approval. CECCOLI, *supra*, at 4.

9. Before a pharmaceutical manufacturer can submit an NDA to the FDA, the manufacturer must put the drug through several phases of testing. CECCOLI, *supra* note 8, at 165–68.

In the preclinical testing phase, the pharmaceutical laboratory tests the drug compound using animal and laboratory studies to evaluate the safety, potential toxicity, and biological activity. *Id.* Preclinical testing lasts on average from three to four years. *Id.* After the pharmaceutical manufacturer has concluded preclinical testing on a new compound, the manufacturer may file an investigational new drug application with the FDA. *Id.* The FDA then has thirty days to reject the application. *Id.* If the FDA does not reject the application, the manufacturer may begin testing on humans. *Id.* In Phase I trials, the compound is tested on a group of twenty to eighty healthy volunteers. In Phase I, researchers attempt to establish the safety and toxicity of the compound as well as monitor the drug's behavior in the body. *Id.* The researchers also settle on drug indications and dosage requirements during Phase I. Researchers ordinarily spend one year on Phase I clinical testing. *Id.* In Phase II, researchers conduct controlled studies on 100–300 subjects who are suffering from the disease under consideration. *Id.* The researchers assess the effectiveness of the drug and any possible side effects. Phase II typically takes two years to complete. *Id.* In Phase III, researchers perform controlled testing on 1000–3000 patients who, like in Phase II, are afflicted with the disease under consideration. *Id.* In this phase, the researchers' goals are to determine the long-term effects in the body from drug use and to establish the efficacy of the drug. *Id.* In addition, researchers perfect the dosage requirements and monitor long-term side effects and adverse reactions from the drug. *Id.* Typically, testing in Phase III takes the form of randomized double-blind, placebo-controlled clinical investigations where neither the researcher nor the subject knows where the placebo lies. *Id.* Generally, Phase III takes three years. *Id.*

10. Bruce Patsner, *Marketing Approval Versus Cost of New Medical Technologies in the Era of Comparative Effectiveness: CMS, Not FDA, Will Be the Primary Player*, 3 J. HEALTH & LIFE SCI. L. 38, 54 (2010).

11. *Id.*

12. Joel Lexchin, *The Pharmaceutical Industry and the Pursuit of Profit*, in THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING 11, 13 (Jillian Claire Cohen, Patricia Illingworth & Udo Schüklenk eds., 2006).

specific use, but not safe across the board.¹³ FDA-approved drugs have a label that sets forth the approved uses for that product.¹⁴ Pharmaceutical companies may only promote FDA-approved, or “on-label,” uses to prescribers and customers.¹⁵ A pharmaceutical company may not engage in “off-label promotion”—promoting a drug for a use that is not on-label.

A. Off-Label Use and Promotion

Although pharmaceutical manufacturers may not engage in off-label promotion, doctors have the discretion to prescribe drugs for off-label uses. A doctor prescribes a drug off-label whenever the prescription varies in any way from the label.¹⁶ Thus, a doctor may prescribe a drug for a use that is not listed on the label or in a way that is not listed on the label, such as varying the dosage. Doctors have the discretion to prescribe drugs off-label when their independent medical judgment supports the prescription.¹⁷ The FDA does not prohibit off-label prescriptions because they do not want to deny patients medication that may be effective for the treatment of their medical problems.¹⁸ Nor does the FDA want to interfere with medical innovation or judgment.¹⁹ The FDA recognizes that “off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care.”²⁰ Although there are risks to using drugs in ways that have not been fully vetted by the FDA, there are also many benefits to doing so. FDA evaluation of NDAs is often a slow process and may not be able to keep pace with cutting edge medical advances that use FDA-approved drugs for off-label

13. CECCOLI, *supra* note 8, at 165–68.

14. Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074, 64075 (Dep’t Health & Human Servs. Dec. 3, 1977) (notice).

15. See 21 C.F.R. § 201.100(d) (2006) (describing labeling requirements of new drugs).

16. *Id.* (explaining that off-label prescriptions include prescribing a drug for a purpose not designated on the labeling, prescribing to a person in a group other than those for which the FDA approved the drug, that is prescribing a drug to a child that was approved for an adult or prescribing for an interval of time that surpasses the time indicated on the label).

17. 21 U.S.C. § 396 (2006) (explaining that the FDCA does not “limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship”). Although the government does not place limitations on physicians prescribing drugs for off-label uses, the government has placed limits on Medicare reimbursement for drugs that have been prescribed for off-label uses. To be reimbursed for an off-label use, the off-label use of the drug must be recognized in one or more of several named compendia. See, e.g., 42 U.S.C. §§ 1395x(t)(2), 1395w-102(e)(1), 1396r-8(k)(6).

18. 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 (2008).

19. *Id.*

20. FOOD AND DRUG ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERVS., 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 3 (2009) [hereinafter FDA, GOOD REPRINT PRACTICES], available at www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf.

uses. In addition, some rare medical conditions have no on-label treatments because the pharmaceutical companies cannot justify the expense of clinical trials for such a small patient population.²¹ In particular, oncology and pediatric patients are often recipients of off-label therapies.²² Further, there is little financial incentive to incur the cost of a supplemental drug approval process if the drug will soon lose its patent protection because generic drug manufacturers will enter the market and compete with the patented drug.

1. The Government's Interest in Off-Label Promotion

While there are undoubtedly benefits to prescribing drugs for off-label uses, the FDA does not look favorably upon pharmaceutical manufacturers that promote their drugs for off-label uses. The Federal Food Drug and Cosmetic Act (FDCA) and the FDA's implementing regulations generally prohibit manufacturers of new drugs from distributing products in interstate commerce for any "intended use" that the FDA has not approved as safe and effective or, in the case of generic drugs, cleared through a substantial equivalence determination.²³ Drug manufacturers engage in off-label promotion whenever they "promote or advertise their products for purposes, to users, in dosages, or in combinations other than the FDA-approved ones."²⁴ "Promotion" means all proactive activities (written, oral, or otherwise) that directly or indirectly market, sell, or support product sales and use, or that contribute to the sales growth of a company's products.²⁵ For example, the FDA views promotion as including written labeling and advertising materials, interactions with sales representatives, company websites, dissemination of journal articles, and, in some cases, trade show presentations, physician training, and reimbursement advice.²⁶ Certain Continuing Medical Education (CME) activities also can stray into promotional conduct if undertaken for the purpose of inducing commercial sales. While it is true that many medications have been used off-label successfully, the FDA rules prohibiting off-label promotion are meant to serve as an incentive for pharmaceutical manufacturers to conduct the clinical studies necessary to demonstrate safety and efficacy and ultimately gain FDA approval.²⁷

In the government's view, off-label marketing presents a danger to patients' health because the drugs have not been proven safe for their marketed uses.²⁸ The drugs have either not been through clinical testing for the unapproved use, or

21. Kesselheim, *supra* note 7, at 237.

22. *See id.* at 226–38; Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 193 (1999) ("Pediatric prescriptions are especially likely to be off-label because many drugs are not tested for use by children.").

23. *See, e.g.*, Federal Food, Drug, and Cosmetic Act §§ 505(a), 502(o), 501(f)(1)(B), 301(a), 301(d), 21 U.S.C. §§ 355, 352(o), 351(f)(1)(B), 331(a), 331(d) (2006).

24. Salbu, *supra* note 22, at 191.

25. *See id.*

26. *See* FDA, GOOD REPRINT PRACTICES, *supra* note 20.

27. *See* Salbu, *supra* note 22, at 187.

28. Kesselheim, *supra* note 7, at 239.

worse, the FDA explicitly rejected the drug as unsafe for the unapproved use based on clinical testing. Thus, when doctors prescribe drugs to patients for off-label uses, the patients can potentially suffer severe health problems or even death. Further, if a drug manufacturer were able to freely engage in off-label marketing, it would have little to no incentive to study a drug's uses and obtain definitive data on safety and efficacy. Instead, the manufacturer would simply find the use for which testing could be done most cheaply and FDA approval obtained most quickly. The manufacturer would then go on to market the drug for other applications that have not been proven safe. This would be an end-run around the FDA's efficacy standard.²⁹ More importantly, the public would be denied necessary safety and efficacy information regarding the drug.

2. Pharmaceutical Companies' Interest in Off-Label Promotion

Pharmaceutical manufacturers want the largest market possible for their products because a larger market means more profit. Thus, when developing drugs, manufacturers focus on finding the next "blockbuster" drug³⁰ that will guarantee the company at least \$1 billion in profits per year.³¹ In turn, drugs that will not likely reach blockbuster status are often not developed.³² As a result, the pharmaceutical companies rely upon a small number of blockbuster drugs to carry the company.³³ Initially, however, the market for the product is largely dependent on the outcome of clinical research.³⁴ If the clinical research does not support multiple indications for the drug, the FDA may only approve it for limited uses, which is a major obstacle to substantial profits.³⁵

The other important variable for a blockbuster drug is price. Pharmaceutical manufacturers in the United States are not subject to price controls.³⁶ Thus, they are

29. John N. Joseph, David Deaton, Houman Ehsan & Mark A. Bonanno, *Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?*, 2 J. HEALTH & LIFE SCI. L. 73, 78 (2009).

30. CECCOLI, *supra* note 8, at 2 ("Blockbuster drugs are superior selling drugs whose revenues ensure a continual stream of company profits.").

31. Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 324 (2010).

32. Lexchin, *supra* note 12, at 12.

33. See, e.g., Gregory J. Glover, Statement on Behalf of Pharmaceutical Research and Manufacturers of America Before the Federal Trade Commission and the Department of Justice-Antitrust Division: Competition in the Pharmaceutical Marketplace 6 (Mar. 19, 2002) [hereinafter Glover Statement], available at <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf> ("[Manufacturers] must rely upon a handful of flagship products for the majority of their sales, and the commercial life of a drug – from market launch to patent expiration – is generally less than seven years. Consequently, even major companies must develop a block-buster every two to three years, or face massive financial contraction.").

34. Lexchin, *supra* note 12, at 13.

35. *Id.* at 13–14 (explaining that drugs that are not found to be as safe or effective as other drugs used to treat the same or similar condition would pose a significant financial risk to the pharmaceutical company and can sometimes lead to biases in the outcome of clinical trials or failure to publish unfavorable results).

36. Lexchin, *supra* note 12, at 15 (explaining that the United States is one of the only

able to set prices for blockbuster drugs higher than they would be in Canada or Europe.³⁷ When setting the price of drugs, drug manufacturers are concerned with recouping the cost of research and development as well as generating enough profit to begin research and development of the next generation of drugs.³⁸ In 2001, drug manufacturers claimed that the average research and development costs for each new drug brought to market were \$802 million.³⁹ That figure has been widely disputed, but industry outsiders do not have access to pharmaceutical companies' records to assess the accuracy of that estimate.

The level of competition in the marketplace also influences the price considerations. Even if the drug does not have any direct competition at the time that the manufacturer introduces it, competition is heavily influenced by patent protection for blockbuster drugs. In most cases, pharmaceutical manufacturers do not have the entire twenty-year patent life to recoup their research and development costs before generic competitors enter the market.⁴⁰ Because manufacturers must

developed countries without price controls and that the pharmaceutical lobby ensured that the government would not be capable of negotiating price discounts for the new Medicare drug benefits in 2006).

37. *Id.*

38. *Id.*

39. *Cost to Bring New Drug to Market: \$802m*, HEALTHCARE ECONOMIST (April 29, 2006), <http://healthcare-economist.com/2006/04/29/802m/> (citing Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003)).

40. A pharmaceutical patent lasts for twenty years. 35 U.S.C. § 154(a)(2) (2006). The patent holder, however, does not have the full twenty years to enjoy patent protection and prevent generic manufacturers from entering the market. The patent holder loses a portion of the patent life while seeking the FDA's approval of the patented drug. RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 59 (2006). Under the Hatch-Waxman Act, some of the time spent on FDA approval is reinstated. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271). One day of patent life is restored for every two days spent on the clinical study process and for each day the FDA spent reviewing the NDA. EPSTEIN, *supra*, at 59–60. The maximum amount of patent time that may be reinstated is five years. Despite the returned patent period of up to five years, pharmaceutical patents have useful lives of nine to thirteen years while other industries enjoy useful patent lives of more than eighteen years. *Id.* at 60. The Hatch-Waxman Act also limits the ability of patent holders to prevent generic copies of their drugs from entering the market. Under the Act, generic manufacturers are permitted to both test and manufacture their drug during the patent holder's patent period, which puts the generic manufacturer in a position to sell the generic equivalent immediately upon patent expiration. *Id.* at 60; 35 U.S.C. § 271(e)(1). The Hatch-Waxman Act also simplifies the drug approval process for generic manufacturers. Generic manufacturers simply have to demonstrate bioequivalence to gain approval of the generic drug rather than safety and efficacy through clinical trials. EPSTEIN, *supra*, at 62. Bioequivalence means that the generic drug "act[s] in the body in the same way as the original innovator drug." NIHCM FOUNDATION, A PRIMER: GENERIC DRUGS, PATENTS, AND THE PHARMACEUTICAL MARKETPLACE 4 (2002). To gain FDA approval, generic manufacturers must prove that the generic has the same active ingredient, strength, dosage form, and route of administration as the branded drug. *Bioequivalence*, GENERIC PHARMACEUTICAL ASSOCIATION, <http://www.gphaonline.org/issues/bioequivalence>.

apply for a patent during the clinical testing stage, there may only be ten years to recoup their investment rather than twenty years.⁴¹ Once a patent expires, the manufacturer has little incentive to aggressively market the drug, because after generic manufacturers enter the market, the price of the blockbuster drug will fall substantially. In addition to competition from generic manufacturers at the end of the patent life of the blockbuster drug, pharmaceutical manufacturers may also face competition from other drug makers that introduce drugs to treat the same disease.⁴²

To maximize profit potential, drug manufacturers must price blockbuster drugs high and market them aggressively during the patent period. Drug manufacturers are banned from promoting drugs for off-label uses, but prescribers are not prohibited from prescribing drugs for off-label uses if, based on their medical judgment, they believe the drug will be beneficial for the patient. Thus, from a pharmaceutical company's perspective, there is a huge market that can be tapped by convincing prescribers that their drug is beneficial for off-label uses. If a drug manufacturer wants to exploit the untapped market for a drug, it has two choices. The drug manufacturer can either apply to the FDA to have an off-label use added to a drug's labeling (another costly approval process) or it can circumvent the FDA and promote the drug to prescribers for off-label uses. Because the pharmaceutical industry is largely motivated by profit, manufacturers often choose the latter path.

B. Regulatory Environment

When aggressive marketing crosses the line into off-label promotion, there are numerous federal and state agencies involved in enforcement. Because Corporate Integrity Agreements (CIAs) are entered into with the federal government, this Article focuses on the federal agencies charged with regulating the promotional activities of pharmaceutical companies.

The FDA is responsible for the approval of new drugs and for monitoring the promotional activities of pharmaceutical manufacturers, but the FDA plays a relatively small role in enforcement because of the relationship to Medicare and Medicaid. Medicare is a federally funded insurance program for individuals who are age sixty-five or older.⁴³ Medicaid is a joint federal-state program that supports states' coverage of medical care and other support services for certain categories of low-income individuals.⁴⁴ The federal government pays a share, known as the

41. EPSTEIN, *supra* note 40, at 59.

42. See, e.g., Glover Statement, *supra* note 33, at 8 (“[B]reakthrough drugs generally face competition within their initial patent life from other branded drugs of the same therapeutic class. This sets up a competitive environment in which branded rivals rely heavily on product differentiation to achieve competitive advantage over other branded rivals.”).

43. 42 U.S.C. §§ 1395–1395h; *Medicare Program—General Information: Overview*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/MedicareGenInfo/> (noting that Medicare provides coverage to those aged sixty-five and older, individuals with certain disabilities, and individuals with end-stage renal disease).

44. *Id.*

Federal Medical Assistance Percentage (FMAP), of each state's Medicaid costs.⁴⁵ Once the FDA has approved a drug, Medicare and Medicaid provide reimbursements for prescription drug costs. On the federal level, both programs are run by the Center for Medicare and Medicaid Services (CMS). Because the promotion of drugs for off-label uses can lead to off-label prescriptions that are reimbursed by CMS, the FDA is not the only government agency concerned with the promotional activities of pharmaceutical manufacturers.

CMS does not cover prescription drug costs for Medicare and Medicaid patients without regard to whether the FDA has approved the drug, but FDA approval is not the sole consideration in reimbursement decisions. CMS will pay prescription drug claims for any on-label use for prescription drugs that have been approved under the FDCA.⁴⁶ For off-label prescriptions, however, the reimbursement is contingent on whether there is a "medically accepted indication" for the drug.⁴⁷ To constitute a "medically accepted indication" for the drug, the use of the drug in an off-label manner must be "included or approved for inclusion" in one of the three endorsed drug compendia.⁴⁸ A drug compendium is a complete listing of FDA-approved drugs and biologics that includes an explanation of how each drug works, proper dosing, and whether the drug is recommended for treatment for specific diseases.⁴⁹ Because scientific information may support the use of particular drugs for indications not approved by the FDA, the compendium may recommend uses that are not a part of the FDA-approved label for the drug. Thus, if an off-label use is endorsed in one of the three approved drug compendia, CMS will likely reimburse for the off-label prescription. CMS also determines the rate of reimbursement for a particular drug.⁵⁰ Unlike the FDA's decision making, which is one of "benefit versus risk," CMS's coverage-for-reimbursement decision "is first one of benefit per se, and then one of benefit versus cost."⁵¹ If a state makes an improper Medicaid payment to a health care provider for an off-label use that is not listed in one of the drug compendia, there will be a corresponding improper federal payment by CMS because Medicaid is a matching program.⁵²

45. See THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED, THE MEDICAID PROGRAM AT A GLANCE 2 (2010), available at <http://www.kff.org/medicaid/7235.cfm>.

