

Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010

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EXECUTIVE SUMMARY

Background

U.S. spending on prescription drugs has increased from \$40 billion in 1990 to \$234 billion in 2008. In this era of rapidly rising drug costs, the illegal pharmaceutical company activities that have contributed to such inflated spending have garnered a significant amount of media attention. Recent billion-dollar settlements with two of the largest pharmaceutical companies in the world, Eli Lilly and Pfizer, provide evidence of the enormous scale of this wrongdoing. However, the total size, varied nature, and potential impact of these illegal and potentially dangerous activities have not been previously analyzed. This study examined trends from 1991 to the present in federal and state criminal and civil actions against pharmaceutical companies in order to address these questions.

Analysis

The purpose of this study was to compile a comprehensive database of all major criminal and civil settlements between federal and state governments and pharmaceutical companies. Press releases from both federal and state governments, in addition to existing online databases, were used to identify all settlements of at least \$1 million during the past 20 years.

Main Findings

- Of the 165 settlements comprising \$19.8 billion in penalties during this 20-year interval, 73 percent of the settlements (121) and 75 percent of the penalties (\$14.8 billion) have occurred in just the past five years (2006-2010).
- Four companies (GlaxoSmithKline, Pfizer, Eli Lilly, and Schering-Plough) accounted for more than half (53 percent or \$10.5 billion) of all financial penalties imposed over the past two decades. These leading violators were among the world's largest pharmaceutical companies.
- While the defense industry used to be the biggest defrauder of the federal government under the False Claims Act (FCA), a law enacted in 1863 to prevent defense contractor fraud, the pharmaceutical industry has greatly overtaken the defense industry in recent years. The pharmaceutical industry now tops not only the defense industry, but all other industries in the total amount of fraud payments for actions against the federal government under the False Claims Act.
- The practice of illegal off-label promotion of pharmaceuticals has been responsible for the largest amount of financial penalties levied by the

federal government over the past 20 years. This practice can be prosecuted as a criminal offense because of the potential for serious adverse health effects in patients from such activities.

- Deliberately overcharging state health programs, mainly Medicaid fraud, has been the most common violation against state governments and is responsible for the largest amount of financial penalties levied by these governments. This type of violation is also the main factor in the considerable increase in state settlements with pharmaceutical companies over time.
- Former pharmaceutical company employees and other “whistleblowers” have been instrumental in bringing to light the most egregious violations and have been responsible for initiating the largest number of federal settlements over the past 10 years. From 1991 through 2000, *qui tam* (whistleblower) cases made up only 9 percent of payouts to the government, but from 2001 through 2010, they comprised 67 percent of total payouts.

Conclusion

Over the past two decades, especially during the past 10 years, there has been a marked increase in both the number of government settlements with pharmaceutical companies and the size of the accompanying financial penalties. The reasons for these increases are likely related to a combination of increased violations by companies and increased enforcement on the part of federal and state governments.

The danger to public safety and the loss of state and federal dollars that comes with these violations require a more robust response than the government’s current practices. Given the relatively small size of current financial penalties when compared to the perpetrating companies’ profits, both increased financial penalties and appropriate criminal prosecution of company leadership may provide a more effective deterrent to unlawful behavior by the pharmaceutical industry.

Introduction

In the past few years, the pharmaceutical industry has come under increasing scrutiny for myriad criminal and civil violations.¹ It seems as if almost every week, a new settlement is announced. Why this is happening is a question for debate. But what is clear is that pharmaceutical companies are being more aggressive than ever before in the marketing and sales of their products and in maximizing their profit margins.^{2, 3}

Governments have struggled to keep pace with the increase in these companies' aggressive tactics. The federal government has imposed some of the largest criminal fines ever for activities such as off-label promotion.⁴ And as state Medicaid programs have struggled with high enrollments⁵ and dire budgetary conditions, an increased focus has been placed on rooting out Medicaid fraud.⁶

This study examines trends in, and details of, major federal and state government settlements with pharmaceutical companies over the past two decades. A database of civil and criminal settlements involving these companies was compiled, including the type of violation and the amount of money paid as a result of each settlement. From this database we explore various aspects of this serious problem, such as time trends in company payouts, individual company totals, the nature of actions taken (civil vs. criminal, federal vs. state), and major laws that were allegedly violated. To our knowledge, this is the first study that attempts to document and analyze all major pharmaceutical company settlements with both federal and state governments.

Methods and Definitions

This study sought to compile a comprehensive database of all major federal and state government settlements finalized against pharmaceutical companies over the past 20 years (1991-2010), through November 1, 2010. Cases were excluded if the company was not predominantly a pharmaceutical manufacturer, if the total financial penalty for a settlement was less than \$1 million, or if the wrongdoing concerned a product that was not a pharmaceutical (e.g., if the product was a medical device). After determining inclusion and exclusion criteria, we created a database of relevant entries using an Excel spreadsheet. To obtain data, we searched a number of different publicly available databases.

We obtained at least one official state or federal government press release for all included cases. A single case was defined as involving one or more companies

in which there was a single settlement with the federal and/or state government. In cases where documentation of the exact details of original settlements could not be obtained, the language of related government press releases was used to determine how many separate cases were involved. If a release mentioned a singular “settlement,” regardless of how many companies or states were involved, it was counted as one case in our database. If a release mentioned plural “settlements” and there was a breakdown of amount paid by company, then each company’s settlement was counted as a separate case. For further details of the Methods, see Appendix 1.

Laws Being Violated and Legal Definitions

Details of various laws pertaining directly to the violations described in this paper are presented below:

The False Claims Act (FCA) is a commonly used legal tool to prosecute fraud against the government. Originally enacted in 1863 during the Civil War to combat defense contractor fraud, the FCA was weakened in 1943 in the midst of World War II. Responding to a growing awareness of contractor fraud against the federal government, the FCA was strengthened by Congress through various amendments in 1986. These amendments included protection of whistleblowers from employer retaliation and increased financial rewards for coming forward.⁷ The *qui tam* (whistleblower) provisions are a key part of the act, allowing private citizens to bring to light illegal activities that may initiate prosecution of the offending companies. These amendments have made the FCA a central tool in fighting corporate fraud against the federal government. In the 2005 Deficit Reduction Act (DRA), Congress provided incentives for individual states to enact or strengthen their own FCAs to encourage prosecution of Medicaid fraud. As of 2009, 14 states had FCAs that were DRA-compliant.⁸ In 2009 and 2010, the FCA was further amended to close an existing loophole (2009) and to further encourage whistle blowers to come forward (2010).⁹ Violations of the FCA result in civil, rather than criminal, penalties.

The other major federal law used to take action against certain pharmaceutical activities is the Food, Drug, and Cosmetic Act (FDCA), which covers regulatory violations against the Food and Drug Administration (FDA). The FDCA, enacted in 1938 and since amended, forms the basis for the regulation of pharmaceuticals, including the prohibition of making false therapeutic claims about a product, including off-label promotion.¹⁰ Violations of the FDCA that involve illegal off-label marketing can be prosecuted as criminal or civil violations, with the decision to pursue criminal charges depending on such factors as the seriousness of the violation and the level of threat to public safety.¹¹ Other

federal laws cited to prosecute the companies include the Anti-Kickback Statute, the Foreign Corrupt Practices Act, and various environmental laws, such as the Clean Air Act.

In addition to state FCA laws, several states have laws specifically covering Medicaid fraud (e.g., Texas Medicaid Fraud Prevention Act) and consumer protection (e.g., West Virginia Consumer Protection Act) that have been invoked to hold pharmaceutical companies accountable for violations.

Violation Types

In this study, federal and state violations were classified into nine general categories: overcharging government health programs, unlawful promotion, monopoly practices, kickbacks, concealing study findings, poor manufacturing practices, environmental violations, financial violations, and illegal distribution. (Explanations of each category are shown in Table 1.) These violations do not necessarily coincide with the actual laws allegedly violated (see legal definitions above).

Table 1. Types of Violations by Pharmaceutical Companies.

Type of Violation	Description
Overcharging Government Health Programs	Inflating the average wholesale price (AWP) of products, failing to give the lowest market price to government health programs, or failing to pay required rebates to any government health program
Unlawful Promotion	Off-label promotion of drug products or other deceptive marketing practices (e.g., downplaying health risks of a product)
Monopoly Practices	Unlawfully attempting to keep monopoly patent pricing privileges on products, or collusion with other companies undertaken with the purpose of increasing the market share of a particular product
Kickbacks	Kickbacks (e.g., monetary payments) to providers, hospitals, or other parties to influence prescribing patterns in favor of the company
Concealing Study Findings	Concealing results of company-sponsored studies from either the federal or state governments
Poor Manufacturing Practices	Selling drug products that fail to meet FDA standards or specifications (e.g., contaminated or adulterated products, or products that fail to meet size or dosage specifications)
Environmental Violations	Clean Air Act and Clean Water Act violations, or failing to meet federal emissions standards
Financial Violations	Accounting or tax fraud, or insider trading
Illegal Distribution	Distributing an unapproved pharmaceutical product

Criminal vs. Civil Settlements

Criminal settlements, or criminal components of larger settlements, were defined as those in which there was a financial penalty labeled a “criminal” fine for violation of a law or if a penalty was ordered to be paid as part of a court criminal judgment or plea agreement. All other financial penalties were defined as civil (e.g., FCA violations). Civil-criminal settlements were defined as those containing both civil and criminal financial penalties.

Federal and State Analyses

Once a complete list of cases was compiled, we classified cases as either federal or state settlements. Cases were classified as state settlements if there was no involvement of any federal government agency in either the investigation or

negotiation phases of the settlement. All other cases were classified as federal, including joint federal-state cases (e.g., those involving Medicaid).

FCA Analysis

In analyzing FCA violations in the defense and pharmaceutical industries, all totals represent only the portion of the civil settlement paid to the federal government. For pharmaceutical industry totals, settlements in our database in which the federal portion was not specified were excluded from the total amount. Federal FCA statistics for the Department of Defense, the Department of Health and Human Services (HHS), and all other industries combined were obtained from the Department of Justice (DOJ) at the following URL:

<http://www.justice.gov/civil/frauds/fcastats.pdf>.¹² The DOJ statistics represent total settlement monies paid out by fiscal year (FY) to the federal government. However, settlement dates in our data set do not necessarily correlate with the actual dates that monies were paid out to the federal government, leading to a possible discrepancy in annual totals when comparing our data with that of the federal government.

In addition, data were obtained from the Office of Inspector General of HHS and the DOJ that presented total annual (FY) settlement monies with both federal and state governments involving each sector within the healthcare industry for all violations. The FCA portion was not specified.¹³

Annual pharmaceutical industry FCA totals were calculated from our data, as described above. We used the total settlement data within other (non-pharmaceutical) sectors of the health industry to see how the pharmaceutical industry FCA payouts compared to each of these other health sectors, such as durable medical equipment (e.g., medical device) providers, hospitals, etc.

