



EMORY
LAW

Emory Corporate Governance and Accountability
Review

Volume 3 | Issue 2

2016

A Failure of Remedies: The Case of Big Pharma (An Essay)

Paul J. Zwier

Emory University School of Law

Reuben Guttman

Follow this and additional works at: <https://scholarlycommons.law.emory.edu/ecgar>

Recommended Citation

Paul J. Zwier & Reuben Guttman, *A Failure of Remedies: The Case of Big Pharma (An Essay)*, 3 Emory Corp. Governance & Accountability Rev. 42 (2016).

Available at: <https://scholarlycommons.law.emory.edu/ecgar/vol3/iss2/2>

This Essay is brought to you for free and open access by the Journals at Emory Law Scholarly Commons. It has been accepted for inclusion in Emory Corporate Governance and Accountability Review by an authorized editor of Emory Law Scholarly Commons. For more information, please contact law-scholarly-commons@emory.edu.

**A FAILURE OF REMEDIES
THE CASE OF BIG PHARMA
(AN ESSAY)[†]**

Paul J. Zwier^{*}
Reuben Guttman^{**}

*“The lower the rate of a fraud’s detection, the higher the multiplier
required to ensure that crime does not pay.”*

—Chief Judge Esterbrook
United States v. Rogan (7th Circuit 2008)

INTRODUCTION

This Article examines the U.S. pharmaceutical industry and the harms imposed on individual patients and healthcare consumers—including private and government third party payers—from practices proscribed by Federal and State laws regulating marketing and pricing.¹

The Article pays particular attention to the False Claims Act (FCA), which has become the government’s primary civil weapon against fraudulent and/or wrongful conduct causing the expenditure of government dollars.

Passed by Congress in 1863, and amended most recently in 2010, the FCA² allows the government to pursue an individual or entity that has filed, or caused to be filed, a “false or fraudulent” claim for payment with funds that in whole or in part came from the government. In addition to treble damages, the statute allows for civil penalties of between \$5,000 and \$11,000 for each “claim.” The FCA is unique in that it has a “qui tam” provision allowing

[†] This essay was prepared for the Remedies Discussion Forum, Paris, June 2015. We are grateful for the research assistance of Luciana Devisate and Chelsea Brewer. Authors also wish to thank Nicholas Torres and Nicole Fukuoka for their assistance on this essay.

^{*} Paul J. Zwier is a Professor of Law, Emory University School of Law.

^{**} Reuben Guttman is a partner in the firm of Guttman, Buschner & Brooks, PLLC and a Senior Fellow and Adjunct Professor at Emory Law School. He has represented whistleblowers in cases against Abbott, Glaxco-Smith Kline, Pfizer, Amgen, Wyeth, Celgene, Pharmacia, Omnicare, and Community Health Systems.

¹ This Article is written as a catalyst to encourage debate during the 2016 election year.

² See False Claims Act, 31 U.S.C. §§ 3729–33 (2012). In addition to the Federal False Claims Act, a number of states have passed their own False Claims Acts focusing on fraud on state and municipal funds. A list of the state FCA’s can be found at www.whistleblowerlaws.com.

private citizens to bring suit in the name of the government provided that their suit is not based on “public information” or, alternatively, that the individual bringing the suit is an “original source” of that information.³

In *United States v. Neifert-White Co.*,⁴ the Court explained that the FCA is a “remedial statute” which “reaches beyond ‘claims’ which might be legally enforced to all fraudulent attempts to cause the Government to pay out sums of money.”⁵ Yet, to the extent that common law fraud requires proving the element of “reliance,” the FCA is actually more expansive than a fraud statute because it captures claims or statements made recklessly in furtherance of government reimbursement; hence, the statute captures false or fraudulent claims.⁶

Generally, where Medicare and Medicaid payers reimburse for drugs that are marketed through misrepresentations about safety, efficacy, quantity or pricing, or where sales have been tainted by “kickbacks,” the Government may be entitled to recovery under the FCA.⁷ In other words, to the extent that a drug is “misbranded” under the Food, Drug, and Cosmetics Act (FDCA), redress is available under the FCA where the wrongful conduct caused the expenditure of government monies.

In addition to treble actual damages, i.e. the amount of money expended for each prescription times three, the Government is entitled to a civil penalty for each prescription submitted or caused to be submitted for payment or approval.⁸

Under the Park Doctrine, theoretically, the government can seek prison sentences for those who are in charge of companies when these illegalities occur,⁹ however, these remedies are almost never invoked. In 2015, Deputy Attorney General, Sally Yates, issued the much-publicized “Yates Memo”

³ See, e.g., *Vermont Agency of Nat. Res. v. United States ex Rel Stephens*, 529 U.S. 765 (2000) (Explaining that because a qui tam ‘relator’ is assigned a portion of the recovery as a bounty, the relator has met the U.S. Const. Article III “injury in fact” standing requirements).

⁴ *United States v. Neifert-White Co.*, 390 U.S. 228 (1968).

⁵ *Id.*

⁶ See, e.g., *United States ex rel. Harrison v. Westinghouse Savannah River Corp.*, 176 F.3d 776 (4th Cir. 1999).

⁷ See *infra* text of Part II.

⁸ 31 U.S.C. § 3729 (2012).

⁹ *United States v. Park*, 421 U.S. 658 (1975).

which encouraged a focus on the criminal and civil prosecution of corporate insiders who have steered their corporate ship on a criminal course.¹⁰

Despite available remedies, the questions for legislators, regulators, candidates for office, and members of the media are: 1) whether available compliance enforcement mechanisms are being used and 2) whether proper remedies that have deterrent value are being imposed on both corporations and the individuals who run them. These are important questions because pharmaceutical fraud is a substantial drain on the economy and places citizens at physical peril.

Historically, the lion's share of settlements with drug manufacturers have involved significant cash payments and the institution of Corporate Integrity Agreements (CIA), but no admission of wrongdoing, no loss of patents, and no restrictions on the particular company's ability to sell its drugs in the marketplace.¹¹ There is neither disclosure of core documents, nor evidence unearthed during the investigation, which may help reset the market for honest medical information about a pharmaceutical product. The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) indicated that it will be more aggressive in imposing different remedies, including lifetime bans on individuals and companies that engage in off-label marketing or other kickback schemes.¹² This has not occurred, even though OIG also has issued guidelines regarding when it might revoke a patent, sell it, or otherwise take profits from the big companies.¹³

To be fair, the blame does not rest solely with the Department of Justice (DOJ). In civil enforcement, the DOJ acts as the law firm for client agencies, including the Centers for Medicare and Medicaid Services (CMS), which is a part of HHS. CMS implements the Medicare program through vendors and lacks the fundamental ability to directly and expeditiously track expenditures,¹⁴

¹⁰ See Sally Yates, *Individual Accountability for Corporate Wrongdoing*, U.S. DEP'T OF JUSTICE MEMO (Sept. 9, 2015), <http://www.justice.gov/dag/file/769036/download>.

¹¹ See generally *infra* note 147 (explaining the purpose and function of Corporate Integrity Agreements).

¹² Office of Inspector Gen. et al., *Practical Guidance for Health Care Governing Boards on Compliance Oversight*, OIG.HHS.GOV (April 20, 2015), <https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>; see also Office of Inspector Gen. et al., *Compliance Program Guidance for Pharmaceutical Manufacturers*, OIG.HHS.GOV (April 2003), https://oig.hhs.gov/fraud/docs/complianceguidance/042803_pharmacymfgnonfr.pdf.

¹³ *Id.*

¹⁴ *The Patient Protection and Affordable Care Act*, CMS.GOV 1, 8–9 (Dec. 10, 2010), <https://www.cms.gov/Regulations-and-Guidance/Legislation/LegislativeUpdate/Downloads/PPACA.pdf> (relating to Prescription Drugs).

or to monitor whether the vendors are making reimbursement payments in accordance with regulation.¹⁵ A glaring consequence of this inability is the payment for drugs for uses that are not medically supported. The question of whether the use—if not within the FDA approved indication—is medically supported, is another problem. CMS has by regulation identified private contractors—i.e. the ‘Compendia’—who are responsible for determining whether an off-label use is medically supported.¹⁶ These contractors often rely on industry paid doctors for guidance, as their conflicts of interest policies do not proscribe industry relationships.¹⁷ CMS has simply neglected to properly monitor Compendia publishers.

Without a CMS’ handle on expenditures, the DOJ seems to have entered settlements absent any transparent damage models with the litmus test for fairness seemingly hinging on whether the settlement has the optics of deterrence. Unfortunately, when viewed from an historical context, remedies have had little impact on the behavior of the big pharmaceutical companies in their pricing and marketing practices.¹⁸

Big Pharma¹⁹ practices present a case study for determining whether agencies should use other remedies to bring about better behaviors and whether courts, in approving settlements, should exercise diligence in determining the applicability of remedies. The question is why traditional remedies have failed to provide the necessary deterrence and what practical solutions exist. This Article provides analysis of the problem and raises the prospect of long term and short term solutions which include:

¹⁵ *Id.*

¹⁶ *Medicare Prescription Drug Benefit Manual*, CMS.GOV (Feb. 19, 2010), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter6.pdf>.

¹⁷ *Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians*, CMS.GOV (July 2014), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf.

¹⁸ See *infra* text of Part II.

¹⁹ For a definition of Big Pharma, we use the criteria developed by SEBASTIAN HELD ET AL., *IMPACT OF BIG PHARMA ORGANIZATIONAL STRUCTURE ON R&D PRODUCTIVITY* 17 (2009). (The criterion they use for defining Big Pharma are, pharmaceutical firms reaching at least \$ 2 billion in sales a year, selling in at least 3 dominant markets, US, Europe and Japan, ongoing R&D marketing efforts in a minimum of 5 separate therapeutic fields, and maintain completely integrated marketing operations including internal R&D, manufacturing, clinical, regulatory, marketing and sales. Using this criterion as of 2009, twelve companies fit the category: Pfizer, (leads the way with over \$ 46 billion in sales and a 7.6 market share, in 2009), GlaxoSmithKline, Novartis, Sanofi-Aventis, Johnson & Johnson, AstraZeneca, Merck & Co, Roche, Abbot, Amgen, Wyeth, Lilly, (other at or just missing the \$ 2 billion in sales and making up about 2% of the market are Bayer, Bristol Meyers Squibb, and Boehringer Ingelheim)).

- The promulgation of formal DOJ guidance on settlements with pharmaceutical manufacturers and others in the stream of commerce, including a requirement that Civil Penalties under the FCA not be waived;
- The issuance of DOJ reports, which make public the facts and documents unearthed during investigations that result in settlements of cases that lacked the transparency of formal litigation;
- The release, under the Freedom of Information Act, of all documents maintained by the FDA with regard to a drug or product that was the subject of a settlement of misbranding or kickback allegations;
- Legislation allowing CMS to bargain with manufactures or to use price referencing systems—as exists in Europe and Canada—to lower the cost of drugs;
- The imposition of criminal and civil penalties on corporate officials who oversee marketing activities that have the potential to place patients at peril; and
- Complete oversight of CMS to analyze whether inherently public functions are imprudently privatized and whether functions properly performed by private vendors are monitored for compliance with regulatory obligations.

Part 1 of this Article looks at the market for pharmaceuticals, its profitability, and its risks. It evaluates pricing of pharmaceuticals and the incentives in the market that seem to cause institutional behaviors that drive illegal conduct. In addition, it briefly examines why faith in the free market, which theoretically should moderate the behavior of actors out of fear that consumers will simply choose a different provider, fails in the case of pharmaceuticals.

Part 2 of this Article examines the failures of the existing traditional remedies in the FCA and the related actions to adequately compensate, deter, and punish for Big Pharma's illegality. In particular, it examines repeat offenders in the pharmaceutical market, and notes that the problem may lie most with companies without either real competition for their particular drugs, or a diversified portfolio of generic products as part of their offerings. It also examines the promise of CIAs to bring more integrity into the relationship of manufacturers and consumers. It questions why such agreements that contain promises—including that a court can ban companies that persist if they engage

in future off-label marketing—have not been enforced in settlements with the DOJ. It also demonstrates how revoking a company’s patent can disrupt future patients’ ability to get the appropriate drugs they need, and as a result make the remedy unattractive. At least until the generic market can meet this need, the court may be hesitant to revoke the patent. It examines whether as a matter of remedies, the court should be empowered to count as damages future sales of the patented drug as a basis for deterring the fraudulent behavior. It illustrates how such remedies may run afoul of the Constitution. As a result, the company may bet that its ability to continue to sell the drug in its markets will make up for the risks it incurs in engaging in deceitful behavior in establishing the market in the first place. Without the ability to confiscate future profits as a remedy, it is unlikely that the behavior of Big Pharma will be significantly deterred, as the gains are too tempting, and chances that any one individual gets caught are too low.

Finally, we conclude by proposing a combination of remedies and ask whether pricing regulation, either through CMS, or by allowing insurance companies to combine forces to negotiate lower price, needs to be a necessary part of these remedies to Big Pharma’s illegal practices.

I. PHARMACEUTICALS, PROFITS AND RISKS

Among corporations, pharmaceutical companies are unique. Their brand and reputation is premised on the notion that they cater to patients in perilous health by producing products that are safe and effective. Although not bound to the Hippocratic Oath taken by doctors who order their products through prescriptions, their brand implies the same level of obligation—“do no harm.” Yet the question of whether the patient is the customer is a murky matter; a doctor writes the prescription for a person whose bill is often paid by third parties, many of whom disperse federal and state health care dollars. Obligations to investors and efforts to maximize stock price for the benefit of corporate officers, desiring to cash in on stock options, are externalities driving unlawful behavior. And at an emotional level, there is undoubtedly the perception—on Wall Street and within the corporation itself—that no regulator is going to face the political backlash of jeopardizing the long-term viability of businesses manufacturing pills that prolong life.

Against this backdrop, Big Pharma was able to fly under the radar with business practices placing consumers’ safety in jeopardy, while causing the

unnecessary expenditure of government health care dollars.²⁰ The Federal Bureau of Investigation estimates that health care fraud costs American taxpayers \$60 billion a year.²¹ Some estimates contend the Medicare program alone constitutes over \$600 billion lost to fraudulent activity by the health care profession, generally, in the last ten years.²² Based on these numbers alone, it is astonishing that candidates for office and the journalists who pose the questions in debates have not made this a focal point for political discourse.

As part of the settlements, many companies are required to enter into self-policing agreements called CIAs.²³ Notwithstanding their existence, repeat offenders are common, as in the case of companies including Abbott and Pfizer.

With fraud unchecked, medical costs continue to rise far in excess of inflation.²⁴ More troubling is that the increase in the cost of health care is mostly attributable to rising pharmaceutical prices.²⁵ Dan Muro, a frequent contributor to *Forbes* magazine who closely follows health care costs, noted the following:

An estimated 576,000 Americans spent more than the median household income on prescription medications in 2014. This population of patients grew an astounding 63% from 2013. Further, the population of patients with costs of \$100,000 or more nearly tripled during the same time period, to nearly 140,000 people. The total cost impact to payers from both patient populations is an unsustainable \$52 billion a year.²⁶

²⁰ See generally U.S. Dep't of Justice, *The Settlement Agreement*, JUSTICE.GOV (May 7, 2012), <http://www.justice.gov/sites/default/files/opa/legacy/2012/05/07/SettlementAgreement.pdf> (indicating that the US brought a cause of action against Abbott, and Abbott must pay the United States a lump sum of money for violations of the FCA).

²¹ See *Fixing the False Claims Act: The Case For Compliance-Focused Reforms*, U.S. CHAMBER FOR LEGAL REFORM (Oct. 23, 2013), <http://www.instituteforlegalreform.com/research/fixing-the-false-claims-act-the-case-for-compliance-focused-reforms> [hereinafter *Fixing the False Claims Act*].

²² *Id.*

²³ See generally *Settlements*, *supra* note 23 (stating within the settlement agreement that Abbott agrees to enter into a Corporate Integrity Agreement); see *infra* note 147.

²⁴ Dan Munro, *Annual Healthcare Cost for Family of Four Now at \$24,671*, FORBES (May 19, 2015, 11:02 AM), <http://www.forbes.com/sites/danmunro/2015/05/19/annual-healthcare-cost-for-family-of-four-now-at-24671/> (discussing the increase in the average cost for families of four with employer-provided PPO insurance coverage and the annual increase in spending split by employer and employee portions).

²⁵ *Id.*

²⁶ *Id.* (quoting Glen Stettin, *Super Spending: U.S. Trends in High-Cost Medication Use*, EXPRESS SCRIPTS LAB (May 13, 2015), <http://lab.express-scripts.com/insights/drug-options/super-spending-us-trends-in-high-cost-medication-use>).