46. Social Security Act § 1927(k)(2)(A)(i), 42 U.S.C. § 1396r-8(k)(2)(A)(i).

47. Social Security Act § 1927(d)(1)(B)(i), (k)(3), (k)(6), 42 U.S.C. § 1396r-8(d)(1)(B)(i), 8(k)(3), 8(k)(6).

48. *Id.* § 1927(g)(1)(B)(i), (k)(6), 42 U.S.C. § 1396r-8(g)(1)(B)(i), (k)(6). The three approved drug compendia include: (1) the American Hospital Formulary Service Drug Information; (2) the United States Pharmacopeia-Drug Information; and (3) the DRUGDEX Information System. *Id.* § 1927(g)(1)(B)(i), 42 U.S.C. § 1396r-8 (g)(1)(B)(i). CMS uses different compendia to determine a "medically accepted indication" for anti-cancer drugs. See *id.* § 1861(t)(2)(A), 42 U.S.C. § 1395x(t)(2)(A).

49. Joshua Cohen, Andrew Wilson & Laura Faden, *Off-Label Use Reimbursement*, 64 FOOD & DRUG L.J. 391, 396 (2009).

50. Patsner, *supra* note 10, at 55.

51. *Id.* ("The CMS standard clearly encompasses financial security so that money is not wasted on expensive medical products with little or no advantage for its beneficiaries over existing, less expensive ones.")

52. *Bolstering the Safety Net: Eliminating Medicaid Fraud: Hearing Before the Federal Financial Management, Government Information, and International Security Subcommittee*

Due to the reimbursement issues involving CMS, the Health and Human Services Office of Inspector General (OIG) is necessarily involved in enforcement. OIG is responsible for eliminating “waste, abuse, and fraud” in Health and Human Services (HHS) programs and operations.⁵³ One of OIG’s chief responsibilities is protecting the integrity of programs such as Medicare and Medicaid. Within OIG, the Office of Investigations is responsible for performing investigative activities related to allegations of fraud, waste, abuse, and mismanagement in HHS programs by applicants, grantees, contractors, or by HHS employees in the performance of their official duties.⁵⁴ In addition, the Office of Investigations serves as the liaison to the Department of Justice (DOJ) on all matters relating to investigations of HHS programs when OIG has reasonable grounds to believe federal criminal law has been violated.⁵⁵ OIG also serves as the liaison with CMS and investigates Medicare and Medicaid fraud by pharmaceutical companies.⁵⁶ Further, OIG serves as the liaison with state licensing boards with regard to exclusion, compliance, and enforcement activities.⁵⁷ OIG also administers CIAs and enforces permissive and mandatory exclusions imposed through liaison with CMS, the DOJ, and other governmental and private sector entities.⁵⁸ Finally, OIG provides industry guidance on compliance with the federal health care laws.⁵⁹

The DOJ is also heavily involved in health care fraud and abuse cases because it has joint responsibility with OIG for pharmaceutical promotional fraud and abuse under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁶⁰ There are several ways that the DOJ can become involved in a pharmaceutical marketing fraud case. First, the FDA may refer a case that involves the FDCA to the Consumer Protection Branch of the Civil Division.⁶¹ The FDCA prohibits the

of the Committee on Homeland Security and Governmental Affairs, 109th Cong. 10 (2006) (testimony of Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services). It should be noted that detection of off-label uses has been a problem because prior authorization is not needed before most pharmaceuticals are dispensed. In those situations, it is difficult to ascertain whether the drugs are being prescribed for off-label uses. Audits are often utilized to determine off-label use. See Cohen et al., *supra* note 49, at 395.

53. *Organizational Structure*, OFFICE OF INSPECTOR GEN., <https://oig.hhsc.state.tx.us/AboutOIG/OrgStructure.aspx>.

54. Office of Inspector General, Statement of Organization, Functions and Delegations of Authority, 69 Fed. Reg. 40,390 (Dep’t of Health and Human Servs. July 2, 2004) (notice).

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.* at 40,391.

59. Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 247 (2006).

60. P.L. 104-191, 110 Stat. 1936 (codified at 42 U.S.C. § 201 (2006)). HIPAA created the Health Care Fraud and Abuse Control Program, an expansive program to address fraud and abuse in health care, including both public and private health plans. This program is under the joint direction of the Secretary of HHS and the attorney general. It is designed to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. 42 U.S.C. § 1320a-7c(a)(1).

61. See U.S. ATTORNEYS MANUAL 4-8.205 (2011). The DOJ’s Consumer Protection Division of the Civil Branch was formerly known as the Office of Consumer Litigation. *Id.*

introduction of any misbranded drug into interstate commerce.⁶² A drug is misbranded when its label is false or misleading or when it has inadequate directions for use.⁶³ All intended uses must have adequate directions for their use, but the drug label may only contain information on approved uses. Therefore, the government's theory under the FDCA when pursuing off-label promotion is that the manufacturer has provided inadequate directions for the intended off-label use of the drug. Because the drug has not been shown to be safe and effective for the off-label use, a drug promoted for uses that are not listed on the label, by definition, must be misbranded because there are no directions for the use.⁶⁴ Alternatively, the government may pursue a pharmaceutical manufacturer for a misbranding violation under the theory that by promoting the drug for off-label uses, the pharmaceutical manufacturer has introduced an unapproved new drug into the market. An FDA-approved drug can be considered a new drug if it is promoted for unapproved uses.⁶⁵ Therefore, promoting an existing drug for a new use is tantamount to introducing an unapproved new drug into interstate commerce.

Second, the DOJ may get involved due to a civil False Claims Act (FCA) case brought by a whistleblower. The FCA makes it unlawful to knowingly present, or cause to be presented, false or fraudulent claims paid by the government.⁶⁶ The FCA allows private citizens, known as "relators," to bring qui tam suits in the name of the government, based on the individual's knowledge of fraud against the government.⁶⁷ Whistleblowers are incentivized to bring suits because they are

at 4-8.010.

62. 21 U.S.C. § 331(a).

63. *Id.* § 352(a), (f). "Adequate directions for use" means that the directions are sufficiently clear that a layperson could use a drug safely and effectively for the intended use. 21 C.F.R. § 201.5 (2010).

64. 21 C.F.R. § 201.100.

65. *Id.* § 310.3(h)(4)–(5). The newness of a drug may arise due to its use in treating a condition "even though such drug is not a new drug when used in another disease . . ." *Id.* § 310.3(h)(4). Further, the newness of a drug may be shown by using an approved drug in a dosage that differs from the label "even though such drug when used in other dosage . . . is not a new drug." *Id.* § 310.3(h)(5).

66. 18 U.S.C. § 287.

67. 31 U.S.C. § 3730(b)(1). To discourage opportunistic relators, the FCA prevents relators from bringing a claim based on publicly disclosed information. JENNIFER STAMAN, CONG. RESEARCH SERV., RS 22743, HEALTH CARE FRAUD AND ABUSE LAWS AFFECTING MEDICARE AND MEDICAID: AN OVERVIEW 10–12 (2010), <http://aging.senate.gov/crs/medicaid20.pdf>. Thus, if there was a public disclosure of information in:

- (1) a criminal, civil, or administrative hearing, (2) in a congressional, administrative, or Government Accountability Office (GAO) report, hearing, audit, or investigation, or (3) from the news media, unless the action is brought by the Attorney General or the relator bringing the action is an "original source" of the information. A relator was defined as an original source if the relator had direct and independent knowledge of the information on which the allegations of the FCA claim are based and had voluntarily provided the information to the government before filing an action.

Id. at 9 (citing 31 U.S.C. § 3730(e)(4)(A)–(B)). The Patient Protection and Affordable Care Act (PPACA) loosens some of these requirements. Under the PPACA, the government is given discretion to determine whether to allow a qui tam suit to go forward despite the fact that the information was publicly disclosed. *Id.* Further, PPACA makes the public disclosure

entitled to a portion of the recovery if the suit is successful. Relators file suit under the FCA for fraud resulting from off-label promotion due to the negative effects it has on state and federally funded programs such as Medicaid, which may prohibit reimbursement for off-label prescriptions. The suit is filed under seal and the government has sixty days to determine whether to take over the case as its own or to leave the case to the relator to litigate.⁶⁸ If the DOJ decides to take over the qui tam case, it may serve a civil investigative demand (CID) to obtain documentary evidence “for the purpose of ascertaining whether any person is or has been engaged in” a violation of the FCA.⁶⁹

The theory of liability under the FCA is that a manufacturer is liable if it knowingly engages in a promotional program that induces third parties to file Medicare or Medicaid reimbursement claims for off-label uses that were not eligible for reimbursement.⁷⁰ The difficulty is that even though the federal government pays for drugs provided to Medicare or Medicaid beneficiaries, the pharmaceutical manufacturers do not bill the federal government directly for their drugs. Thus, the government could not use the normal theory of liability under the FCA—that the pharmaceutical manufacturer submitted a claim to the government for payment of prescriptions that are not reimbursable under Medicare and Medicaid. Because submitting a claim to the government is the touchstone theory of liability under the FCA, the government needed to create the innovative theory concerning inducement to file a claim. This theory has not been tested in court. Indeed, it would be difficult to prove that a particular reimbursement claim is due to off-label promotion as opposed to the doctor’s professional judgment. The government has used the theory to leverage huge settlements with pharmaceutical manufacturers, however, because the manufacturers could not risk testing the government’s theory in court.

In May 2009, Congress simplified the theory of recovery under the FCA when it enacted the Fraud Enforcement and Recovery Act of 2009 (FERA).⁷¹ Under FERA, it is no longer a requirement that a false claim be submitted to the government. Instead, if the false claim is paid out of government funds or with funds that are “spent or used on the Government’s behalf or to advance a Government program or interest,” liability will attach.⁷² Thus, the theory of liability under the FCA is much more straightforward after FERA. If Medicare and Medicaid reimburse a

bar applicable only if the information was obtained from federal government or media sources. It does not apply if the information was learned from a state source. *Id.* at 10. Finally, the PPACA alters the definition of original source.

Under PPACA, an original source is one who (1) has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or (2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing an action.

Id. (citing 31 U.S.C. § 3730(e)(4)(B)).

68. 31 U.S.C. § 3730(b)(2).

69. *Id.* §§ 3733(a)(1), 3733(1)(2). The CID may include document requests, written interrogatories, and depositions. *Id.*

70. Osborn, *supra* note 7, at 329.

71. S. 386, 111th Cong. (2009) (enacted).

72. *Id.*

pharmaceutical manufacturer's products, any violation of the FDCA, such as off-label promotion, is actionable under the FCA.

Third, OIG may refer a case to the DOJ because they have a reasonable belief that federal criminal law, such as the Anti-Kickback Statute (AKS), has been violated. The AKS makes it unlawful to: (1) knowingly and willfully; (2) offer or pay, solicit or receive; (3) any remuneration;⁷³ (4) to induce the referral of an individual to another person or entity for the "furnishing of any item or service"; or to induce the purchasing or ordering of such item or service; (5) payable "in whole or in part" by a federal health care program.⁷⁴ Prior to the Patient Protection and Affordable Care Act (PPACA),⁷⁵ there was a circuit split on whether the mens rea requirement of "knowingly and willfully" required a specific intent to violate the AKS.⁷⁶ The specific intent requirement that some courts imposed made it more difficult to obtain a conviction because defendants could assert that they did not know that their conduct violated the AKS. The PPACA resolved the circuit split, stating: "a defendant does not have to have actual knowledge of, or specific intent to commit a violation of, the anti-kickback statute."⁷⁷ Criminal conviction under the AKS leads to a fine of up to \$25,000, up to five years imprisonment, and mandatory exclusion from participation in Medicare and Medicaid for up to one year.⁷⁸

In addition to being a source for criminal charges, violations of the AKS are often used as the basis for civil actions against pharmaceutical companies under the FCA.⁷⁹ If a person or entity is involved in a kickback scheme involving Medicare or Medicaid, that person or entity may face civil liability under the FCA if the person knowingly submits, or causes a third party to submit, false or fraudulent claims for goods or services tainted by kickbacks.⁸⁰ Prior to the enactment of the PPACA, relators attempting to hold pharmaceutical manufacturers liable under the FCA for violations of the AKS had to prove that the claims submitted were false.⁸¹ It was difficult for relators to prove falsity because even though the AKS may have been violated, the prices for the drugs that were submitted for reimbursement were correct.⁸² Thus, relators alleged that the claim was legally false because the entity or person submitting the claim falsely certified compliance with the AKS.⁸³ An

73. "Remuneration" does not include a discount or other reduction in price obtained by a provider of services or other entity if the reduction in price is properly disclosed and reflected in the costs claimed or charges made by the provider or entity under a federal health care program. 42 U.S.C. § 1320a-7b(b)(3).

74. *Id.* § 1320a-7b(b)(2).

75. Pub. L. No. 111-148, 124 Stat. 121 (2010) (to be codified in scattered sections of 21, 25, 26, 29 & 42 U.S.C.).

76. STAMAN, *supra* note 67, at 4 (citing *Hanlester Network v. Shalala* 51 F.3d 1390, 1399-1400 (9th Cir. 1995) and *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998)).

77. *Id.* at 4-5; Pub. L. No. 111-148, §6402(f)(2), 124 Stat. 121, 759 (codified at 42 U.S.C. § 1320a-7b(h)).

78. STAMAN, *supra* note 67, at 2.

79. *Id.*

80. *See id.* at 8 n.43.

81. *Rost v. Pfizer Inc.*, 736 F. Supp. 2d 367, 375-378 (D. Mass. 2010).

82. *Id.* at 376.

83. "False certification can be express, where the claim is accompanied by an explicit

example may be helpful here. Assume that a pharmaceutical manufacturer has paid doctors to prescribe its drugs in violation of the AKS. The doctor prescribes the manufacturer's drugs to a Medicare or Medicaid patient who then goes to the pharmacy to fill the prescription. After filling the prescription, the pharmacy submits a claim for reimbursement to Medicare or Medicaid. The claim, the theory goes, is tainted by the pharmaceutical manufacturer's kickback and should be considered false. Again, a pharmaceutical manufacturer does not directly submit claims to the government for reimbursement. Therefore, this tainted claim theory under the AKS ran into the most difficulty when the claims were not submitted by a participant in the kickback scheme. In other words, when the claim was submitted by innocent third parties, such as pharmacies, that: (1) were unaware of the kickbacks, (2) only certified their own compliance with the AKS, or (3) did not expressly certify compliance with the AKS,⁸⁴ the government could not demonstrate falsity under the FCA.

The PPACA does away with the falsity requirement for claims submitted by an innocent third party. The amendment to the AKS states that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the FCA]."⁸⁵ It does not matter whether the doctor who was part of the kickback scheme submits the tainted claim or an innocent third party submits the claim. Thus, relators no longer need to claim that the innocent third party expressly or impliedly certified compliance with the AKS to prove that there was a false claim under the FCA. Thus, the PPACA removed a major hurdle to holding pharmaceutical manufacturers liable under the FCA for claims tainted by the AKS.

In sum, the FDA, OIG, and the DOJ work collectively to enforce the federal health care fraud laws against pharmaceutical manufacturers. Most cases will involve misbranding violations, kickbacks, or false claims. Pharmaceutical manufacturers' potential liability for illegal marketing practices has increased in the last few years through amendments to the FCA by FERA and the PPACA. Further, the PPACA makes it easier to bring cases against pharmaceutical manufacturers involving kickbacks and false claims.

C. Exclusion

The Social Security Act authorizes the Secretary of HHS (and, through a delegation of authority, OIG) to exclude individuals and entities that have engaged in fraud or abuse from participation in federal health care programs, such as Medicare and Medicaid.⁸⁶ OIG sets its own policies with respect to its exclusion authority: "Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under

statement of compliance, or implied, where the act of submitting the claim implies compliance." *Id.* at 375.

84. *See, e.g., id.* at 367–78 (finding that these types of claims are not false under the FCA).

85. 42 U.S.C. § 1320a–7b(b)(2) (2006).

86. 42 U.S.C. § 1320a-7 (2011). The statutory term "participation" refers to individuals and entities that have entered into an agreement with the Centers for Medicare and Medicaid Services to bill and receive program payment for services furnished to beneficiaries. *Id.*

Medicare, Medicaid and all other federal health care programs until the individual or entity is reinstated by OIG.”⁸⁷ Exclusion for a period of five years is mandatory following a criminal conviction, and is permissive when a provider engages in less serious infractions.⁸⁸ The effect of exclusion is that no federal health care program payment may be made for any items or services either (1) “furnished” by an excluded individual or entity or (2) directed or prescribed by an excluded physician.⁸⁹

In 1992, OIG stated that it would only apply its exclusion authority against participating providers who receive payment directly from the program, such as physicians and hospitals.⁹⁰ Thus, OIG did not assert exclusion authority over indirect providers, such as pharmaceutical and biotechnology companies, because they did not receive Medicare and Medicaid payments directly.⁹¹ In 1997, however, OIG changed course and expanded its exclusion authority to include indirect providers such as pharmaceutical and biotechnology companies.⁹² Under the new rule, the effect of exclusion of a pharmaceutical manufacturer is that “no payment would be made to any direct provider for items and services manufactured, distributed or otherwise provided” by the excluded pharmaceutical manufacturer.⁹³

OIG must follow a standard procedure to exercise its exclusion authority against a pharmaceutical company or any other entity. When OIG wants to exclude an entity, it sends a notice of intent to exclude.⁹⁴ The entity has thirty days to submit a

87. 42 C.F.R. § 1001.2 (1999) (emphasis omitted).