Qui tam Analysis

Only federal settlements were used for the *qui tam* analysis. Settlements identified as *qui tam* cases were those in which there was any mention in the press release of a *qui tam* provision being invoked, or any mention of a whistleblower being responsible for triggering the investigation. The vast majority of *qui tam* cases typically arise under the FCA, but at least four other federal statutes also have *qui tam* provisions.¹⁴

Company Totals

We obtained total settlement amounts by company by reviewing the amount paid by each company in each settlement. A case was attributed to any company that was included in the settlement agreement, regardless of the amount paid by the company. In several cases, the amount paid by each company could not be determined. These cases (representing less than 3 percent of all financial penalties) were therefore excluded when calculating total financial penalties by company. Settlements were recorded in the database under each company's parent company at the time of the final settlement. We used the date of the settlement notice to determine which company should be held accountable when a company with a past violation merged with or was acquired by another company. If the final settlement occurred after the acquisition or merger, then the new parent company was considered the liable party, regardless of when the actual violations took place. When presenting company totals, we used the most current parent company names; for companies not currently existing independently, we used the parent company's name at the time of the most recent settlement.

Results

Overall Trends

Annual pharmaceutical company settlements with both federal and state governments have increased significantly over the past 20 years. In total, 165 civil and/or criminal settlements of \$1 million or more were made between the government and pharmaceutical companies from 1991 to 2010^{*}, with settlement amounts totaling \$19.81 billion. Although there is some variation by year (calendar years are used for all annual totals, unless otherwise indicated), a clear upward trend is evident. Both the number of settlements (Figure 1) and the total amount of financial penalties (Figure 2) have increased, roughly in parallel. Approximately three-fourths of all settlements (73 percent, 121 settlements) and

^{*}Data used in this study are through November 1, 2010. There has been at least one other large federal settlement since these data have been finalized, involving three drug companies (Abbott, B. Braun Medical, and Roxane Laboratories) paying a total of \$421 million dollars in a settlement announced on December 7, 2010: Catan T. Drug Makers Agree to \$421 Million Settlement. Wall Street Journal. 8 Dec 2010. Web. Accessed on December 10, 2010.
<http://online.wsj.com/article/SB10001424052748703296604576005674095414668.html?KEYWORDS=medicare>

total dollars paid out (75 percent, \$14.8 billion) during this 20-year period were made in just the past five years (2006-2010).

From a total of just \$10 million in 1991, pharmaceutical industry financial penalties rose to a peak of \$4.41 billion in 2009. The number of settlements rose from one in 1991 to a peak of 38 in 2009. A similar increase is seen in the average financial penalties paid per settlement, from \$37 million per settlement in the 1990s (1991-2000) to \$128 million per settlement in the current decade (2001-2010). Financial penalties for individual cases ranged from \$1 million (the lowest threshold reported in this study) to \$3.4 billion (in one case in 2006, accounting for the spike in financial penalties that year).

Figure 1. Number of Pharmaceutical Industry Settlements, 1991-2010

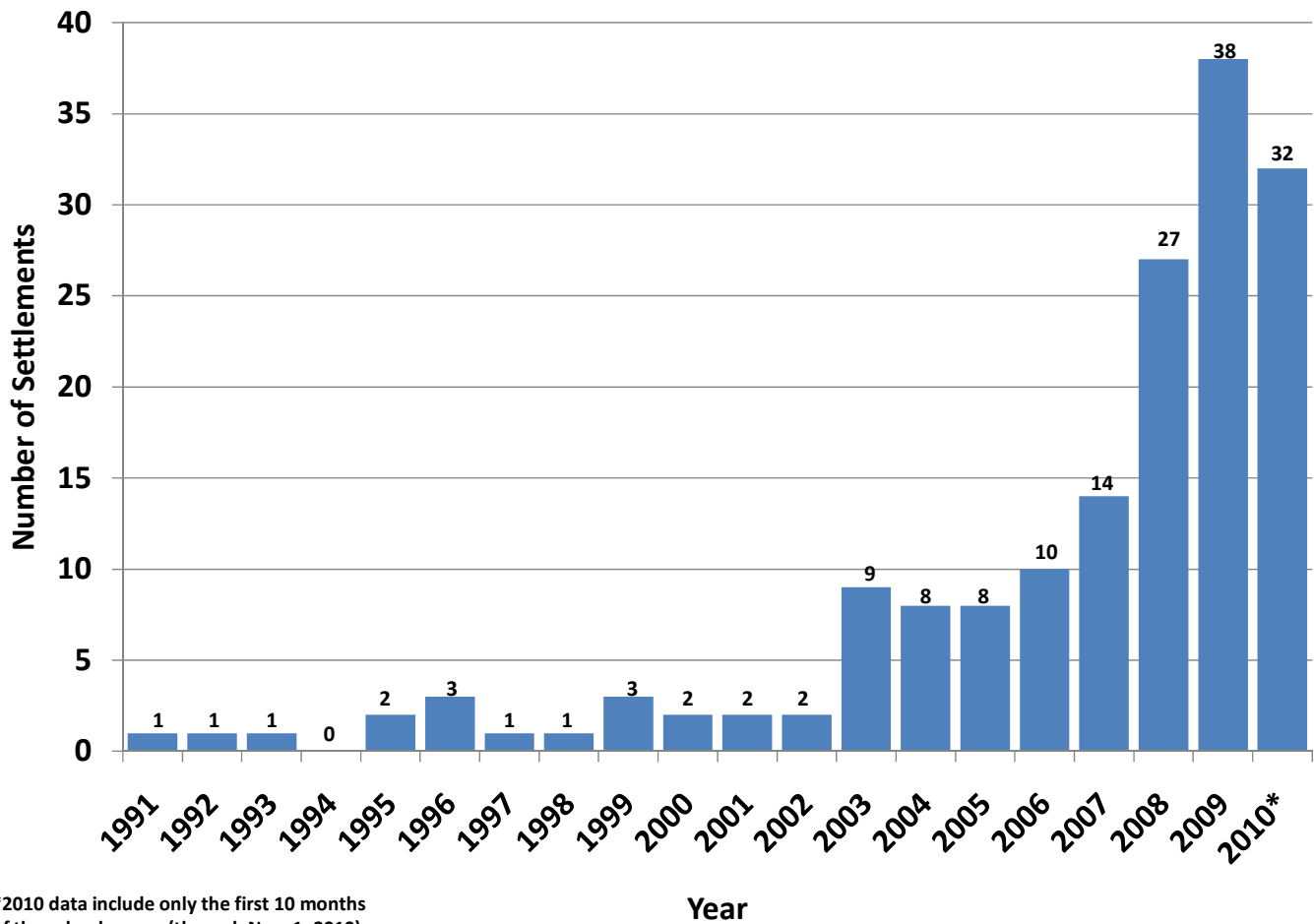
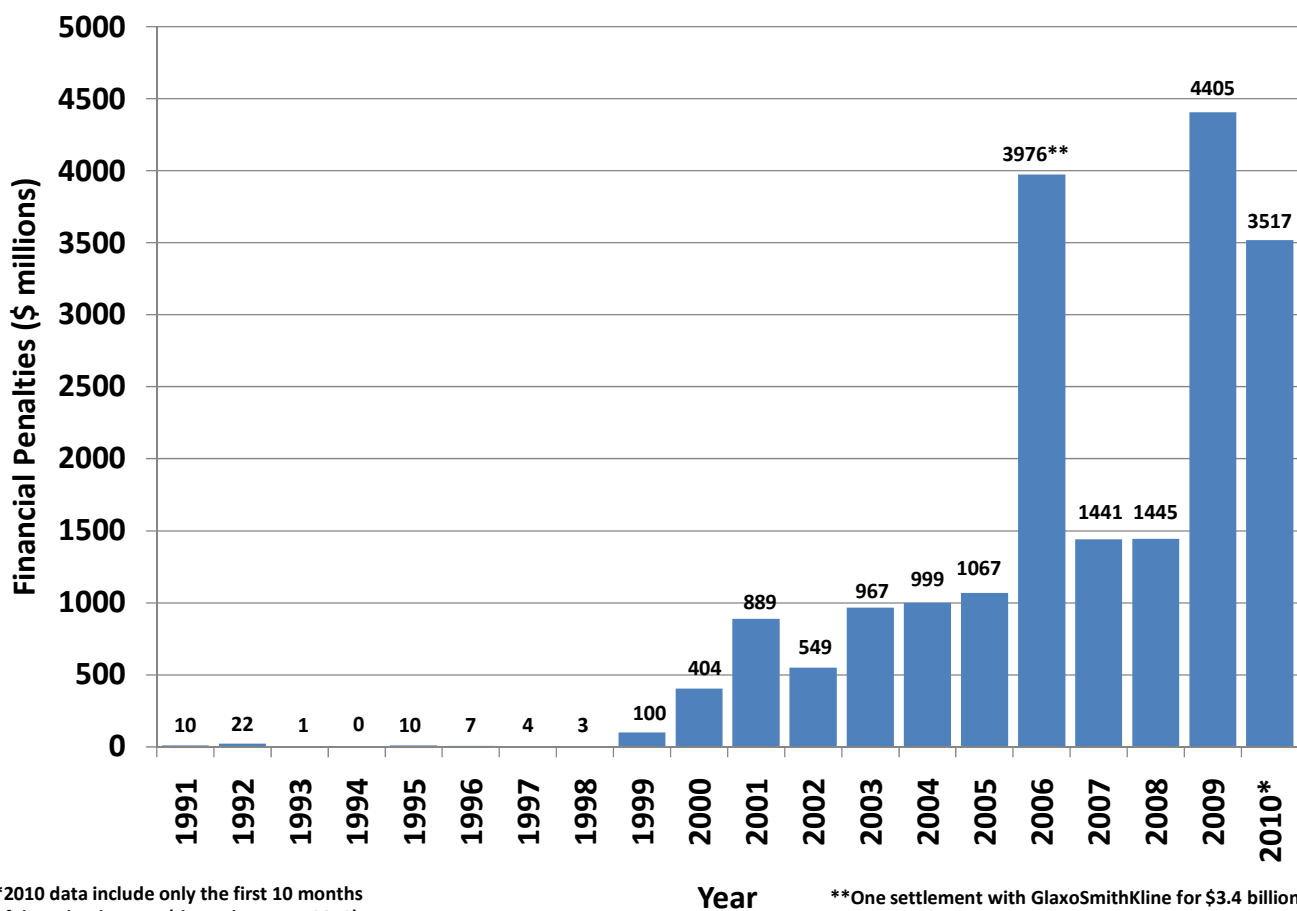


Figure 2. Pharmaceutical Industry Financial Penalties, 1991-2010



*2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

**One settlement with GlaxoSmithKline for \$3.4 billion accounts for the spike in financial penalties in 2006.

Federal and State Settlements

The majority of settlements (99) were brought and settled by states, either individually or as multi-state actions. Sixty-six involved federal government action, including joint federal-state cases. However, federal settlements comprised a greater sum of total financial penalties (\$17.55 billion or 88.6 percent) than state settlements (\$2.27 billion or 11.4 percent). At the federal and state level, both the number and dollar amount of settlements have been increasing substantially since 1991 (Appendix 2, Figures A and B). All but eight of the federal cases were settled, and almost all of the federal financial penalties (99.5 percent) were imposed during or after the year 2001. Almost three-fourths (71 percent) of the number of state settlements have occurred within the past three years (Appendix 2, Figures A and B).