. . . Across the board increases in prescription drug costs were cited as the primary cause for the higher total percentage increase in health care costs (6.3% this year versus 5.4% in 2014).²⁷

The rate at which prescription drug costs increased this year doubled over the average increase of the prior five years. This was driven by a combination of factors, including the introduction of new specialty drugs, a continued increase in compound drugs, and price increases for both brand name and generic drugs.²⁸

There is no evidence of rising overhead or tightened profit margins as causes for price escalation. The World Health Organization estimates that, worldwide in 2014, pharmaceutical companies scored in excess of \$300 billion in profits; with profits headed to \$400 billion over the next three years.²⁹

A look at Medicare disbursements provides insight into the problem. The total amount of Medicare reimbursement for pharmaceuticals in 2015 is estimated at \$85 billion,³⁰ or 14% of the total Medicare health care expenditures. These include both Medicare B plan reimbursements, (for drugs administered in an outpatient or hospital setting), and Medicare D plans, (for drugs outside the hospital setting).³¹ In the U.S., the free market sets the price for drugs except that the largest payer, Medicare, lacks statutory authority to bargain, let alone bargain collectively with other payers.³² Although Medicare has some leverage over what it pays (Medicare will only pay the price of the lowest cost generic, where generics exist, unless doctor provides justification³³), it has little ability to negotiate down the cost of drugs.

²⁷ Munro, *supra* note 26.

²⁸ Scott A. Wetz, Christopher S. Girod & Susan K. Hart, *2015 Milliman Index*, MILLIMAN (Dec. 22, 2015, 9:15 PM), <http://us.milliman.com/MMI/>.

²⁹ *Trade, Foreign Policy, Diplomacy and Health: Pharmaceutical Industry*, WORLD HEALTH ORG., <http://www.who.int/trade/glossary/story073/en/>.

³⁰ *HHS FY2015 Budget in Brief*, U.S. DEP'T. OF HEALTH AND HUMAN SERVS., (June 4, 2014), <http://www.hhs.gov/about/budget/fy2015/budget-in-brief/cms/medicare/index.html> (explaining the distribution of Medicare into four parts including Part B (\$167.8 billion gross fee for service spending in 2015) which pays for “physician, outpatient hospital, ESRD, laboratory, durable medical equipment, certain home health, and other medical services,” and Part D (\$85.2 billion projected gross spending in 2015) which provides a “standard prescription drug benefit”).

³¹ *Id.*

³² Gina Kolata, *Why Drugs Cost More in the US* (May 24, 1991), N.Y. TIMES, <http://www.nytimes.com/1991/05/24/business/why-drugs-cost-more-in-us.html?pagewanted=all>.

³³ *How Do I Appeal if I Gave Medicare Prescription Drug Coverage?*, MEDICARE.GOV, <https://www.medicare.gov/claims-and-appeals/file-an-appeal/prescription-plan/prescription-drug-coverage-appeals.html>.

When one examines the costs by type of drug and compares this with what one who needs the drug has to pay outside the U.S., one can see how the unregulated market for drugs in the U.S. makes for run-away pricing.³⁴ High prices are in place for most categories of drugs sold in the U.S. From cancer drugs to pain-killers,³⁵ cholesterol lowering drugs to nasal sprays, drugs for impotence to asthma to diabetes, U.S. citizens pay much higher prices than Canadians and Europeans.³⁶

Although there are features of the production and patenting of pharmaceuticals that make drugs costly to produce, in contrast to publicly regulated utilities that also have a government sanctioned monopoly, the same transparency is lacking with regard to expenditures or stranded costs. Against this backdrop, the industry claims that the testing and FDA approval process often eats up 10-12 of the 20 years that the owner has the exclusive ability to sell the drug.³⁷ This leaves 8 to 10 years for the owner to recoup costs before generic competition for a successful drug will start. One wonders why then that drug prices, even after generics hit the market, remain so high in the U.S. Why doesn't competition from generics eventually moderate the cost of drugs? There are a number of reasons. Medicare Part B prescriptions make up a relatively small percentage of overall prescriptions in the U.S.³⁸ Other

³⁴ Thom Hartmann, *11 Major Drug Companies Raked in \$85 Billion Last Year, and Left Many to Die Who Couldn't Buy Their Pricey Drugs*, ALTERNET (Apr. 30, 2013), <http://www.alternet.org/11-major-drug-companies-raked-85-billion-last-year-and-left-many-die-who-couldnt-buy-their-pricey> (focusing on the pricing differences for two common drugs, Nexium and Lipitor, between the United States and various other countries in the developed world).

³⁵ David H. Howard, Peter B. Bach, Ernst R. Berndt, & Rena M. Conti, *Pricing in the Market for Anticancer Drugs*, J. ECON. PERSPECTIVES VOL. 29 NO. 1, 139–62 (2015), <http://dspace.mit.edu/openaccess-disseminate/1721.1/96183> (“We find that the average launch price of anticancer drugs, adjusted for inflation and health benefits, increased by 10 percent annually—or an average of \$8,500 per year—from 1995 to 2013.”).

³⁶ *Id.*

³⁷ Dennis S. Fernandez et. al., *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, IP HANDBOOK OF BEST PRACTICES fig.1 (2007), <http://www.iphandbook.org/handbook/ch10/p09/> (describing typical time periods for drug development after patent). The article includes the following assertions:

If you ask executives at America's top pharmaceutical drugs about the high costs of prescription drugs, they'll tell you that high and increasing drug prices are needed to sustain research and development efforts. But numerous studies have debunked those claims.

For example, one study, by the group Families USA, found that America's major drug companies are spending more than twice as much on marketing, advertising and administration than they do on research and development. The report also found that the total profits of America's top pharmaceutical companies far exceed their research and development costs. *Id.*

³⁸ *Id.*

prescriptions are covered by multiple plans and payers.³⁹ The non-generic manufacturer also is taking advantage of the physician's presumptive ethical responsibilities to prescribe without regard to price.⁴⁰ In addition, with many pharmaceuticals, the patient has little say regarding what he or she pays. They may have little information as to the cost, or they may think they do not have a choice; with cancer drugs to heart medications, failure to take the drugs appears to be life threatening. Moreover, Big Pharma engages in repackaging its drugs in strategies that allow it to extend the life of its drug, often in collusion with some generic manufacturers.⁴¹

Finally, antitrust law allows a certain amount of collusion among label and generic manufacturers of drugs.⁴² In order to incentivize the making of generics, a company can submit its application for a generic of a name brand drug to the FDA, subject to the *Orange Book* listing of the name brand drug, in the time leading up to name brand drug's expiration. The name brand manufacturer must look at the formula and determine if it wants to attempt to extend the patent through a supplement or improvement to the existing patent. It can extend the life of the drug by adding features or new methods of delivery. In the process the two can agree to "split up the market" for the drug between them, to insure some spaces to continue to sell the drug under different advertising campaigns.⁴³ As a result, generics end up costing more in the U.S. than elsewhere, where the price may be regulated and physicians continue to prescribe the name brand because they are either confused, worried about the generics being lower quality, or sticking with what works, as opposed to taking risks with the alternatives.⁴⁴

The combination of the uncertain line between extortion and free market pricing by supply and demand, the unique nature of the health care need for certain drugs, the ability of companies to get patents for their drugs, the collusive relationship between named brand manufacturers and generic

³⁹ *Id.*

⁴⁰ Arnold S. Relman, *Cost Control, Doctors' Ethics, and Patient Care*, ISSUES IN SCIENCE AND TECHNOLOGY, <http://www.issues.org/19.4/updated/relman.pdf>. See also 42 C.F.R. § 405.517 (2015) (basing medicare allowances for physician reimbursement of drugs to physicians based on a percentage of the overall cost of the drug).

⁴¹ The Editorial Board, *Sneaky Ways to Raise Drug Profits*, N.Y. TIMES (June 8, 2015), http://www.nytimes.com/2015/06/08/opinion/sneaky-ways-to-raise-drug-profits.html?_r=0.

⁴² See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

⁴³ *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, FDA (July 29, 2009), <http://www.fda.gov/newsevents/testimony/ucm115033.htm>.

⁴⁴ The FDA provides the cover for these agreements. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

manufacturers, the responsibility of doctors for prescribing the drug, and the inability of insurance companies to collectively bargain for price all adds up to a system that routinely gouges society in the prices it pays for its drugs.⁴⁵

II. REMEDIES UNDER THE FALSE CLAIMS ACT, THEIR FAILURE TO ADEQUATELY COMPENSATE AND DETER BIG PHARMA'S BEHAVIOR

The need to deter Big Pharma's fraud by actors cloaked by the cover of large institutional unanimity remains a major challenge for the U.S. brand of free market democracy where the government is both a regulator and a payer for care.⁴⁶ The temptation to commit fraud by big institutions that do business in mass markets for goods—while focusing on maximizing profits and growing shareholder value each year—has always been great,⁴⁷ but it is particularly acute where that business provides life-saving drugs.⁴⁸ Cost sensitivities of individual consumers are absent, the physician intermediary/pharmaceutical coinsurer is often forbidden by medical ethics to take account of the costs, and hospitals often are more than willing to mark-up costs as they also pursue bottom line profits.⁴⁹

⁴⁵ See Robert H. Ballance, *Market and Industrial Structure*, in *CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS* 95, 103–04 (Peter Davis ed., 1996); see also David J. Gross, et al., *Prices for Prescription Drugs: The Roles of Market Forces and Government Regulation*, in *CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS*, 124, 134 (Peter Davis ed., 1996); Patricia M. Danzon, *Pharmaceutical Price Regulation: National Policies Versus Global Interests*, THE AEI PRESS 1, 3–4 (1997), http://www.aei.org/wp-content/uploads/2014/07/-pharmaceutical-price-regulation-global-interests_11361924090.pdf.

⁴⁶ Merrill Matthews, *Medicare and Medicaid Fraud Is Costing Taxpayers Billions*, FORBES (May 31, 2012), <http://www.forbes.com/sites/merrillmatthews/2012/05/31/medicare-and-medicaid-fraud-is-costing-taxpayers-billions/> (discussing former U.S. Attorney General Eric Holder estimated Medicare and Medicaid fraud is between 60-90 billion a year).

⁴⁷ Reuben Guttman & Traci Buschner, *Commentary: Give Big Pharma a Dose of Strong Regulatory Medicine*, MARKETWATCH (Aug. 7, 2013), <http://www.marketwatch.com/story/patients-suffer-from-drug-industrys-chronic-greed-2013-08-07> (explaining that almost every major pharmaceutical manufacturer has been sanctioned either civilly, criminally, or both for unlawfully marketing their drugs); see also James McNair, *The Kickback, Fraud and Drug-Switch Claims That Ail a Louisville Pharmacy Company*, KENTUCKY CENTER FOR INVESTIGATIVE REPORTING (May 21, 2015), <http://kycir.org/2015/05/21/the-kickback-fraud-and-drug-switch-claims-that-ail-a-louisville-pharmacy-company/> (explaining that the drug maker Abbott Laboratories paid rebates to get pharmacy companies to pump up prescriptions of an anti-seizure drug to agitated dementia patients in nursing homes).

⁴⁸ In the case of life-saving drugs, patients are told that they have little choice. Thus, the patients are willing to take the risk. In the case of psychopharmacological drugs, it is difficult to measure ethics and safety concerns; thus, the risk is not immediately measurable.

⁴⁹ Barry Werth, *A Tale of Two Drugs*, MIT TECH. REV. (October 22, 2013), <http://www.technologyreview.com/featuredstory/520441/a-tale-of-two-drugs/>.

Perhaps the reason is confusion in the actors' mind between market place pricing that is set by supply and demand, and behavior that is condemned as extortion, or at the very least exorbitant in nature. Where someone extorts \$1,000 for a loaf of bread to a starving person, or \$500 for a glass of water to a person dying of thirst, the exorbitant nature of the pricing is plain. Where the price is \$100,000.00 for a cancer saving drug, the outrage may be the same, but the nature of the market might cover its extortive characteristics in the language of supply and demand. The "free market" has a difficult time in restricting pricing that takes advantage of one's illness. What further exacerbates the dilemma is that existence of insurance (and its mixed motive—the more it pays, the more it can charge⁵⁰) often makes the cost of the drug hard to discover. Moreover, HHS is forbidden in the U.S. from bargaining collectively with pharmaceutical companies for lower costs for drugs.⁵¹ Despite the fact that Medicare and Medicaid at one time only reimbursed at the price point of the lowest priced generic, private insurers were incentivized against negotiating similar restrictions on what they/it pays.⁵² Individual insurers are immune from antitrust regulations for collusive bargaining over drugs and can engage in pricing agreements with pharmaceutical companies that result in higher prices of drugs on the market.⁵³ Even though the Veterans Administration (VA) pays approximately 40 percent of what the private insurance companies pay for the same drugs, U.S. law is protective of its "free market" and forbids collective bargaining, out of fear that lower prices may restrict the research and development of new drugs.⁵⁴

⁵⁰ See *How Rates are Determined*, OHIO DEP'T INS., <https://www.insurance.ohio.gov/Newsroom/Pages/Howratesaredetermined.aspx> (last visited Oct. 25, 2015).

⁵¹ According to Senator Amy Klobuchar, "Under current law, only individual insurance companies can negotiate Medicare drug prices. The pharmaceutical industry has tried to reassure Americans that this will inevitably produce the lowest prices because of competition. This explanation is unconvincing. Evidence and experience show us that the present system often does not produce the fairest prices. The pharmaceutical companies like to say that Part D Program costs are lower than projected, but beating artificial projections has not resulted in lower prices. Numerous studies show that Part D prices are significantly higher than prices for drugs and programs where negotiation is permitted." 153 CONG. REC. S4, 641 (daily ed. Apr. 18, 2007) (statement of Sen. Klobuchar).

⁵² Caryn Beth Gordon, *Predatory Pricing - Collusion Between Insurers and Drug Companies*, 7 LOY. CONSUMER L. REV. 60 (1995). See generally Judy Whalley, *Priorities and Practices - The Antitrust Division's Criminal Enforcement Program*, 57 ANTITRUST L.J. 569 (1988); Thomas G. Krattenmaker & Steven C. Salop, *Economic Concepts and Antitrust Analysis: A Critical Reexamination Analyzing Anticompetitive Exclusion*, 56 ANTITRUST L.J. 71, 74 (1987).

⁵³ *Id.*

⁵⁴ Kai Rugerri & Ellen Nolte, *Pharmaceutical Pricing: The Use of External Reference Pricing* (2013), http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR240/RAND_RR240.pdf (comparing European and US pharmaceutical company profits).

Curiously, there is some question as to what Big Pharma actually means when it says it puts money into research and development. Is it putting money into studies or trials that will develop data to be submitted to the FDA to secure a new or expanded indications or to meet post marketing requirements, or is it developing data to be used to support journal articles that will be used to spin off label messages causing revenue to be secured from uses outside the FDA approved indication? In other words, are purported Research and Development monies really just expenditures in furtherance of illegal marketing goals as opposed to legitimate regulatory requirements?

The chance of making huge short-term profits with impunity seems to overwhelm a decision-maker's calculation of the consequential harm his or her decision may cause and overwhelms his or her calculation of the risks of getting caught.⁵⁵ The harm caused can be nonetheless significant and the need for strategies of adequate deterrence an important societal priority.

There are three areas in particular where the willingness of institutions to defraud by ignoring health care costs in their pursuit of profits seems to be on the rise. The first is in the area of misbranding and its subcategory, off-label marketing, which is a violation of the FDCA redressable under the FCA. The second is the provision of kickbacks to physicians for prescribing or recommending their drugs. The third are strategies with generic companies to enter into settlements that divide up the market for a particular drug and keep the overall cost of the drugs higher than what can be justified by the drugs' benefits. In the first two cases, the institutions are engaged in Medicare fraud as they charge the public for products of questionable benefit or for uses that raise significant safety concerns.⁵⁶ The number and size of these cases have increased to such an extent that the government itself seems almost complicit

⁵⁵ Though Big Pharma stands out in its continuous choice to put greed over risk of harm, it is not the only industry often overwhelmed by such greed. See, e.g., *US v. Bernard L. Madoff and Related Cases*, THE UNITED STATES ATTORNEY'S OFFICE SOUTHERN DISTRICT OF NEW YORK, <http://www.justice.gov/usao-sdny/programs/victim-witness-services/united-states-v-bernard-l-madoff-and-related-cases> (cases involving securities fraud); Ben Protess & Michael Corkery, *5 Big Banks Expected to Plead Guilty to Felony Charges, but Punishments May Be Tempered*, N.Y. TIMES (May 13, 2015), <http://www.nytimes.com/2015/05/14/business/dealbook/5-big-banks-expected-to-plead-guilty-to-felony-charges-but-punishments-may-be-tempered.html> (fraud in the banking industry); Peter J. Henning, *Many Messages in the G.M. Settlement*, N.Y. TIMES (Sept. 21, 2015), http://www.nytimes.com/2015/09/22/business/dealbook/many-messages-in-the-gm-settlement.html?_r=0 (product defects in mass manufactured goods).

⁵⁶ See *Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013*, DEP'T JUST. (Dec. 20, 2013), <http://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013>; *A Roadmap for New Physicians: Fraud & Abuse Laws*, U.S. DEP'T HEALTH & HUM. SERVS., <http://oig.hhs.gov/compliance/physician-education/01laws.asp> (last visited Oct. 25, 2015).

in the illicit behavior.⁵⁷ The subject institutions pay enormous fines in settlement, so the government drops the cases.⁵⁸ Most troubling, however, is that often the institutions continue their activities—defrauding the markets and the government and paying the fines simply as a cost of doing business.⁵⁹

The available data from the organization, the Project on Government Oversight, Pogo.org/DOJ.org, supports the claim that pharmaceutical companies have not been deterred by the large fines imposed by the DOJ and perhaps consider any amount they might pay for liability as the cost of doing business.