88. STAMAN, *supra* note 67, at 2–3 (citing 42 U.S.C. § 1320a-7a(b)) (“Exclusion is mandatory for those convicted of certain offenses, including (1) a criminal offense related to the delivery of an item or service under Medicare, Medicaid, or a state health care program; (2) a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service; or (3) a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. OIG has ‘permissive’ authority to exclude an entity or an individual from a federal health program under numerous circumstances, including conviction of certain misdemeanors relating to fraud, theft, embezzlement, breach of fiduciary duty or other financial misconduct; a conviction based on an interference with or obstruction of an investigation into a criminal offense; and revocation or suspension of a health care practitioner’s license for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity.”).

89. 42 C.F.R. § 1001.1901.

90. Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from Public Law 100-93, 57 Fed. Reg. 3298, 3300 (Jan. 29, 1992) (to be codified at 42 C.F.R. §§ 1001–06).

91. *Id.* (explaining that although OIG has the authority to do so, they choose not to include entities that furnish items covered by Medicare but that do not receive program payments directly due to the difficulty of administering the exclusions).

92. 42 C.F.R. § 1000.10 (2003) (“*Furnished* refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.” (emphasis in original)).

93. *Id.*

94. 42 C.F.R. § 1001.2001 (2011).

written response.⁹⁵ If OIG reviews the entity's response and decides to exclude, it issues a notice of exclusion to the entity.⁹⁶ Upon exclusion, the entity has the right to an appeal before an administrative law judge (ALJ).⁹⁷ Following the ALJ's decision, the entity has thirty days to appeal the decision to the Departmental Appeals Board.⁹⁸ The Departmental Appeals Board's decision is considered final and may be appealed in federal court.⁹⁹

D. Corporate Integrity Agreements

Despite the fact that exclusion is available as a remedy, it is hardly, if ever, invoked against a pharmaceutical manufacturer. Instead, the government uses the threat of exclusion to convince manufacturers to enter into CIAs and enact far-reaching corporate reforms. CIAs are administrative settlements negotiated with OIG that require organizations to undertake compliance and integrity obligations for a term of three to five years.¹⁰⁰ Organizations enter into CIAs to settle alleged violations of federal health care program requirements such as off-label promotion of drugs, kickbacks, or overbilling of Medicare and Medicaid for health services.¹⁰¹ In most situations, the CIA is one part of a global settlement that involves the DOJ, the FDA, civil litigants, and the states.¹⁰² The organization pays a large fine and, in return, OIG agrees not to pursue exclusion of the organization from Medicare and Medicaid. OIG has entered into hundreds of CIAs in the past ten years.¹⁰³ At the beginning of most CIAs, there is a statement that the company entering into the agreement has a compliance program in place.¹⁰⁴ Next, the CIA will address the

95. *Id.*

96. *See* 42 C.F.R. §§ 1001.2002, 2003 (explaining the notice requirements).

97. *Id.* § 1001.2001; § 1005.2.

98. *Id.* § 1005.21.

99. *See id.*

100. Scott A. Memmott & Betsy McCubrey, *Recent Trends Involving CIAs Significantly Raise Stakes for Health Care Industry Participants*, 11 J. HEALTH CARE COMPLIANCE 51, 55 n.1 (2009).

101. *Id.*

102. For example, in 2009 Pfizer entered into a CIA and a settlement agreement with the DOJ, the TRICARE Management Activity, and the relators in the civil FCA case. *See* CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PFIZER INC. (Aug. 31, 2009) [hereinafter CIA PFIZER 2009], available at http://oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf; U.S. DEP'T OF JUSTICE, SETTLEMENT AGREEMENT (2009), available at <http://www.justice.gov/usao/ma/Press Office - Press Release Files/Pfizer/Pfizer Settlement Agreement.pdf>.

103. For a complete list of CIAs, see Corporate Integrity Agreement Documents, OFF. INSPECTOR GEN. (Nov. 4, 2011), http://www.oig.hhs.gov/fraud/cia/cia_list.asp (listing and providing CIAs beginning in 2003). Many of these CIAs involve named individuals, such as doctors, or health care providers, such as hospitals, but the focus here is on CIAs involving pharmaceutical manufacturers. *See also* Ralph F. Hall, *Corporate Integrity Agreements, in* PUNISHING CORPORATE CRIME: LEGAL PENALTIES FOR CRIMINAL AND REGULATORY VIOLATIONS 97, 99 (James T. O'Reilly et al. eds., 2009).

104. *See* Hall, *supra* note 103, at 100.

scope of the agreement which ordinarily involves: (1) whether the whole company has obligations under the agreement or only certain subsidiaries or divisions; (2) the responsibilities of the individuals within the company; and (3) the kind of business endeavors that are covered.¹⁰⁵ With each of these, the government wants the scope to be as broad as possible, and the company wants it to be narrow to save the expense of compliance and the risk of future violations.¹⁰⁶

Once the term and scope of the agreement have been set forth, the CIA will address the “Corporate Integrity Obligations” that the organization must meet. It is standard for the CIA to require the creation of a compliance committee and the selection of a compliance officer who is a part of senior management and has immediate contact with the board of directors.¹⁰⁷ The organization is required to inform OIG if it changes the compliance officer.¹⁰⁸ In some cases, OIG may dictate to whom the compliance officer should or should not report within the organization.¹⁰⁹ OIG may also specify the members of the compliance committee and the information flow between the compliance committee and other business units within the organization.¹¹⁰ In recent years, OIG has also required the board of directors to take an active role in supervising the compliance program and make certifications regarding its effectiveness.¹¹¹

As the use of CIAs has increased, so too has OIG’s level of sophistication in crafting the Corporate Integrity Obligations. Before 2008, most CIAs required corporate compliance officers to make certifications regarding the effectiveness of the company’s compliance program.¹¹² Beginning with Cephalon, Inc.’s September

105. *Id.* at 100–01. In particular, questions of scope often involve questions about whether the entire company, only certain business units, or a subsidiary of the company will be governed by the agreement. *Id.* at 101.

106. *Id.* at 101–02.

107. *Id.* at 102.

108. *Id.*

109. *Id.*

110. *Id.* at 102–03.

111. *Id.* at 103. Some recent agreements include language specifying that the board is “responsible for the review and oversight of matters related to compliance” and specifying quarterly meetings to review the performance of the compliance officer and department. *Id.* (quoting CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ELI LILLY AND COMPANY 5 (Jan. 14, 2009) [hereinafter CIA ELI LILLY], *available at* http://www.oig.hhs.gov/fraud/cia/agreements/eli_lilly_and_company_01142009.pdf). Further, some CIAs now require the board of directors to adopt “a resolution . . . summarizing its review and oversight of [the company’s] compliance with federal health care program requirements, FDA requirements, and the obligations of this CIA. Each individual member of the Board . . . shall sign a statement indicating that he or she agrees with the resolution.” *Id.* (quoting CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CEPHALON, INC. (Sept. 29, 2008) [hereinafter CIA CEPHALON], *available at* <http://www.oig.hhs.gov/fraud/cia/agreements/cephalon.pdf>). The organization must keep OIG abreast of any changes to the composition of the board. *Id.*

112. *See* Memmott & McCubrey, *supra* note 100, at 53 (explaining that compliance officers had to certify, inter alia, that training had been completed, that policies had been

2008 CIA, however, OIG began requiring certifications from executives and upper management.¹¹³ The new requirements, entitled “Management Accountability and Certifications,” generally require the “certifying employee” to sign a certification stating that: (1) the individual has received training and comprehends the compliance requirements and responsibilities for the individual’s department; (2) the individual’s job responsibilities include ensuring compliance for the individual’s department; and (3) the department is “in compliance with all applicable federal health care program requirements, FDA requirements and the obligations of the CIA.”¹¹⁴ These new certification requirements raise the stakes for management in the event of noncompliance because the certifying individuals may be subject to personal liability.¹¹⁵

In addition to certification requirements, the CIAs require the organization to implement codes of conduct that set forth the compliance rules and obligations, anonymous reporting systems, and a nonretaliation policy.¹¹⁶ Further, CIAs typically require training on the obligations within the CIAs and the company’s compliance program.¹¹⁷ Another common provision of CIAs is the company’s obligation to hire an Independent Review Organization (IRO) to audit systems and transactions within the organization.¹¹⁸ The IRO typically has a limited focus on particular compliance obligations.¹¹⁹ CIAs also mandate a toll-free hotline system that allows individuals to anonymously disclose noncompliance directly to the compliance office.¹²⁰ The organizations must follow up and investigate all reports of noncompliance.¹²¹ There are also substantial reporting requirements for allegations of misconduct.¹²² Further, CIAs require periodic or annual reports to OIG, and OIG retains the right to review the organization’s documents to ensure

reviewed and updated, and that the company is in compliance with all federal health care program requirements).

113. *Id.* Specifically, CIAs may now require certifications from the chairman, president, chief executive officer, executive vice presidents, senior vice presidents, executive directors, business unit sales and marketing vice presidents, chief marketing and operations officer, chief medical officers, business unit sales directors, medical directors of communications and medical science liaisons, national and executive sales directors, brand leaders, and directors of business units of the parent corporation or any affiliate that performs pricing, sales, marketing, contracting, promotion, medical affairs, or medical information functions. *Id.*

114. *See* Hall, *supra* note 103, at 104 (quoting CIA ELI LILLY, *supra* note 111); *see also* Memmott & McCubrey, *supra* note 100, at 53.

115. Hall, *supra* note 103, at 104.

116. *Id.* at 105; *see also* CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PFIZER INC. (May 11, 2004) [hereinafter CIA PFIZER 2004] (on file with author).

117. Hall, *supra* note 103, at 105–06.

118. *Id.* at 106–07; *see* CIA PFIZER 2009, *supra* note 102, at app. B at 1 (“Pfizer shall retain an Independent Review Organization (IRO) to perform reviews to assist Pfizer in assessing and evaluating its systems, processes, policies, procedures, and practices related to Pfizer’s Promotional and Product Related Functions.”).

119. Hall, *supra* note 103, at 107.

120. *Id.* at 107.

121. *Id.*

122. *Id.* at 108.

compliance with the CIA.¹²³ Finally, CIAs specify the terms under which a breach of the agreement will be found and the consequences for that breach. A breach of the CIA can lead to substantial penalties, or, if there is a “material breach,” OIG can pursue exclusion of the company from Medicare and Medicaid.¹²⁴

II. CIAS AND DETERRENCE

OIG has entered into CIAs in lieu of pursuing drug manufacturers civilly or criminally for health care fraud, which would lead to either permissive or mandatory exclusion from Medicare and Medicaid. The main goals of the CIA appear to be reform and rehabilitation. This Part will examine the costs and benefits of CIAs and whether CIAs are an effective deterrent for off-label promotional activities. This Part concludes that CIAs are ineffective deterrents for repeat offenders of the promotional laws.

A. *The Use of CIAs Instead of Exclusion Authority*

1. The Cost-Benefit Analysis of CIAs

CIAs are beneficial to the manufacturer, the government, and the public at large. Because of the CIA, the pharmaceutical manufacturer is able to avoid being excluded from federal health care programs such as Medicare and Medicaid. Medicare and Medicaid revenue brings in millions, or in some cases, billions, of dollars of revenue for pharmaceutical manufacturers every year.¹²⁵ If all of the drugs from a particular manufacturer were excluded from Medicare and Medicaid reimbursement, the manufacturer would be in danger of collapse, which would lead to negative externalities for the employees and patients. The company would lose revenue, and employees would lose their jobs. In addition, the patients would be greatly harmed. Elderly and poor patients would no longer be able to obtain their prescriptions through Medicare and Medicaid. They would have to either pay for the medications themselves or switch to medications produced by a non-excluded pharmaceutical manufacturer. But it is not always the case that there would be a substitutable drug available from another manufacturer. Thus, pharmaceutical companies benefit from the CIA because they are able to avoid these negative consequences. In turn, patients benefit from CIAs because they do not incur the negative externalities that would result from exclusion. Patients are able to continue their treatment without any interruption in benefits because the manufacturer entered into a CIA.

Finally, the government benefits from entering into a CIA because CIAs allow the government to save the expense of trial, collect a large settlement, gain

123. *Id.* at 110.

124. *Id.* at 111.

125. See Centers for Medicare and Medicaid Services, CMS.GOV, https://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage (follow “National Health Expenditures by Type of Service and Source of Funds: Calendar Year 1960–2010” hyperlink).

sweeping reforms, and appear to be tough on health care fraud.¹²⁶ Health care fraud cases, particularly those based on off-label marketing, take years to investigate. In addition, the cases are challenging, multifaceted, and expensive to prosecute.¹²⁷ Pharmaceutical companies have a wealth of resources and will mount a vigorous defense to any charges of wrongdoing.¹²⁸ By settling, the government saves substantial resources that would otherwise be expended to take the case to trial and also avoids the risk that some of their fraud theories may not stand up in court. The government also benefits from settlement because the threat of exclusion assists the government in obtaining huge settlements from drug manufacturers. Further, the money that the government obtains goes straight into the federal treasury, which benefits the public. Inevitably, the settlement includes reforms agreed to by the manufacturer that greatly benefit the public. The government sends out press releases touting the huge settlements and reform concessions that they obtained from pharmaceutical manufacturers, which makes them appear tough on health care fraud. The government appears even tougher when they are able to assert that as part of the settlement, a subsidiary of the drug manufacturer pled guilty to a felony in federal court or the manufacturer itself pled guilty to a misdemeanor in federal court. A guilty plea by a subsidiary, however, is often a sham because the manufacturer is able to transfer assets and operations from the subsidiary to the parent company prior to the exclusion. As a result, the exclusion of the subsidiary does not impact the parent company. Similarly, a plea of guilty to misdemeanor charges does not lead to exclusion of the manufacturer.

Despite the benefits of the CIA, the costs are substantial. The government bears very little of the cost, because the majority of the costs of compliance are paid by the drug manufacturer.¹²⁹ The drug manufacturer must pay the fine, which may range from hundreds of millions of dollars to several billion dollars plus additional costs that spring from the implementation of the CIA.¹³⁰ The costs associated with

126. See *Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion*, *supra* note 6; Press Release, U.S. Dep't of Justice, Pharmaceutical Company AstraZeneca to Pay \$520 Million for Off-Label Drug Marketing (Apr. 27, 2010), available at http://www.justice.gov/usao/pae/Pharma-Device/astrazeneca_release.pdf; Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm.

127. Vikramaditya Khanna & Timothy L. Dickinson, *The Corporate Monitor: The New Corporate Czar?*, 105 MICH. L. REV. 1713, 1721 (2007) (explaining the incentives that the government has to settle corporate crime cases).

128. *Id.*

129. 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, 100 (2009).

130. See 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), available at <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>; Press Release, U.S. Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in its History (Sept. 2, 2009), available at <http://www.justice.gov/opa/pr/2009/September/09-civ-900.html>; Press Release, U.S. Dep't of Justice, Novartis Pharmaceuticals Corporation to Pay \$422.5 Million for Off-Label Drug Marketing (Sept. 30, 2010), available at

the CIA may include: hiring an independent review organization (IRO); changes to the corporate compliance program; changes to the corporate structure in the area of corporate compliance and legal counsel; and training programs.¹³¹ Nevertheless, it is in the best interests of the manufacturer to enter into a CIA no matter how onerous the terms because the company must consider the potential loss of revenue from Medicare and Medicaid. The manufacturer simply cannot risk the loss of revenue and damage to the company that would result from exclusion from Medicare and Medicaid. Thus, for the manufacturer, the government, and the public, the benefits of CIAs far outweigh the costs.

2. The Repeated Use of CIAs: The Case of Pfizer

Although government investigations into health care fraud pose substantial risks for pharmaceutical manufacturers, manufacturers realize that the government is not going to pursue them in court and seek exclusion because of the substantial harm to patients. At most, the government will require the pharmaceutical manufacturers to enter into new CIAs. The problem is the moral hazard that this enforcement reality creates. Even when a pharmaceutical manufacturer that is already under a CIA engages in off-label promotion of drugs, the government simply waives the manufacturer's liability for violating the existing CIA, imposes an even larger fine, and enters into a new CIA.¹³² Thus, there is little incentive for the manufacturer to cease the wrongful conduct as long as the profits from off-label promotion greatly exceed the fines.

The Pfizer story illustrates the issues surrounding the use of successive CIAs. Pfizer acquired Warner-Lambert in 2000.¹³³ At the time of the acquisition, Warner-Lambert was under investigation by the government for off-label marketing of the drug Neurontin and had been sued civilly under the FCA.¹³⁴ In its promotion of Neurontin, Warner-Lambert promoted the drug for uses for which it was not approved, paid doctors to induce them to promote and prescribe Neurontin for off-label uses, and made false statements regarding the uses for which the FDA approved Neurontin.¹³⁵ In 2004, OIG settled with Pfizer for \$430 million plus interest and entered into a CIA whereby OIG agreed not to pursue exclusion from Medicare and Medicaid for Pfizer.¹³⁶ In addition, Warner-Lambert pled guilty to violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1), and 355.¹³⁷ Because

http://www.justice.gov/usao/pae/Pharma-Device/novartis_release.pdf.

131. See Boozang & Handler-Hutchinson, *supra* note 129, at 100–01.

132. See Christopher A. Wray & Robert K. Hur, *Corporate Criminal Prosecution in a Post-Enron World: The Thompson Memo in Theory and Practice*, 43 AM. CRIM. L. REV. 1095, 1168 n.344 (2006).

133. See Matthew Herper, *Pfizer's Warner-Lambert Acquisition Has Side Effects*, FORBES.COM (June 21, 2000, 2:55 PM), <http://www.forbes.com/2000/06/21/mu5.html>.