Civil vs. Criminal Settlements

Overall, civil cases made up the majority of settlements (83 percent or 137) and total financial penalties (77 percent or \$15.3 billion). (See Appendix 2, Figures C and D.) This was true at both the federal and state levels. However, criminal penalties have increased significantly in the past five years to comprise one-fourth (25 percent) of all financial penalties, compared to only 16 percent of all penalties in the preceding fifteen years.

Federal False Claims Act (FCA): During the past decade, the pharmaceutical industry has significantly overtaken the defense industry—and all other industries—in defrauding the federal government under the FCA

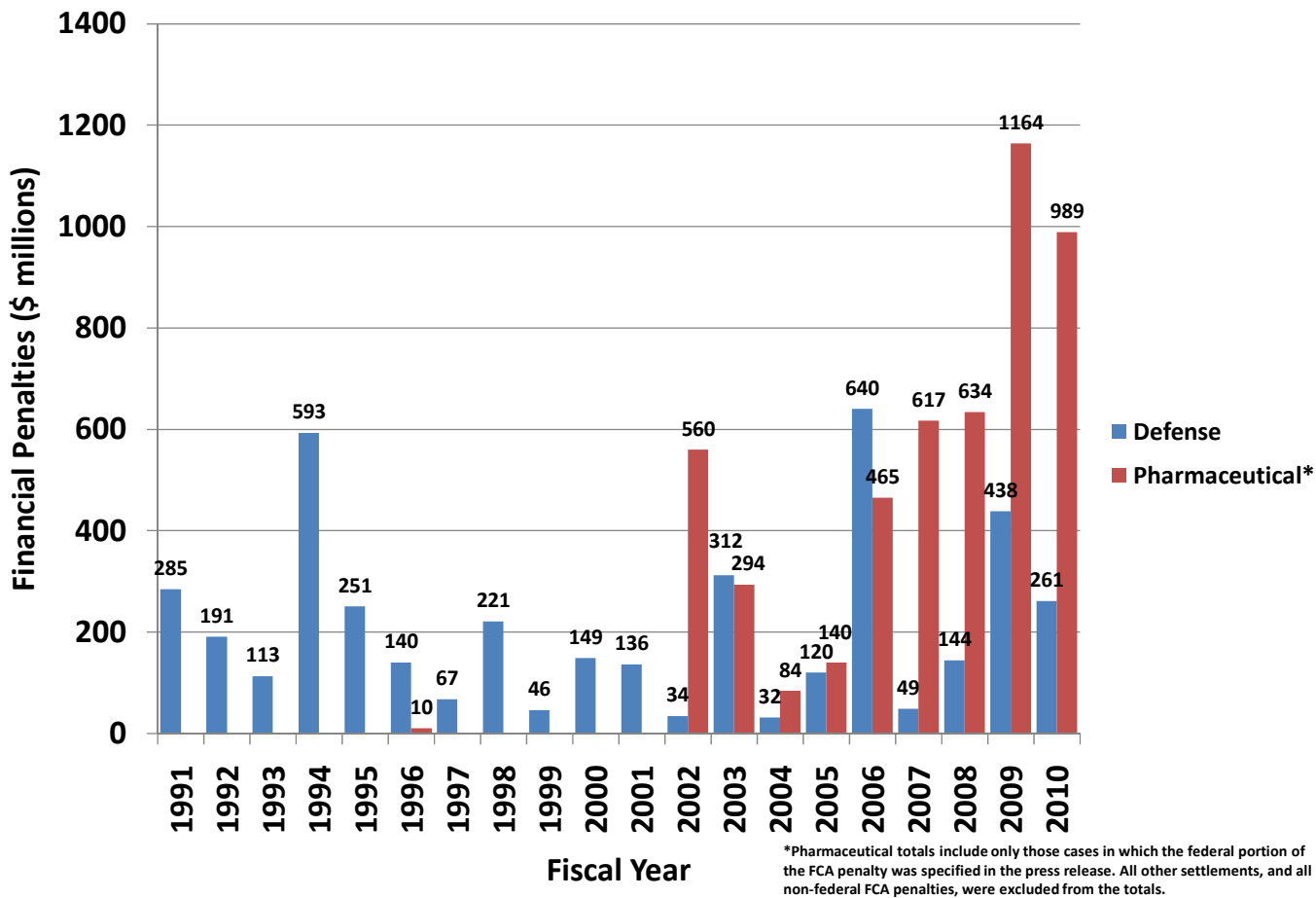
Data from the Department of Justice¹⁵ shows that annual federal FCA settlement totals for all industries have increased dramatically over the past 20 years, from \$341 million in fiscal year (FY) 1991 to \$3 billion in FY 2010. The proportion attributed to all Health and Human Services (HHS) cases (i.e., cases that involve pharmaceuticals and other health care industries), increased from 4 percent of the total in FY 1991 to 84 percent in FY 2010. The totals for the pharmaceutical industry during these intervals are from our study, and represent only those cases in which the federal portion of the FCA penalty could be determined from the press release. Therefore, the amounts presented below are an underestimate of the actual pharmaceutical industry total.

Figure 3 shows a comparison of federal FCA financial penalties paid out over time by the defense and pharmaceutical industries. While the defense industry constituted a much larger proportion of federal FCA totals during the 1990s (30 percent from FYs 1991-2000) compared to the pharmaceutical industry (0.15 percent from FYs 1991-2000), the pharmaceutical industry became the predominant offender of the two in the current decade. As shown in Figure 3, the pharmaceutical industry did not comprise a substantial portion of federal FCA penalties until FY 2002, when it overtook the defense industry for the first time. For every year since and including FY 2007, the pharmaceutical industry total has far exceeded the defense industry total.

As stated above, the total healthcare industry (as represented by HHS totals), has been the biggest defrauder of the federal government under the FCA for most of the past decade. Defense industry payments and the combined total for all other (non-defense and non-HHS) sectors each represent an amount smaller than the pharmaceutical industry total alone since FY 2007.¹⁶ In addition, since FY 2008, the pharmaceutical industry's FCA payments have exceeded the **total** law-violation payments of each of the other sectors within the health industry.¹⁷

Therefore, because the pharmaceutical industry’s FCA payouts exceed those of all other industries outside of HHS and all of the other sectors within HHS, the pharmaceutical industry has been the single largest defrauder of the federal government under the FCA for the past three fiscal years (since FY 2008).

**Figure 3. Federal False Claims Act (FCA):
Financial Penalties by Industry**



Qui tam (whistleblower) Settlements

The *qui tam* provisions of the FCA have resulted in *qui tam* settlements becoming an increasingly large proportion of both the number of settlements and the total financial penalties paid to the government (Appendix 2, Figures E and F, respectively). From 1991 through 2000, *qui tam* cases made up only 12 percent of the number of all federal settlements and 9 percent of the total payouts to the

government. From 2001 through 2010, however, they comprised 59 percent of settlements and 67 percent of total payouts. Over the 20-year period, *qui tam* settlements also yielded a greater average per-settlement total (\$335 million; median \$150 million) than all other federal settlements (\$188 million; median \$25 million).

Worst Offenders and Largest Settlements

Individual Companies: Total Penalties, 1991-2010

Table 2 details the 20 pharmaceutical companies that paid a total of at least \$100 million each in financial penalties over the past 20 years. The four worst offenders, with at least \$1 billion in penalties each, were GlaxoSmithKline, Pfizer, Eli Lilly, and Schering-Plough. Together they accounted for more than half (53 percent) of all financial penalties paid out by pharmaceutical companies.

Twenty Largest Settlements, 1991-2010

The 20 largest settlements over the past two decades are shown in Table 3. In the largest settlement of the past 20 years, GlaxoSmithKline agreed to pay the federal government \$3.4 billion in 2006 for failing to pay required taxes over a 17-year period.¹⁸ The second and third largest settlements included the two largest criminal fines ever levied by the federal government against any company. In January 2009, Eli Lilly was forced to pay \$515 million (the largest criminal fine ever received by a corporation at that time) and Pfizer, later that year, was fined \$1.2 billion (the largest criminal fine ever imposed in the U.S.). Both companies were fined for illegal off-label promotion.^{19, 20} The majority (14) of the 20 largest settlements have occurred within the past five years (2006-2010), consistent with the dramatic increase in pharmaceutical industry financial penalties in recent years. Of note, almost all cases (16 of 20) involved violations of the federal FCA, at least in part. Multiple blockbuster drugs (i.e., those with sales exceeding \$1 billion per year), such as Neurontin (gabapentin), were involved in these settlements. For example, in the Pfizer case of 2004, the company was charged with illegal off-label promotion of Neurontin, a drug which in 2002 generated 94 percent of its \$2.27-billion revenue from off-label use.²¹

Table 2. Pharmaceutical Company Penalties: Worst Offenders

Company*	Total Financial Penalties 1991-2010**(\$ millions)	Percent of Total (%)***
GlaxoSmithKline	4501	22.7
Pfizer	2935	14.8
Eli Lilly	1712	8.6
Schering-Plough	1339	6.8
Bristol-Myers Squibb	890	4.5
AstraZeneca	883	4.5
TAP Pharmaceutical Products	875	4.4
Merck	806	4.1
Serono	704	3.6
Purdue	620	3.1
Allergan	600	3.0
Novartis	524	2.6
Cephalon	425	2.1
Johnson & Johnson	353	1.8
Forest Laboratories	313	1.6
Sanofi-aventis	310	1.6
Bayer	301	1.5
Mylan	267	1.3
Teva	181	0.9
King Pharmaceuticals	167	0.8
Other****	595	3.0

*Parent company names are current names without corporate (e.g. inc. or plc) designations. If company is non-existent now, name at time of most recent settlement was used.