A survey of settlements between the Justice Department and Big Pharma since 2009, in excess of \$75 million, provides plenty of troubling examples. We take our reports of cases and settlements from the following sources: *Justice News*, DEPARTMENT OF JUSTICE, <http://www.justice.gov/justice-news>; and, PROJECT ON GOVERNMENT OVERSIGHT, <http://www.pogo.org> (survey by research assistant of Justice Department reports, and POGO listings).⁶⁰

Settlements between pharmaceutical companies and the Justice department since 2009 consisting—time of publication—of \$75 million or more:

Company Name, Drug Name, Settlement, Date

1. GlaxoSmithKline, Paxil, and Wellbutrin, \$3 billion, 2012
2. Pfizer, Bextra, \$2.3 billion, 2009
3. Abbott Laboratories, Depakote, \$1.5 billion, 2012
4. Eli Lilly, Zyprexa, \$1.4 billion, 2009
5. Amgen, Aranesp, \$762 million, 2012

⁵⁷ See Evan Albright, *Medicare Reports Fraud And Waste Grew In 2013 After Years Of Decline*, FORBES (Dec. 20, 2013, 3:50 PM), <http://www.forbes.com/sites/insidpatientfinance/2013/12/20/medicare-reports-fraud-and-waste-grew-in-2013-after-years-of-decline/>.

⁵⁸ See Kelly Kennedy, *Drugmakers Have Paid \$8 Billion in Fraud Fines*, USA TODAY, <http://usatoday30.usatoday.com/news/washington/story/2012-03-05/health-drugmakers-fraud-fines/53372792/1> (last updated Mar. 6, 2012, 8:43 AM).

⁵⁹ See Austin B. Frakt, Steven D. Pizer & Roger Feldman, *Should Medicare Adopt The Veterans Health Administration Formulary?*, 21 HEALTH ECONOMICS 485 (2012), available at http://www.readcube.com/articles/10.1002%2Fhec.1733?r3_referer=wol&tracking_action=preview_click&show_checkout=1&purchase_referrer=onlinelibrary.wiley.com&purchase_site_license=LICENSE_DENIED.

⁶⁰ Founded in 1981, POGO originally worked to expose outrageously overpriced military spending on items such as a \$7,600 coffee maker and a \$435 hammer. In 1990, after many successes reforming military spending, including a Pentagon spending freeze at the height of the Cold War, POGO decided to expand its mandate and investigate waste, fraud, and abuse throughout the federal government. Throughout its history, POGO's work has been applauded by Members of Congress from both sides of the aisle, federal workers and whistleblowers, other nonprofits, and the media. See generally, *About POGO*, <http://www.pogo.org/about/>.

6. GlaxoSmithKline, Kytril/Bactroban/Paxil CR/Avandamet, \$750 million, 2010
7. Allergan, Botox, \$600 million, 2010
8. AstraZeneca, Seroquel, \$520 million, 2010
9. Ranbaxy Laboratories, Gabapentin, \$500 million, 2013 (Indian)
10. Novartis, Trileptal, \$423 million, 2010
11. Merck, Vioxx, \$322 million, 2011
12. *Forest Laboratories, Levothroid, Celexa, Lexapro, \$313 million, 2010-off-label promotion*
13. Dey Pharma, Albuterol Sulfate/Albuterol MDI, Cromolyn Sodium/Ipratropium Bromide, \$280 million, 2010—False Claims Act over reported prices—or getter payment rates
14. *Wyeth Pharmaceuticals, Rapamune, \$256.4 million, 2013-off-label promotion*
15. Johnson and Johnson, Topamax, \$81 million, 2010
16. Johnson and Johnson, Risperdal/Invega/Natrecor, \$2.2 billion, 2013-off-label promotion
17. Endo Pharmaceuticals, Lidoderm, \$171.9 million, 2014
18. Sanofi, Hyalgan, \$109 million, 2012 (French)
19. Elan, Zonegran, \$203.5 million, 2010
20. *Boehringer Ingelheim, Aggrenox, Atrovent/Combivent, Micardis, \$95 million, 2012*

A list of pharmaceutical companies that have been penalized multiple times by the DOJ since 2001 follows. This partial list includes information compiled from Pogo.org and DOJ.org. POGO is an independent watchdog organization that describes itself as follows:

Company And Date of Settlement	Conduct Type	Settlement And net profit reported when known	Synopsis
Johnson & Johnson 2001	Fraudulent Pricing	\$3,750,000	
2013	Off-label Marketing	\$2.2 Billion NP (2007-2012): \$4,858,000,000 (Risperdal) + \$424,000,000 (Invega) + \$441,000,000	J&J and its subsidiaries, Janssen Pharmaceuticals and Scios Inc., paid \$2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal,

		(Natrecor)	Invega and Natrecor, including promotion for uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider. In addition to monetary sanctions, this settlement placed J&J under a five-year CIA.
Abbott Laboratories 2001	Fraudulent drug pricing of Lupron and kickbacks	\$568 million Net profit was reported after the settlement payout. This amount was a 4% increase over the prior year (2000).	TAP Pharmaceutical, a subsidiary of Abbott Laboratories and Takeda Industries, set and controlled the price at which the Medicare program reimbursed physicians for the prescription of Lupron by reporting its average wholesale price ("AWP"). The AWP reported by TAP was significantly higher than the average sales price TAP offered physicians and other customers for the drug. The Government alleged that TAP marketed the spread between its discounted prices paid by physicians and the significantly higher Medicare reimbursement based on AWP as an inducement to physicians to obtain their Lupron business. The Government further alleged that TAP concealed the true discounted prices paid by physicians from Medicare, and falsely advised physicians to report the higher AWP, rather than their real discounted price for the drug.

The Government further alleged that TAP set its AWP of Lupron at levels far higher than the price for which wholesalers or distributors actually sold the drug, resulting in falsely inflated prices that were neither the physician's actual cost nor the true wholesaler's average price. As part of this settlement, TAP agreed to comply with the terms of a sweeping CIA which changes the manner in which TAP supervises its marketing and sales staff, and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs.

2003	Fraudulent pricing of enteral feeding products	\$382 million (2003)\$2,855,000,000	In July 2003, Abbott Laboratories, Inc., entered into a \$600 million combined criminal and civil resolution of allegations against its Ross Products division relating to the manner in which it marketed its enteral feeding products. According to the complaint, Abbott was counseling DME suppliers to submit "bundled" claims to the Medicare program for feeding pumps and tubing. The bundled claims resulted in two products being billed as a single product at a higher price than if billed separately. As part of the settlement, Abbott entered into a five-year CIA.
2010	Fraudulent	\$126 million	Abbott agreed to pay

	pricing of several drugs	(2009): \$7.86 Billion	\$126,500,000 for reporting false and inflated prices for numerous pharmaceutical products. The actual sales prices for the products were far less than what Abbott reported. The difference between the resulting inflated government payments and the actual price paid by healthcare providers for a drug is referred to as the "spread." The larger the spread on a drug, the larger the profit for the health care provider or pharmacist who gets reimbursed by the government. The government alleges that Abbott created artificially inflated spreads to market, promote and sell dextrose solutions, sodium chloride solutions, sterile water, vancomycin and erythromycin.
2010	Off-label marketing of Advicor and kickbacks	\$41 million (2009): \$7.86 Billion	Kos Pharmaceuticals, a subsidiary of Abbott Laboratories, paid more than \$41 million to resolve criminal and civil liability arising from conduct relating to its drugs Advicor and Niaspan. Specifically, the civil settlement resolves allegations that Kos offered and paid doctors, other medical professionals, physician groups and managed care organizations, illegal kickbacks in the form of money, free travel, grants, honoraria and other valuable goods and services, in violation of the Anti-Kickback Statute to get them to prescribe or recommend Niaspan and Advicor.

			<p>In addition, the United States contends that Kos promoted the sale and use of Advicor for use as first-line therapy for management of mixed dyslipidemias (a disruption of the lipids in the blood). Such an off-label use was not approved by the Food and Drug Administration nor was it a medically-accepted indication for which the United States and state Medicaid programs provided coverage for Advicor. As part of the settlement, Kos has entered into a deferred prosecution agreement. The DOJ agreed to enter into a deferred prosecution agreement with Kos based in part on the company's undertaking of a thorough internal investigation of misconduct; its reporting of information from the investigation to the department on a regular basis; its continued and ongoing cooperation with the department's investigation of the matter; and in recognition of the remedial measures undertaken by the company.</p>
2012	Off-label marketing of Depakote	\$1.5 Billion \$5. 12 Billion	<p>Abbott agreed to pay \$1.5B to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the Food and Drug Administration (FDA). The company misbranded Depakote by promoting the drug to control agitation and aggression in elderly</p>

2013	Kickbacks	\$5,475,000 2013 2.6 Billion	<p>dementia patients and to treat schizophrenia when neither of these uses was FDA approved. In addition to the criminal and civil resolutions, Abbott also executed a CIA. The five-year CIA requires, among other things, that Abbott's board of directors review the effectiveness of the company's compliance program, that high-level executives certify to compliance, that Abbott maintain standardized risk assessment and mitigation processes, and that the company post on its website information about payments to doctors. Abbott is subject to exclusion from federal healthcare programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches</p> <p>Abbott knowingly paid prominent physicians for teaching assignments, speaking engagements and conferences with the expectation that these physicians would arrange for the hospitals with which they were affiliated to purchase Abbott's carotid, biliary and peripheral vascular products.</p>
Glaxo Smith Kline 2003	Fraudulent Pricing	87.6 million	<p>GSK agreed to pay the government a civil fine of \$87.6 million for failing to give the Medicaid program the lowest price charged to any consumer for anti-depressant Paxil and nasal allergy spray Flonase. GSK</p>

			was accused of hiding its lowest prices from Medicaid by repackaging or relabeling its products under a middleman's name, who then sold them at a deep discount not reported to the government.
2004	Failure to disclose side effects	2.5 million	GSK suppressed the results of studies which failed to prove Paxil's effectiveness and which suggested a possible increased risk of suicidal thoughts and acts in certain individuals. GSK was further alleged to have failed to disclose this information in medical information letters it sent to physicians.
2005	Fraudulent Pricing	150 million	GlaxoSmithKline paid over \$150 million to settle allegations of fraudulent drug pricing and marketing of the anti-emetic drugs Zofran and Kytril. GSK allegedly engaged in a scheme to set and maintain inflated prices for Zofran and Kytril. The government also alleged GSK engaged in a "double dipping" billing scheme with respect to Kytril by encouraging customers to pool leftover vials of Kytril to create an extra dose, which would then be administered to a patient and re-billed to government healthcare programs.
2010	Fraudulent marketing of Avandia	Settlement amount: pending	GlaxoSmithKline marketed its Avandia diabetes drug as a new "wonder drug" that would reduce cardiovascular risks for diabetics at a time when studies found that Avandia significantly increased cardiovascular

2010	Fraudulent Pricing	10 Million	risks. The state of Hawaii settled with dozens of pharmaceutical companies, including GlaxoSmithKline, which were accused of gouging Hawaii's Medicaid program for more than a decade by fraudulently inflating their prescription drug prices.
2010	Deceptive Marketing	\$3,750,00	GlaxoSmithKline agreed to pay \$3,750,000 to settle allegations of deceptive or false marketing of the anti-nausea drugs Kytril and Zofran. The complaint alleged that GSK improperly inflated the average wholesale price (AWP) for the drugs.
2010	Manufacturing of adulterated drugs	750 million	SB Pharmco Puerto Rico Inc., a subsidiary of GlaxoSmithKline, agreed to plead guilty to felony charges relating to the manufacture and distribution of certain adulterated drugs made at GSK's, now closed, Cidra, Puerto Rico, manufacturing facility. The resolution included a criminal fine and forfeiture totaling \$150 million and a civil settlement under the FCA for \$600 million. The drugs, manufactured at the plant between 2001 and 2005, included Kytril, Bactroban, Paxil CR and Avandamet.
2011	Attempt to sell adulterated drugs	\$40.75 million	GlaxoSmithKline agreed to pay nearly \$41 million to settle charges that the company tried to sell drugs made in a Puerto Rican plant that failed to meet manufacturing standards. The attorneys general alleged that,

2012	Fraudulent Marketing of Paxil, Wellbutrin, and failure to disclose safety data, and fraudulent pricing	\$3 Billion	<p>between 2001 and 2004, GlaxoSmithKline and its SB Pharmco Puerto Rico subsidiary engaged in unfair and deceptive practices when they manufactured and distributed certain lots of Kytril, Bactroban, Paxil CR, and Avandamet, produced in a plant in Cidra, Puerto Rico. GlaxoSmithKline agreed to plead guilty and to pay \$3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of Paxil, Wellbutrin and Avandia, its failure to report certain safety data, and its civil liability for alleged false price reporting practices. From April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. From January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. Between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. Between 1994</p>
------	--	-------------	---

			and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under the Medicaid Drug Rebate Program. GSK also executed a five-year CIA.
Pfizer 2002	Fraudulent Pricing	\$49 Million	In October 2002, Pfizer and its subsidiaries Warner-Lambert and Parke-Davis paid \$49 million to resolve FCA charges that it had fraudulently avoided paying rebates owed to state and federal health programs by failing to report best prices for its cholesterol drug Lipitor.
2004	Off-label marketing of Neurontin	\$420 million	In 1993, the FDA approved Neurontin solely for anti-seizure use by epilepsy patients. However, Warner-Lambert, a Pfizer subsidiary, aggressively marketed Neurontin for a variety of other treatments, including bipolar disorder (even though scientific studies had shown that a placebo worked better for this disorder), none of which had been approved by the FDA. As part of the settlement agreement, Pfizer also agreed to enter into a CIA with the Department of Health and Human Services.
2005	Off-label marketing of Bextra	\$2.3 Billion	Pfizer and its subsidiary Pharmacia & Upjohn (Pharmacia) promoted the sale of Bextra for uses and at dosages the FDA specifically declined to approve for safety reasons. Under the terms of this settlement, Pfizer entered into a five-year CIA.
2010	Fraudulent	\$8.2 million	The state of Hawaii settled

	Pricing		with dozens of pharmaceutical companies, including Pfizer, which were accused of gouging Hawaii's Medicaid program for more than a decade by fraudulently inflating their prescription drug prices.
2011	Off-label marketing of Detrol	\$14.5 Million	Pfizer illegally marketed Detrol, a drug for the treatment of overactive bladder, for use in male patients suffering from benign prostatic hypertrophy and several allied conditions, notably lower urinary tract symptoms and bladder outlet obstruction—all uses for which the FDA had not approved the drug as safe and effective. Since August 2009, Pfizer has been under a CIA with the Department of Health and Human Services, which remains in effect.
2012	Foreign Bribery	\$15 Million	Pfizer agreed to pay a \$15 million penalty to resolve an investigation of Foreign Corrupt Practices Act (FCPA) violations. Pfizer admitted that between 1997 and 2006, it paid more than \$2 million of bribes to government officials in Bulgaria, Croatia, Kazakhstan and Russia in order to improperly influence government decisions in these countries regarding the approval and registration of Pfizer Inc. products.
2012	Off-label marketing of Protonix	\$55 million	Protonix is a proton pump inhibitor (PPI) that was used by physicians to treat various forms of gastro-esophageal reflux disease (GERD). Wyeth, a Pfizer subsidiary, sought and obtained approval

2013	Off-label marketing of Rapamune	\$490.9 million	<p>from the FDA to promote Protonix for short-term treatment of erosive esophagitis—a condition associated with GERD that can only be diagnosed with an invasive endoscopy. However, the government alleges that Wyeth fully intended to, and did, promote Protonix for all forms of GERD, including symptomatic GERD, which was far more common and could be diagnosed without an endoscopy. In addition, Wyeth allegedly promoted Protonix as the “best PPI for night-time heartburn.” even though there was never any clinical evidence that Protonix was more effective than any other PPI for night-time heartburn. Since August 2009, Pfizer has been under a CIA with the Department of Health and Human Services, which remains in effect. Wyeth Pharmaceuticals Inc., a pharmaceutical company acquired by Pfizer Inc. in 2009, agreed to pay \$490.9 million to resolve its criminal and civil liability arising from the unlawful marketing of the prescription drug Rapamune for uses not approved as safe and effective by the U.S. FDA. Rapamune is an immunosuppressive drug that prevents the body’s immune system from rejecting a transplanted organ. In 1999, Wyeth received approval from the FDA for Rapamune use in renal (kidney) transplant patients. However,</p>
------	---------------------------------	-----------------	--