134. United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001).

135. SETTLEMENT AGREEMENT AND RELEASE 3–4 (May 13, 2004) (on file with author).

136. See *id.* at 5–10; Press Release, Office of Inspector General, OIG Report Highlights Progress Against Waste, Abuse, and Fraud (Dec. 9, 2004), available at <http://www.oig.hhs.gov/publications/docs/press/2004/120904Release.pdf>

137. Letter from Michael J. Sullivan, United States Attorney for the District of Massachusetts, to Robert B. Fiske, Jr., Attorney for Warner-Lambert Company, LLC (May

Pfizer had acquired Warner-Lambert, however, the guilty plea did not lead to Pfizer's exclusion from participation in Medicare and Medicaid.¹³⁸

The 2004 Pfizer CIA had many of the standard provisions, including, *inter alia*, Pfizer's agreement to institute voluntary compliance measures such as appointing a compliance officer and committee, mandatory training regarding Pfizer's code of conduct, and reporting obligations.¹³⁹ The CIA required that both the compliance officer and the deputy compliance officers be members of senior management who make reports directly to the board of directors.¹⁴⁰ It further required Pfizer to have written policies and procedures regarding compliance with FDA and federal health care program requirements. Specifically, it required Pfizer to create, *inter alia*, a policy that conformed to the FDA's requirements regarding: (1) the method of selling and marketing information concerning off-label uses of Pfizer's products; (2) disclosure of financial support of Continuing Medical Education (CME) programs; (3) sponsorship of grants; and (4) sponsorship or funding of research such as clinical trials.¹⁴¹ The CIA also specified that training should include "all applicable Federal health care program requirements" such as the False Claims Act and the federal Anti-Kickback Statute.¹⁴² Finally, Pfizer was required to retain an Independent Review Organization to "assist Pfizer in assessing and evaluating its systems, processes, policies and practices related to . . . Promotional and Product Services Related Functions."¹⁴³

At the time that Pfizer entered into the CIA with OIG and promised not to engage in illegal marketing activities, Pfizer was actively engaged in an extensive campaign to market its drug Bextra for off-label uses. Pfizer did not cease its off-label promotion of Bextra as a result of the 2004 CIA, nor was the illegal promotion discovered by the new compliance program. Bextra is a painkiller known as a Cox-2 inhibitor¹⁴⁴ that Pharmacia & Upjohn Company, Inc.

13, 2004) (on file with author).

138. For a detailed discussion of the Neurontin case, see 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, 115 n.224 (2008).

139. CIA PFIZER 2004, *supra* note 116, at 5, 12.

140. *Id.* at 6.

141. *Id.* at 8–10.

142. *Id.* at 12.

143. *Id.* at 14.

144. The Cox-2 class of drugs was specially designed painkillers that relieved inflammation and pain similar to other painkillers, but without the gastrointestinal side effects that other painkillers caused. Information at ¶ 12 *United States v. Pharmacia & Upjohn Company, Inc.* (D. Mass. Aug. 31, 2009), <http://www.justice.gov/usao/ma/news/Pfizer/Information.pdf>. As part of the agreement between the DOJ and Pfizer, Pharmacia & Upjohn Company pled guilty to the August 31, 2009 Information, and the government declined prosecution of Pfizer. Under the agreement, "Pharmacia expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the attached Information and is in fact guilty of the offense . . ." Letter from Michael K. Loucks, Acting United States Attorney District of Massachusetts, to Brien T. O'Connor (Aug. 31, 2009), *available at* <http://www.justice.gov/usao/ma/news/Pfizer/Side%20Letter%20Agreement.pdf>. Thus, all allegations in the Information are taken as true for the purposes of this Article.

(“Pharmacia”) introduced into the market in February 2002.¹⁴⁵ Pfizer acquired Pharmacia in April 2003, but jointly promoted the drug Bextra with Pharmacia prior to the acquisition.¹⁴⁶ Pharmacia’s New Drug Application (NDA) for Bextra sought approval to promote Bextra for the prevention and treatment of acute pain in adults. The Bextra NDA claimed that administering Bextra prior to surgery would reduce postsurgical pain.¹⁴⁷ In addition, Pharmacia sought approval of Bextra for the treatment of primary dysmenorrhea (painful menstrual cramps), osteoarthritis, and adult rheumatoid arthritis.¹⁴⁸ On November 16, 2001, the FDA approved Bextra for the treatment of primary dysmenorrhea, adult rheumatoid arthritis, and osteoarthritis.¹⁴⁹ The FDA did not approve Bextra for postsurgical pain due to safety concerns.¹⁵⁰

Pharmacia’s marketing team promoted Bextra for acute pain, including surgical pain, even though the FDA did not approve Bextra for those uses.¹⁵¹ The marketing team created materials that directed Pharmacia’s sales force to aggressively pursue written surgical and pain management standing orders for Bextra for both approved and unapproved uses.¹⁵² In addition, the marketing team aggressively distinguished Bextra from competitors on the market, such as Pharmacia’s drug, Celebrex, which was used for chronic pain conditions, and Merck’s drug Vioxx, another Cox-2 inhibitor.¹⁵³ The marketing team created visual aids stating that Bextra was for “acute pain” and Celebrex was for “chronic pain.”¹⁵⁴ Pharmacia also had its sales representatives tell doctors to replace Vioxx with Bextra even though Vioxx was approved by the FDA for acute pain and Bextra was not.¹⁵⁵ The sales representatives also claimed that Bextra was safer and more effective than Vioxx, despite the fact that no studies existed to back up the claim.¹⁵⁶ In addition, the sales representatives told doctors that the cardiovascular concerns that existed with Vioxx were specific to Vioxx and not all Cox-2 inhibitors.¹⁵⁷ Thus, they convinced doctors that there was no proportional increase of hypertension or edema with the

145. Information, *supra* note 144, at ¶ 3.

146. *Id.* ¶ 2. Pharmacia holds the patent for Bextra. *Id.* ¶ 3.

147. *Id.* ¶ 14.

148. *Id.*

149. *Id.* ¶ 15.

150. *See id.* ¶ 18. When Bextra was studied in patients undergoing coronary artery bypass graft surgery, there was an excess of serious cardiovascular thromboembolic events. *Id.* In October 2004, a second study on the use of Bextra on coronary artery bypass graft surgery patients was made public. It showed a “statistically significant increase in thromboembolic cardiovascular events” in those patients. *Id.* ¶ 20. Thus, the FDA had a warning added to Bextra’s product label that stated that Bextra was “contraindicated” for treatment of post-surgical pain following coronary artery bypass graft surgery. *Id.* ¶ 21.

151. *Id.* ¶ 23.

152. *Id.* ¶ 25.

153. *Id.* ¶¶ 24–27.

154. *Id.*

155. *Id.* ¶ 55.

156. *Id.*

157. *See id.* ¶ 56.

use of Bextra, notwithstanding the fact that the label clearly indicated that there was a problem.¹⁵⁸

In addition to using the sales force to promote Bextra for off-label uses, Pharmacia also promoted Bextra through remuneration to physicians and physician consulting arrangements. Pharmacia targeted physicians to participate in advisory boards or consultant meetings to transform high-prescribing physicians into Pharmacia Cox-2 “advocates.”¹⁵⁹ Pharmacia paid the cost of airfare and two-to-three days’ accommodations at luxury resorts for the influential physicians to attend consultant meetings.¹⁶⁰ They also paid for recreational activities such as golf and spa treatments, and Pharmacia paid doctors from \$1000 to \$2000 to attend.¹⁶¹ From late 2001 to late 2003, Pharmacia held approximately 100 consultant meetings and promoted unapproved uses of Bextra to over 5000 health care professionals.¹⁶² Pharmacia also paid these physician advocates to present at lunches and dinners where they would promote the drug for unapproved uses.¹⁶³

Further, Pharmacia funded CME programs for the purpose of promoting Bextra for acute pain and surgical pain. Pharmacia hired advertising agencies to prepare promotional slides for Bextra and then had other vendors certify the slides as CME.¹⁶⁴ The slides were then distributed to the “advocates” so that they could use the slides at CME events as well.¹⁶⁵ In addition to the slides, Pharmacia initiated, funded, sponsored, and sometimes drafted or hired medical writer vendors to write articles about Bextra for unapproved uses and dosages in order to promote these uses and dosages, without appropriately disclosing Pharmacia’s role in the process.¹⁶⁶ Pharmacia actually had a “manuscript development” process where it planned potential publications and found authors for them. The goal of the process was to promote messages such as “Acute Pain: BEXTRA Provides Rapid, Powerful Pain Relief in surgical pain.”¹⁶⁷

As was the case with Neurontin, Pfizer’s illegal promotion of Bextra came to light because of several whistleblower suits brought under the FCA.¹⁶⁸ It was not

158. *Id.* ¶¶ 55–58.

159. *Id.* ¶ 33.

160. *Id.* ¶ 36.

161. *Id.*

162. *Id.* ¶ 37.

163. Information, *supra* note 144, at ¶ 38.

164. *Id.* ¶¶ 69–71.

165. *Id.*

166. *Id.* ¶ 73.

167. *Id.* ¶¶ 74–75.

168. The qui tam actions against Pfizer included: *United States ex rel. Collins v. Pfizer, Inc.*, No. 04-11780-DPW (D. Mass. 2004); *United States ex rel. Kopchinski v. Pfizer, Inc.*, No. 05-CV-12115 (D. Mass. 2005); *United States ex rel. Spencer v. Pfizer, Inc.*, No. 05-12326 (D. Mass. 2005); *United States ex rel. DeMott v. Pfizer*, No. 05-12040 (D. Mass. 2005); *United States ex rel. Farber v. Pfizer*, No. 07-10304 (D. Mass. 2007); *United States ex rel. Rainero v. Pfizer*, No. 07-11728 (D. Mass. 2007); *United States ex rel. Westlock v. Pfizer, Inc.*, No. 08-11318 (D. Mass. 2008); *United States ex rel. Liter v. Pfizer*, No. 06-00176 (E.D. Ky. 2006); and *United States ex rel. Kruszewski v. Pfizer, Inc.*, No. 07-4106 (E.D. Pa. 2007). U.S. DEP’T OF JUSTICE, SETTLEMENT AGREEMENT 1–2 (Aug. 31, 2009), available at <http://www.justice.gov/usao/ma/news/Pfizer/Pfizer%20Settlement%20>

discovered through the monitoring or compliance efforts that Pfizer undertook as part of its 2004 CIA. In the end, the government was either unable or unwilling to pull the trigger by taking Pfizer to court and pursuing the remedy of blanket exclusion from federal health care programs. Instead, Pfizer and the government settled for \$2.3 billion and entered into another CIA to replace the CIA that was still in effect at the time of the illegal promotional activities.¹⁶⁹ As part of the settlement with the government, Pfizer created a shell company that was a subsidiary of Pharmacia to plead guilty to a felony and be excluded from Medicare and Medicaid.¹⁷⁰ The shell subsidiary never bought, sold, or marketed a single drug. The exclusion was a façade to cover the fact that the government protected Pfizer.

The 2009 Pfizer CIA, much like the 2004 CIA, required Pfizer to have a compliance officer and committee. The 2009 CIA, however, forbids Pfizer's general counsel (GC) or chief financial officer (CFO) from being the compliance officer.¹⁷¹ It also prohibits the compliance officer from being subordinate to either the GC or CFO.¹⁷² In addition, the 2009 CIA makes Pfizer's audit committee "responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA."¹⁷³ As part of its responsibilities, the audit committee must evaluate the effectiveness of Pfizer's compliance program and adopt a resolution documenting its review and oversight of the compliance program.¹⁷⁴ The 2009 CIA also has a "Management Accountability and Certifications" section that requires the presidents of Pfizer's business units and the finance director of each business unit within World Pharmaceutical Operations to certify that "the leadership teams of the respective [business unit] have taken all appropriate steps to ensure compliance, that the leadership team has not directly or indirectly encouraged policy violation, and that controls are operating effectively."¹⁷⁵ Thus, the 2009 CIA attempted to

Agreement.pdf.

169. See CIA PFIZER 2009, *supra* note 102, at 1 (acknowledging 2004 CIA).

170. Drew Griffin & Andy Segal, *Feds Found Pfizer Too Big To Nail*, CNN (Apr. 2, 2010, 4:44 PM), <http://www.cnn.com/2010/HEALTH/04/02/pfizer.bextra/index.html> (explaining that the "[p]ublic records show that the subsidiary was incorporated in Delaware on March 27, 2007, the same day Pfizer lawyers and federal prosecutors agreed that the company would plead guilty in a kickback case against a company Pfizer had acquired a few years earlier.").

171. CIA PFIZER 2009, *supra* note 102, at 4.

172. *Id.*

173. *Id.* at 5.

174. *Id.* The CIA states that the resolution must include the following language:

The Audit Committee has made a reasonable inquiry into the operations of Pfizer's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. Based on its inquiry, the Audit Committee has concluded that, to the best of its knowledge, Pfizer has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.

Id. The resolution must be signed by each member of the Audit Committee. *Id.*

175. *Id.* at 6. The certification must state that the certifying individual:

increase accountability for compliance by requiring people higher in the organization to certify compliance. Additionally, Pfizer was required to provide notice of the settlement for off-label promotion to health care providers and entities.¹⁷⁶ Pfizer was also required to post on its website a list of all payments made to physicians during the term of the CIA.¹⁷⁷

Remarkably, despite the egregious nature of the violations and the fact that they were taking place at the same time that Pfizer was entering into the 2004 CIA, the government spared Pfizer from the more onerous certification requirements imposed on some of its competitors. Unlike Eli Lilly and Cephalon—which entered into CIAs in 2008 for off-label promotion of drugs—Pfizer was not required to have the CEO certify compliance with the federal health care laws, FDA regulations, and the CIA.¹⁷⁸ Nor was Pfizer required to plead guilty to a misdemeanor misbranding charge, unlike Eli Lilly and Cephalon. Instead, Pfizer was allowed to create a shell subsidiary that then went into court, pled guilty to a felony misbranding charge, and was excluded from Medicare and Medicaid. Of course in each case, the government crafted the guilty plea so as to save the pharmaceutical manufacturer from exclusion from Medicare and Medicaid.

Perhaps the government settled because it was apprehensive about its untested theories for finding misbranding violations based on off-label promotion. But if there was ever a strong case for such a theory, it was this case. The evidence clearly demonstrated that Pfizer was engaging in deceitful promotional activities. This was not a case where Pfizer was simply disseminating truthful medical or scientific information regarding the off-label uses of its product. Instead, Pfizer was promoting its product as if it were safe for uses that the FDA had clearly determined were not safe. Thus, it was probably not the uncertainty of a conviction

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- 1) has reviewed the following: (a) reports from an internal group within Pfizer formed to conduct promotional quality assessments; (b) summary reports of speaker programs, advisory boards, consultant payments, travel; and entertainment expenses; (c) sales compensation exclusion criteria; and (d) corporate compliance group statistics; and
 - 2) is currently aware of no violations of law, regulation, Pfizer policy, or the CIA requirements; or,
 - 3) in the event that a potential issue has been identified, the certifying individual has referred the potential violations to the Corporate Compliance Group or a member of the Pfizer legal division for further review and follow up. The certification shall also state that the signatory understands that certification is being provided to and relied upon by the United States.

Id.

176. *Id.* at 35–36.

177. CIA PFIZER 2009, *supra* note 102, at 36–38. Payments under the agreement include all payments “made in connection with physicians serving as speakers, participating in speaker training, or serving as Consultants or Authors; payments or compensation for services rendered; grants; fees; payments relating to research; payments relating to education; and payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred.” *Id.* at 38.

178. See CIA CEPHALON, *supra* note 111, at 6 (requiring certification by the CEO and Chairman); CIA ELI LILLY, *supra* note 111, at 6–7 (requiring certification by President and CEO).

that kept this case out of court. It is more likely that the government settled with the pharmaceutical giant and entered into another CIA because it was concerned about the collateral consequences for Pfizer, its employees, and millions of patients.

It is also possible that the government was motivated by financial considerations. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Program under the joint direction of the Attorney General and the Secretary of HHS, acting through OIG.¹⁷⁹ Under this program, the DOJ and OIG can use their civil and criminal fraud recoveries to expand their budgets, staff, and authority.¹⁸⁰ HIPAA requires that an amount equaling recoveries from health care investigations—including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution and compensation to the victim agency—be deposited in the Medicare Trust Fund.¹⁸¹ HIPAA then appropriates monies from the Medicare Trust Fund in amounts that the Secretary of HHS and Attorney General jointly certify as necessary to finance antifraud activities.¹⁸² In 2006, the Tax Relief and Health Care Act (TRHCA) amended HIPAA so that funds allotted from the account are available until expended.¹⁸³ TRHCA also allowed for yearly increases to the account based on the change in the consumer price index for all urban consumers. During fiscal year 2009, the DOJ and OIG certified \$266,425,206 in mandatory funding for appropriation to the account.¹⁸⁴ Additionally, Congress appropriated \$198 million in discretionary funding.¹⁸⁵ By settling with the pharmaceutical companies rather than taking them to court, OIG is guaranteed a large cut of the settlements. Further, the threat of blanket exclusion is enough to transform a questionable fraud case into a multimillion dollar settlement.

The government's motivations for entering into a CIA with Pfizer in 2009 are not completely clear. What is clear, however, is that the government's use of successive CIAs with Pfizer rather than exclusion is not an isolated incident. In 2005, Eli Lilly paid \$36 million and entered into a consent decree with the government to settle charges related to its off-label promotion of its osteoporosis drug Evista for the prevention of breast cancer.¹⁸⁶ The FDA had approved Evista for osteoporosis but rejected it for the prevention of breast cancer.¹⁸⁷ The consent

179. See THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2009 3–4 (May 2010) [hereinafter FRAUD & ABUSE REPORT 2009], available at <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2009.pdf>.