**Data for 2010 include only the first 10 months of the calendar year (through Nov. 1, 2010)

***Percent of \$19.813 billion in overall penalties. Percents do not add up to 100% as some cases were excluded due to inability to determine individual company share in settlement

****Other companies (in order of total penalties paid): Abbott; Genentech; Boehringer Ingelheim; BASF; AkzoNobel; InterMune; Biovail Pharmaceuticals; Dey; KV Pharmaceutical; UCB; Sandoz; Jazz Pharmaceuticals; Baxter; Amgen; Geneva Pharmaceuticals; Bolar; Cell Therapeutics; Medicis; Novo Nordisk; Modern Wholesale Drug Midwest; Warner Chilcott; Barr Pharmaceutical; Lonza; Perrigo; Actavis; Warrick Pharmaceuticals; Warner-Lambert; Otsuka; Alpharma; Circa Pharmaceuticals; Takeda; Watson; McNeil Consumer Products; Mitsui; Evonik; Sumitomo; Vertellus; Nepera; Mitsubishi; Tanabe; Chinook; Daiichi; Eisai; Andrx

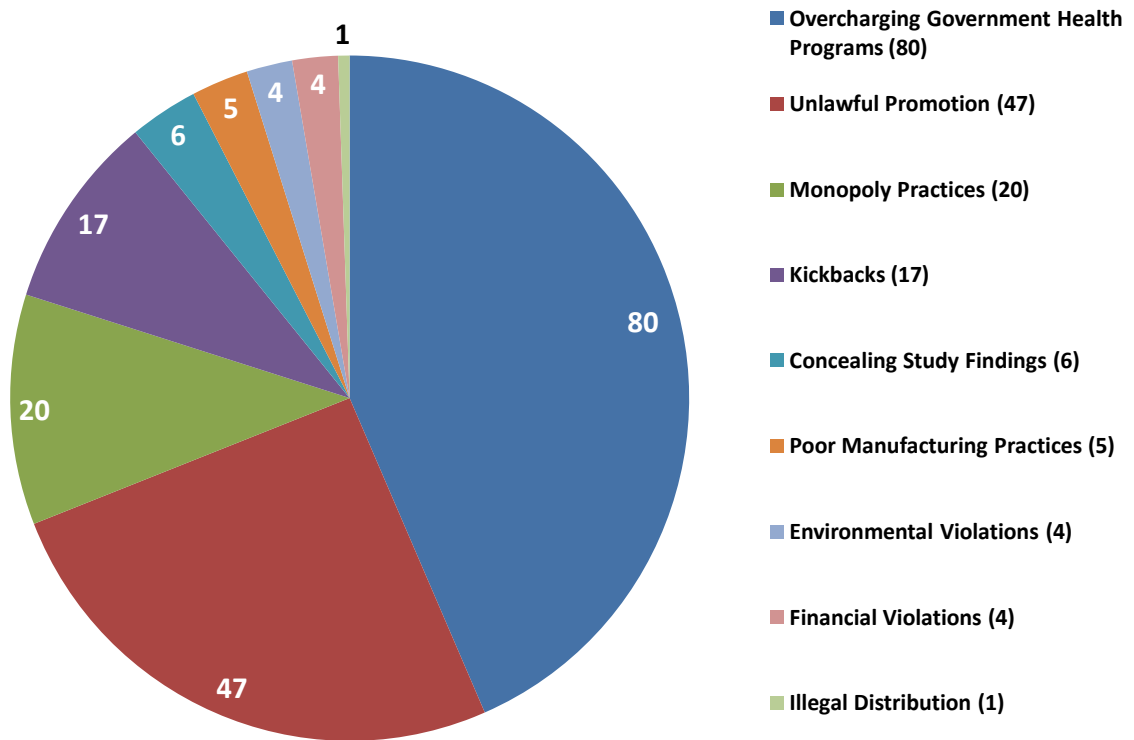
Table 3. Top 20 Largest Pharmaceutical Company Settlements, 1991-2010

Company	Total Penalty	Violation(s)	Year	Major Drug Products Involved	Laws Allegedly Violated (if applicable)
GlaxoSmithKline	\$3.4 billion	Financial Violation	2006		
Pfizer	\$2.3 billion	Unlawful Promotion; Kickbacks	2009	Bextra; Geodon; Zyvox; Lyrica	False Claims Act; Food, Drug, and Cosmetics Act
Eli Lilly	\$1.4 billion	Unlawful Promotion	2009	Zyprexa	False Claims Act; Food, Drug, and Cosmetics Act
TAP Pharmaceutical Products	\$875 million	Overcharging Govt Health Programs; Kickbacks	2001	Lupron	False Claims Act; Prescription Drug Marketing Act
GlaxoSmithKline	\$750 million	Poor Manufacturing Practices	2010	Kytril; Bactroban; Paxil CR; Avandamet	False Claims Act; Food, Drug, and Cosmetics Act
Serono	\$704 million	Unlawful Promotion; Kickbacks; Monopoly Practices	2005	Serostim	False Claims Act
Merck	\$650 million	Overcharging Govt Health Programs; Kickbacks	2008	Zocor; Vioxx; Pepcid	False Claims Act; Medicaid Rebate Statute
Purdue	\$601 million	Unlawful Promotion	2007	Oxycontin	False Claims Act
Allergan	\$600 million	Unlawful Promotion	2010	Botox	False Claims Act; Food, Drug, and Cosmetics Act
AstraZeneca	\$520 million	Unlawful Promotion; Kickbacks	2010	Seroquel	False Claims Act
Bristol-Myers Squibb	\$515 million	Unlawful Promotion; Kickbacks; Overcharging Govt Health Programs	2007	Abilify; Serzone	False Claims Act; Food, Drug, and Cosmetics Act
Schering-Plough	\$500 million	Poor Manufacturing Practices	2002	Claritin	FDA Current Good Manufacturing Practices
Schering-Plough	\$435 million	Unlawful Promotion; Kickbacks; Overcharging Govt Health Programs	2006	Temodar; Intron A; K-Dur; Claritin RediTabs	False Claims Act; Food, Drug, and Cosmetics Act
Pfizer	\$430 million	Unlawful Promotion	2004	Neurontin	False Claims Act; Food, Drug, and Cosmetics Act
Cephalon	\$425 million	Unlawful Promotion	2008	Actiq; Gabatril; Provigil	False Claims Act; Food, Drug, and Cosmetics Act
Novartis	\$423 million	Unlawful Promotion; Kickbacks	2010	Trileptal	False Claims Act; Food, Drug, and Cosmetics Act
AstraZeneca	\$355 million	Overcharging Govt Health Programs	2003	Zoladex	Prescription Drug Marketing Act
Schering-Plough	\$345 million	Overcharging Govt Health Programs; Kickbacks	2004	Claritin	False Claims Act; Anti-Kickback Statute
Forest Laboratories	\$313 million	Unlawful Promotion; Concealing Study Findings; Kickbacks; Illegal Distribution	2010	Levothyroid; Celexa; Lexapro	False Claims Act; Food, Drugs, and Cosmetics Act
Johnson & Johnson (State settlement)	\$258 million	Unlawful Promotion	2010	Risperdal	Medical Assistance Program Integrity Law

Types of Violations

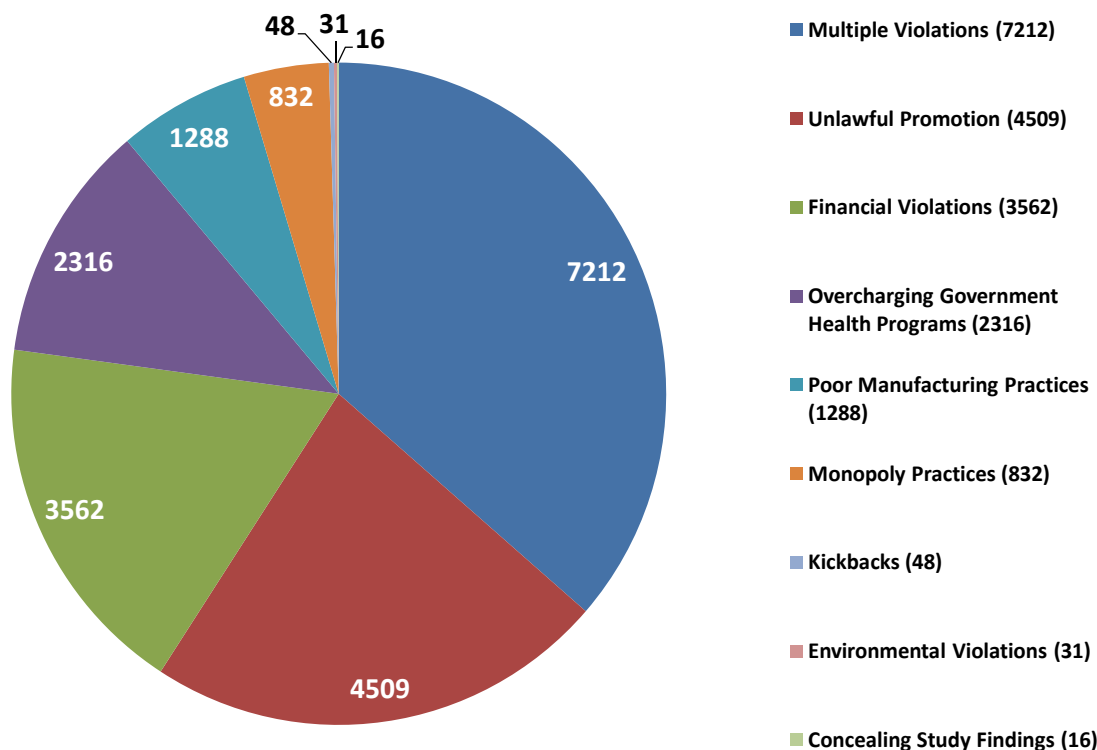
Violations were classified into nine general categories (as explained in Table 1). The frequency and total financial penalties for each violation are shown in Figures 4 and 5, respectively. Overcharging government health programs comprised the largest number of settlements (Figure 4), while unlawful promotion resulted in the single largest amount of financial penalties (Figure 5). Several categories of violations had financial penalties disproportionate to the number of settlements they comprised, demonstrating that certain violations (financial violations, such as tax fraud) were penalized more severely than others (overcharging government health programs like Medicaid). This was partly explained by the extent to which the violations were part of federal or state settlements, as state settlements had much lower financial penalties than federal settlements. For example, overcharging government health programs constituted 43 percent of all violations, but only 12 percent of total financial penalties. The majority of these violations (71 percent) were part of smaller state settlements. In contrast, for financial violations, one case (in which the penalty was \$3.4 billion) accounted for almost all financial penalties (\$3.56 billion).

Figure 4. Types of Pharmaceutical Industry Legal Violations, 1991-2010 (n=184)*



*Through Nov. 1, 2010. Some settlements involved more than one type of violation.