Sanofi-Aventis 2007	Fraudulent pricing	\$190.4 million	Wyeth encouraged sales force members, through financial incentives, to target all transplant patient populations to increase Rapamune sales.
2009	Fraudulent pricing	\$95 million	Aventis Pharmaceuticals agreed to pay \$190.4 million “to resolve allegations that the company caused false claims to be filed with Medicare and other federal health programs as a result of the company’s alleged fraudulent pricing and marketing of drugs.” The case involved the pricing between 1997 and 2004 of Anzemet, a treatment given to cancer patients after chemotherapy. The government alleged Aventis engaged in a scheme to set fraudulent and inflated prices for Anzemet. As part of the settlement, Aventis agreed to enter into a CIA that will require the company to report accurate average sales prices and average manufacturers’ prices for its drugs. Aventis Pharmaceutical Inc., a wholly owned subsidiary of Sanofi-Aventis, agreed to pay the United States \$95.5 million to settle allegations that it violated the FCA by misreporting drug prices in order to reduce its Medicaid Drug Rebate obligations. The settlement resolves allegations that between 1995 and 2000, Aventis and its corporate predecessors knowingly misreported best prices for the steroid-based anti-inflammatory nasal sprays Azmacort, Nasacort and Nasacort AQ. In order to

2012	Kickbacks	\$109 million	<p>avoid triggering a new best price that would obligate it to pay millions of dollars in additional drug rebates to Medicaid, Aventis entered into “private label” agreements with the HMO Kaiser Permanente that simply repackaged Aventis’ drugs under a new label. As a result, Aventis underpaid drug rebates to the Medicaid program and overcharged certain Public Health Service entities for these products. Sanofi-Aventis agreed to pay \$109 million to resolve allegations that Sanofi US violated the FCA by giving physicians free units of Hyalgan, a knee injection, in violation of the Anti-Kickback Statute, to induce them to purchase and prescribe the product. The settlement also resolves allegations that Sanofi US submitted false average sales price (ASP) reports for Hyalgan that failed to account for free units distributed contingent on Hyalgan purchases.</p>
Amgen 2012	Off-label marketing of Aranesp	\$762 million	<p>Aranesp is an erythropoiesis-stimulating agent (ESA) that was approved by the FDA at certain doses for certain patient populations suffering from anemia. Amgen illegally misbranded Aranesp by promoting it for “off-label” doses that the FDA specifically rejected and for an “off-label” treatment that the FDA never approved. For example, Amgen illegally</p>

2013	Kickbacks	\$24.9 million	<p>promoted Aranesp to treat anemia caused by cancer, irrespective of whether the patient had been prescribed chemotherapy—a use for which Aranesp was never approved. In fact, in 2007, the FDA mandated that a “black box” warning be added to Aranesp’s label stating that when administered to certain target levels Aranesp “increased the risk of death” in patients with cancer who were not receiving chemotherapy or radiation. Further, Amgen offered illegal kickbacks to a wide-range of entities in an effort to influence health care providers to select its products for use, regardless of whether they were reimbursable by federal healthcare programs or were medically necessary. As part of the global settlement, Amgen also agreed to enter into a CIA.</p> <p>The settlement resolves allegations that Amgen paid kickbacks to long-term care pharmacy providers Omnicare Inc., PharMerica Corporation and Kindred Healthcare Inc. in return for implementing “therapeutic interchange” programs that were designed to switch Medicare and Medicaid beneficiaries from a competitor drug to Aranesp. The government alleged that the kickbacks took the form of performance-based rebates that were tied to market-share or volume thresholds. The government further alleged</p>
------	-----------	----------------	--

2013	Kickbacks	\$15 million	<p>that, as part of the therapeutic interchange program, Amgen distributed materials to consultant pharmacists and nursing home staff encouraging the use of Aranesp for patients who did not have anemia associated with chronic renal failure. Xgeva, which is the brand name of the drug Denosumab, was approved by the FDA in late 2010 for use with certain cancer patients undergoing chemotherapy. It is most commonly prescribed for patients with metastatic bone disease in order to prevent skeletal-related adverse events.</p> <p>In order to increase sales of Xgeva, Amgen used data purchase agreements—which the company called the “Deep Dive” contracts—to provide financial incentives to oncologists and urologists to prescribe Xgeva. The original plan for the Deep Dive contracts called for Amgen to pay doctors to fill out a short survey on the Internet on how they were treating patients with bone cancer, including which drugs were used—whether or not Xgeva was prescribed. However, Amgen altered the original Deep Dive program design by increasing the amount of money it would pay doctors, and by offering such payments only to doctors who prescribed Xgeva for their patients. Amgen’s Xgeva marketing team also was not supposed to know the identities of the doctors who</p>
------	-----------	--------------	--

			<p>received Deep Dive contracts, but team members had access to that information. Additionally, in a further effort to influence doctors to prescribe Xgeva, Amgen provided cash payments characterized as honoraria to oncologists and urologists for participating in audience response sessions, data market research surveys, and “treatment trends” advisory board programs which touted the benefits of Xgeva.</p>
Merck 2008	Fraudulent pricing and kickbacks	\$650 million	<p>Merck was accused of violating the Medicaid Rebate Statute in marketing its cholesterol drug Zocor, its prescription pain medication Vioxx, and its anti-heartburn drug Pepcid. Merck allegedly offered hospitals large discounts for all three products if hospitals used them instead of competitors’ brands. The law requires companies to sell drugs to Medicaid at the best price they offer to any customer, but in this instance Merck did not offer similar discounts to Medicaid. Merck was also alleged to have induced physicians to use its products through the payment of illegal kickbacks. Merck also entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.</p>
2009	Fraudulent pricing	\$69 million	<p>The settlement resolved allegations that Warrick Pharmaceuticals, a subsidiary of Merck deliberately inflated</p>

2010	Fraudulent pricing	\$31 million	the Average Wholesale Prices (AWPs) of the asthma drug Albuterol. Since 2004, Schering has been operating under a CIA that addresses Schering's pricing of its drugs to government programs. Schering-Plough, a subsidiary of Merck, and the state of Missouri settled a lawsuit in which the state accused the company of inflating prices for the drugs it sold to pharmacies participating in Missouri's Medicaid program.
2010	Fraudulent pricing	\$27 million	Schering, a subsidiary of Merck, agreed to pay the United States and the state of Texas \$27 million to settle allegations of health care fraud. It was alleged that Schering subsidiary Warrick submitted false pricing information and caused providers to submit fraudulently inflated reimbursement claims to the state and federally funded Texas Medicaid program for drugs used to treat asthma and other respiratory conditions.
2010	Fraudulent pricing	\$28 million	The state of Hawaii settled with dozens of pharmaceutical companies, including Merck, which were accused of gouging Hawaii's Medicaid program for more than a decade by fraudulently inflating their prescription drug prices.
2011	Off-label Marketing	\$950 million	Merck agreed to pay to resolve allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety. Between May 1999 and April

2011	Fraudulent pricing	\$24 million	<p>2002, Merck promoted the drug for treating rheumatoid arthritis before that use was approved by the FDA. Further, Merck was accused of making inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug and making false statements to state Medicaid agencies about the cardiovascular safety of Vioxx. As part of the settlement, Merck agreed to enter into an expansive CIA. Merck agreed to settle a lawsuit accusing Merck of knowingly reporting inflated prices to industry price reporting services between 1995 and 2003. The lawsuit alleged that Merck reported false and inflated prices for three albuterol products, a drug used to treat asthma and other respiratory diseases.</p>
2011	Kickbacks	\$44.3 million	<p>Each company's annual shareholder report revealed not a single company reported a loss. On the contrary, the reported annual net profit is often double or triple the amount of the one-time fine. For example, in 2003, Abbott settled for a lawsuit over the fraudulent pricing of its feeding tubes for \$600 million. That same year, Abbott's enteral nutrition division reported profits of almost \$3 billion. Similarly, the year Abbott agreed to pay \$1.5 billion for the off-label marketing of Depakote, its specialty division reported a profit of over \$5 billion.</p>

III. MISCONDUCT SETTLEMENTS (REPEAT OFFENDERS)

While the size of the fines imposed by the DOJ seem large in total dollars, they are dwarfed by the revenue streams attributable to unlawful behavior. First, most settlements under the FCA only account for the expenditure of Medicare, Medicaid, Tricare, and VA dollars. Damages incurred by state, municipal health, and welfare funds are excluded even though they are actually encompassed by some state FCAs. This occurs presumably because State Attorney Generals who receive an FCA complaint delegate the investigation to the National Association of Medicaid Fraud Control Units (NAMFCU), which is the body that coordinates State Attorney General Investigation of FCA cases. NAMFCU, as it is known, does not concern itself with investigating non-Medicaid damages. Second, to the extent the FCA only encompasses public payers, damages incurred by private payer—including Taft-Hartley Health and Welfare Funds—are also left out of settlements.

The data available strongly supports the claim that large pharmaceutical companies have handled large fines as the price of doing business, but it also suggests that neither the fines, nor the CIAs, have altered their behavior. Fourteen companies can be categorized as repeat offenders including Johnson and Johnson and GlaxoSmithKline.⁶¹ All have had to pay multiple settlements stemming from similar allegations: fraudulent pricing, payment of kickbacks, and/or off-label marketing.⁶² All of those settlements are in the millions of dollars and most of the settlements are significantly greater than \$100 million. Despite the size of the settlements, it appears that all companies are still reporting large net-profit gains.⁶³

The overall problem is compounded by an important public perception issue: in a down economy, if big players appear immune to thorough prosecution for massive wrongdoing, then lesser players are sure to follow.⁶⁴

⁶¹ See, Sammy Almathat et al., *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010*, PUB. CITIZEN (Dec. 16, 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 also *Drug Safety and Risk Management Advisory Committee Roster*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/default.htm> (last updated Dec. 16, 2015).

⁶² *Id.* See *infra* note 90.

⁶³ See Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223>.

⁶⁴ Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1061 (2012).

Isn't the public justified in thinking that the government is complicit in not holding the major players fully accountable?

In most cases, actions are brought under the False Claims Act; initially investigated and filed by whistleblowers; the U.S. intervenes, and then the cases are disposed of when the government enters into a civil settlement.⁶⁵ Although these cases are technically about the misspending of government monies, the subtext is always medical necessity and by implication patient safety. While these cases involve matters of public concern, they are filed under seal so that the DOJ can conduct an investigation. As a practical matter, the DOJ uses the seal process to investigate and to negotiate a settlement using the fruits of the investigation. Often—as in the case with billion dollar settlements involving Abbott, Pfizer, and Johnson and Johnson—the settlement is announced absent any public litigation. The medical community is left without a full understanding of the derelictions while the investor community is told that the corporation has placed its wrongful conduct behind. An analysis of Big Pharma settlements indicates that settlements have little or no impact on market capitalization and/or may even give the market a confirmation that because the wrongdoing is a thing of the past, the company is worth more.⁶⁶

A. *The False Claims Act*⁶⁷

The False Claims statute is a statute with a long history. Enacted during the Civil War, its initial focus was on military contractors that cheated the government. Most often these cases were brought against contractors that had sold shoddy goods or failed to deliver services or products according to specification. While the Federal False Claims Act is designed to capture the loss of federal dollars, a number of states, and some cities, have their own statutes, which can be used to capture the loss of state and municipal monies.⁶⁸

Under the FCA, the essential elements are as follows: The FCA imposes civil liability upon “[a]ny person” who, among other things “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or

⁶⁵ See Reuben Guttman & Jennifer Williams, *Controlling Government Contractors: Can the False Claims Act be More Effective?*, 14 SEDONA CONF. J. 1 (Sept. 2013) [hereinafter *Controlling Government Contractors*]; see, e.g., *GSK, Enforcement Officials Finalize \$3B Settlement*, 21 NO. 6 FDA ENFORCEMENT MANUAL 3 (Food & Drug Admin., Silver Spring, Md.), Aug. 2012, at 3.

⁶⁶ See *Controlling Government Contractors*, *supra* note 68.

⁶⁷ The False Claims Act, 31 U.S.C. §§ 3729-33 (2012).

⁶⁸ See www.whistleblowerlaws.com for a complete list.

approval.”⁶⁹ The term “claim” has a broad definition to include any effort to seek money that in whole or in part comes from the government; it can include efforts to secure payment from private vendors who are using government monies, as well as efforts to defraud foreign governments that are making purchases with, for example, foreign military assistance dollars.⁷⁰

B. Types of Illegal Behaviors by Pharmaceuticals

Over the course of its illustrious 100 years plus history, the types of cases brought under the FCA have expanded. Pharmaceutical manufacturers, for profit education companies, military contractors, Department of Transportation (DOT) and Department of Energy Contractors (DOE) have all been targets of FCA litigation. Prior to 2001, the largest recoveries under the FCA were secured in litigation against the oil industry over schemes to cheat the government out of royalties from oil and gas recovered from federal leases.⁷¹ Yet, the overall recovery against the nation’s largest oil producers, including Shell and Chevron, was a collective \$300 million.

With the turn of the century, and the enactment of Medicare Part D in 2003, DOJ targeted health care fraud as a priority. This can explain one reason for the popularity of the FCA as a weapon against healthcare. However, perhaps there is another reason—one that is less obvious and routed in a common denominator among health care cases. The largest recoveries under the FCA have come against health care targets that benefit from government monies through non-direct procurement relationships. There is an inference to be drawn from this. In a direct procurement case, an allegation of wrongdoing implicates not only wrongdoing by the contractor but also an oversight error by the contracting officer. In a non-direct procurement case, there is no government official who is immediately at fault. Nor is there a government official who is capable of defending or protecting the contractor.

1. Kick-backs

Violation of the Anti-Kickback (AKS) statute,⁷² a criminal law, is a per se violation of the FCA.⁷³ In addition to the Attorney General, a private

⁶⁹ See 31 U.S.C. § 3729(a)(1)(A) (2012).

⁷⁰ See 31 U.S.C. § 3729(b)(2) (2012).

⁷¹ See, e.g. U.S. ex rel. Johnson v. Shell, 33 F. Supp. 2d 528 (E.D. Tex. 1999).

⁷² See 42 U.S.C. § 1320a-7b (2012).

⁷³ See U.S. ex rel. Brown v. Celgene Corp., No. 10-3165, 2014 WL 3605896 at *3 (C.D. Ca. July 10, 2014).

whistleblower may seek civil redress under the FCA alleging a predicate violation(s) of the anti-kickback statute.

The AKS is broadly written to proscribe payments made for the purpose of causing the “ordering” or “recommending” of a product or service that is paid for under a Federal healthcare program. The key to investigation lies in understanding that payments are often disguised as compensation for services that may be legitimate or have the appearance of being legitimate. A number of circuits have determined that if one purpose of the payment is unlawful, the arrangement violates the statute.⁷⁴ The following are examples of AKS violations: (1) fees to refer patients for services or to use products, (2) rebates paid by manufacturers to Long Term Care (LTC) pharmacies or Pharmacy Benefit Managers (PBM), and (3) gifts, trips, or products given to those—including doctors and nurses—who can order or recommend ordering a product. Within the orbit of suspect relationships are industry sponsored promotional speaker programs where Key Opinion Leaders are identified to give pre-packaged presentations for which they receive handsome compensation. These relationships are particularly suspect—and have a high capability of poisoning the market for honest medical information—when the speakers are chosen with the input of company marketers. Often, no attention is given to the actual medical qualifications of the speaker; when the return on investment analysis correlates speeches with sales, speakers will be rewarded with additional lucrative opportunities and travel.

2. *Misbranding*

Misbranding is also a predicate to violation of the FCA. Under the FDCA,⁷⁵ a drug is misbranded if its labeling “is false or misleading.” Labeling is construed broadly to mean not only the package insert that comes with the drug, but also statements, handouts, press releases or any communication about or used to promote the drug. The FDCA precludes the “introduction or delivery for introduction into interstate commerce of any food, drug, device, [. . .] or cosmetic that is adulterated or misbranded.”⁷⁶

A form of misbranding is off-label marketing, or marketing a drug for purposes that are outside the drug’s approved indication. The term “indication” refers to what specific disease state the drug is approved to treat; the dosing;

⁷⁴ See, e.g., *U.S. v. Greber*, 760 F.2d 68, 72 (3rd Cir. 1985).

⁷⁵ See 21 U.S.C. § 352 (2012).

⁷⁶ See 21 U.S.C. § 331(a) (2012).

whether the drug is to be used as a mono therapy or in conjunction with other specific drugs; and the ages of the patients who will be given the drug. The indication—found on the package insert—is the result of analysis of data providing information on safety and efficiency. While a manufacturer is not allowed to market its drug for off-label purposes, a doctor is free, on his or her own, to prescribe a drug for off-label use.⁷⁷ In theory, doctors do so because they have read the literature, understand the mechanism of action, understand the potential side effects, and have looked at the viability and availability of on-label treatments.

Understanding that doctors can legally write prescriptions for off-label use, manufacturers have historically engaged in off-label promotion arguing that sales exceeding any projections for on-label use were the result of doctors making their own decisions absent company influence.

To avoid detection, and to create plausible deniability once accused, companies have engaged in at least facially neutral conduct to drive unlawful behavior and results.⁷⁸ For example, manufacturers drive their sales representatives to push off-label uses by paying them bonuses on both off-label and on-label use. Manufacturers also encourage their sales representatives to challenge doctors to try a drug in place of a competitor's product, which may have a different indication. Manufacturers also may arm their sales force with publications that are often the result of undisclosed company sponsored publications strategies. Once in the hands of the sales representative, he or she will “cherry pick” certain passages in convincing a doctor that there is indeed basis for use of the drug off-label.

Off-label marketing escalates prescription writing, and is dangerous, because it is a strategy premised on spin and not science. While the industry argues that there is a First Amendment Right to engage in off-label marketing,⁷⁹ speech that is false or misleading is not protected and, as a practical matter, it is virtually impossible to engage in a pervasive off-label effort without false representations.