180. *Id.*

181. *Id.*

182. *Id.*

183. Pub. L. No. 109-432, § 303 120 Stat. 2922, 2949–50 (to be codified at 26 U.S.C. § 233).

184. See FRAUD & ABUSE REPORT 2009, *supra* note 179, at 3–4 (describing the process).

185. *Id.*

186. Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion, *supra* note 6.

187. Two years after the settlement, the FDA approved Evista for the prevention of breast cancer. Press Release, Eli Lilly, FDA Approves Lilly's Osteoporosis Drug EVISTA® (raloxifene HCl) to Reduce The Risk of Invasive Breast Cancer in Two Populations of Postmenopausal Women (Sep. 14, 2007), available at <http://newsroom.lilly.com/>

decree had many of the provisions common in CIAs, including certification requirements, training requirements, and review by an IRO.¹⁸⁸ Eli Lilly pled guilty to a misdemeanor misbranding charge, which did not lead to exclusion from Medicare and Medicaid.¹⁸⁹ In 2009, Eli Lilly paid \$1.415 billion and entered into a CIA with the government to settle charges related to its off-label promotion of Zyprexa.¹⁹⁰ As previously mentioned, the 2009 Eli Lilly CIA requires certifications of compliance by the company's president and CEO.¹⁹¹ Eli Lilly also pled guilty to a misdemeanor misbranding charge as part of the agreement, again not leading to exclusion of the drug maker from Medicare and Medicaid.¹⁹²

In 2005, Novartis Pharmaceuticals entered into a CIA due to its payment of kickbacks involving nutritional products.¹⁹³ Its subsidiary, OPI Products, pled guilty and was excluded from Medicare and Medicaid.¹⁹⁴ In May of 2010, Novartis settled with the government for \$72.5 million to resolve false claims allegations concerning its drug TOBI.¹⁹⁵ There was no CIA or admission of guilt involved in the settlement.¹⁹⁶ Later that same year, in September of 2010, Novartis settled with the government for \$422.5 million for off-label promotion of its drug Trileptal and entered into a CIA.¹⁹⁷ As part of the CIA, Novartis was required to have the president of Novartis Pharmaceuticals Corporation (NPC) and head pharma, North America, executive vice president and North American region head, oncology, and many other executive vice presidents certify compliance with the federal health care laws and FDA regulations.¹⁹⁸ Novartis Pharmaceuticals, a wholly owned subsidiary of Novartis, pled guilty to a felony misbranding charge and was excluded from Medicare and Medicaid, sparing its parent Novartis from exclusion.¹⁹⁹

releasedetail.cfm?releaseid=264036.

188. Consent Decree of Permanent Injunction, *U.S. v. Eli Lilly and Company* (2005) (on file with author).

189. Information, *U.S. v. Eli Lilly and Company* (2005) (on file with the author).

190. Press Release, U.S. Dep't of Justice, Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing (Jan. 15, 2009), available at <http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf>.

191. CIA ELI LILLY, *supra* note 111, at 6–7.

192. Information, *United States v. Eli Lilly & Co.*, (E.D. Pa. 2009), <http://www.justice.gov/usao/pae/News/2009/jan/lillyinfo.pdf>.

193. THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2005 16 (Aug. 2006) [hereinafter FRAUD AND ABUSE CONTROL REPORT FY 2005], available at <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2005.pdf>.

194. *Id.* at 15.

195. Press Release, U.S. Dep't of Justice, Novartis Vaccines & Diagnostics to Pay More than \$72 Million to Resolve False Claims Allegations Concerning TOBI (May 4, 2010), available at <http://www.justice.gov/opa/pr/2010/May/10-civ-522.html>.

196. *See id.*

197. Press Release, U.S. Dep't of Justice, Novartis Pharmaceuticals Corporation to Pay \$422.5 Million for Off-Label Drug Marketing (Sept. 30, 2010), available at http://www.justice.gov/usao/pae/Pharma-Device/novartis_release.pdf.

198. CIA CEPHALON, *supra* note 111, at 7–8.

199. Information, *United States v. Novartis Pharm.*, (E.D. Pa. 2010), http://www.justice.gov/usao/pae/Pharma-Device/novartis_information.pdf.

In 2004, Schering Sales Corporation, a wholly owned subsidiary of Schering-Plough Corporation, pled guilty, entered into a CIA, and paid \$52.5 million to settle charges related to a kickback arrangement involving its drug Claritin.²⁰⁰ In 2006, Schering-Plough Corporation paid \$435 million to settle civil and criminal charges related to kickbacks and off-label promotion of its drugs Temodar and Intron A.²⁰¹ To settle the criminal charges, Schering Sales Corporation pled guilty to one count of criminal conspiracy to make false statements to the FDA regarding illegal promotional activities.²⁰² Schering Sales was subsequently excluded from participation in Medicare and Medicaid.²⁰³ Schering-Plough's 2004 CIA was amended to require the manufacturer "to continue extensive work that the Company has undertaken in the last two years to monitor and correct the shortcomings in Schering's drug sales, marketing and pricing activities."²⁰⁴ In addition, there are other pharmaceutical companies that have entered into CIAs to resolve claims of off-label promotion or kickbacks that are currently under investigation for marketing violations.²⁰⁵

On the one hand, the government is using the threat of exclusion to win large settlements and get sweeping reforms in CIAs. On the other hand, the government is unwilling to go to court, obtain a conviction, and exclude a pharmaceutical manufacturer because the harm to the company, its shareholders, and, most importantly, its patients, would be too great. As the prosecutor in the Pfizer case

200. DEP'T OF HEALTH AND HUMAN SERVS. AND DEP'T OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2004 (2004), *available at* <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2004.htm>.

201. Press Release, U.S. Dep't of Justice, Schering to Pay \$435 Million for the Improper Marketing of Drugs and Medicaid Fraud (Aug. 29, 2006), *available at* <http://www.justice.gov/usao/ma/news/Schering-Plough/press%20release.pdf>.

202. *Id.*

203. *Id.*

204. *Id.*; ADDENDUM TO CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SCHERING- PLOUGH CORP. (Aug. 25, 2006), *available at* <http://www.justice.gov/usao/ma/news/Schering-Plough/Integrity%20Agreement.pdf>. In 2009, Merck purchased Schering-Plough. *See* David Jolly, *Merck Agrees to Acquire Schering-Plough for \$41 Billion*, N.Y. TIMES (Mar. 9, 2009), <http://www.nytimes.com/2009/03/09/business/worldbusiness/09iht-drug.html>. Merck is no stranger to CIAs. Merck paid the government \$650 million and entered into a CIA for its illegal kickback scheme involving the drugs Zocor and Vioxx in 2008. Press Release, U.S. Dep't of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), *available at* http://www.justice.gov/opa/pr/2008/February/08_civ_094.html.

205. For example, in 2010 Johnson & Johnson's subsidiary, Ortho-McNeil-Janssen Pharmaceuticals, entered into a CIA and paid \$81 million to resolve allegations that it promoted its drug Topamax for off-label uses. Ortho-McNeil Janssen Pharmaceuticals is also currently under investigation for off-label promotion of its drug Risperdal. *See* CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (2010), *available at* http://oig.hhs.gov/fraud/cia/agreements/ortho_mcnail_janssen_04282010.pdf; Margaret Cronin Fisk & David Voreacos, *J&J Unit Marketed Risperdal Off-Label, Ex-Workers Say (Update2)*, BLOOMBERG BUSINESSWEEK (Mar. 6, 2009, 4:46 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=akvy0MGjJcGY>.

said, the payment of large fines for off-label marketing is simply “a cost of doing business.”²⁰⁶ The same could be said about hiring a compliance officer and enacting an extensive compliance program. A pharmaceutical company can make billions in sales from marketing a drug for off-label uses over the course of several years. In the event that the drug manufacturer gets caught, it pays a fine that is only a fraction of the revenue that it earned through its illegal marketing practices.²⁰⁷ Pfizer’s experience with the drug Neurontin is telling. In the year 2000 alone, Neurontin earned \$2.3 billion, and 78% of Neurontin prescriptions (approximately \$1.8 billion) were for off-label uses.²⁰⁸ The settlement for Neurontin was \$430 million.²⁰⁹

So long as the revenue from marketing a drug for off-label uses eclipses the fine to be imposed for the illegal practice, the pharmaceutical manufacturers will continue to engage in illegal marketing activities. Indeed, the fine can never truly match the profits generated because not all of the off-label prescriptions are reimbursed by Medicare and Medicaid and the government can only recover what they were defrauded. The trend is disturbing because of the message that it sends to pharmaceutical manufacturers—it is permissible to deceive the public about the safety and efficacy of your drugs because you will not be excluded from Medicare and Medicaid so long as you are willing to pay a fraction of your profits to the government and enter into a CIA. Indeed, repeat offender Pfizer is so sure of that proposition that it recently acquired Wyeth Pharmaceuticals, despite the fact that Wyeth is under investigation for off-label promotion of its kidney drug Rapamune.²¹⁰

206. John Loucks, who was the prosecutor in the Pfizer case regarding off-label promotion of Bextra, explained that the money to be earned from off-label promotion “is so great” that pharmaceutical companies may consider any fines paid to the government as a business cost. Griffin & Segal, *supra* note 170; see also George S. Craft, Jr., Comment, *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 HOUS. J. HEALTH L. & POL’Y 103, 105 (2007) (“Off-label promotion can be an extremely profitable and common marketing strategy for pharmaceutical companies.”).

207. SAMMY ALMASHAT & TIMOTHY WATERMAN, PUB. CITIZEN’S HEALTH RESEARCH GRP., *RAPIDLY INCREASING CRIMINAL AND CIVIL MONETARY PENALTIES AGAINST THE PHARMACEUTICAL INDUSTRY: 1991 TO 2010*, at 21 (2010), available at <http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf> (“Thus, these financial penalties, although increasing, remain a very small fraction of company net profits and therefore do not provide a sufficient deterrent against further violations.”).

208. Melody Petersen, *Pfizer Nears Drug Settlement*, N.Y. TIMES (Mar. 12, 2003), http://cyber.law.harvard.edu/cyberlaw2005/sites/cyberlaw2005/images/Neurontin_NYTimes_Article.pdf.

209. Press Release, U.S. Dep’t of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm.

210. Duff Wilson, *U.S. Joins Pfizer Suit over Drug’s Marketing*, N.Y. TIMES, Sept. 22, 2010, at B3, available at <http://www.nytimes.com/2010/09/22/business/22drug.html>.

B. Theories of Punishment

The crucial issue is whether CIAs are an effective remedy for pharmaceutical manufacturers' marketing violations. By entering into a CIA, the manufacturer is able to safeguard its business and largely escape corporate criminal liability and the collateral consequences that flow from it. In particular, manufacturers are spared from exclusion. Thus, an examination of criminal liability and exclusion as compared to CIAs is integral to the question of the effectiveness of CIAs.

Corporations are vicariously liable for the criminal acts of their employees if the employees were acting (1) within the scope of their employment and (2) for the benefit of the corporation.²¹¹ Thus, there is no doubt that if a sales person's promotion of drugs for off-label use is criminal, then a pharmaceutical manufacturer would be held criminally responsible for that conduct, because drug sales are within the employee's scope of employment and the company would benefit from the increased sales. It would not matter for purposes of the manufacturer's liability if the sales person engaged in off-label promotion to increase her own commissions or if her actions were contrary to company policy.²¹² Although scholars have rightfully criticized both the existence of and the standards for imposing corporate criminal liability,²¹³ it is a doctrine that is unlikely to change in the near future. Thus, this Article takes the notion of corporate criminal liability and the current standard as a given. This Part will examine both the goals of corporate criminal punishment and the goals of the statutorily provided health care

211. Corporations are fictional persons that may only act through their agents. A corporation is liable for the criminal acts of its employee if the individual acted within the scope of employment and with the intent to benefit the corporation. Katrice Bridges Copeland, *Preserving the Corporate Attorney-Client Privilege*, 78 U. CIN. L. REV. 1199, 1201 (2010).

212. *See id.*; *United States v. Sun-Diamond Growers of Cal.*, 138 F.3d 961 (D.C. Cir. 1998) (upholding firm's conviction despite the fact that the firm was also defrauded by its agent's scheme); *United States v. Hilton Hotels Co.*, 467 F.2d 1000, 1004 (9th Cir. 1972) ("[A] corporation is liable for acts of its agents within the scope of their authority even when done against company orders.").

213. *See, e.g.*, Miriam Hechler Baer, *Insuring Corporate Crime*, 83 IND. L.J. 1035 (2008) (arguing that corporate criminal liability should be eliminated and replaced with an insurance system that would cover civil-related penalties associated with individual employees' criminal conduct); Pamela H. Bucy, *Corporate Criminal Liability: When Does It Make Sense?*, 46 AM. CRIM. L. REV. 1437 (2009) (arguing that an effective compliance program should be an affirmative defense to corporate criminal liability); John Hasnas, *The Centenary of a Mistake: One Hundred Years of Corporate Criminal Liability*, 46 AM. CRIM. L. REV. 1329 (2009) (arguing that there is no theoretical justification for corporate criminal liability); Barry J. Pollack, *Time to Stop Living Vicariously: A Better Approach to Corporate Criminal Liability*, 46 AM. CRIM. L. REV. 1393 (2009) (arguing that corporations should only be held criminally liable for the acts of their employees when those acts manifest the collective criminal intent of the corporation); Andrew Weissman, *A New Approach to Corporate Criminal Liability*, 44 AM. CRIM. L. REV. 1319 (2007) (arguing that, to establish corporate criminal liability, the government should have to show that the corporation did not have an effective compliance program).

fraud criminal punishments, and whether those goals can be reached through the use of civil administrative settlements (in this case, CIAs).

1. Justification for Corporate Criminal Liability

There are many policy reasons for holding corporations criminally liable for the acts of their employees. One justification that has been advanced by Professor Pamela Bucy is that corporations should be subject to criminal liability because they take actions that have the potential to harm many people.²¹⁴ The act of promoting drugs for unsafe uses, for example, could potentially harm millions of patients. Patients could suffer adverse consequences or even die if drugs are used improperly. Because criminal prosecution is the strongest sanction that we have, it should be imposed on any societal actor that engages in misconduct with the potential to harm many people.²¹⁵

Second, Professor Bucy argues that “corporations pose unique opportunities for unlawful behavior to occur.”²¹⁶ As a result, it is more difficult to control organizations than it is to control individuals who are working outside of the corporate form.²¹⁷ Criminal activity can flourish within a corporation due to group dynamics putting pressure on individuals to acquiesce in the wrongdoing.²¹⁸ Indeed, as Professor Samuel Buell has explained, “pressures on the individual in the group setting can make it extremely difficult to recognize, reveal, or stop harmful behavior once it begins.”²¹⁹ In addition, criminal activity can prosper within a corporation because the corporate form may make it difficult to detect violations of the law.²²⁰

Another key justification for corporate criminal liability is that it encourages corporations to monitor their employees and punish them for any misconduct. As Professor John Hasnas explains, because the current standard for corporate criminal liability has such a low threshold, “organizations can avoid criminal liability only by preventing their employees from violating the law.”²²¹ But this goal can only be

214. Bucy, *supra* note 213, at 1437.

215. *Id.*

216. *Id.*

217. *Id.*

218. *Id.* Due to group dynamics, individuals may “suspend their own judgment and disregard their usual sense of caution. Because of the pressure to hold on to a job, or please the boss and coworkers, the workplace presents especially strong temptations to ‘go along.’” *Id.* at 1437–38.

219. Samuel W. Buell, *The Blaming Function of Entity Criminal Liability*, 81 *IND. L.J.* 473, 496 (2006). Professor Buell explains that “[a]n institutional actor who commits a first, perhaps small violation of a norm or rule is likely to rationalize the violation to herself in order to avoid signaling guilt and insecurity to peers and supervisors. Incrementally worse violations will be equally rationalized in order to maintain cognitive consistency. As the seriousness of violations increases, the actor may eventually appreciate the depth of her predicament and take increasing risks, causing greater harm, in order to avoid detection of what began as a minor transgression.” *Id.*

220. Bucy, *supra* note 213, at 1437.

221. John Hasnas, *Ethics and the Problem of White Collar Crime*, 54 *AM. U. L. REV.* 579, 639 (2005).

achieved if the corporation engages in information gathering and “intense” monitoring of all actions those employees take within the scope of their employment.²²²

2. Justifications for Criminal Punishment

There are two basic justifications for criminal punishment—utilitarian and retributivist. The utilitarian, or “consequentialist,” justification for punishment is based on the future benefits it will provide.²²³ The future benefit most often mentioned is deterrence. Thus, punishment is beneficial if it helps to prevent future crimes.²²⁴ A retributivist, or “just deserts” view, on the other hand asserts that punishment is valuable in and of itself if it gives the wrongdoer what she deserves for prior misconduct.²²⁵ Thus, a utilitarian punishes because of the future benefit and a retributivist punishes because it is morally right to do so. Therefore, many scholars consider these two views of punishment to be diametrically opposed.²²⁶ This Article will focus on utilitarianism because it is the stated goal of both the exclusion statute and the justification for CIAs.