Figure 5. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991-2010* (\$ millions)



*Through Nov. 1, 2010

On the federal level, the type of violation that accounted for a major part of the increase in total financial penalties over time was unlawful promotion, of which illegal off-label promotion was the main offense. From 1991 through 2005, unlawful promotion constituted only 16 percent of all violations, comprising only \$516 million in financial penalties. Over the past five years (2006-2010), unlawful promotion came to comprise over half (53 percent) of all violations, totaling at least \$3.3 billion in financial penalties, a six-fold increase in financial penalties for this violation compared with the previous fifteen years. In comparison, total financial penalties for all violations increased just three-fold over this same time period.

On the state level, the most common violation was the overcharging of government health programs, such as Medicaid. Since the first case was settled in 2005, state settlements involving this violation have accounted for two-thirds (66 percent) of cases (Appendix 2, Figure G) and almost half (47 percent) of all financial penalties.

Discussion

Violations Are Increasing

In general, the amount of money paid out by pharmaceutical companies in response to government action against their illegal activities is increasing at both the federal and state levels. The past five years have seen the sharpest rise in both number of settlements and total financial penalties. Although it is not precisely clear why such a dramatic increase has occurred, it is likely attributable to a combination of increased pharmaceutical company violations and increased enforcement activities.

On the federal level, unlawful promotion was the violation resulting in the single largest amount of financial penalties overall, and it was a major factor in the dramatic increase in total penalties over time. This category mainly consists of off-label promotion of drugs for indications not approved by the FDA, a practice that can be dangerous to patients. For example, in 2009, Pfizer was charged with illegally promoting Bextra (a pain medicine) for unproven, unapproved uses. The FDA later removed Bextra from the market due to its dangerous side effects.²²

One reason why off-label promotion has become so widespread may involve the fact that a decreasing number of important new drugs have come onto the market over the past few years.²³ Thus, companies are likely under pressure to maximize sales of their existing products by any means, including by illegally promoting off-label use. This has been evident in the systematic and widespread company practices²⁴ designed to increase market share. Studies have shown that perhaps one of every five prescriptions dispensed are for off-label uses, with even higher rates for certain medication classes, such as seizure and heart medications.²⁵

On the state level, overcharging of government health programs, mainly Medicaid, was the violation most responsible for the increase in settlements over time, and it was the violation resulting in the largest number of state settlements overall. This violation occurred primarily in the form of companies publishing an average wholesale price (AWP) higher than the price the companies would actually charge providers and pharmacies. Most state Medicaid programs rely on these published AWP's to determine how much to reimburse providers and pharmacies for drugs,²⁶ meaning that they end up paying greatly inflated prices for the drugs. In some cases, state Medicaid programs were paying providers as much as 12 times the actual cost of a drug.²⁷

One reason certain companies were responsible for a larger proportion of violations than others may be that these illegal activities and subsequent financial

penalties are related to the financial position of the company. GlaxoSmithKline and Pfizer were the worst offenders in terms of total financial penalties paid out, and have been the two largest pharmaceutical companies in the world in total sales for at least five of the past seven years.²⁸ Market share also is probably a major factor. The federal FCA is structured to recoup “triple damages,” that is, three times the amount of money lost to the federal government through fraud. It follows that the greater the market share of a particular product, the greater the cost to the government resulting from any violations related to that product, leading to greater financial penalties under the FCA.

Current Enforcement Mechanisms

States are increasingly realizing the critical role of FCAs in combating Medicaid fraud. The federal government provided incentives for states, through the Deficit Reduction Act (DRA) of 2005, to enact strong FCA laws, with the primary goal being to fight Medicaid fraud. As of 2009, although 32 states had enacted FCAs, only 14 states had laws that met the DRA standard.²⁹ To ensure that states’ FCAs meet DRA standards, the Office of Inspector General (OIG) of HHS examines the laws and makes sure they conform to four criteria, including having sufficiently high financial penalties and strong *qui tam* provisions.³⁰ For example, after an OIG review, Louisiana made its existing FCA law compliant with the DRA by, among other things, increasing the minimum civil penalties that would be levied for violations of the law.³¹ As state Medicaid programs continue to experience budget crises,³² and with the predicted growth of Medicaid over the next ten years due to the Affordable Care Act (ACA), it is likely that state enforcement of laws against Medicaid fraud will become more of a priority.

On the federal level, the major driver of increased enforcement in recent years has been the dramatic increase in *qui tam* cases in the past five to ten years, now constituting the majority of federal settlements. These cases are initially brought by former employees of pharmaceutical companies, and then are taken up by federal and/or state enforcement agencies. However, the amendments to the FCA, which afforded increased protection for whistleblowers, in addition to increased financial rewards for coming forward, were enacted in 1986.³³ Thus, it does not explain the more recent spike in these cases. More likely, the increased publicity these settlements have been receiving may have emboldened more industry insiders to come forward.

The Current System of Enforcement Is Not Working

Clearly, the continuing increase in violations by pharmaceutical companies despite such large financial settlements is an indication that the current system of enforcement is not working. The lack of criminal prosecution that would result in jailing of company executives has been cited as a major reason for the continuing large-scale fraud, in addition to the fact that current settlement payouts may not be a sufficient deterrent. For example, GlaxoSmithKline and Pfizer have paid out a combined total of \$7.44 billion in financial penalties over the past 20 years. These two companies made a combined \$16.5 billion in global net profits in one year alone.³⁴ Thus, these financial penalties, although increasing, remain a very small fraction of company net profits and therefore do not provide a sufficient deterrent against further violations. Increased punishments may be needed, such as significantly larger financial penalties and, if appropriate, felony prosecution—including jail—for company executives engaging in criminal behavior. Eric Blumberg, the FDA Deputy Chief Counsel for Litigation, addressed this issue recently, indicating that the government is considering criminal prosecution of pharmaceutical company executives for violations such as off-label promotion in the future. He noted:

“...unless the government shows more resolve to criminally charge individuals—at all levels in the corporate hierarchy—...we can not expect to make progress in deterring...off-label promotion.”³⁵

This more aggressive level of enforcement would be based on applying the “Park doctrine,” a legal precedent that holds top corporate executives liable for illegal conduct within their company, even if they didn’t know about or participate in it. The main purpose of employing this standard is to force companies to “...implement measures that will prevent [these] violations in the first instance,”³⁶ particularly in cases where public safety is at risk. In addition to the prospect of jail time for individual executives, a felony conviction could result in their companies becoming ineligible for reimbursement from federal and state health programs,³⁷ a critical source of pharmaceutical company revenues.

Limitations and Future Directions

There are several limitations to this study. First, this data set may not be complete and may therefore understate the extent of criminal and civil violations by the pharmaceutical industry. It was compiled based on official press releases from federal and state government websites; some settlements may not have been made public. To our knowledge, there is no official, comprehensive, publicly available source for all government actions taken against named pharmaceutical

companies. In addition, there was considerable variability in the availability of press releases from state Attorney General websites, with older releases generally not as readily available as new releases. This may have biased the trend data towards seeming like a greater increase in state settlements over time than is actually the case. Finally, the study documents trends in settlements by settlement date, which does not reflect the date(s) during which the actual violations occurred (typically several years prior to the settlement date). In other words, the study does not reflect real-time trends in unlawful behavior by companies.

Future research could look further into the reasons for the increased trend in settlements and penalties over the past 20 years. This study also could be expanded upon through analysis of more comprehensive data sources, such as DOJ and individual state attorney general records if they were to be made available. In addition, subsequent research could quantify the effect of certain enforcement activities on trends in violations at the state level, particularly as more states enact FCAs and strengthen whistleblower provisions.

Conclusion

Over the past two decades, there has been a marked increase in the number of settlements between pharmaceutical companies and the federal and state governments, as well as in the size of the accompanying financial penalties paid by these companies. The reasons for these increases are unclear, but are likely related to a combination of increased violations by the companies and increased enforcement on the part of federal and state governments. Despite increased government enforcement, illegal pharmaceutical company activities continue to endanger public safety and rob the government of increasingly scarce state and federal resources. These offenses require a more robust response. Given the small size of current financial penalties relative to these companies' profits, we believe that both significantly increased financial penalties and criminal prosecution-including jail- of company leadership would provide a more effective deterrent to this unlawful behavior.

Appendix 1: Methods and Data Sources

Federal Cases

For federal cases, the following data sources were accessed between July 2010 and November 2010: 1) U.S. Department of Justice website (www.justice.gov), 2) an archive website (www.archive.org) containing Department of Justice websites dating back to 1994, 3) the Securities and Exchange Commission website (www.sec.gov), 4) a web slide show prepared by the law firm Patton Boggs LLP entitled “The InterMune Settlement: Deferred Prosecution Agreements in the Context of Off-Label Investigations,”³⁸ 5) a web document prepared by the law firm EpsteinBeckerGreen entitled, “Pharmaceutical and Medical Device Manufacturers: Recent Settlements and Investigations Related to Marketing, Pricing and Associated Activities—Public Settlements and Investigations,”³⁹ 6) a web publication by the law firm Mitchell & DeClerck entitled, “Medical Fraud Under the False Claims Act,”⁴⁰ 7) the Taxpayers Against Fraud (TAF) Education Fund website called the False Claims Act Legal Center,⁴¹ 8) a web publication by the law firm Crowell & Moring LLP entitled “False Claims Act Settlements 2000-2010,”⁴² and 9) the Federal Contractor Misconduct Database website.⁴³

Relevant items from the Department of Justice website were found by going to the part of the website entitled “Briefing Room,” and then going to “Justice News.” Press releases from 2009 and 2010 were searched for the dollar sign (\$) in the press release. Relevant findings were entered into the database. The search was performed again on November 1, 2010.

Because older Department of Justice press releases were not posted on the website, the archive website (www.archive.org) was used. On this website, the term “www.usdoj.gov” was typed into the search box. From there, links to press releases were used. Sometimes the link would say “Press Releases,” and other times it would say “Office of Public Affairs Press Releases,” depending on the iteration of the archived website. The archive went as far back as 1994, though some of the material referenced cases going back to 1991.

To search the Securities and Exchange Commission website, the link to “Press Releases” was used, and then each year was searched (1997-2010) using a dollar sign in the search function, similar to the way the Department of Justice website was searched. The search was repeated on November 1, 2010.

Various methods were used to verify cases, with the goal of finding an official state or federal press release for each civil and criminal action taken. This method was used to verify the material from Patton Boggs LLP,

EpsteinBeckerGreen, Mitchell & DeClerck, the False Claims Act Legal Center, Crowell & Moring, and the Federal Contractor Misconduct Database.

The majority of federal settlements were found in Department of Justice press releases, both current and archived. The earliest federal settlement in the database was in 1991.