⁷⁷ Certain drugs, such as growth hormones, cannot be prescribed for off-label purposes.

⁷⁸ *See, e.g., Griggs v. Duke Power Co.*, 401 U.S. 424 (1971) (applying to the FCA as a primer in corporations driving unlawful behavior through facially neutral programs).

⁷⁹ *See U.S. v. Caronia*, 703 F.3d 149, 161 (2nd Cir. 2012) (arguing that Caronia was never found to have conspired to place false or deficient labeling on a drug).

3. *Inflating the Price of Pharmaceuticals*

In some instances, Medicare and Medicaid determine the price doctors receive as reimbursement for certain medications prescribed based upon a figure known as the Average Sales Price (ASP), calculated based on reports by the drug manufacturers.⁸⁰ The Act provides for civil monetary penalties for any manufacturer's misrepresentations of ASP data.⁸¹ The Secretary of the Department of Health and Human Services (the Secretary) has the authority to adjust the ASP for a drug if the Secretary finds that the ASP does not accurately reflect actual market prices.⁸² Manufacturers have manipulated the Average Wholesale Price (AWP) in an effort to induce pharmacists and pharmacies to promote and prescribe their drugs but physicians claim the spread did not cover the actual costs of administering the drugs.⁸³ Under the 2003 Act, the physician is now reimbursed for 106% of the cost of the drug.⁸⁴ What remained was a way for the actual price that pharmacies and physicians pay for a drug to be substantially less than what the government will reimburse them for. This is referred to in the pharmaceutical world as "marketing the spread."⁸⁵ This results in a bad debt or deduction, when the higher price is not paid, and serves to lower the amount that the company may have to declare as income.⁸⁶ The need for government monitoring of these costs is crucial to the

⁸⁰ Anna Kraus, Ellen Flannery, & Peter Safir, *Average Wholesale Price Reform Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, COVINGTON & BURLING (Dec. 11, 2003), <https://www.cov.com/-/media/files/corporate/publications/2003/12/oid9743.pdf>. The ASP is computed using included sales divided by the number of units sold. The Act exempts certain sales from inclusion in the computation of ASP, including (a) sales exempt from inclusion in the determination of "best price" under section 1927(c)(1)(C)(i) of the Social Security Act, and (b) "such sales as the Secretary identifies as sales to an entity that are merely nominal in amount." H.R. 1 § 303(c)(1), adding new section 1847A to the Social Security Act. Rebates and discounts include "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under section 1927)." For years after 2004, the Secretary may include "other price concessions . . . that would result in a reduction of the cost to the purchaser." *Id.*

⁸¹ Social Security Amendments of 1972, Pub. L. No. 92-603, § 303(c), 86 Stat. 1329, 1484; Social Security Act, 42 U.S.C. § 1847A(8)(c)(d)(4) (1935).

⁸² 42 U.S.C. § 1847A(8)(c)(d)(4) (2012).

⁸³ *Medicare Part B Drug Average Sales Price*, CSV.GOV, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?%20redirect=/McrPartBDrugAvgSalesPrice/10_VaccinesPricing.asp (last updated March 30, 2015).

⁸⁴ See Patrick Mullen, *The Arrival of Average Sale Price*, 4(3) BIOTECHNOL.HEALTHC. 48, 48-53 (Jun. 2007), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3541838/>.

⁸⁵ *Pharmaceutical Fraud*, FALSE CLAIMS ACT RESOURCE CENTER, <http://www.falseclaimsact.com/common-types-of-fraud/pharmaceutical-fraud> (last visited Jan. 13, 2015).

⁸⁶ *Topic 453 – Bad Debt Deduction*, INTERNAL REVENUE SERVICE, www.irs.gov/taxtopics/tc453.html (last updated Dec. 30, 2015).

calculation of the ASP to accurately reflect the free market change as opposed to the initial price that is set by the drug manufacturer.

C. Remedies Under the False Claims Act

Assessing damages to the government is not a straightforward analysis because the government engages in procurement for its direct benefit and for the benefit of citizens. Whenever procurement misdeeds occur, the government must bear the burden of any long-term impact, as in the case of providing care for patients who have been injured by drugs prescribed for purposes outside the FDA's approved labeling.

While the damage scenarios are complicated, the FCA provides a simple statement about damages. The defendant is liable for treble damages and a civil penalty of between \$5,500 and \$11,000 per claim.⁸⁷ This simple provision raises some important questions about how claims are to be counted, and also how damages are to be calculated. This is especially true as to calculating the figure for the treble penalty that should be imposed. Is the amount trebled the amount of money the U.S. paid for the good, or is it only the lost benefit to the U.S. that counts in the calculation? What happens if the contract involves certified functional bulletproof vests according to design specification but, instead, the specifications were not met? Would the answer to the previous question change if soldiers were killed because of defective vests? What if financial fraud injured the market more generally? If the fraud caused a financial liability far greater than any harm to the U.S. government directly? Can the U.S. take into account broader market injury when calculating the harm done by a fraudulent defendant? These are all questions of interest that must be addressed.

While current provisions of the FCA impose treble damages and civil penalties of up to \$11,000 per claim on violators under 31 U.S.C. § 3729(a), there is some debate as to whether consequential damages to compensate the government for the costs associated with rectifying the false claims should be permitted as well. Since the Act itself does not expressly address the issue of consequential damages, it is left to the courts to interpret the statute and award damages accordingly.

⁸⁷ *The False Claims Act: A Primer*, DEP'T OF JUSTICE, (Apr. 22, 2011), http://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

Significantly, no settlement agreement executed by the DOJ has broken down actual or “straight line” damages, or set forth whether that number has been multiplied. Moreover, no settlement sets forth the amount—if any—paid in civil penalties. To the contrary, in securing settlements, it has been the government’s position to wave civil penalties and seek less than treble actual damages.

1. *Compensatory Damages*

As noted above, the FCA imposes treble damages on violators.⁸⁸ Under 31 U.S.C. § 3729(a), the classification of treble damages as either purely compensatory or including punitive element is far from an exact science; “the tipping point between payback and punishment defies general formulation, being dependent on the workings of a particular statute and the course of particular litigation.”⁸⁹

In *Cook County v. U.S. ex rel. Chandler*, the Court clarified that although the FCA’s treble damages remedy “is still punitive,” the treble damages provision “does not equate with classic punitive damages” where the jury has open ended discretion to determine punitive damages.⁹⁰ In FCA cases, the jury determines actual damages and the actual damage number is later trebled by the Court.⁹¹ The Court in *Cook County* also noted that the trebling accounts for a bounty—of as much as 30 percent of the recovery—to be paid to the Relator.⁹²

2. *Are Consequential Damages Available under the FCA?*

The next question is whether consequential damages may be awarded under the FCA. A look at the history of the Act and the Congressional legislative record discussing the 1986 Amendments to the FCA is fundamental in answering this question. In considering whether consequential damages may be awarded, it is critical to understand exactly what actions are deemed unlawful by the FCA, and therefore, form the basis for calculating the award amount. As discussed above, prior to the 1986 Amendments, the FCA imposed double damages and a \$2,000 per claim civil penalty.⁹³ In the *Aerodex* case,

⁸⁸ *Id.*

⁸⁹ *Cook County v. U.S. ex rel. Chandler*, 538 U.S. 119, 130 (2003).

⁹⁰ *Id.*

⁹¹ *Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 786 (2000).

⁹² *Cook County*, 538 U.S. at 130.

⁹³ *See Vt. Agency of Natural Res.*, 529 U.S. at 769.

the Court stated that the unlawful “act” which violates the FCA is the actual submission of a false claim for payment.⁹⁴ The Court distinguished the *action of filing the false claim* for payment from the *action of not delivering the product* that the Defendant was contractually obligated to deliver (Defendant delivered faulty ball bearings for aircraft engines).⁹⁵ Based on that assertion, the Court denied recovery of any consequential damages, reasoning “the language of the False Claims Act does not include consequential damages resulting from the delivery of defective goods . . . the submission of these vouchers was not the cause of the Government’s consequential damages.”⁹⁶ The delivery and installation of the bearings in the airplanes, not the filing of the false claims, caused the consequential damages.⁹⁷

The passage of the 1986 Amendments to the FCA, and just as importantly the legislative history surrounding it, provide a rather strong answer to the FCA consequential damages question. During the legislative session in which the Amendments to the FCA were discussed, the Senate passed a version of the bill including treble damages plus consequential damages, while the House’s version included double damages plus consequential damages.⁹⁸ Senator Grassley then offered an amendment with treble damages, but deleted any mention of consequential damages, explaining that the House and the Senate had met and agreed to this version of the bill to reconcile their differences.⁹⁹ This version of the bill was passed into law, resulting in the FCA containing no overt guidance as to the availability of consequential damages.

The omission of consequential damages in the final version of the 1986 Amendments to the FCA, after their initial inclusion in both the House and Senate bills, has led courts to conclude that they are not an available remedy. The Supreme Court has explicitly stated that the “FCA does not expressly provide for the consequential damages that typically come with recovery for fraud.”¹⁰⁰ With consequential damages seemingly unavailable as a remedy, courts have been forced to look elsewhere to accomplish the driving purpose behind the FCA to “make the government whole.”¹⁰¹

⁹⁴ United States v. Aerodex, Inc., 469 F.2d 1003 (5th Cir. 1973).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* at 1011.

⁹⁸ Brian C. Elmer & Andy Liu, “*Because of*”: FCA Damages and Penalties, CROWELL & MORING, https://www.crowell.com/documents/Because-of_FCA-Damages-and-Penalties.pdf (last visited Jan. 15, 2016).

⁹⁹ 132 CONG. REC. S15515 (daily ed. Oct. 7, 1986) (statement of Sen. Grassley).

¹⁰⁰ *Cook County*, 538 U.S. at 131.

¹⁰¹ United States ex rel. Roby v. Boeing Co., 79 F. Supp. 2d 877, 892 (S.D. Ohio 1999).

With this framework in place, the next question must be: what measure of damages will make the government whole? The *Roby* court answered: “damages awarded under the False Claims Act typically are calculated to ensure that they ‘afford the government complete indemnity for the injury done it.’”¹⁰² When analyzing what damages were caused by the unlawful “act,” the Court stated that damages “must be determined by the application of proximate causation and foreseeability.”¹⁰³ It would therefore be advantageous for those filing actions on behalf of the government under the FCA to establish a strong connection of foreseeable harm that resulted from the Defendant’s submission of a false claim.

3. *Civil Penalties under the FCA*

As discussed above, treble damages are not the only remedy provided by the FCA. Violators of the Act are subject to a fine of between \$5,000 and \$11,000 per claim submitted.¹⁰⁴ One purpose of this penalty is to reimburse the government for the time and money associated with handling the false claim.¹⁰⁵ In calculating this amount, the courts look at the conduct of the person from whom the government intends to collect the forfeitures, and the fine is then applied to *each false claim submitted*, not the number of false/defective products or shipments.¹⁰⁶

One of the reasons why the FCA has been unable to deter institutional greed is because the statute’s damages provisions are read in the light of the context of civil fraud, where damages are tied to the harm that has been done to the individual who has been relying on the statements that have been made.¹⁰⁷ Where the U.S. government is the one harmed, U.S. citizens, taxpayers, and those directly affected by the goods purchased or sold, are all

¹⁰² *Id.* (quoting *United States ex rel. Compton v. Midwest Specialties*, 142 F.3d 296, 304 (6th Cir. 1998); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 549 (1943)).

¹⁰³ *Roby*, 79 F. Supp. 2d at 892.

¹⁰⁴ 31 U.S.C. § 3729 (2012).

¹⁰⁵ *United States v. Woodbury*, 359 F.2d 370, 378 (9th Cir. 1966).

¹⁰⁶ *Id.* at 387; *United States v. Bornstein*, 423 U.S. 303, 529 (1976).

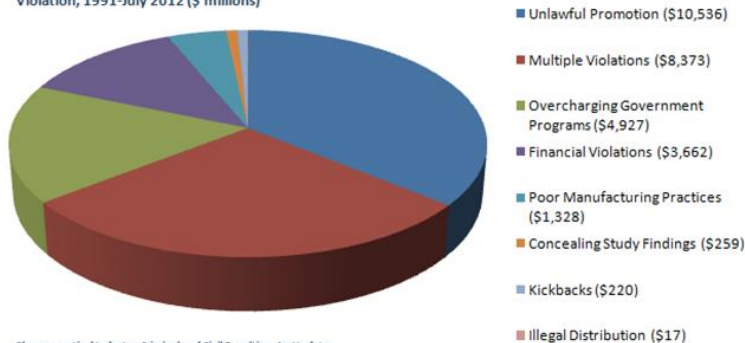
¹⁰⁷ The Federal Drug Administration published guidelines for determining sanctions for pharmaceutical company misbehavior. Specifically, the FDA said the criteria include whether: 1) the violation involves actual or potential harm to the public; 2) the violation is obvious; 3) the violation reflects a pattern of illegal behavior or failure to heed prior warnings; 4) the violation is widespread; 5) the violation is serious; 6) the quality of the legal and factual grounds supports prosecution; and 7) the proposed prosecution is a prudent use of agency resources. *Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm> (last updated June 19, 2015).

harm by the fraud. Part of the problem, where the U.S. acts for those harmed, is whether they should rely on the secondary market: lawsuits by those directly injured by the fraud, or whether the U.S. should be seen as an intervener on behalf of the individual victims, to create a fund to compensate those injured by the fraud. What are the chances that individuals will sue, or that plaintiff's class action lawsuits will be brought, or that criminal penalties and jail time will also be imposed? In other words, it falls to the U.S. attorney to be the advocate for the U.S., not only as an institution, but also for the society as a whole.¹⁰⁸ This is particularly true in cases where the harm is the violation of a regulation written into a contract solely for the benefit of citizens. Classic examples include compliance with Department of Labor regulations.

By an objective standard, the monetary consequences have been great for violating the FCA. According to publically available data, well over \$19 billion has been collected from pharmaceutical companies.¹⁰⁹ The Department of Justice has represented that it has recovered fifteen dollars for every one

¹⁰⁸ Tobacco litigation teaches us how this works. The settlements with states were supposed to compensate the state's Medicare and Medicaid funds or county governments funds that will be drawn against in the future because of the fraud perpetrated on the public by the tobacco industry. See Cezary Podkul & Claire Kelloway, *Investors Haul In Nearly Half the Tobacco Settlement Cash*, PROPUBLICA (Sept. 11, 2014, 8:00 AM), <http://www.propublica.org/article/investors-haul-in-nearly-half-the-tobacco-settlement-cash>. The chart below shows Prohibited Behaviors Under the FCA and the amount paid per category of behavior.

Pharmaceutical Industry Financial Penalties by Type of Violation, 1991-July 2012 (\$ millions)



Pharmaceutical Industry Criminal and Civil Penalties: An Update
September 27, 2012 ; www.citizen.org

Sammy Almashat & Sidney Wolfe, *Pharmaceutical Industry Criminal and Civil Penalties: An Update*, PUBLIC CITIZEN (Sept. 27, 2012), <http://www.citizen.org/documents/20731.pdf>.

¹⁰⁹ See, *Pharmaceutical Fraud*, FALSE CLAIMS ACT RESOURCE CENTER, <http://www.falseclaimsact.com/common-types-of-fraud/pharmaceutical-fraud> (last visited on Feb. 10, 2016).

dollar that it costs to prosecute these companies.¹¹⁰ Of course, these settlements are not measured or contrasted with the unlawful revenue stream that flowed from the proscribed behavior. The optics, unfortunately, have created a dynamic where the press and legislators conducting oversight have not been incentivized to ask hard questions.

In addition to monetary damages, theoretical consequences include exclusion from government programs. The effect of exclusion is that pharmaceutical companies and physicians will receive absolutely no payments made by any Federal health care program for any products or services performed.¹¹¹ “The scope of an exclusion under Title 11 of the Social Security Act is from all Federal healthcare programs, including Medicare, Medicaid, and all other plans and programs that provide health benefits funded directly or indirectly by the United States.”¹¹² This exclusion applies to the excluded person, anyone who employs the excluded person, and anyone else with whom the excluded person comes in contact with through his employment.¹¹³ The result of exclusion would be tremendous losses to any health care professional or company because Medicaid and Medicare patients bring in the majority of most practice’s revenues.¹¹⁴ Unfortunately, such exclusions have seldom, if ever, been enforced.¹¹⁵

a. Constitutional Considerations on the Award of Damages under the FCA

In addition to 8th Amendment concerns for civil fines discussed earlier,¹¹⁶ *Mackby*, 261 F.3d. at 821, there are also other Constitutional considerations that constrain the amount of settlements against Big Pharma. These include Due Process considerations for awarding excessive punitive damages.

Remedies and punitive damages scholarship generally have argued for three different purposes that damages serve in civil and criminal law. Damages

¹¹⁰ Thomas & Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES (June 7, 2012), http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html?_r=0.

¹¹¹ *Exclusions FAQ*, OFFICE OF INSPECTOR GENERAL U.S. DEP’T OF HEALTH AND HUMAN SERV., <https://oig.hhs.gov/faqs/exclusions-faq.asp> (last visited on Feb. 10, 2016).