Utilitarianism is concerned with reducing crime while minimizing societal costs.²²⁷ Negative societal costs include the crime itself, increased fear in others, the impact on the victim of the crime, crime prevention, crime enforcement, and the pain that the criminal endures due to the punishment.²²⁸ On the other hand, society benefits from punishment when it deters future criminal conduct.²²⁹ Deterrence has two aspects—general deterrence and specific deterrence. Punishment furthers general deterrence when the threat of punishment deters potential offenders in the general community.²³⁰ Punishment also furthers specific deterrence when punishing a convicted defendant makes that defendant less likely to engage in future crime.²³¹ Under the economic theory of criminal law, an individual will be deterred from engaging in criminal conduct when the individual “feel[s] ‘costs’ equivalent to the

222. *Id.*

223. Paul H. Robinson & John M. Darley, *The Utility of Desert*, 91 NW. U.L. REV. 453, 454 (1997).

224. *See id.*

225. *Id.* at 454.

226. *Id.* As Robinson and Darby explain, the debate over the justification for punishing criminals has a long history. Although Jeremy Bentham is credited with announcing the deterrence theory of punishment and Immanuel Kant is credited with the “just deserts” theory of punishment, the justifications can be traced back to Plato and Aristotle, respectively. *Id.* at 455.

227. Erik Luna, *Punishment Theory, Holism, and the Procedural Conception of Restorative Justice*, 2003 UTAH L. REV. 205, 208 (2003) (“The primary consequentialist theory—utilitarianism—imposes criminal penalties only to the extent that social benefits (utility) outweigh the costs of punishment.”).

228. Carl Emigholz, Note, *Utilitarianism, Retributivism and the White Collar-Drug Crime Sentencing Disparity: Toward a Unified Theory of Enforcement*, 58 RUTGERS L. REV. 583, 599 (2006).

229. *Id.*

230. Luna, *supra* note 227, at 209.

231. *Id.*

harm they cause society, modified by the probability that they will be punished.”²³² Thus, the individual will decide not to engage in criminal conduct when the costs of committing the crime outweigh the net benefits of doing so.²³³ The costs of engaging in criminal conduct include both the punishment that the individual will receive upon conviction and the harm to the individual’s reputation.²³⁴ In the corporate context, there are other collateral consequences of conviction, such as the loss of government contracts, suspension and debarment, and exclusion from federal health care programs.²³⁵

Deterrence can be achieved through increasing either the likelihood of detection or the severity of punishment.²³⁶ In order for deterrence to be effective, however, the potential criminal must understand the threat of punishment, which means weighing the potential benefits of the crime against the chance of being caught, the chance of being convicted, and the severity of punishment.²³⁷ Corporate actors are viewed as deterrable because they regularly engage in cost/benefit analyses when making business decisions.²³⁸ The difficulty lies in the fact that many offenders, particularly in the white collar context, may be “unrealistically optimistic about the precautions they take to avoid being caught, or the simple likelihood of being caught, and thus may underestimate that probability.”²³⁹ Further, potential criminals often discount the cost of punishment because they believe that if they are actually convicted, any punishment will take place in the distant future.²⁴⁰ This concern is heightened in the health care fraud context due to the multi-year investigations that precede any imposed sanction. The question is: at what point does an increase in the cost of punishment equal the corresponding reduction in benefits from that cost?²⁴¹

If one ascribes to neoclassical criminal law and economics, then the criminal sanction should be set roughly at the value of the harm caused by the defendant adjusted for the probability of her punishment.²⁴² Because sanctions and harm are not always monetary in nature, the government sanction may not precisely replicate the harm the defendant causes, even if one accounts for the probability of detection and punishment.²⁴³ As such, there may be an over- or under-deterrence problem

232. Miriam H. Baer, *Evaluating the Consequences of Calibrated Sentencing: A Response to Professor Kolber*, 109 COLUM. L. REV. SIDEBAR 11, 11 (2009) (citing Gary S. Becker, *Crime and Punishment: An Economic Approach*, 76 J. POL. ECON. 169 (1968)).

233. Luna, *supra* note 227, at 209.

234. Richard A. Posner, *An Economic Theory of the Criminal Law*, 85 COLUM. L. REV. 1193, 1205 (1985) (“Almost every criminal punishment imposes some nonpecuniary disutility in the form of a stigma . . .”).

235. Copeland, *supra* note 211, at 1202 n.17.

236. Geraldine Szott Moohr, *An Enron Lesson: The Modest Role of Criminal Law in Preventing Corporate Crime*, 55 FLA. L. REV. 937, 956–57 (2003).

237. See Luna, *supra* note 227, at 212.

238. See Bucy, *supra* note 213, at 1438.

239. Robinson & Darley, *supra* note 223, at 460.

240. *Id.* at 460–62.

241. See Emigholz, *supra* note 228, at 599.

242. Baer, *supra* note 232, at 13 (citing Gary S. Becker, *Crime and Punishment: An Economic Approach*, 76 J. Pol. Econ. 169 (1968); Posner, *supra* note 234).

243. See *id.* at 13–14.

associated with the government-chosen sanction. If an individual is over-deterred by the government sanction, she will be risk averse. In the corporate context, this can lead to increased costs and lost business opportunities.²⁴⁴ On the other hand, if an individual is under-deterred by the government-set sanction, she will commit more crimes and cause more harm to society because she does not view the sanction as an impediment. In the corporate setting, under-deterrence can be even more detrimental because of the potential for harmful conduct to impact a greater number of people.²⁴⁵ Thus, it is important to strike the correct balance in punishing corporations.

3. The Exclusion Provision and Deterrence

The overarching purpose of the five-year mandatory exclusion period is remedial in nature. As the Senate Finance Committee Report states:

The basic purpose of the [Medicare and Medicaid Patient and Program Protection Act] is to improve the ability of the Secretary and the Inspector General of [HHS] to protect Medicare, Medicaid, [and other social services programs] from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care.²⁴⁶

The committee report also states, however, that the law “should provide a clear and strong deterrent against the commission of criminal acts.”²⁴⁷ On its face, the exclusion provision applies both to individual doctors and to manufacturers.

a. Exclusion of Doctors

When it comes to individual doctors and medical practices, the exclusion remedy is an effective deterrent against the commission of health care fraud. Doctors who commit health care fraud often engage in practices that result in Medicare and Medicaid being overcharged for medical services, such as overbilling for services performed, performing and billing for unnecessary procedures, billing for services that have not been provided, and billing for patients who do not exist.²⁴⁸ In addition, physicians can be convicted of health care fraud for taking kickbacks on prescriptions or referrals.²⁴⁹ Because billing practices are complicated, it is difficult to detect violations, which makes the likelihood of

244. See Baer, *supra* note 213, at 1062.

245. See Bucy, *supra* note 213, at 1437 (“[C]orporations often engage in activity that harm lots of people. Mislabeling drugs, shipping contaminated food, dumping pollutants into waterways, and falsifying financial data are a few obvious examples.”).

246. S. REP. NO. 100-109, at 1–2 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682.

247. *Id.* at 5.

248. See Diane E. Hoffmann, *Physicians Who Break the Law*, 53 ST. LOUIS U. L.J. 1049, 1051–52 (2009).

249. *Id.* at 1052.

detection low.²⁵⁰ When doctors are caught committing health care fraud, however, OIG has not shied away from invoking the exclusion remedy.²⁵¹

The exclusion of a doctor from Medicare and Medicaid can have a far reaching impact on the doctor. An excluded doctor can no longer be reimbursed for treating Medicare or Medicaid patients. Thus, the doctor would have to stop treating Medicare and Medicaid patients. In some situations, the doctor will lose his or her license due to the fraudulent activities and will need to close the practice. Although patients will potentially be harmed by a disruption in treatment, patients can switch to non-excluded doctors to receive treatment.²⁵² The punishment of exclusion is exceptionally high, but it is appropriate because the chance of detection is very low.

More importantly, the exclusion remedy is vigorously enforced against doctors. In fiscal year 2009, 2556 individuals and entities were excluded from Medicare and Medicaid; 1057 of those exclusions resulted from criminal convictions for program-related crimes, 239 for patient abuse and neglect, and 895 based on license revocations.²⁵³ Thus, even if the likelihood of detection is not exceptionally high, once fraud is detected, the likelihood of exclusion is high. Because the exclusion remedy is regularly applied to doctors, it has the ability to deter physicians from engaging in health care fraud. As the government regularly excludes doctors who engage in health care fraud, doctors may begin to associate the punishment of exclusion with the act of overbilling Medicare and Medicaid, and will constrain their conduct even if they are not sure they will be caught.

b. CIAs Replace Exclusion of Pharmaceutical Companies

In the case of the exclusion provisions, it seems that blanket exclusion from federal health care programs would be a remedy that would over-deter pharmaceutical manufacturers. Under the threat of blanket exclusion, one would think that pharmaceutical companies would be overly cautious about off-label promotion and would not even engage in activities that are probably permissible under the statute, such as distributing truthful and non-misleading medical and scientific information regarding off-label uses, due to fear that if they were overzealous in promotion, they would be excluded from Medicare and Medicaid. One would also think that the exclusion remedy would lead manufacturers to monitor their employees to make sure that they are not committing any marketing violations that would lead to exclusion of the manufacturer. Ironically, the opposite has occurred. For years, pharmaceutical manufacturers have engaged in egregious violations of the laws regarding off-label promotion of drugs by promoting the drugs for purposes that the scientific data does not support. This is largely due to both under-enforcement of the blanket exclusion remedy against pharmaceutical

250. *See id.* at 1052–53.

251. *See* U.S. Dep't of Justice, Exclusions Program, <http://oig.hhs.gov/fraud/exclusions.asp>.

252. Admittedly, the harm will be greater for patients who live in a rural area with few doctors or who are being treated for a rare disease by a specialist. In those situations, however, the Secretary has the authority to waive the exclusion. *See* 42 U.S.C. § 1320a-7(c)(3)(B) (2006).

253. FRAUD AND ABUSE CONTROL REPORT FY 2005, *supra* note 193, at 35.

manufacturers and the low likelihood of detection.²⁵⁴ Understandably, the government also has been unwilling to inflict harm on innocent patients and employees through its pursuit of blanket exclusion of pharmaceutical manufacturers.²⁵⁵ The government has replaced the blanket exclusion remedy with CIAs, thereby undermining the statutory scheme created by Congress to deter Medicare and Medicaid participants from engaging in health care fraud.

“[D]eterrence is a function of both the sanction level and the probability that it will be imposed.”²⁵⁶ The five-year exclusionary period that was meant to remedy and deter has been replaced with the five-year CIA that is meant to create “structural reform.”²⁵⁷ If one subscribes to utilitarianism, the substitution makes some logical sense. Under utilitarianism, criminal penalties will only be imposed to the point where social benefits outweigh the costs of punishment.²⁵⁸ In this situation, the government has determined that the costs to patients, employees, and shareholders that would result from excluding pharmaceutical manufacturers from Medicare and Medicaid outweigh the social benefit of punishing pharmaceutical manufacturers.

Indeed, the cost of exclusion will not be captured entirely by the manufacturer. The reality is that the cost will “spill over” onto innocent third parties.²⁵⁹ As Professor John Coffee explains, “when the corporation catches a cold, someone else sneezes.”²⁶⁰ Professor Coffee has identified four levels of harm from spillover.

First, the penalty is passed on to stockholders who will see a reduction in the value of their securities.²⁶¹ Arguably, the stockholders also benefited from the increase in stock prices that came along with the unlawful activities. Nevertheless, a drop in stock price after exclusion would likely be devastating to stockholders.

Second, the penalty impacts bond and credit holders who will also see a decline in the value of the securities that secure the investments.²⁶² A large pharmaceutical company that has been excluded from Medicare and Medicaid due to illegal marketing activities and has thereby lost Medicare and Medicaid revenue for the period of exclusion will likely be a riskier investment than a smaller non-excluded manufacturer.

Third, if the penalty is severe and jeopardizes the solvency of the company, the penalty harms innocent employees who had no involvement in the inappropriate

254. See *supra* notes 168–70, 186–206 and accompanying text.

255. Tracy L. Meares, Neal Katyal & Dan M. Kahan, *Updating the Study of Punishment*, 56 STAN. L. REV. 1171, 1185 (2004) (explaining the “inverse sentencing effect” of high penalties—people are not as willing to enforce high penalties because of the disproportionate impact on those caught).

256. *Id.* at 1178.

257. Brandon L. Garrett, *Structural Reform Prosecution*, 93 VA. L. REV. 853, 853–61 (2007) (explaining that in “structural reform prosecution,” prosecutors use the threat of prosecution to secure cooperation and internal reforms).

258. Luna, *supra* note 227, at 208.

259. John C. Coffee, Jr., “No Soul to Damn: No Body to Kick”: *An Unscandalized Inquiry into the Problem of Corporate Punishment*, 79 MICH. L. REV. 386, 401–02 (1981).

260. *Id.* at 401.

261. *Id.*

262. *Id.*

conduct.²⁶³ This is likely due to the fact that the corporation may be forced to fire employees to save money. Exclusion would lead to the loss of billions of dollars in revenue that would inevitably lead to a reduction in production and work force.²⁶⁴

Fourth, Professor Coffee explains that consumers will bear the brunt of the penalty in the form of higher prices for goods.²⁶⁵ Even though the prices of pharmaceutical drugs are often negotiated with health care plans through pharmacy benefit managers and may not be able to be changed right away, in all likelihood manufacturers would attempt to raise the prices of their drugs to compensate for the loss in revenue from Medicare and Medicaid. Consumers will pay the higher prices for essential drugs without a close substitute because their demand for drugs is somewhat inelastic to price.²⁶⁶ In the event that there is a close competitor on the market, consumers may still pay the high prices rather than encountering any switching costs that may result from obtaining a new prescription and dealing with any side effects of the competitor drug. More importantly, the Medicare and Medicaid patients with prescriptions for drugs manufactured by an excluded company would suffer severe consequences. Without Medicare or Medicaid to pay for their drugs, patients would need to switch to a competitor product (if one is on the market) or pay for the drugs themselves. If they could afford the drugs, they probably would not be on Medicare or Medicaid in the first place.

A lesser penalty makes sense in this situation because the penalty of exclusion will exceed the harm inflicted by manufacturers and, more importantly, innocent third parties will suffer undue harm. It is not clear, however, that CIAs are an effective deterrent for pharmaceutical manufacturers that engage in illegal promotional activities. To begin with, CIAs are watered down versions of deferred prosecution agreements (DPAs). DPAs are used when the prosecutor and the

263. *See id.* at 401–02.

264. In 2010, the federal government spent more than \$59 billion on Medicare prescription drugs and over \$20 billion on Medicaid prescription drugs. *See* Centers for Medicare and Medicaid Services, *supra* note 125. Pfizer has 12% of the U.S. prescription drug market. Pfizer Press Release, *Pfizer to Acquire Wyeth, Creating the World's Premier Biopharmaceutical Company* (Jan. 26, 2009), http://www.pfizer.com/news/press_releases/pfizer_press_release_archive.jsp#guid=20090126005624en&source=RSS_2009&page=13 (explaining that the combined Pfizer/Wyeth company would have a market share of 12%). Pfizer's financial statements do not specify what portion of their annual revenue comes from Medicare and Medicaid. If you assume, however, that Pfizer receives a portion of the Medicare and Medicaid payments that is proportional to their share in the market, that amount would be over \$9 billion of revenue in one year from Medicare and Medicaid.

265. *Id.* at 402. “If the corporation competes in a product market characterized by imperfect competition (a trait of most of the ‘real world’), then the fine may be recovered from consumers in the form of higher prices. If this happens, the ‘wicked’ corporation not only goes unpunished, but the intended beneficiary of the criminal statute (*i.e.*, the consumer) winds up bearing its penalty.” *Id.*

266. Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 677 n.66 (1988) (explaining that inelastic demand “means that demand does not respond, or responds only slightly, to changes in price”); Natalie J. Tanner, Note, *Understanding the Disparity in Availability of Prescription Drugs in the United States: Compromise May Be The Answer*, 2 IND. HEALTH L. REV. 267, 274–75 (2005).

corporation agree that the prosecutor will not seek immediate criminal action in exchange for the corporation's agreement to a specific set of terms laid out in the DPA.²⁶⁷ In most cases, the corporation will admit guilt to the criminal conduct in the DPA and agree to hire monitors that have "sweeping powers to gather information, promulgate policies, and oversee compliance."²⁶⁸ The federal prosecutor will file a formal charging document simultaneously with the DPA. If the prosecutor finds that the corporation has complied with all of the conditions of the DPA over the specified time period, the prosecutor will withdraw the formal charging document.²⁶⁹ If the corporation violates the DPA, however, the government will pursue criminal conviction of the corporation (which will be easy to obtain due to the admission of guilt in the DPA).²⁷⁰ Thus, DPAs should be effective in accomplishing specific deterrence of the corporation. It is in the corporation's best interest to avoid repeating the criminal conduct during the term of the agreement. The government has not shied away from prosecuting corporations that violate the terms of DPAs.²⁷¹ The ability of DPAs to promote general deterrence is less clear because even though the government often issues press releases touting the DPAs, the agreements are not always made publicly available, nor are they accessible in one central location.²⁷² Further, when corporations hire monitors as part of a DPA, the monitors are not required to make their findings regarding potential problems or compliance measures at the corporations public.²⁷³ Thus, it is not easy for other corporations to determine what conduct the government has determined to be unlawful and to conform their conduct accordingly. Government regulators and scholars have widely questioned whether DPAs, with their focus on monitors and compliance programs, are effective at general deterrence.²⁷⁴

267. Candace Zierdt & Ellen S. Podgor, *Corporate Deferred Prosecutions Through the Looking Glass of Contract Policing*, 96 KY. L.J. 1, 1 (2007–08).

268. Garret, *supra* note 257, at 897.

269. Peter Spivack & Sujit Raman, *Regulating the 'New Regulators': Current Trends in Deferred Prosecution Agreements*, 45 AM. CRIM. L. REV. 159, 180 (2008).