State Cases

For those cases involving state governments only, two sources were used. Information on individual and multi-state settlements was obtained from a search of press releases available on each state's Attorney General website. All press release titles were either searched individually for relevant cases, or a text search was employed, utilizing the following four terms: "drug", "pharma", "pharmaceutical", and "settle". To access older press releases not available on the current Attorney General websites, the archive website www.archive.org was used, with either the current state Attorney General web address or an alternative URL (e.g., "www.ag.[state name].gov" or "ag.state.[state name].us"), typed into the search box. Sufficient numbers of resulting links for each state were selected to yield all accessible past iterations of the websites.

For verification of state antitrust and Medicaid fraud cases, two data sources from the National Association of Attorneys General (NAAG)⁴⁴ were used: 1) For antitrust cases, the following URL was accessed: <http://naag.org/antitrust.php>. "Multistate Litigation Database" was selected, and then "Search Civil only" was selected. Titles were searched individually for cases related to the pharmaceutical industry. In addition, "Antitrust Press Releases," an archive of antitrust press releases, was selected and titles were searched individually for relevant cases; 2) For Medicaid fraud cases, the National Association of Medicaid Fraud Control Units (NAMFCU) website was accessed at <http://www.namfcu.net/>. The "Resources" tab and the "Medicaid Fraud Reports" link were selected. This archive contained a partial list of voluntarily submitted press releases from state Attorneys General. Within each bimonthly report, the word "pharmaceutical" was typed into the full-text search box and relevant cases were found.

Almost all of the information on state cases was obtained from individual states' Attorney General websites, and therefore there was considerable variability in the information that was available. The earliest year of press releases found ranged from 1994 to 1995 in some states to as recent as 2009 in others, meaning that

the sample obtained was likely not comprehensive of all state settlements. The earliest state settlement was in 1992.

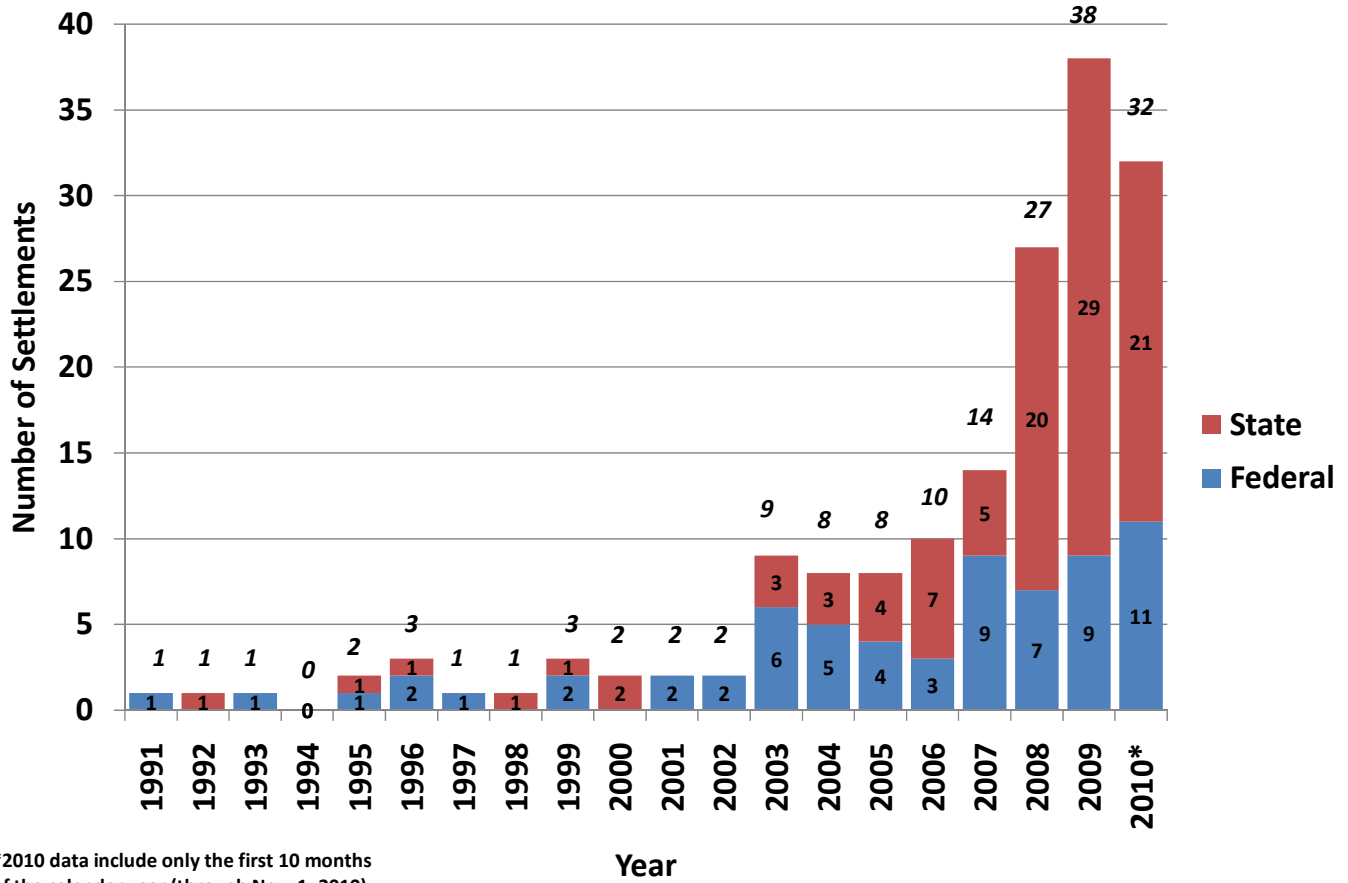
All state cases were retrieved between October 4, 2010 and October 22, 2010. All current state Attorney General websites were accessed again on November 1, 2010, to look for any additional cases.

False Claims Act

All federal FCA violations by pharmaceutical companies, involving either a pharmaceutical product or general company violations, were compiled 1) from cases in which a violation of the FCA was explicitly stated in the database press release or, 2) from a cross-check with the database entitled "False Claims Act Settlements 2000-2010" from Crowell & Moring LLP.⁴⁵