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 24.

¹¹⁵ *See*, Frakt, et al., *supra* note 62.

¹¹⁶ U.S. CONST. amend. VIII.

seek to compensate the party injured, seek to deter future conduct, and seek some punishment or retribution against the wrongdoer, separate and apart from deterrence.¹¹⁷ Some scholars have argued that retribution or punishment is inappropriate to consider in deciding damages because it is a non-rational factor that should be picked up in any accurate deterrence calculation.¹¹⁸ So, Polinsky and Shavell argue that if a fact finder would calculate damages by factoring in a multiplier that makes getting caught a certainty, then deterrence would provide the adequate incentives in the market place and there would be no need for retribution.¹¹⁹ It has been argued elsewhere, that focus on the damage caused by the actor may not get at the right level of deterrence.¹²⁰ In cases of Big Pharma, deterrence based on compensation is inadequate for a number of reasons. Looking at deterrence from the perspective of damage caused by the actor may not adequately deter the conduct especially where the law restricts consideration of damages to the jurisdiction where the action is brought, or by limiting class action remedies to narrow groups of injured parties rather than to the damages caused by the actions to society more broadly, or, as in the case of the FCA, where the consideration of consequential damages—including the cost of treating physical injury caused by wrongful marketing practices—may be complicated by law or sheer calculation.¹²¹

Recent Supreme Court cases illustrate the problems. The majority in *State Farm v. Campbell*, narrowed its focus to the damage the defendant caused one individual, the plaintiff, and did not consider the damage the defendant caused a group of individuals—not parties to the case—within the State of Utah.¹²² To Justice Ginsburg, this restricted the punitive damages too narrowly,¹²³ As a result it had too small an effect, meaning that—punitive damages would not adequately deter future insurers from employing practices that would damage a wide group of individuals for disparate types of damages. In other words, the incentives to the company to defraud its insurers by denying them coverage were not adequately set by focusing only on deterrence. The majority argued

¹¹⁷ See generally DOUGLAS LAYLOCK, MODERN AMERICAN REMEDIES, 16 (Aspen Law & Bus. ed., 3rd ed. 2002); *BMW of N. Am. v. Gore*, 517 U.S. 559, 585-586 (1996).

¹¹⁸ See Paul Zwier, *The Utility of a Nonconsequentialist Rationale for Civil-Jury-Awarded Punitive Damages*, 54 U. KAN. L. REV. 403, 404-47 (2006) (for a review of these arguments).

¹¹⁹ See A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869, 890-91 (1998).

¹²⁰ Zwier, *supra* note 121.

¹²¹ *Id.*

¹²² *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 423 (2003).

¹²³ See *id.* at 438 (Ginsburg, J., dissenting).

that retribution could be used to pick up the limits placed on the fact-finder in figuring damages that were caused.¹²⁴ The Court held that due process did allow for a decision about the amount of punitive damages to include a “retribution” factor. A retribution factor might justify a high multiplier of compensatory to punitive damages. The Court signaled, however, in a footnote that punitive damages would seldom exceed 10 times the amount of compensatory damages awarded in a case.¹²⁵

In a subsequent case, *Phillip Morris, USA, v. Williams*, Justice Breyer attempted to describe how the jury could consider the total amount of the harm done generally to help it value the retribution factor, without considering damages done to people outside the jurisdiction.¹²⁶ Justice Breyer wrote:

The Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury inflicted on strangers to the litigation. For one thing, a defendant threatened with punishment for such injury has no opportunity to defend against the charge. See *Lindsey v. Normet*, 405 S.S. 56, 66, 92 S.Ct. 862, 31 L. Ed. 2d 36. For another, permitting such punishment would add a near standardless dimension to the punitive damages equation and magnify the fundamental due process concerns of this Court’s pertinent cases—arbitrariness, uncertainty, and lack of notice. Finally, the Court finds no authority to support using punitive damages awards to punish a defendant for harming others. False Respondent argues that showing harm to others is relevant to a different part of the punitive damages constitutional equation, namely, reprehensibility. While evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk to the general public, and so was particularly reprehensible, a jury may not go further and use a punitive damages verdict to punish a defendant directly for harms to those nonparties. Given the risks of unfairness, it is constitutionally important for a court to provide assurance that a jury is asking the right question; and given the risks of arbitrariness, inadequate notice, and imposing one State’s policies on other States, it is particularly important that States avoid procedure that unnecessarily deprives juries of proper legal guidance.¹²⁷

¹²⁴ See *id.* at 439, n.1.

¹²⁵ See *id.*

¹²⁶ *Philip Morris USA, v. Williams*, 549 U.S. 346, 353 (2007).

¹²⁷ See *id.* at 347.

In practice, however, this nuance is elusive at best.¹²⁸ What is missing from the traditional analysis is that profit is motivating the decision-maker to take inappropriate risks with the health and safety of the public, whether it be in his or her defrauding the public in mislabeling drugs, or selling defective drugs, or creating long term risks to the markets generally. Profit, in the way of money that has been stolen from others, including the government, is a measure of how much the society has been damaged. Profit is not the flipside of harm. It is itself a measure of the harm or damages. Especially when traditional damage calculations have been limited by other procedural rules, taking away profits or multiples of profits that came to the defendant is the only adequate deterrence mechanism that can operate in the marketplace.

A focus on taking away profits, or multiples of profits also provides the notice and constitutional protections the court worries are lacking in other calculations that focus on harm. The notice to the defendant is simply this: we will calculate how much you have profited from your lie or deceit, and take that away from you, even where your profits exceed the damages you have caused to a particular plaintiff or relator.

In addition, a fact-finder's use of profit as a factor in determining damages that was done to society generally gets at the current difficulties of regulating market incentive to value short-term gains against "tail-end" risks. The market currently is set up to value short-term gains over long-term risks. The corporate decision makers are usually long gone before the corporate fraud is revealed. The shareholders are not adequately incentivized during the short run to monitor for fraud, because shareholder desires for short-term profits are aligned with management.

In any event, current Constitutional holdings prohibit taking profits as a measure of punishment, without taking into account other due process principles, (size of fines, ratio to compensatory damages, and need for retribution.) Where consequential damages are not part of the equation under the FCA, the ability of the court to consider them in determining the need for retribution is substantially hampered. Using them as a damages variable to treble the amount of profits the company has and will obtain from its behavior, is not part of the equation. In other words, corporate fraud—whether

¹²⁸ See *id.* (Stevens, J., dissenting). Perhaps well intentioned to try to provide consistency between capital punishment considerations and punitive damages, the different contexts of these jury decisions justifies treating punishment decisions putting people to death for crimes differently for decisions that try to deter institutional decision-makers from harming the public in its desire for profits.

concerning Medicare and Medicaid fraud by pharmaceutical companies, or fraud by government contractors—is not adequately deterred by market forces, if damages are calculated in relationship to direct harm done to the government. Government regulation is too little too late, and Big Pharma is encouraged to see the end game as its ability to establish a market for its drugs. The morality of the market that values short-term profits over long risks is left undeterred.

4. *Criminal Sanctions under Anti-Racketeering Statutes.*¹²⁹

Finally, what is theoretically on the table during the settlement of claims against Big Pharma are Federal Anti-Racketeering Statutes. Typically, these fall out of the discussion during the resolution of cases involving FCA or kick-back pricing schemes. Perhaps this is because of burden of proof claims (beyond a reasonable doubt) or difficulties wrapped up in proving criminal intent. You can see from an examination of these claims that the companies and their executives deny any criminal wrongdoing, and the sanctions associated with that wrongdoing are not invoked. Denying one of these major players access to a market, or forfeiture of profits, or requiring anyone to actually serve time in jail has never been part of any settlement with any of the Big Pharma companies.¹³⁰

5. *Who are the Parties in Big Pharma Cases and How Do Their Motivations Impact on Deterrence?*

a. *The Role of Whistleblower*

In the world of these settlements, the U.S. Attorney is relying in part on the whistleblowers and their counsel. The FCA provides that where a qualifying whistleblower is involved, that person is entitled to a “relator share” for blowing the whistle on the company’s wrongdoing.¹³¹ The whistleblower, or relator, is entitled to a bounty of up to 30 percent of the government’s

¹²⁹ RICO (Racketeer Influenced and Corrupt Organization) prohibits the acquisition of any enterprise through the investment of racketeering proceeds, as well as the acquisition or operation of an enterprise through a pattern of racketeering activities. 18 U.S.C. § 1961 (2012); 18 U.S.C. § 1962 (1988), (providing for forfeiture of the “racketeers’ “ interest in the enterprise along with a 20-year sentence for the violation of any of the RICO subsections); 18 U.S.C. § 1963 (2012); see G. Robert Blakey, *The RICO Civil Fraud in Context: Reflections on Bennett v. Berg*, 58 NOTRE DAME L. REV. 237 (1982).

¹³⁰ See Frakt et al., *supra* note 62. There is no settlement discussed in the document.

¹³¹ 31 U.S.C. § 3730 (2012).

recovery.¹³² As a result, the relator has a statutory interest in the case which the Supreme Court has noted as the justification for meeting the U.S. Const. Article III ‘injury in fact’ standing requirement.¹³³

The relator may have taken substantial personal risk to expose the fraud and the harm to the public as a result of the fraud. When the relationship works, the relator and his/her counsel work closely with the DOJ starting with the provision of a disclosure statement, which is the road map for the investigation. The statement provides an index of relevant documents, identifies witnesses and lays out the facts, and legal theories. The disclosure statement is a document that can be handed off to any government agent assigned to the case.

Whistleblower’ complaints must meet both the “specificity” requirements of FRCP 9(b) and comply with the overall pleading standards established by the Supreme Court in *Iqbal* and *Twombly*.¹³⁴ This means that the investigation and fact-finding should be “front loaded” to meet pleading requirements.

Again, where the damages recoverable are simply financial, the recovery is fairly straightforward. The U.S. wants the return of the money it paid for the drug, up to three-times. However, when the amount it paid does not compensate the harm done to the public by the fraud, how should the damages be calculated?

From the perspective of the U.S. Attorney one can see how criminal plea-bargaining experiences can affect the amount of these settlements. The U.S. Attorney is affected by his ability to prove the case. So, the prosecuting attorney discounts down from the total amount of the fine to take into account problems with proving knowledge of falsity and materiality. Second, the U.S. Attorney is concerned about the market. In some ways the government has an interest in market stability and the perception that the market is clean. So, settling a case for less settles the market and brings it certainty, which is good for the market, and decreases volatility. Finally, the U.S. government has a tricky political problem. It wants to punish bad actors but protect U.S. business interests. Many pensions and unions, states, and institutions may own stock in the institution that it is investigating. Putting these companies out of business often will harm investors. Moreover, like a plaintiff attorney, it wants to cover

¹³² *Id.*

¹³³ *See* Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000).

¹³⁴ *See* Ashcroft v. Iqbal, 556 U.S. 662 (2009); Bell Atlantic Corp. v. Twombly, 525 U.S. 366 (2007).

its costs in the suit. So, while at a minimum it wants to cover its own costs of investigation, it does not represent the individual harmed. They may have separate suits for fraud and wrongful death, but these victims may not even know that they have such claims. Any fund created to compensate those that may have been harmed are expensive to administer and often beyond the expertise of the Justice Department. The temptation is to settle the case without requiring an admission of guilt on the part of the defendant.¹³⁵

b. U.S. Attorney's Guidelines in Settlement

Should there be published guidelines, or an internal-factors analysis for use by the U.S. Attorney's Office charged with negotiating settlements with defendants in whistleblower cases in order to bring about more transparency and help develop settlements that lead to better deterrence? The need to get the amount of the settlement right is vital to the integrity or rule of law effects as a result of these settlements. If the settlement is too low, the settlement can soon appear to be the cost of doing business; in the worst case a bribe to permit the actor to get away with its profits for the illegal activity. If the settlement cannot be correlated to other settlements, then it also can look to the public as if it is a result of some special deal or political favor. In other words, it is important for the DOJ to develop a set of criteria to evaluate and guide settlement. Currently no such guidance exists.

What factors should the DOJ take into account when determining what position it ought to take with regard to monetary settlements?¹³⁶

1. What is the amount of gross revenue the defendant made as a result of its wrongful conduct?
2. Can "cash" be seized?
3. Does taking a fine per false certification, trebled, produce an amount that approximates the expected gross revenue from the activity?
4. Is the defendant a repeat offender? Or does the institution show any indication that it considers its duty to tell the truth fundamental

¹³⁵ Edward Wyatt, *Settlements Without Admissions Get Security*, N.Y. TIMES (Feb. 24, 2012), http://www.nytimes.com/2012/02/25/business/neither-admit-nor-deny-settlements-draw-judges-scrutiny.html?_r=0.

¹³⁶ See Brian C. Elmer & Alan W.H. Gourley, *FCA SETTLEMENTS: A Practical Guide For Defense Counsel*, CROWELL MORING, http://www.crowell.com/documents/DOCASSOCFKTYPE_PRESENTATIONS_440.pdf (last visited Sept. 15, 2015) (arguing there are no guidelines for the Justice Department for FCA settlements).

to the workings of an effective market place? For example, during discovery or investigation, did the government learn that the officers of the organization approved of the illegal activity? Did they try to bribe the whistleblower into not revealing its fraud? Did the defendant—or its employees—obstruct justice during the fact investigation process? Was the whistleblower threatened or intimidated? Did they cooperate with the investigation, and make available pertinent information in order to determine whether the certifications they were making were true or false?

5. Did the conduct cause harm to the market?
6. Did the fraud cause consequential harm and or the deaths of others?
7. Was the conduct analogous to a RICO violation, in that it involved a conspiracy to lie, and then cover up over a period of time in order that they could maximize their profits while they stole from those who did not know about the lie? Did they try payoffs, bonuses, or kickbacks to prolong the fraud?
8. Will the company have gained from their actions an advantage in the market for its drug that will produce future benefits beyond whatever they have to pay in terms of damages for past false claims?

The problem, however, with this factors analysis is that the decision lies with the DOJ in individual cases, and there is a lack of information from case-to-case (unless the same whistleblower attorney is involved or the same Justice Department attorney involved) so that the U.S. attorney can act consistently across cases. Again our analysis of settlements reached since 2001 shows little rhyme or reason in the amount of settlements.¹³⁷ Even where the settlements were in the hundreds of millions of dollars, these settlements seemed to have little impact on the company's stock price, ability to continue to market the drug, or future market strategies.¹³⁸

Perhaps some help in incentivizing new tougher standards that might come from the Park Doctrine (also known as the Responsible Corporate Officer Doctrine).¹³⁹ The Park Doctrine has long occupied an obscure corner of

¹³⁷ See Table *infra*, pp. 118-137.

¹³⁸ *Id.*

¹³⁹ See *Park*, 421 U.S. 658; Cory L. Andrews & Richard A. Samp, *Restraining Park Doctrine Prosecutions Against Corporate Officials Under the FDCA*, THE FEDERALIST SOCIETY (Sept. 19, 2015), <http://www.fed-soc.org/publications/detail/restraining-park-doctrine-prosecutions-against-corporate-officials->

American criminal law. It allows corporate officers to be charged with a crime for wrongdoing that occurred “on their watch,” without any showing of personal fault or even knowledge on their part—other than a showing that they were “in charge” at the time the wrongdoing occurred.¹⁴⁰ Such no-fault crimes are rare in American jurisprudence, but the Supreme Court has upheld such convictions under narrow circumstances.¹⁴¹ At least one Court of Appeals has recently ruled that it did apply in a case of egregious behavior by a small pharmaceutical company.¹⁴² Perhaps this will be the start then of the Justice Department thinking of taking an approach that seeks disgorgement of any and all profits from the sale of a drug promoted through off-label marketing or kick-backs.