270. *See id.* at 161 n.9.

271. *See* Daniel J. Grimm, *The Foreign Corrupt Practices Act in Merger and Acquisition Transactions: Successor Liability and Its Consequences*, 7 N.Y.U. J. L. & BUS. 247, 280 n.151 (2010) (detailing instances where the government prosecuted corporations for violating the terms of deferred prosecution agreements).

272. *See* Spivack & Raman, *supra* note 269, at 160–61 (explaining that DOJ does not have a uniform policy regarding the publication of pre-trial diversion agreements); Garret, *supra* note 257, at 938 n.326 (explaining that he compiled DPAs from the DOJ website and the individual websites of each U.S. Attorneys' office that entered into a DPA) .

273. Garret, *supra* note 257, at 897.

274. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-110 CORPORATE CRIME: DOJ HAS TAKEN STEPS TO BETTER TRACK ITS USE OF DEFERRED AND NON-PROSECUTION AGREEMENTS, BUT SHOULD EVALUATE EFFECTIVENESS 20 (2009) (explaining that DOJ intends for these agreements to "promote corporate reform," but "does not have performance measures in place to assess whether this goal has been met. Therefore, it could be difficult for DOJ to justify its increasing use of these tools."); Cristie Ford & David Hess, *Can Corporate Monitorships Improve Corporate Compliance?*, 34 IOWA J. CORP. L. 679, 703 (2009); Garret, *supra* note 257; Khanna & Dickinson, *supra* note 127; Kimberly D.

CIAAs are less stringent than DPAs because manufacturers are not required to admit guilt to criminal charges and the threat of criminal punishment for violating the agreement does not loom over the manufacturer. Thus, the CIA's effectiveness as a specific deterrent is lessened by the fact that criminal liability is not a real threat for the manufacturer even if it violates the CIA. Certainly, CIAAs instruct manufacturers to monitor their employees. The mere fact that manufacturers must certify compliance with the requirements of the CIA, however, does little to encourage active monitoring because there is no threat of criminal liability or other increased sanctions for the drug maker if it fails to comply with the agreement. Indeed, as Pfizer, Novartis, Eli Lilly, and others have learned, the punishment for multiple offenses is simply another CIA and another fine. The government has repeatedly shown its unwillingness to raise the stakes for manufacturers by holding them criminally liable and using the exclusion remedy. Instead, if the government does decide to impose criminal liability, it crafts the guilty pleas to ensure that the drug makers go unharmed.

Although CIAAs have the potential to promote general deterrence, the government's use of them frustrates that potential. CIAAs have some ability to promote general deterrence in that they are made public and posted on the OIG website.²⁷⁵ Because enforcement actions are the principal method of developing the law, making the CIAAs public allows pharmaceutical companies to learn about the conduct the government judges to be unlawful and the specified remedy. Thus, pharmaceutical companies can view the requirements of another manufacturer's CIA and decide to abandon any behavior that is similar to the conduct engaged in by that manufacturer. Manufacturers could also decide to engage in lawful behavior because they fear the onerous conditions of the CIA. Further, drug manufacturers may choose to enact compliance programs modeled on the programs included in the CIAAs. Ultimately, however, CIAAs fail as a replacement for blanket exclusion, because the government has demonstrated that even if a pharmaceutical company violates the provisions of a CIA, it will waive the violation and enter into another CIA with the manufacturer. This is in sharp contrast to the government's reaction to the violation of a DPA, which leads to criminal charges. Because the penalty for one, two, or even three more marketing violations is still just a CIA, the penalty itself does not work to provide additional deterrence. This is particularly true because the second or third time that a pharmaceutical company enters into a CIA, it will not have to make a huge financial outlay to enact a compliance program or comply with government reporting requirements, because those programs already exist.²⁷⁶ While successive CIAAs might increase the reporting requirements, it is unlikely that large scale restructuring of the organization will be required. The government's method of increasing the severity of the penalty on the second CIA—requiring the pharmaceutical company to designate a subsidiary, which has never bought, sold, or marketed a single drug, to go into court to plead guilty and be

Krawiec, *Cosmetic Compliance and the Failure of Negotiated Governance*, 81 WASH. U. L.Q. 487 (2003); Donald C. Langevoort, *Monitoring: The Behavioral Economics of Corporate Compliance with Law*, 2002 COLUM. BUS. L. REV. 71 (2002); Zierdt & Podgor, *supra* note 267.

275. U.S. Dep't of Health and Human Servs., *Corporate Integrity Agreement Documents*, OFF. INSPECTOR GEN., available at http://oig.hhs.gov/fraud/cia/cia_list.asp.

276. See *supra* notes 168–74 and accompanying text.

excluded from Medicare and Medicaid—has little impact on the manufacturer.²⁷⁷ Thus, the government's failure to enforce the CIAs only further lessens the ability of CIAs to deter drug manufacturers. The end result is that drug manufacturers are underdeterred from engaging in off-label marketing.²⁷⁸

CIAs are an inadequate deterrent for pharmaceutical companies because the fines imposed by and the costs of complying with them are too low in comparison with the profits that can be gained from engaging in off-label promotion. The cost of the crime—a CIA plus a fine—is simply not high enough to deter drug manufacturers from committing the crime.

III. ALTERNATIVES TO CIAS

The remedy of blanket exclusion is often used against doctors but seldom used against large pharmaceutical manufacturers, because, when it comes to pharmaceutical manufacturers, the resulting harm to innocent patients from exclusion is too great to justify imposition of the sanction. In place of exclusion, the government has employed an enforcement strategy aimed at financial recovery and organizational reform. Simply recouping large sums of money from pharmaceutical manufacturers and requiring compliance programs, however, does little to deter them from engaging in fraudulent activities in the future. This Part examines alternatives to CIAs, including required funding for clinical trials, compulsory licensing, corporate officer liability, and a more targeted exclusion remedy. The appropriate choice among these alternatives depends on the harm that the government is trying to combat. Some of the possibilities include the failure to perform clinical research, defrauding the government, and unjust enrichment. No matter what the identifiable harm may be, however, it is important that any remedy be a deterrent for future misconduct. The appropriate choice among the alternatives will ultimately depend on the circumstances of the violation.

A. Funding of Clinical Trials

If the tangible harm from off-label promotion is that the public will be deprived of an important commodity, namely clinical research on the off-label claim, then one possible remedy is to require that the manufacturer fund clinical trials on the off-label claim. This remedy could potentially be added to CIAs. Thus, in addition to any fine and compliance measures, the CIA would require the manufacturer to provide money to the National Institutes of Health (NIH) to fund clinical trials. This remedy would have the potential to greatly aid the public because there would be definitive proof to either support or rebut the claim that the drug is safe for the off-label use.

277. As Lewis Morris of HHS admitted, “[i]t is true that if a company is created to take a criminal plea, but it’s just a shell, the impact of an exclusion is minimal or nonexistent.” Griffin & Segal, *supra* note 170.

278. Meares et al., *supra* note 255, at 1186 (explaining that when a penalty is increased to the point that it is out of step with the norms of the community, “it may reduce deterrence instead of promoting it”).

If the FDA does not approve the drug for the off-label use because it finds that the research does not support a finding of safety and efficacy, however, then requiring the manufacturer to fund clinical research could potentially be a meaningless exercise. In that situation, it is possible that there is not a lack of clinical research. Instead, there is a misrepresentation of the research. When the true harm is a misrepresentation of clinical research rather than a lack of research, a remedy that requires research does little to address the harm or prevent future misconduct. On the other hand, it could be the case that the initial research is simply not adequate for the FDA to make a finding of safety and efficacy. Certainly, there have been cases in the past where the FDA has not approved a drug for safety reasons only to approve that drug a few years later after additional research.²⁷⁹ If the research is inadequate, then requiring the manufacturer to fund the research could aid the public by providing it with crucial information regarding drug safety.

Although this remedy addresses the lack of clinical research, its effectiveness as a deterrent may vary based on when the manufacturer is caught promoting its drugs for off-label uses. If the drug is early in its patent period, then requiring clinical research may not be that harmful to the manufacturer's bottom line. In the event that the research demonstrates that the product is safe for off-label use, the manufacturer will apply to the FDA to make the off-label use an approved use and will have the time and opportunity to recoup the cost of the trials because of the larger market for its product. Indeed, the profits from the additional use may far eclipse the cost of the research. Even if the research demonstrates that the drug is not safe for the off-label use, the manufacturer may be able to compensate for the loss if the drug is a blockbuster drug and continues to have high sales. Because of the complicated pricing structures for pharmaceutical drugs,²⁸⁰ the manufacturer will probably be able to pass the costs on to the consumer.

Conversely, if it is late in the patent period, the manufacturer may not be the sole beneficiary of learning that the drug is safe for off-label uses. Instead, generic manufacturers may reap some benefits from that finding as they enter the market to produce the drug when it goes off patent. There may be some ability, however, to recoup the research costs if the FDA grants approval for the new use. In those situations, the manufacturer may be able to get an additional time period to prevent generic manufacturers from entering the market, termed "market exclusivity," for a

279. See, e.g., Natasha Singer, *Erasing Frown Lines (and Migraine's)*, N.Y. TIMES, Sept. 9, 2010, at B1, available at <http://www.nytimes.com/2010/09/09/business/09botox.html>; Press Release, U.S. Food and Drug Administration, *Evista Approved for Reducing Breast Cancer Risk* (Sept. 17, 2007), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048474.htm>.

280. See, e.g., DEPARTMENT OF HEALTH & HUMAN SERVS., REPORT TO THE PRESIDENT: PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES 95–96 (2000), available at <http://aspe.hhs.gov/health/reports/drugstudy/c3.pdf> (explaining that the prices that customers pay for drugs can vary based on, among other things, whether the individual is a cash customer without insurance, someone who has insurance, or some other third-party payer and whether the insurance company has negotiated substantial rebates from the drug manufacturer to offset the price of the drugs).

period of three years.²⁸¹ On the other hand, if the research shows that the drug is unsafe for the off-label use, the manufacturer will not have the opportunity to recoup the cost of the drug trial. Thus, the remedy would be most effective as a deterrent late in the patent period regardless of whether the drug is ultimately proven safe because the manufacturer will have very little, if any, time to recover the costs of the clinical trial.

One could also argue, however, that funding clinical research will be an effective deterrent in all cases because the manufacturer will not know ahead of time whether the illegal activities will be discovered early or late in the patent period. As such, the manufacturer will want to avoid the substantial costs involved in conducting clinical research for the off-label uses. The best way to avoid those costs will be to vigorously monitor employees to make sure that they are not engaging in off-label promotion. The incentive to monitor, however, may be low in the beginning of the patent period, where any additional research costs could potentially be passed on to the consumer. As the patent nears its expiration date, however, the incentive to monitor rises because of the manufacturer's inability to recoup the full research costs if required to perform additional clinical research. Thus, manufacturers may be more lenient on offending employees at the beginning of the patent period than at the end of the period.

Despite the potential positive impact of the clinical research remedy, there is the possibility that it could lead to gamesmanship on the part of pharmaceutical companies. Pharmaceutical manufacturers will want to extend their monopoly for as long as possible. Thus, their employment of strategies to delay generic entry may increase due to this remedy and the resultant cost to the manufacturer. Although a discussion of these strategies is beyond the scope of this Article,²⁸² their use could lead to increased profits for the pharmaceutical companies and higher drug costs for consumers because of the delay in availability of generic drugs. While consumers will suffer due to increased costs, there is no consumer benefit to offset the costs.

On balance, requiring pharmaceutical manufacturers to fund additional clinical research on their drugs will lead to a more informed public and will encourage manufacturers to monitor their employees more carefully. Although the incentives to monitor may go up and down throughout the patent period, it is likely to be an effective deterrent due to the high cost associated with additional research—likely hundreds of millions of dollars—that the manufacturer may not be able to recoup.

B. Compulsory Licensing

Another way to look at the harm from off-label promotion is that it constitutes unjust enrichment to the manufacturer because the manufacturer is able to profit

281. *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace*, NAT'L INST. FOR HEALTH CARE MGMT. FOUND. 4–5 (June, 2002), <http://www.nihcm.org/pdf/GenericsPrimer.pdf>.

282. *See, e.g.,* Stacey B. Lee, *Is a Cure on the Way?—The Bad Medicine of Generics, Citizen Petitions, and Noerr-Pennington Immunity*, 20 KAN. J.L. & PUB. POL'Y 98, 107–08 (2010). *See generally* FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

from an unapproved use for a drug. One way the government can recover the gain is by taking away the future profit potential of the drug. The key to pharmaceutical profit is patent protection. A patent gives a pharmaceutical manufacturer complete control over the pricing, production, and sale of a given drug during the patent period.²⁸³ In the pharmaceutical industry, patents are granted to spur future innovation and to generate new and improved medicines that will benefit the public.²⁸⁴ The patent offsets the cost of innovation and the risks involved in developing a new drug because it prevents competitors from imitating and producing the drug during the patent period.²⁸⁵ But patents only exist through congressional enactment.²⁸⁶ Thus, the government could restrict the patent rights of an offending drug company by granting a compulsory license. A compulsory license would require the drug maker to permit another manufacturer to produce and sell the patented drug for a pre-established fee or, because the license is a penalty, no fee at all.²⁸⁷

Compulsory licenses have been used as a remedy in the antitrust context for anticompetitive behavior.²⁸⁸ Some federal statutes provide for compulsory licensing.²⁸⁹ They have also been proposed as a solution to the problem of high drug costs.²⁹⁰ In addition, the Bayh-Dole Act gives the government the power to compel a license if the patented invention was federally funded.²⁹¹ As a remedy in an off-label promotion case, the compulsory license essentially takes away the profit potential of a patented drug because the patent owner is forced to grant a license for a rate that the government judges to be “reasonable” rather than a rate that would compensate the manufacturer for lost profits.²⁹²

283. See 35 U.S.C. § 271(a) (2006) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

284. Samuel Mark Borowski, *Saving Tomorrow from Today: Preserving Innovation in the Face of Compulsory Licensing*, 36 FLA. ST. U. L. REV. 275, 284 (2009) (“[The] incentive to innovate and invent is a function of four interrelated variables: (1) the costs of innovation and invention, (2) the risks, (3) the rewards for success, and (4) the rate at which competitive imitation occurs.”).

285. See *id.* at 284–86.

286. The U.S. Constitution grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8.

287. Fauver, *supra* note 266, at 667 (“Compulsory licensing enables the government granting the patent to force the patentee to license the invention if the government does not approve of the patent’s use. Consequently, another individual or company is allowed to make and sell the invention.”); Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 300 (1994).

288. Fauver, *supra* note 266, at 670.

289. See, e.g., Clean Air Act, 42 U.S.C. § 7608 (2006); Atomic Energy Act, 42 U.S.C. § 2183.

290. Tanner, *supra* note 266, at 267.

291. Bayh-Dole Act, 35 U.S.C. §§ 200–12.

292. Fisch, *supra* note 287, at 300 (internal quotation marks omitted).

A compulsory license would revoke the manufacturer's monopoly and thereby greatly reduce profitability. Thus, it provides a strong disincentive to violate off-label prohibitions, as the gap between monopoly pricing (as the owner of the patent) and competitive pricing (as a licensor) is very large.²⁹³ It would also likely encourage vigorous monitoring of employees. Unlike in the clinical research context, the incentive to monitor may be higher during the beginning of the patent period and lower at the end of the patent period. This runs counter to the normal marketing practices of pharmaceutical companies to try to make the market for the drug as large as possible in the early patent period to ensure blockbuster status and high profits. It is the attempt to increase the market size that often leads to off-label promotion. Thus, in addition to monitoring, the remedy of compulsory licensing may require pharmaceutical companies to make some reforms to change their incentive structures.

There are, however, some potential problems with this remedy. First, compulsory licensing might stifle innovation.²⁹⁴ Manufacturers may be unwilling to risk making a substantial investment in drug development if the reward from that investment can be taken away as a remedy for illegal marketing practices. Even with a serious monitoring program, there is no guarantee that an employee would not promote the drug for off-label uses leading to liability in the form of licensing of the patent for the corporation. Without a guarantee of the patent benefits, some manufacturers may choose not to invest in research and development. As a result, society would lose out on potentially life-saving drugs. Second, it might overdeter manufacturers. Because manufacturers would risk the loss of their patent rights, manufacturers may be overzealous in monitoring their employees. It may even deter manufacturers from conducting additional research on approved drugs for fear that some of their salespeople will begin to inform doctors of the new findings. Third, if the manufacturer is not the patent holder, it may be difficult for the government to craft the compulsory license to punish the manufacturer without harming the patent holder. Finally, Congress may have difficulty mustering the political will to authorize this type of remedy. The pharmaceutical lobby would vehemently oppose compulsory licensing of its products as a remedy for health care fraud.

Despite the challenges that may exist for the use of compulsory licenses, it is hard to deny that their use would substantially raise the stakes for manufacturers. If a CIA is the first line of defense, but manufacturers know that a repeat offense will result in a compulsory license, the manufacturer will be less likely to become a repeat offender. Ultimately, the success of compulsory licenses as a sanction will depend on the government's willingness to impose the remedy on a repeat offender. If the government were willing to make an example out of one manufacturer, other manufacturers would be on notice that compulsory licenses are a plausible remedy and would curb their illegal marketing practices to avoid that sanction.

293. See Charles E. Mueller, *Sources of Monopoly Power: A Phenomenon Called 'Product Differentiation,'* 18 AM. U. L. REV. 1, 2-5 (1968).