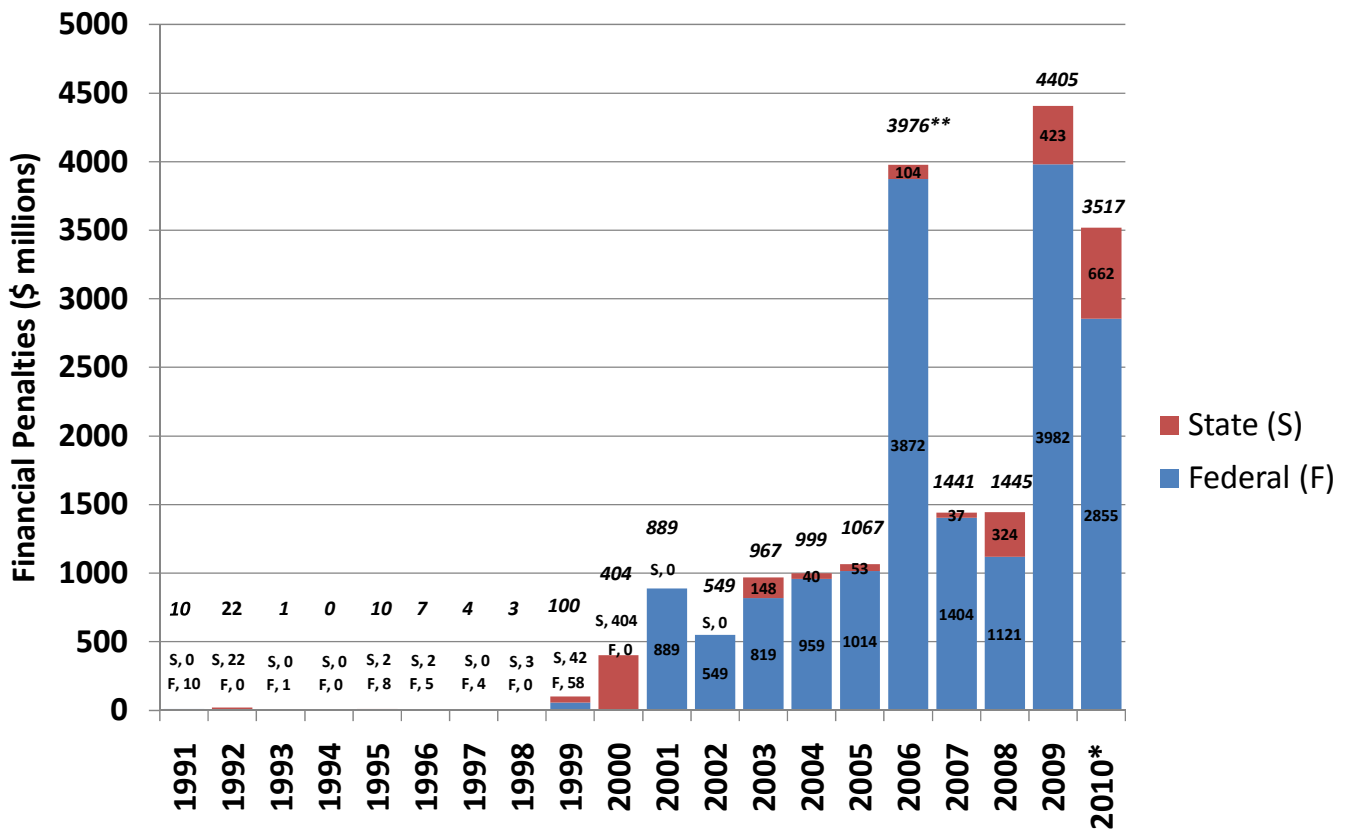
Appendix 2: Additional Figures

Figure A. Number of Pharmaceutical Industry Settlements:
State vs. Federal



*2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

**Figure B. Pharmaceutical Industry Financial Penalties:
State vs. Federal**

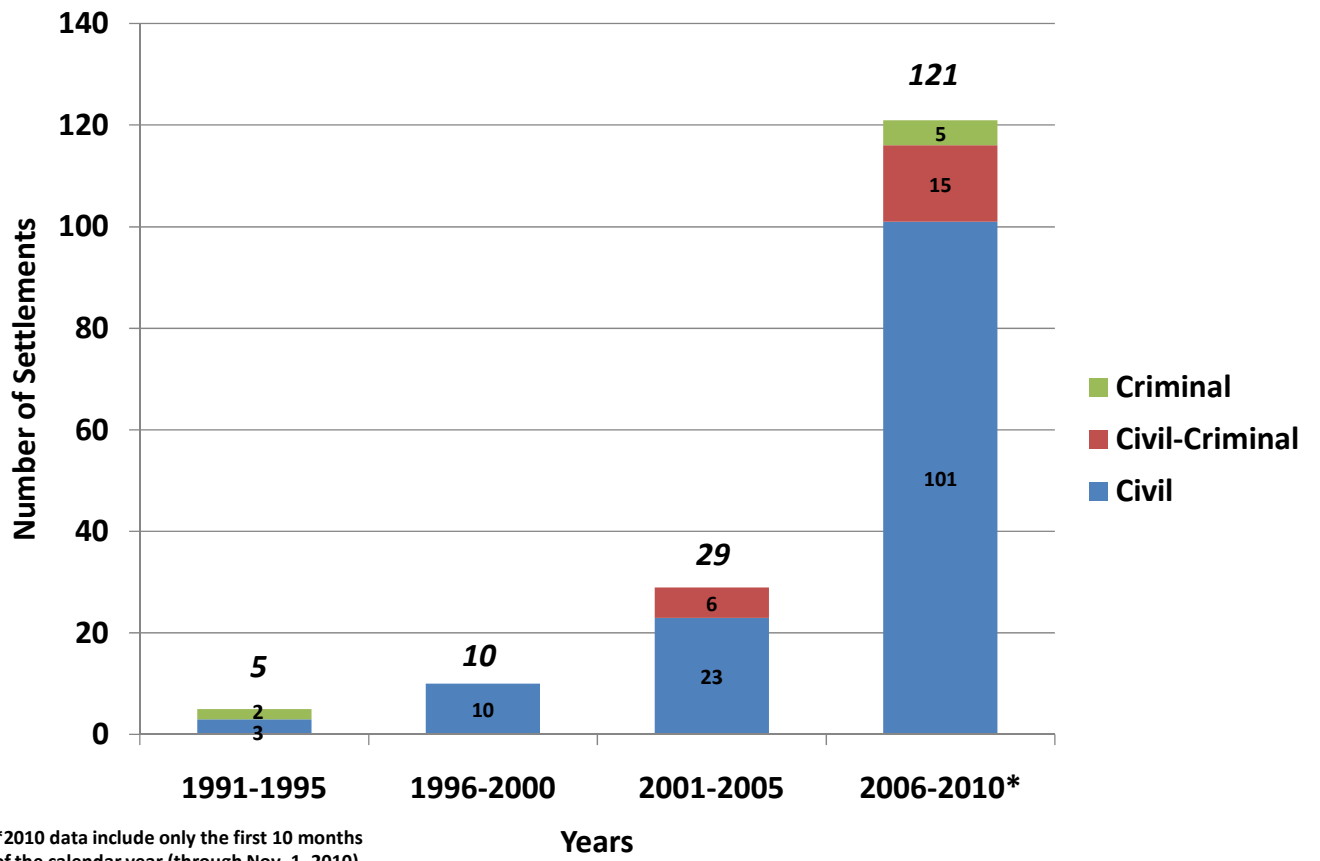


*2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

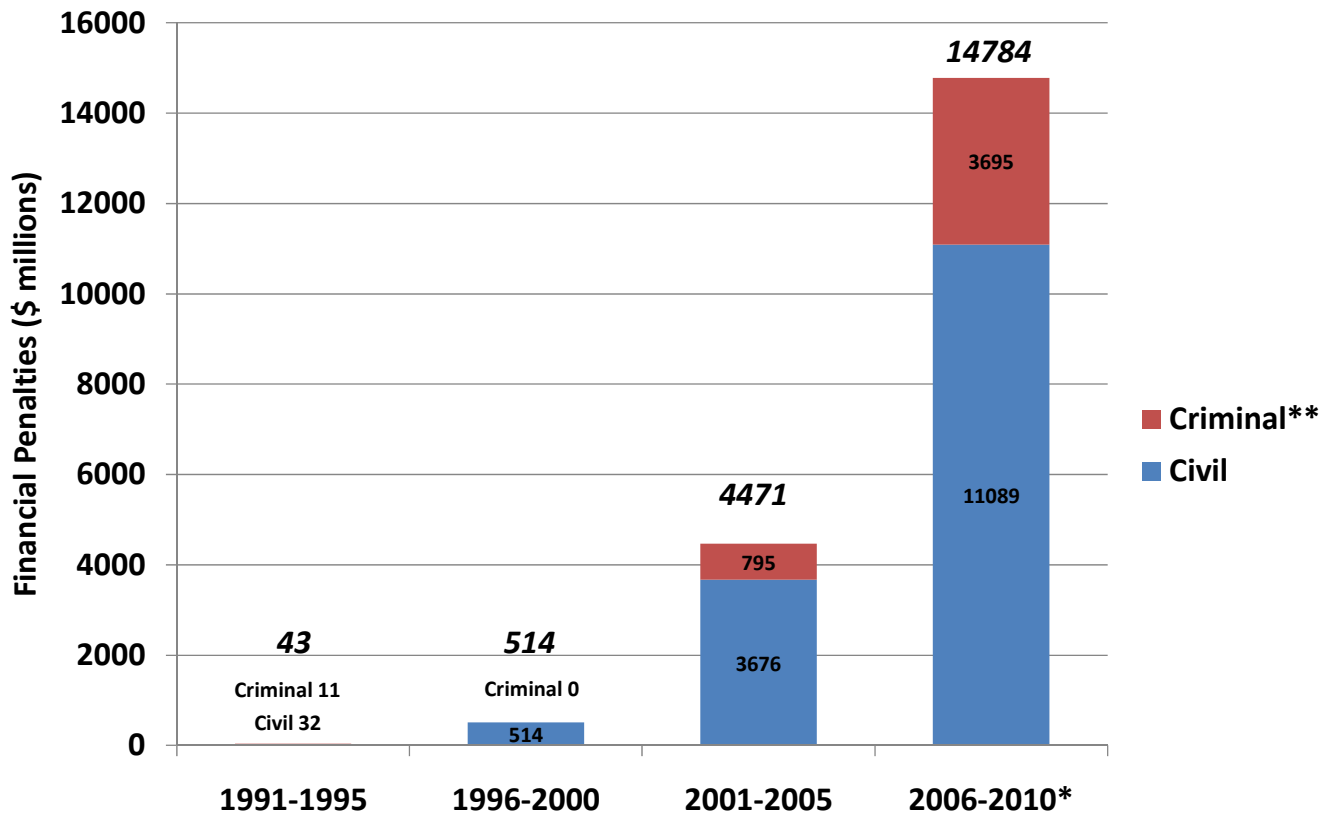
Year

**One settlement with GlaxoSmithKline for \$3.4 billion accounts for the spike in financial penalties in 2006.

**Figure C. Number of Pharmaceutical Industry Settlements:
Civil vs. Criminal**



**Figure D. Pharmaceutical Industry Financial Penalties:
Civil vs. Criminal**



*2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

**In mixed civil-criminal settlements, the civil and criminal portions were separated out and added to their corresponding categories here

Figure E. Qui Tam (“Whistleblower”) Cases and other Categories of Federal Pharmaceutical Industry Settlements