Let’s take a second example from the pharmaceutical industry and see if the Park Doctrine might apply. Let’s say a pharmaceutical company markets an antiepileptic drug for “off-label” purposes. Though the drug is approved to treat seizures, the manufacturer markets the drug to nursing homes to sedate patients with dementia. To get the drug into the nursing home market, the manufacturer pays market share rebates to the long-term care pharmacies that encourage nursing home doctors to try the drug to sedate patients with dementia. The off-label use of the drug is synergistic for both the manufacturer and the nursing home. The manufacturer expands its revenue stream, and the nursing home can cut staff by sedating the patients. While the scheme has economic benefits for the manufacturer, the nursing home, and the long term care pharmacy that skims an extra profit, sedated patient’s face the risk that they will fall, roll out of bed, and live on their remaining years in a sedated state. It is a scheme that costs the government, which pays the bills for a drug that should not have been prescribed. It is a scheme that causes the government to pay for nursing home services that may not meet quality of care standards as staffing has been cut. It is a scheme that places patients at risk and bonus checks in the hands officials at the drug company, the long term care pharmacy and the potentially the nursing home.

under-the-fdca; Dahlia Rin, John P. Pucci, & Robert L. Ullmann, *The Misinterpretation of the Park Doctrine as Creating Strict Liability*, FDLI UPDATE 8, 9 (Nov. 2011), http://www.nxtbook.com/ygsreprints/FDLI/g22793fdli_novdec/index.php?startid=8 (criticizing the Justice Department and FDA’s interpretation of the Park Doctrine). We argue that better deterrence can occur if the government can recoup the profits from the product that have occurred and will occur in the future. Here is where the Justice Department might perform a unique role in settling damages claims where the public has been lied to, there has been harm, and there are decision makers who have profited from the activity.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² See *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

The above example is not atypical. Unlawful marketing practices are not just about calculating lost dollars. The practices have real patient impact; people are being caused to ingest products that may cause physical harm. Though these wrongs are perceived of as white-collar crimes or civil frauds, they can also be analyzed through the traditional lens of the tort of “battery” as in an unpermitted contact. Often the patient, as in the nursing home example, lacks the ability to engage in informed consent or make a decision about his or her treatment. The result is litigation under the FCA that really involves the subject of elder abuse. In these cases, at least, the Park Doctrine is an appropriate consideration.

c. Alternatives to Liability Under the FCA: Corporate Integrity Agreements

CIAs are contracts negotiated between a corporation and the Office of Inspector General of the United States Department of Health and Human Services to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other federal healthcare programs.¹⁴³ These negotiated settlements are essentially a chance at redemption.¹⁴⁴ As part of a deferred prosecution agreement, the DOJ will ask the defendant corporation to enter into a CIA to police its own behavior.¹⁴⁵ These agreements are usually a stipulation of settlement agreements providing for release of liability under the FCA. As a result of release of liability, the government agrees not to seek the company’s “exclusion from participation in Medicare, Medicaid, and other federal healthcare programs.”¹⁴⁶

“Although the terms and conditions of these CIAs vary depending on the nature and extent of the alleged fraudulent or abusive activity, they have many similar elements.”¹⁴⁷ According to the OIG, CIAs typically contain a duration

¹⁴³ See *Corporate Integrity Agreements*, HEALTH LAW RESOURCES, [https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Corporate%20Integrity%20Agreements%20\(CIAs\).aspx](https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Corporate%20Integrity%20Agreements%20(CIAs).aspx) (last visited Feb. 10, 2016).

¹⁴⁴ *Corporate Integrity Agreements*, METRICSTREAM, <http://www.metricstream.com/industries/healthcare/corporate-integrity-agreements-compliance.htm> (last visited on Feb. 10, 2016).

¹⁴⁵ Caroline Poplin, *Corporate Integrity Agreements: Asking the Companies to Police Themselves, Please*, WHISTLEBLOWERLAWS (Aug. 12, 2010), <http://www.whistleblowerlaws.com/corporate-integrity-agreements-asking-the-companies-to-police-themselves-please/>.

¹⁴⁶ *Corporate Integrity Agreements*, OFFICE OF INSPECTOR GEN. U.S DEP’T OF HUMAN AND HEALTH SERV., <http://oig.hhs.gov/compliance/corporate-integrity-agreements/> (last visited on Feb. 10, 2016).

¹⁴⁷ Thomas Herrmann, *Meeting the Challenge of Corporate Integrity Agreements and Independent Review Organizations*, COMPLIANCE.COM (Jan. 2013), <http://compliance.com/challenge-of-corporate-integrity-agreements-and-independent-review-organizations>.

requirement of five years and include requirements to hire a compliance officer and/or appoint a compliance committee, develop written standards and policies, implement a comprehensive employees' training program, retain an independent review organization to conduct annual reviews, establish a confidential disclosure program, restrict employment of ineligible people, report overpayments, reportable events, and ongoing investigations/legal proceedings, and provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.¹⁴⁸

For example, Johnson & Johnson's CIA mandates that the company make changes to current executive pay structure in an effort to effectuate change in corporate behavior.¹⁴⁹ The OIG hopes that by imposing non-monetary measures and requiring compliance with CIAs, the agreement will increase accountability among key players and foster transparency.¹⁵⁰ The five-year CIA implemented as a result of Johnson & Johnson's 2013 settlement with the DOJ supersedes an existing CIA in place.¹⁵¹ This begs the question of whether these agreements are essentially toothless. Between the civil and criminal complaint, Johnson & Johnson ultimately settled over six allegations of egregious misbehavior, all occurring while Johnson & Johnson had a CIA in place.¹⁵² This would seem to suggest that the CIAs are not particularly effective, at least with some of the major pharmaceutical companies.

In another settlement, Daiichi agreed to enter into a CIA, mandating that the company implement compliance reforms for the next five years.¹⁵³ As *Daiichi* is the most recent settlement reached, we see some changes that were not present in former CIAs.¹⁵⁴ Notably, unlike most other CIAs, Daiichi refused to implement a new financial incentive structure for its sales representatives.¹⁵⁵ However, the new trend in these agreements, which is included in Daiichi's CIA, is the monitoring and oversight of the company's

¹⁴⁸ *Id.*

¹⁴⁹ Thomas & Schmidt, *supra* note 113.

¹⁵⁰ *Id.*

¹⁵¹ Thomas Sullivan, *Johnson and Johnson 2013 Settlement and Corporate Integrity Agreement*, POLICY AND MEDICINE (Nov. 5, 2013), available at <http://www.policymed.com/2013/11/johnson-and-johnson-2013-settlement-and-corporate-integrity-agreement.html>; The False Claims Act: A Primer, *supra* note 90.

¹⁵² See generally *id.*; Thomas & Schmidt, *supra* note 113.

¹⁵³ Thomas Sullivan, *Daiichi Sankyo Settlement and Corporate Integrity Agreement*, POLICY & MEDICINE (Jan. 13, 2015, 05:30:00 AM), <http://www.policymed.com/2015/01/daiichi-sankyo-agrees-to-pay-39-million-to-resolve-off-label-and-kickback-allegations-enters-into-co.html>.

¹⁵⁴ See *id.*

¹⁵⁵ *Id.*

social media presence.¹⁵⁶ Companies are now expected to also watch what they disseminate in posts as direct-to-consumer marketing.¹⁵⁷

How exactly are CIAs implemented? Most companies implement a compliance program and designate a compliance officer and/or a compliance committee to ensure that the objectives of the CIA are being accomplished.¹⁵⁸ The CIA typically requires the filing of reports certifying compliance with the terms of the CIA every year.¹⁵⁹ CIAs cover the conduct of all owners, excluding shareholders owning a negligible amount, officers, directors, employees who are engaged in activities relating to federal health programs, and it also extends to third parties that are engaged in or have job responsibilities relating to the sale of or billing for items or services payable by the federal health programs.¹⁶⁰ Some CIAs impose a cut-off for certain part-time employees.

The government is trying to accomplish several important goals with CIAs and other regulations placed on health care companies. CIAs are intended to improve the overall quality of health care experienced by patients and to promote adherence to the current healthcare regulations.¹⁶¹ It is important to protect the general public from proscribed practices and attempt to hold accountable those who commit healthcare fraud.¹⁶² Another worthy goal of CIAs and prosecution by the government of healthcare companies is to promote transparency and create pressure to conduct business in an ethical manner.¹⁶³

There are several ways in which the government hopes to effectuate compliance with CIAs.¹⁶⁴ One such way is by requiring the companies' individual committees to meet, sometimes quarterly, to review and oversee the compliance program. Another is for each reporting period to have the board adopt a resolution signed by each member summarizing its review and oversight of the company's compliance with Federal health care program

¹⁵⁶ *See id.*

¹⁵⁷ *See id.*

¹⁵⁸ *See, e.g., Corporate Integrity Agreement Between the Office Inspector General of the Department of Health and Human Services and Johnson & Johnson*, 1, 6 OFFICE OF INSPECTOR GEN. (2013), http://oig.hhs.gov/fraud/cia/agreements/Johnson_Johnson_10312013.pdf.

¹⁵⁹ *See, e.g., id.* at 53.

¹⁶⁰ *Id.*

¹⁶¹ Sullivan, *supra* note 154.

¹⁶² *See The False Claims Act: A Primer*, *supra* note 90.

¹⁶³ *Id.*

¹⁶⁴ Poplin, *supra* note 148.

requirements and the obligations of their particular CIA. This is done in an effort to hold each director or officer personally liable for ensuring compliance. In the alternative, if the board is unable to provide such a conclusion in its resolution, the board shall provide a written explanation of the reasons for why it is unable to certify compliance and the steps the company will take in order to implement an effective compliance program.

Some CIAs require changes to executive compensation programs, including claw-back of annual bonuses or other long-term incentives. This requirement would apply to current and former executives. CIAs may also require more transparency in reporting on research practices, publications, social media presence, and payments to doctors.

The effect of non-compliance with an internal CIA, whether it was entered into voluntarily or involuntarily, is essentially the same consequences as if the company had been prosecuted through the adjudication process.¹⁶⁵ If a CIA is breached, the OIG reserves the right to impose additional sanctions including monetary penalties and permissive exclusion from all Federal healthcare programs.¹⁶⁶ Yet, the fines associated with such violation are much lower, usually ranging from \$1,000 to \$2,500 per violation.¹⁶⁷

Since May of 2009, CIAs have been a part of most settlements between Big Pharma and the Justice Department. At that time the Fraud Enforcement and Recovery Act of 2009 (“FERA”) was signed into law, implementing the most significant amendments to the FCA since 1986.¹⁶⁸ Furthermore, in March of 2010, the Patient Protection and Affordable Care Act was signed into law by President Obama, further amending and broadening the scope of the FCA.¹⁶⁹ Since the enactment of these two laws, countless other settlements, besides the four large ones described above, have contributed to over \$7 billion dollars in settlement payments just within the last few years.¹⁷⁰

¹⁶⁵ See *The False Claims Act: A Primer*, *supra* note 90.

¹⁶⁶ *Exclusions FAQ*, *supra* note 114.

¹⁶⁷ Poplin, *supra* note 148.

¹⁶⁸ 31 U.S.C. § 3729 (2012).

¹⁶⁹ 31 U.S.C. § 3730 (2012).

¹⁷⁰ Companies seem to pass on the costs of these settlements to the future price they charge for the drug, despite the practices they used to establish the drug’s place in the market. They also use the settlement as a new “development cost,” getting the double benefit of a tax write off, and a justification for setting a higher wholesale price, going forward. These troubling examples, in chronological order, include companies such as:

1. Eli Lilly*; \$1.415 billion; for its off-label promotion of Zyprexa; settled in January 2009 (*Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa*, DEP’T OF JUSTICE (Jan. 15, 2009), <http://www.justice.gov/archive/opa/pr/2009/January/>

09-civ-038.html). Eli raised its price following the settlement of Zyprexa and its other drugs. <http://www.cbsnews.com/news/lilly-q1-price-rises-end-of-zyprexa-woes-boost-the-numbers/>.

2. Alpharma; \$42.5 million; off-label promotion of Kadian; March 2010 (*Alpharma to Pay \$42.5 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Kadian*, DEP'T OF JUSTICE (March 16, 2010), <http://www.justice.gov/opa/pr/alpharma-pay-425-million-resolve-false-claims-act-allegations-connection-promotion-drug>). Following settlement extended patent by developing an extended release capsule. Raised price of drug. 100 mg capsule (manufactured by Actavis, NDC 46987-0324-11) with AWP of \$21.1193 per capsule, Annual cost of regimen = \$22,808.84, Cost of regimen over claimant's life expectancy = \$684,265.20. The generic competitor set its price close to Kadian's initial price. Conversion to Generic Morphine Sulfate Extended-Release 300mg per day, 100mg capsule (manufactured by Watson Pharma, NDC 00591-3453-01) with AWP of \$18.2471 per capsule, Annual cost of regimen = \$19,706.87, Cost of regimen over claimant's life expectancy = \$591,206.10 (*FDA Approves Generic Equivalents of Kadian*, MEDVAL (Dec. 7, 2011) <https://www.medval.com/2011/12/07/fda-approves-generic-equivalents-of-kadian/>).
3. AstraZeneca*; \$520 million; off-label promotion of Seroquel; illegal kick-backs; settled in April 2010 (*Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-label Drug Marketing*, DEP'T OF JUSTICE (Apr. 27, 2010), <http://www.justice.gov/opa/pr/pharmaceutical-giant-astrazeneca-pay-520-million-label-drug-marketing>). Consumer Reports reported at 88% raise in the average retail prescription price of Seroquel for its 2007 price to 2012. *Knowing when Prescription Prices are high and how to avoid Overspending*, CONSUMER REPORTS (Nov. 2012), <http://www.consumerreports.org/cro/2012/11/where-high-drug-costs-hide/index.htm>.
4. Ortho-McNeil-Janssen; \$81 million; off-label marketing of Topamax; settled in April 2010 (*Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax*, DEP'T OF JUSTICE (Apr. 29, 2010), <http://www.justice.gov/opa/pr/two-johnson-johnson-subsidiaries-pay-over-81-million-resolve-allegations-label-promotion>). Raised its price for name brand, and then raised the price to over \$200 a prescription or over double generic prices. *Best Buy Drugs*, CONSUMER REPORTS, <https://www.consumerreports.org/health/resources/pdf/best-buy-drugs/Anticonvulsants-FINAL.pdf> (last visited Feb. 10, 2016).
5. Novartis*; \$72.5 million; off-label promotion of TOBI; illegal kick-backs; settled in May 2010 (*Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI*, DEP'T OF JUSTICE (May 4, 2010), <http://www.justice.gov/opa/pr/novartis-vaccines-diagnostics-pay-more-72-million-resolve-false-claims-act-allegations>). Extends patent for "Podhaler" TOBI (treating cystic fibrosis) and raises prices. *FDA approves Novartis TOBI® Podhaler™ for certain cystic fibrosis patients, the first and only dry powder inhaled antibacterial in US*, FIERCE PHARMA (MARCH 25, 2013), <http://www.fiercepharma.com/press-releases/fda-approves-novartis-tobi-podhaler-certain-cystic-fibrosis-patients-first-0>.
6. Allergan*; \$600 million; off-label promotion of Botox; settled in September 2010 (*Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox®*, DEP'T OF JUSTICE (Sept. 1, 2010), <http://www.justice.gov/opa/pr/allergan-agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox>). Price increases held to 3% a year till last year. See Cafépharmaceutical message boards, <http://cafepharmaceutical.com/boards/threads/botox-price-increase-again.572609/>.
7. Forest Laboratories*; \$313 million; off-label promotion of Levothroid, Celexa, and Lexapro; settled in September 2010 (*Drug Maker Forest Pleads Guilty; To Pay More Than \$313 Million to Resolve Criminal Charges and False Claims Act Allegations*, DEP'T OF JUSTICE (Sept. 15, 2010), <http://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false>).
8. Novartis*; \$422.5 million; off-label promotion of Trileptal; settled in September 2010 (*Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-label Promotion and*

-
- Kickback Allegations*, DEP'T OF JUSTICE (Sept. 30, 2010), <http://www.justice.gov/opa/pr/novartis-pharmaceuticals-corp-pay-more-420-million-resolve-label-promotion-and-kickback>).
9. Kos Pharmaceuticals; \$41 million; off-label promotion of Advicor and Niaspan; settled in December 2010 (*Kos Pharmaceuticals to Pay More Than \$41 Million to Resolve Kickback and Off-Label Promotion Allegations*, DEP'T OF JUSTICE (Dec. 7, 2010), <http://www.justice.gov/opa/pr/kos-pharmaceuticals-pay-more-41-million-resolve-kickback-and-label-promotion-allegations>).
 10. Elan*; \$203 million; off-label promotion of Zonegran; settled in December 2010 (*Pharmaceutical Companies to Pay \$214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran*, DEP'T OF JUSTICE (Dec. 15, 2010), <http://www.justice.gov/opa/pr/pharmaceutical-companies-pay-2145-million-resolve-allegations-label-promotion-zonegran>).
 11. Dey Pharma LP; \$280 million; inflating published drug prices; settled in December 2010 (*Pharmaceutical Manufacturer to Pay \$280 Million to Settle False Claims Act Case*, DEP'T OF JUSTICE (Dec. 20, 2010), <http://www.justice.gov/opa/pr/pharmaceutical-manufacturer-pay-280-million-settle-false-claims-act-case>).
 12. UCB*; \$34 million; off-label promotion of Keppra; settled in June 2011 (*U.S. Subsidiary of Belgian Pharmaceutical Manufacturer Pleads Guilty to Off-Label Promotion; Company to Pay More Than \$34 Million*, DEP'T OF JUSTICE (June 9, 2011), <http://www.justice.gov/opa/pr/us-subsidiary-belgian-pharmaceutical-manufacturer-pleads-guilty-label-promotion-company-pay>).
 13. Novo Nordisk*; \$25 million; off-label promotion of NovoSeven; settled in June 2011 (*Danish Pharmaceutical Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-Label Promotion of Novoseven*, DEP'T OF JUSTICE (June 10, 2011), <http://www.justice.gov/opa/pr/danish-pharmaceutical-novo-nordisk-pay-25-million-resolve-allegations-label-promotion>).
 14. Pfizer*; \$14.5 million; off-label promotion of Detrol; settled in October 2011 (*Pfizer to Pay \$14.5 Million for Illegal Marketing of Drug Detrol*, DEP'T OF JUSTICE (Oct. 21, 2011), <http://www.justice.gov/opa/pr/pfizer-pay-145-million-illegal-marketing-drug-detrol>). 2012-2015 average increase of branded drugs, 14.33 percent; *Massive, unexpected drug price increases are happening all the time*, QUARTZ (Oct. 1, 2015), <http://qz.com/514553/massive-unexpected-drug-price-increases-are-happening-all-the-time/>.
 15. Merck, Sharp & Dohme*; \$441 million; off-label marketing of Vioxx and false statements about the drug's cardiovascular safety; April 2012 (*U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx*, DEP'T OF JUSTICE (Apr. 15, 2012), <http://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-sentenced-connection-unlawful-promotion-vioxx>). 2012-2015 Merck's average increase of branded drugs, 9.9 percent. *Massive, unexpected drug price increases are happening all the time*, QUARTZ (Oct. 1, 2015), <http://qz.com/514553/massive-unexpected-drug-price-increases-are-happening-all-the-time/>.
 16. GlaxoSmithKline*; \$1.043 billion; off-label promotion of Paxil, Wellbutrin, Advair, Lamictal, Zofran; settled in July 2012 (*GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data*, DEP'T OF JUSTICE (July 2, 2012), <http://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>). The Wall Street journal reports price increases at Glaxo for name brands and generics, for 2015. Ron Winslow, *Cost of Skin Drugs Rising Rapidly, Study Shows*, THE WALL STREET JOURNAL (Nov. 26, 2015) <http://www.wsj.com/articles/prescription-skin-drugs-explode-in-costs-study-shows-1448467254>.
 17. Boehringer Ingelheim*; \$95 million; off-label promotion of Aggrenox; settled in October 2012 (*Boehringer Ingelheim to Pay \$95 Million to Resolve False Claims Act Allegations*, DEP'T OF JUSTICE, (Oct. 29, 2012), <http://www.justice.gov/opa/pr/boehringer-ingelheim-pay-95-million-resolve-false-claims-act-allegations>). Price information on Aggrenox not available.
 18. Amgen*; \$612 million; off-label promotion of Aranesp, Enbrel, Neulasta; illegal kick-backs; settled in December 2012 (*Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY.; Pays*