294. See, e.g., Glover Statement, *supra* note 33, at 6 (“[C]ompanies would not be able to invest the huge amount of time and money it takes to discover and develop a new medicine if they did not have a sufficient opportunity to make a sufficient return before generic competitors copy and market the drug at greatly reduced cost.”).

C. Corporate Officer Liability

The harm in off-label promotions may be that the pharmaceutical companies have defrauded the government. If the main goal of criminal prosecution of corporations is to encourage monitoring of lower level employees, then one possibility is to pursue corporate officers criminally. Although responsibility for illegal promotional activities is often scattered throughout an organization, it may be possible for the government to pursue responsible corporate officers. This type of strategy allows the government to put a face on the fraud. Indeed, the FDA recently called for more prosecutions of responsible corporate officers under the FDCA.²⁹⁵

Under the responsible corporate officer (RCO) doctrine, officers are subject to both criminal and civil liability for corporate violations of statutes involving public welfare offenses, such as health care fraud.²⁹⁶ The RCO doctrine provides that a defendant may be guilty if he or she had, “by reason of his [or her] position in the corporation, responsibility and authority either to prevent in the first instance, or

295. See Letter from Margaret Hamburg, FDA Comm’r, to the Honorable Charles E. Grassley, Ranking Member of the Senate Fin. Comm. 2 (Mar. 4, 2010), available at <http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>. The FDA commissioner explained:

A third recommendation from the committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Criteria now have been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions.

Id.

296. The U.S. Supreme Court first articulated the RCO doctrine in *United States v. Dotterweich*, 320 U.S. 277 (1943). In *Dotterweich*, the Court upheld the conviction of a drug company’s president and general manager for the company’s shipping of misbranded and adulterated drugs in interstate commerce. *Id.* at 278, 285. The employees had repackaged drugs from the manufacturer and shipped them out to fulfill a doctor’s order. *Id.* at 278. Although the Court acknowledged the hardship on individuals whose “consciousness of wrongdoing be totally wanting” but found it necessary to protect the public from the hazard of misbranded and adulterated drugs. *Id.* at 284. In 1975, the Supreme Court once again approved the application of liability under the RCO doctrine in *United States v. Park*, 421 U.S. 658 (1975). In *Park*, the Court affirmed the conviction of a president of a national food chain whose warehouses were suffering from a rat infestation. *Id.* at 661. As a result of the infestation, the food became contaminated. *Id.* at 662. The president had delegated warehouse operations to subordinates. *Id.* at 663. Although someone had notified Park of unsanitary conditions at another warehouse, and he instructed his subordinates to take corrective actions, Park had no personal knowledge of unsanitary conditions at the warehouse in question. *See id.* at 664–65. The Court explained:

The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

Id. at 672.

promptly to correct,” the alleged violations of law.²⁹⁷ Thus, the individual need not have directly participated in the criminal conduct for liability to attach under the RCO doctrine. Instead, the burden is put on an individual “otherwise innocent but standing in responsible relation to a public danger.”²⁹⁸ The U.S. Supreme Court has, however, recognized an impossibility defense when the defendant was “powerless to prevent or correct the violation.”²⁹⁹ Thus, there needs to be some level of “blameworthiness” for the doctrine to be imposed, but the Supreme Court has not been clear on the threshold requirement for responsibility.³⁰⁰ The DOJ would most likely use the RCO doctrine to charge high-ranking individuals of pharmaceutical manufacturers with misdemeanor misbranding violations under the FDCA because of the lack of an intent requirement for that crime. If the individuals are found guilty, they could face imprisonment, criminal fines, and exclusion from Medicare and Medicaid.³⁰¹

The biggest concern with employing the RCO doctrine is that individuals who are not culpable in the traditional sense may be punished with substantial fines and exclusion from federal health care programs. If sticking with a purely utilitarian justification for punishment, then it is sometimes justifiable to punish the innocent if the benefit to society outweighs the harm.³⁰² It is not clear that is the case here. The government would essentially be using these prosecutions to make examples out of high-level officials in the company. But this sends a bad message to individuals within the health care industry. It is one thing to structure enforcement of the laws to encourage supervision and monitoring and to penalize the corporation for its failure to do so. It is another thing to single out executives who did not have a hand in the wrongdoing for punishment based, in large part, on their positions in the company. The government would likely argue, however, that prosecuting executives who fail to prevent or correct illegal conduct is “no more stringent [a standard] than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.”³⁰³ That reasoning probably holds true in an egregious case where the executive turns a blind eye to

297. *Park*, 421 U.S. at 673–74.

298. *Dotterweich*, 320 U.S. at 281.

299. *Park*, 421 U.S. at 673 (quoting *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964)) (internal quotation marks omitted).

300. *Id.*

301. As the law currently stands, OIG may exclude an executive of a convicted corporation from Medicare and Medicaid, but if the executive resigned from the corporation before conviction, he or she could escape exclusion. 42 U.S.C. 1320a-7(b)(15) (2006) (referring to an individual “who is an officer or managing employee” (emphasis added)). Thus, U.S. Representative Pete Stark recently introduced bipartisan legislation that would close this loophole and allow OIG to pursue exclusion of executives that have left their companies. See Strengthening Medicaid Anti-Fraud Measures Act of 2010, H.R. 6130, 111th Cong. (2010), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h6130ih.txt.pdf (changing the language of the Social Security Act to apply to an individual who currently is or “was such an officer or managing employee at the time of any of the conduct that formed a basis for the conviction”).

302. See *Robinson & Darley*, *supra* note 223, at 454.

303. *Park*, 421 U.S. at 672.

misconduct. If the employees are hiding the misconduct, however, it is hard to understand how society benefits from using the moral condemnation of the criminal law against the executive rather than the employee.

Although the Supreme Court did indicate the need for some “blameworthiness” on the part of the prosecuted individual, it is not clear how stringently the FDA will apply this requirement. The FDA recently amended its Regulatory Procedures Manual to instruct FDA personnel to consider “the individual’s position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation.”³⁰⁴ But that is nothing more than a recitation of the standard the Supreme Court set forth in *Park* and *Dotterweich*. The Regulatory Procedures Manual also sets forth seven factors for FDA personnel to consider, including (1) whether the violation harmed or could harm the public; (2) “[w]hether the violation is obvious”; (3) whether the violation is part of a pattern of misconduct; (4) “[w]hether the violation is widespread”; (5) the seriousness of the violation; (6) the quality of the evidence in support of the prosecution; and (7) whether the prosecution is a good use of agency resources.³⁰⁵ With respect to blameworthiness, one could certainly argue that if a violation is obvious, serious, widespread, and part of a pattern of misconduct, then the executive in charge is at fault for not identifying and correcting the misconduct. But, as the FDA notes in its Regulatory Procedures Manual, “it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act.”³⁰⁶ Thus, the guidance is not a guarantee that the FDA will use the RCO doctrine sparingly or only in the most egregious circumstances. After its success prosecuting Purdue Pharma executives under the RCO doctrine,³⁰⁷ it is possible that the FDA will shift its enforcement strategy to prosecuting individuals. If the FDA begins to use the RCO doctrine aggressively, it may discourage talented compliance professionals or other executives from working for large health care companies for fear that they will be held criminally liable for millions of dollars or excluded from participation in Medicare or Medicaid, which would make them unemployable in the health care industry.³⁰⁸

304. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, SPECIAL PROCEDURES AND CONSIDERATIONS FOR PARK DOCTRINE PROSECUTIONS § 6-5-3 (2011), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3>.

305. *Id.*

306. *Id.*

307. *See infra* note 308.

308. *See, e.g.*, CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PURDUE PHARMA L.P. (2007), available at <http://oig.hhs.gov/fraud/cia/agreements/CIAPurdue.pdf>. Purdue Pharma’s former president and CEO, the Chief Legal Officer, and the Chief Medical Officer pled guilty to misdemeanor misbranding charges in 2007. *Friedman v. Sebelius*, 755 F. Supp. 2d 98, 100–02 & 101 n.5 (D.D.C. 2010). In total, they paid \$34.5 million in criminal fines. *Id.* at 102 n.7. The three executives were charged as Responsible Corporate Officers. *Id.* at 100. After the executives’ guilty pleas, OIG moved to exclude them from federal health care programs for twenty years under the agency’s permissive exclusion authority in 42 U.S.C. § 1320a-7b (2006). *Id.* at 102–03. That statute permits exclusion of individuals

One way to address the potential criticism of the RCO doctrine on fairness grounds is to only use it to pursue officers of a repeat offender. Thus, it may be appropriate to use a CIA and require upper management to make certifications of compliance the first time that a drug maker runs afoul of the law. If a manufacturer that is subject to a CIA, or a recently expired CIA, is under investigation for further marketing violations, the government could pursue the individuals who were responsible for making certifications under the previous CIA. Because those individuals would understand that they could be held personally liable for failing to monitor their employees, they would have a very high incentive to diligently oversee the marketing activities of their subordinates.

The question, however, is whether punishing individuals within the company would be a more effective deterrent than pursuing the corporation. Although some may argue that prosecution of individuals is more likely to deter corporate actors than prosecution of corporations, scholars such as Professor Geraldine Szott Moohr have argued that corporate crime does not occur simply because of the “ethical and moral lapses of executives and employees.”³⁰⁹ The fact is that pharmaceutical manufacturers can encourage illegal conduct through the policies that they employ.³¹⁰ For example, the incentive structure for pharmaceutical sales representatives encourages them to engage in off-label promotional activities. A sales representative is incentivized by the number of calls, that is, drug detailing visits to a physician, and by the number of prescriptions written by that physician and filled by a pharmacy. “In a standard [drug] detailing session, a rep[resentative] generally describes a drug’s approved uses and provides an overview of the safety profile.”³¹¹ Because a representative details numerous physicians, the representative often collects anecdotal evidence of how doctors are prescribing products for additional indications. Representatives then share that information with clients even if it deviates from the approved detail for the product because it may expand the product uses and increase the likelihood of prescription, thus adding to the representative’s income.³¹² Ethical drug promotion requires vigilance from the company and financial remuneration that does not encourage these practices.³¹³

Even if deterrence is better served by prosecuting corporations, the reality is that the government is not going to prosecute the company because of its concern of

convicted of a misdemeanor “related to fraud . . . in connection with the delivery of a health care item or service.” *Id.* at 103; *see also* 42 U.S.C. § 1320a-7b(a). The HHS Departmental Appeals Board upheld the exclusion but reduced it to twelve years. *Friedman*, 755 F. Supp. 2d at 104. On December 13, 2010, a federal district court judge upheld the exclusion order. *See id.* at 117.

309. Geraldine Szott Moohr, *Of Bad Apples and Bad Trees: Considering Fault-Based Liability for the Complicit Corporation*, 44 AM. CRIM. L. REV. 1343, 1346–47 (2007).

310. *See id.* at 1347.

311. Jonathan Pan, *Off-Label Use: A Double-Edged Sword for the Pharmaceutical Industry*, SCIENTIA ADVISORS BLOG (Jan. 4, 2011), <http://www.scientiaadv.com/blog/2011/01/04/off-label-use-%E2%80%93-a-double-edged-sword-for-the-pharmaceutical-industry/>.

312. *See id.*

313. *Id.*; *see also* Lynne L. Dallas, *A Preliminary Inquiry into the Responsibility of Corporations and Their Officers and Directors for Corporate Climate: The Psychology of Enron’s Demise*, 35 RUTGERS L.J. 1, 34–35 & nn.198–207 (2003) (presenting research demonstrating that compensation based on outcomes, like reaching profit goals, does not lead to ethical decision making).

harming innocent individuals. Thus, the advantage to the use of the RCO doctrine is that there will be criminal responsibility for the illegal conduct.

D. Targeted Exclusion

If the harm from off-label promotion is that the government and the public have been defrauded, then some form of exclusion may be needed to protect the government and the public from the unscrupulous manufacturer. Congress could amend the Social Security Act to provide a new exclusion remedy for use against pharmaceutical companies.³¹⁴ In particular, if a pharmaceutical company is convicted of fraud due to its promotion of a drug for off-label uses or the payment of kickbacks, the Social Security Act should permit HHS to exclude the improperly promoted drug from the federal health care programs. If, for example, Pfizer were convicted of fraud in connection with marketing Bextra for off-label uses, Bextra would be excluded from reimbursement under the federal health care programs. As a result, the Medicare and Medicaid programs would not reimburse patients for Bextra prescriptions but would reimburse for all other Pfizer drugs.

To avoid the resultant harm to patients who use the excluded drug, however, the Social Security Act would also need to be amended to require the manufacturer to cover the cost of the excluded drug for Medicare and Medicaid patients who have prescriptions for that drug. This is necessary to prevent an interruption in treatment for innocent patients. Once a patient has found a drug that works well for the treatment of a disease, the patient should not have to become a guinea pig for other medications simply because the drug manufacturer engaged in misconduct.

A targeted exclusion remedy is likely to deter drug manufacturers more than the continued use of CIAs because the higher likelihood of enforcement will force drug manufacturers to reevaluate the potential penalty that they will face upon detection of the fraud. The penalty will include: the fine imposed as a result of violating the FCA and FDCA; the loss of Medicare and Medicaid revenue from the excluded drug over the five-year exclusion period; and the cost of providing the excluded drug free of charge to Medicare and Medicaid patients for the five-year exclusion period. The addition of the requirement that manufacturers provide the excluded drug to Medicare and Medicaid patients is warranted because the added benefit it brings—reduction of harm to innocent patients—outweighs the harm that it imposes on the culpable manufacturer. After reevaluating the penalty to be imposed, pharmaceutical manufacturers should reach the conclusion that the increased profit to be gained from off-label promotion would be outweighed by the cost of the fine and the five-year exclusion of the improperly promoted drug.

Unlike the current exclusion remedy, there is little deterrence spillover onto innocent employees and patients. Although the exclusion of an improperly marketed drug from reimbursement under Medicare and Medicaid would cut off a significant source of revenue for a pharmaceutical company, it would not be nearly as devastating to the company, its employees, and patients as blanket exclusion. The likelihood of the manufacturer collapsing is dramatically lower than with

314. Although this Article focuses on pharmaceutical manufacturers, the new exclusion remedy would be equally applicable to medical device manufacturers.

blanket exclusion. Further, the manufacturer would not need to engage in a cost-cutting campaign to compensate for a huge reduction in revenue. Admittedly, as with any fine, the cost may be passed onto consumers in the form of higher drug prices. Because the remedy is targeted squarely at the manufacturer that caused the harm, however, there is a greater likelihood that the government will be willing to enforce the remedy.

A targeted exclusion remedy would give the government a credible remedy to use against pharmaceutical manufacturers that engage in health care fraud and abuse. The government would no longer need to make the empty threat of blanket exclusion. Ultimately, however, the deterrent effect of a targeted exclusion remedy would largely depend on whether the government is willing to change its enforcement strategy from repeated use of CIAs to the use of both CIAs (when appropriate) and targeted exclusion. If the government decides that its first strategy is to pursue reform through a CIA, it must be willing to go after the manufacturer and seek exclusion if the manufacturer violates the CIA by engaging in improper promotion during the period of the CIA. Otherwise, the targeted exclusion remedy, just like the blanket exclusion remedy, will underdeter pharmaceutical manufacturers.

One of the biggest costs of targeted exclusion will be that the government likely will spend money administering and/or supervising the pharmaceutical company's fulfillment of the requirement of covering the cost of the excluded drug for Medicare and Medicaid patients. There could be great difficulty in compiling a list of Medicare and Medicaid patients who would be eligible for the excluded drug at no cost. The list also would require constant updates as new Medicare and Medicaid patients obtain prescriptions for the excluded drug. In addition, unlike CIAs where manufacturers bear the cost of monitoring, here the government would incur the cost either because the government is administering the fund or because it is supervising the manufacturer's administration of the fund.

Perhaps this proposal would increase the number of cases that actually go to court, thus placing more of a burden on the judicial system. But the upside would be that the administration of justice would be furthered. Prosecutors would be forced to test their legal theories (misbranding, introduction of a new drug, etc.) regarding off-label promotion, and the adjudication of these cases will clarify the law of off-label promotion. Thus, instead of simply having guidance documents from the FDA on what will or will not violate the laws prohibiting off-label marketing, we will have definitive opinions from the courts interpreting the FDCA. Importantly, in addition to clarifying the law, targeted exclusion would prevent the exclusion remedy from being circumvented. Prosecutors would not have to agree to exclude a subsidiary to prevent the exclusion from having an adverse impact on the manufacturer. Instead, the illegally marketed drug would be excluded, which would be more in line with the statutory purpose.

CONCLUSION

The current approach of using Corporate Integrity Agreements as a one-size-fits-all solution to health care fraud is not sustainable. The large penalties and CIA-demanded reforms that are intended to deter manufacturers from re-engaging in illegal promotional practices have become nothing more than the

cost of doing business. Pharmaceutical manufacturers have all too often returned to their pre-CIA illegal promotional activities because they know that the government will not harm innocent third parties by imposing blanket exclusions. Thus, CIAs underdeter manufacturers because the government does not have a plausible remedy of increasing severity to impose in the event that the manufacturer violates the CIA. Therefore, the government needs to consider alternative remedies to CIAs that could be used for repeat offenders of the marketing rules. Each of the remedies discussed in this Article—funding clinical trials, compulsory licensing, corporate officer liability, and targeted exclusion—could be used to increase the severity of punishment if a manufacturer violates a CIA. The government would need to weigh the costs and benefits of the various alternatives before deciding which sanction would be most appropriate given the circumstances of the offender and the offense. The ultimate choice among the alternatives matters little. The important thing is that the government raises the stakes for pharmaceutical manufacturers so that they will think twice before violating an existing CIA. This change of course is necessary if the government is serious about enforcing integrity in drug promotion.