Of the twenty-four companies that settled with the DOJ within the past seven years, seventeen have included a stipulation for implementation of and compliance with CIAs as a condition of settlement. (All except for Alpharma, Dey Pharma LP, Ortho-McNeil-Janssen, Kos Pharmaceuticals, Wyeth, CareFusion, and Sanofi-Aventis).¹⁷¹ According to data, there has been a dramatic decrease in the number of CIAs in 2014.¹⁷² However, this can mainly be attributed to the fact that the majority of the large pharmaceutical companies already have a mandated CIA in place.¹⁷³ Eight out of the ten

\$762 Million to Resolve Criminal Liability and False Claims Act Allegations, DEP'T OF JUSTICE (Dec. 19, 2012), <http://www.justice.gov/opa/pr/amgen-inc-pleads-guilty-federal-charge-brooklyn-ny-pays-762-million-resolve-criminal>). Price information on subject not yet available.

19. Sanofi-Aventis; \$109 million; illegal kick-backs; lowering of effective price of Hyalgan; settled in December 2012 (*Sanofi US Agrees to Pay \$109 Million to Resolve False Claims Act Allegations of Free Product Kickbacks to Physicians*, DEP'T OF JUSTICE (Dec. 19, 2012), <http://www.justice.gov/opa/pr/sanofi-us-agrees-pay-109-million-resolve-false-claims-act-allegations-free-product-kickbacks>). Price information on subject not yet available.
20. Par Pharmaceutical*; \$22.5 million; off-label promotion of Megace ES; settled in March 2013 (*Par Pharmaceuticals Pleads Guilty and Agrees to Pay \$45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing*, DEP'T OF JUSTICE (March 5, 2013), <http://www.justice.gov/opa/pr/par-pharmaceuticals-pleads-guilty-and-agrees-pay-45-million-resolve-civil-and-criminal>). Price information on subject not yet available.
21. Wyeth Pharmaceuticals; \$257.4 million; off-label promotion of Rapamune; settled in July 2013 (*Wyeth Pharmaceuticals Agrees to Pay \$490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses*, DEP'T OF JUSTICE (July 30, 2013), <http://www.justice.gov/opa/pr/wyeth-pharmaceuticals-agrees-pay-4909-million-marketing-prescription-drug-rapamune-unapproved>). Price information on subject not yet available.
22. CareFusion; \$40.1 million; off-label promotion of ChloroPrep; settled in January 2014 (*CareFusion to Pay the Government \$40.1 Million to Resolve Allegations That Include More Than \$11 Million in Kickbacks to One Doctor*, DEP'T OF JUSTICE (Jan. 9, 2014), <http://www.justice.gov/opa/pr/carefusion-pay-government-401-million-resolve-allegations-include-more-11-million-kickbacks>). Price information on subject not yet available.
23. Endo Pharmaceuticals*; off-label promotion of Lidoderm; settled in February 2014 (*Endo Pharmaceuticals and Endo Health Solutions to Pay \$192.7 Million to Resolve Criminal and Civil Liability Relating to Marketing of Prescription Drug Lidoderm for Unapproved Uses*, DEP'T OF JUSTICE (Feb. 21, 2014), <http://www.justice.gov/opa/pr/endo-pharmaceuticals-and-endo-health-solutions-pay-1927-million-resolve-criminal-and-civil>). Price information on subject not yet available.
24. Shire Pharmaceuticals*; \$56.5 million; off-label promotion, settled in September 2014 (*Shire Pharmaceuticals LLC to Pay \$56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices*, DEP'T OF JUSTICE (Sept. 41, 2014), <http://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug>). Price information on subject not yet available.

*Indicates that the company has implemented a CIA as a condition of settlement with the DOJ.

¹⁷¹ See *id.*

¹⁷² See Sullivan, *supra* note 154.

¹⁷³ See *id.*

biggest pharmaceutical companies are currently operating under a CIA, and some have already violated earlier agreements multiple times.¹⁷⁴

There are several issues regarding how CIAs are currently implemented and monitored for compliance. One main issue with CIAs is that the government is assuming that the internally appointed compliance officer or other so-designated person will be able to perform their role objectively and without company bias.¹⁷⁵ These settlements include agreements that all criminal and civil charges are dropped, and typically each company refuses to admit any fault or wrongdoing.¹⁷⁶ This is inadequate to accomplish the objective of holding directors and officers, the ones in charge calling the shots, personally liable in a way that would force them to change their fraudulent tactics. For example, Johnson & Johnson expressly denied all allegations and further stood behind its promotion of the drug they were charged with improperly promoting.¹⁷⁷ Most importantly, there is no system currently in place for the imposition of liability on individual actors, whether criminal or civil. No individuals were charged in any of the large pharmaceutical settlements of Glaxo, Johnson & Johnson, or Abbott Laboratories.¹⁷⁸ Officers, owners, and directors, the ones that actually implement unlawful policies, are able to hide behind the corporate veil. There are only a few instances of any personal liability:

- Synthes: In 2011, four executives were sentenced to less than one year in prison for conducting clinical trials that were not approved by the FDA.¹⁷⁹
- A former executive of KV Pharm was sentenced to only thirty days in jail and fined \$1 million for selling misbranded tablets.¹⁸⁰ The previous year, the DHHS excluded him from conducting business with the federal government.¹⁸¹

¹⁷⁴ See Maria Szalavitz, *Top 10 Drug Company Settlements, Pharma Behaving Badly*, TIME (Sept. 17, 2012), <http://healthland.time.com/2012/09/17/pharma-behaving-badly-top-10-drug-company-settlements/>.

¹⁷⁵ See Poplin, *supra* note 148.

¹⁷⁶ See, e.g., Sullivan, *supra* note 154.

¹⁷⁷ *Id.*

¹⁷⁸ Thomas & Schmidt, *supra* note 113.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* (a finding where personal liability was imposed).

¹⁸¹ *Id.*

Since the implementation of CIAs many companies may simply consider the large settlement payments as just a cost of doing business.¹⁸² For example, Glaxo's \$3 billion settlement for a half dozen drugs over 10 years represents only a portion of what Glaxo made on the drugs; 11% to be exact.¹⁸³ Wellbutrin made the company \$5.9 billion, Avandia brought in over \$5.9 billion, and Paxil generated over \$11.6 billion.¹⁸⁴ Three billion dollars seems like a drop in the bucket when placed in context. The gaudy sums are unlikely to curb the industry's reliance on fraudulent activities because the practices are simply too lucrative to give up.¹⁸⁵ Eliot Spitzer, former New York Attorney General, is quoted as saying: "what we're learning is that money doesn't deter corporate malfeasance."¹⁸⁶

CIAs are therefore mostly self-enforcing.¹⁸⁷ Some have notice provisions that require any action taken by the government on the CIA to be preceded by notice and a chance for the company to respond.¹⁸⁸ Because implementation of and compliance with CIAs can be very costly, (from having to potentially hire an outside reviewer and all the other time and efforts that come along with ensuring compliance) one wonders whether those auditing will either be co-opted, or given other tasks that detract from their focus on searching for illegal activity.¹⁸⁹ The regulations tend to be complex and many companies struggle to effectively implement a system to comply with the onerous auditing, reporting, and monitoring requirements.¹⁹⁰ Moreover—and not to be overlooked—is that analysis of the big schemes indicates that unlawful behavior is driven by facially neutral conduct, which is often hard to detect. While CIAs may actually monitor for obvious facially neutral drivers—as in bonuses to sales representatives for both on-label and off-label sales—the industry has been clever enough to continually develop new ways to drive unlawful revenue streams.

¹⁸² *Id.*

¹⁸³ *Id.*; Szalavitz, *supra* note 177.

¹⁸⁴ Thomas & Schmidt, *supra* note 113.

¹⁸⁵ Michael Bobelian, *J&J's \$2.2 Billion Settlement Won't Stop Big Pharma's Addiction To Off-Label Sales*, FORBES (Nov. 12, 2013), <http://www.forbes.com/sites/michaelbobelian/2013/11/12/jjs-2-2-billion-settlement-wont-stop-big-pharmas-addiction-to-off-label-sales/>.

¹⁸⁶ Thomas & Schmidt, *supra* note 113.

¹⁸⁷ *See* Poplin, *supra* note 148.

¹⁸⁸ *See id.*

¹⁸⁹ *See id.*

¹⁹⁰ *See id.*

CONCLUSION

The special features of Big Pharma's ability to dictate the pricing of drugs in the U.S. healthcare market creates seemingly insurmountable incentives for it to extract exorbitant prices. Traditional common law remedies do not provide deterrence. In addition, given the seemingly ineffective results when implemented by pharmaceutical companies, an argument can be made that CIAs are toothless.¹⁹¹ And, one might wonder whether OIG guidelines will produce any better results, especially in light of OIG lack of legislative authorization for ordering divestitures. Critics argue that damages are not enough to deter drug companies from unlawful behavior.¹⁹² Exclusion from Federal healthcare programs has only occurred in a negligible amount of cases and never in the case of any of the larger pharmaceutical companies.¹⁹³ The OIG might be very reluctant to follow through on its permissive exclusion power because of the drastic and far-reaching effect it could have on innocent parties, including employees and patients who rely on these drugs.¹⁹⁴

Perhaps a new approach will be taken by the OIG that will enforce as a consequence of non-compliance the forced divestiture of a business unit or product.¹⁹⁵ Many in the industry believe this move signals the OIG's willingness to achieve compliance through novel uses of its enforcement authority.¹⁹⁶ While seeming like an effective way to scare a company into compliance, this could raise serious legal concerns.¹⁹⁷ Divestiture is not one of the enforcement tools specifically granted to the OIG by Congress, and its use could be considered an over-reaching and abuse of discretion.¹⁹⁸ Because it is

¹⁹¹ See *id.*

¹⁹² Thomas & Schmidt, *supra* note 113.

¹⁹³ See Table *infra* pp. 118-137.

¹⁹⁴ John Bentivoglio, Jennifer L. Bragg, Michael K. Loucks, Gregory M. Luce & Alexander R. Cohen, *Violations of Corporate Integrity Agreement Trigger Divestiture Action by HHS OIG*, SKADDEN (June 14, 2010), <http://www.skadden.com/insights/violations-corporate-integrity-agreement-trigger-divestiture-action-hhs-oig>. In an effort to improve the current system regarding CIAs, the OIG held a round table meeting, the first of its kind, with representatives of several health care companies, entitled "Focus on Compliance—The Next Generation of Corporate Integrity Agreements." Herrmann, *supra* note 150. While no specific recommendations were proffered as a result of this discussion, it was reported that the health care companies urged the OIG to supply additional compliance guidance to the industry. *Id.*

¹⁹⁵ Bentivoglio, Bragg, Loucks, Luce & Cohen, *supra* note 197 (explaining that the OIG forced a company that violated its CIA to divest a subsidiary as a condition for the parent to avoid exclusion from federal health care programs).

¹⁹⁶ See *id.*

¹⁹⁷ See *id.* at ¶10.

¹⁹⁸ See *id.* ("Congress has provided the OIG with specific enforcement tools, including civil money penalties and exclusion, while forced divestiture is not among these enumerated sanctions.").

not among the OIG's enumerated tools, there is little direction as to how it can be utilized or applied across the board, which could lead to very inconsistent results.¹⁹⁹ This recent trend by the OIG could potentially lead to the creation of more issues than it is designed to solve.

Another, seemingly obvious possible solution is to impose heftier fines, and make the companies really appreciate the loss associated with their wrongdoing.²⁰⁰ If companies were forced to write a check for damages that resulted in an amount higher than 11% of their annual profit, it might make them reconsider their practices.²⁰¹ But this might raise Constitutional concerns, if a lost profits variable is not made explicitly part of any remedies that can be prescribed.

There needs to be a regulatory system where individuals are held liable for the misconduct they either personally participate in or encourage through their numerous sales incentives or the way they train their employees to interact with physicians or market their products. Only when prosecutors single out individual executives for punishment will practices begin to change.²⁰² CIAs typically include provisions relating to the OIG's right to inspect and audit the company and its compliance records.²⁰³ It is not clear how often this task is actually undertaken, but following through on the inspection right could lead to discovery of non-compliance and false reporting.

Perhaps, big Pharmaceutical companies should be regulated much like public utilities. Like public utilities and water, electricity, heat, there will always be a demand for pharmaceutical products. The consumers need them and they are fundamental to a meaningful life. If the government further regulated the industry's pricing, as it has in public utilities, this would likely promote more competition between companies and drive the prices lower, benefitting all, but most importantly, the government in its repayment of Medicaid and Medicare pricing.

The government should also implement stricter regulations regarding the actions of a company's key players. In the spirit of transparency, the compliance officer, board of directors, and any other employee responsible for compliance should be required to sign compliance certificates, acknowledging

¹⁹⁹ *See id.*

²⁰⁰ *See Szalavitz, supra* note 177.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ Herrmann, *supra* note 150.

that all of the health care requirements have been complied with. As such, each signor should be held personally liable for any deviation from or failure to comply with such regulations. At that point, it is on each individual to perform the necessary investigation confirming that what they are acknowledging has actually been complied with. If their signature actually meant they had something to lose, it will likely ensure that the standards will actually be met. This certification could form the basis of a potential FCA claim and imposition of criminal sanctions.

Since the nature of CIAs are voluntary and allow large companies to avoid huge fines and any liability, there should be a give-and-take. This is possibly the trend of the future, with at least one company implementing this theory of personal liability into its CIAs.²⁰⁴ The CIA placed additional liabilities on a company's board of directors, based upon the notion of the duty of care and loyalty that such actors owe the company.²⁰⁵

If the government insists on continuing to use CIAs as a way to enforce health care regulation compliance, another effective solution would be to require an addition of provisions to forthcoming agreements. These provisions might provide for greater regulation, including inspections rights, open-book requirements, and personal liability, and better transparency regarding the setting of prices. This could hopefully accomplish what their predecessors failed to: forcing companies to change their current business model and tactics.

Still, one wonders how these remedies deter the setting of prices in context of supply and demand, where supply is often exclusively provided by the patent holder and the demand is driven by the health impact of going without the drug.²⁰⁶ In a society that is extremely distrustful of a government agency setting prices, one might wonder whether common law civil remedies can ever sufficiently deter against illegal activities. Even in the case of disgorgement, the question is who will get the profits. If they go to the government, the government has an interest in seeking such remedies. At stake is the distinction between private and public ownership of pharmaceuticals. The dilemma then is whether disgorgement or forced sales will ever be implemented, or whether like the nuclear options, they will ever be used.

²⁰⁴ Szalavitz, *supra* note 177.

²⁰⁵ *Id.*

²⁰⁶ See David H. Howard, Peter B. Bach, Ernst R. Berndt & Rena M. Conti, *Pricing in the Market for Anticancer Drugs*, 29 J. ECON. PERSP. 139, 140, 141 (2015).

Perhaps then, Big Pharma is an example of a market where traditional remedies just do not work.²⁰⁷ But even then troubling questions remain. Do single payer options really assist in moderating the price of drugs in the long run? Will single payer systems divide the government from the patient and the patient's overall health, and end up bringing about incentives that will not provide for sufficient research and development of new drugs. Is the answer some sort of pricing regulations? As a result of any of these solutions, will overall health care suffer?

²⁰⁷ *Id.* at 158-159 (suggesting that European or Canadian price referencing may be needed in the U.S., especially for cancer-fighting drugs).