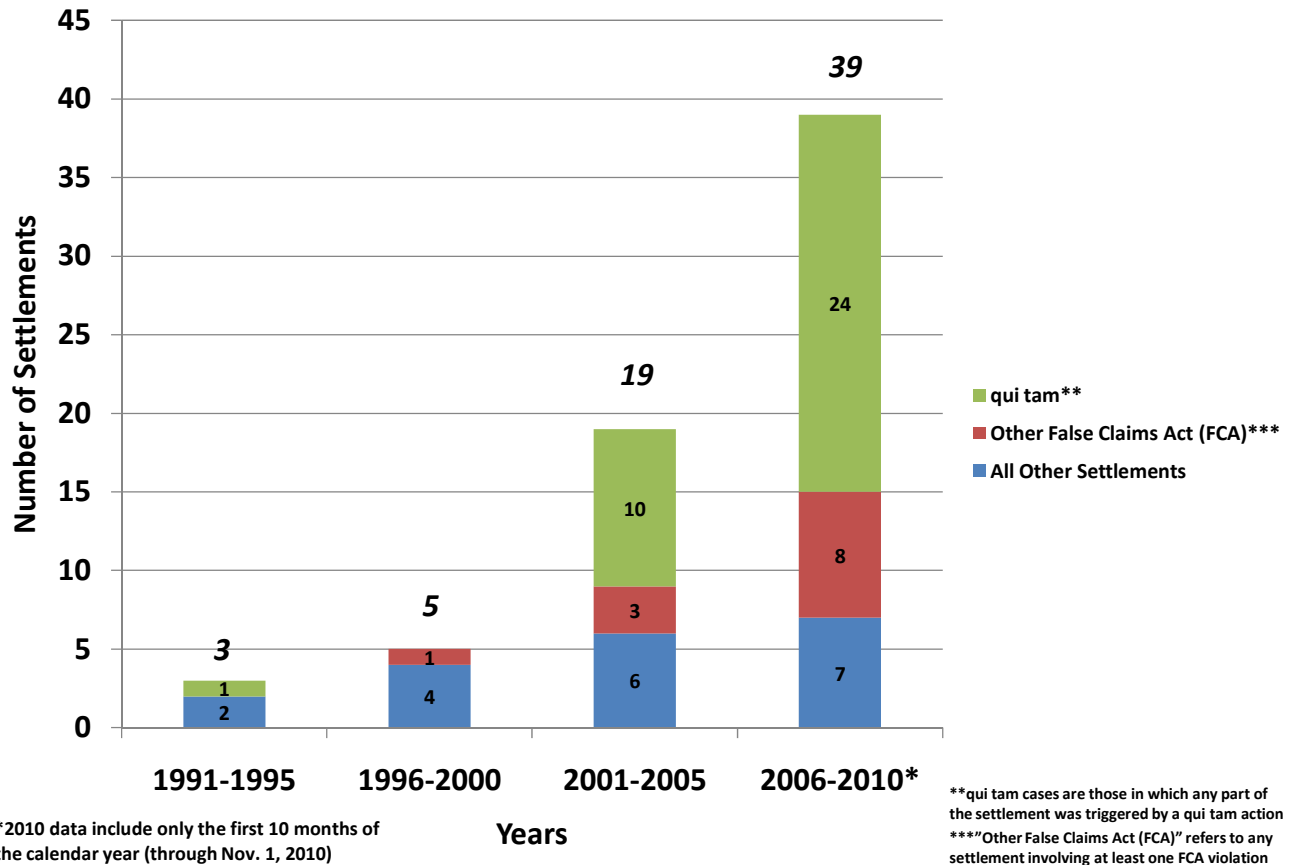
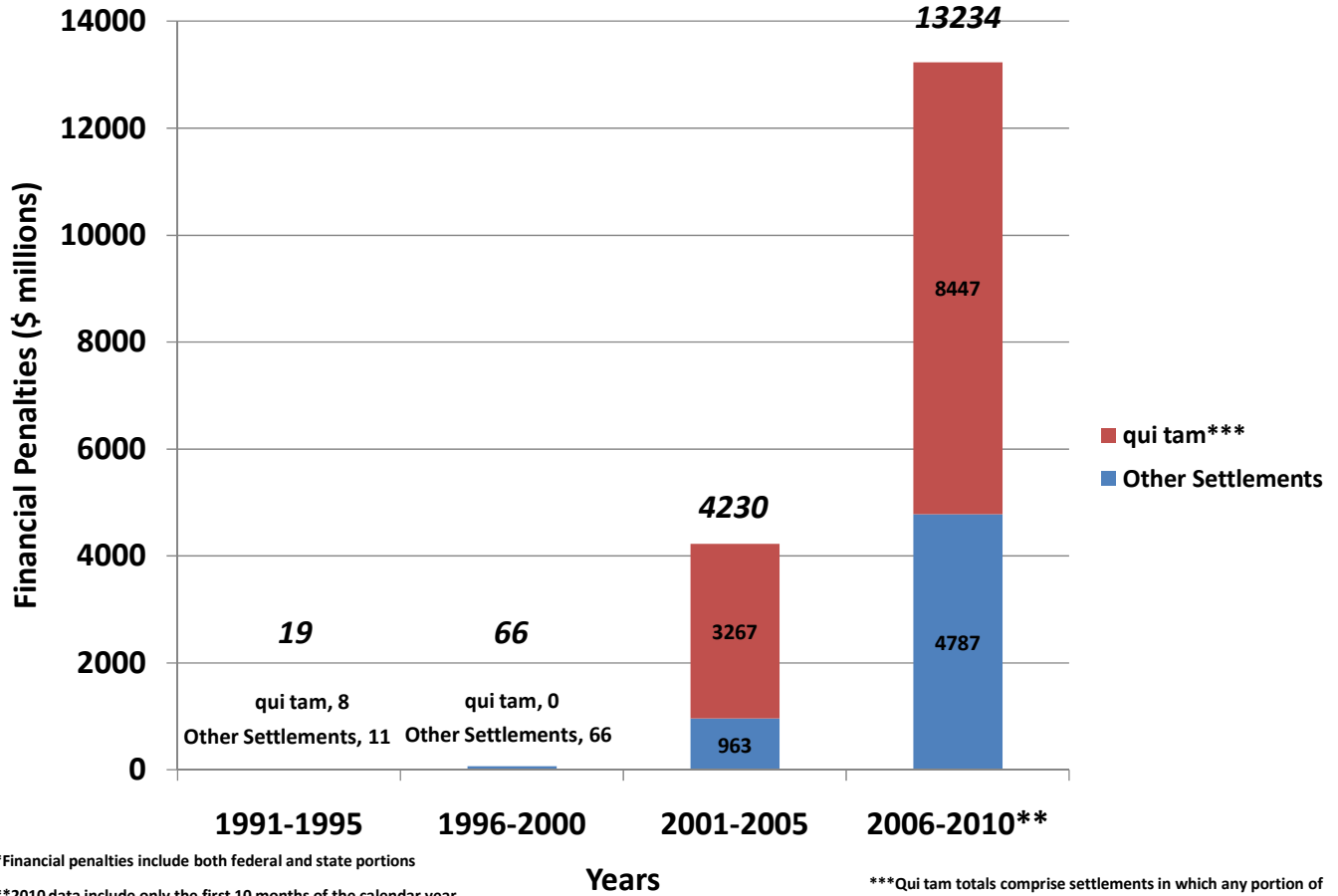


Figure F. Qui Tam (“Whistleblower”) Federal Pharmaceutical Industry Settlements:
Financial Penalties (\$ millions)*

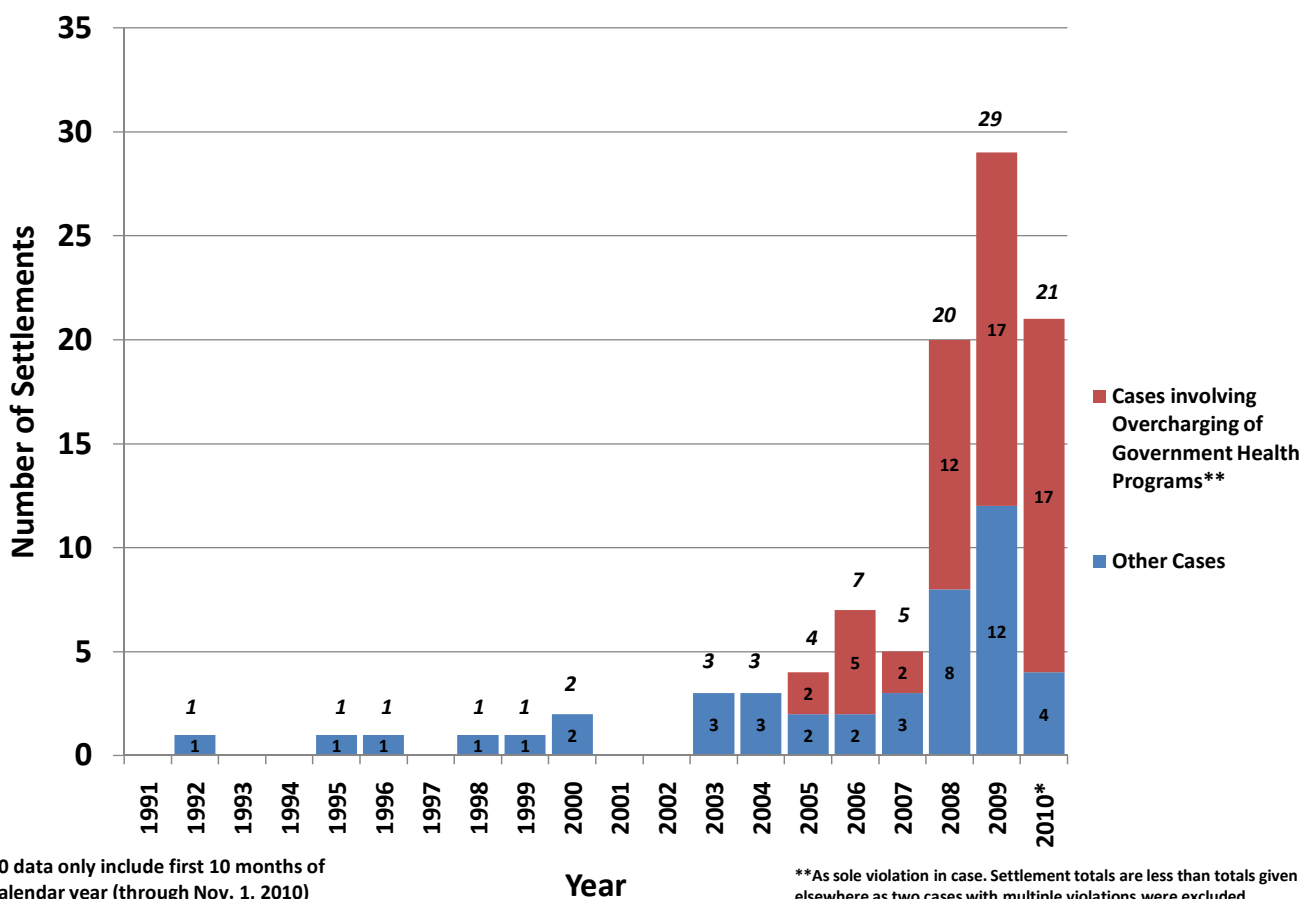


*Financial penalties include both federal and state portions

**2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

***Qui tam totals comprise settlements in which any portion of the settlement stemmed from a qui tam action

**Figure G. State Pharmaceutical Industry Settlements by Type of Violation:
Overcharging Government Health Programs**



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² Evans, D. When Drug Makers' Profits Outweigh Penalties. 21 Mar 2010. Washington Post. Web. Accessed on November 13, 2010. <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html>

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⁴ Evans, D. When Drug Makers' Profits Outweigh Penalties. 21 Mar 2010. Washington Post. Web. Accessed on November 13, 2010. <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html>

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⁷ Krause, J. "Twenty-five Years of Health Law through the Lens of the False Claims Act" in *Annals of Health Law* 19(1): 13-17. Loyola University Chicago School of Law.

⁸ Kaiser Family Foundation. States that have enacted a False Claims Act, 2009. Web. Accessed on November 1, 2010. <http://www.statehealthfacts.org/comparetable.jsp?ind=260&cat=4>

⁹ The Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617, amended the FCA to close a loophole for claims paid by government contractors rather than the government itself. FERA makes clear that liability attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the government, without regard to whether the wrongdoer deals directly with the government or with a third party recipient of government funds. The Patient Protection and Affordable Care Act of 2010 (PPACA), Pub. L. No. 111-148, 124 Stat. 119, amended the FCA to encourage meritorious qui tam suits by narrowing the public disclosure bar and expanding its original source exception.

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¹¹ Blumberg, E. "The Park Doctrine". Speech given to the Food and Drug Law Institute. October 13, 2010.

¹² Fraud Statistics – Overview. Civil Division, U.S. Department of Justice. Web. Accessed on November 23, 2010. <http://www.justice.gov/civil/frauds/fcastats.pdf>

¹³ Information on total penalties for health care industry violations, broken down into individual health industry sectors was obtained from the HHS Office of the Inspector General and from the Department of Justice.

¹⁴ 35 U.S.C. § 292 (false patent marking); 25 U.S.C. § 81 (contracting with Indians in an unlawful manner); 25 U.S.C. § 201 (violating Indian protection laws); and 17 U.S.C. § 1326 (false marking and advertising of vessel hull designs).

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¹⁶ Fraud Statistics – Overview. Civil Division, U.S. Department of Justice. Web. Accessed on November 23, 2010. <http://www.justice.gov/civil/frauds/fcastats.pdf>

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- ²² Evans, D. When Drug Makers' Profits Outweigh Penalties. 21 Mar 2010. Washington Post. Web. Accessed on November 13, 2010. <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html>
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³² Yarrow, A. State Budget Crises Mount as Medicaid Rolls Soar. 8 Sep 2010. The Fiscal Times. Web. Accessed (from Kaiser Health News) on November 27, 2010.

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³³ Krause, J. "Twenty-five Years of Health Law through the Lens of the False Claims Act" in *Annals of Health Law* 19(1): 13-17. Loyola University Chicago School of Law.

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⁴³ Federal Contractor Misconduct Database. Top 100 Contractors. Web. Accessed on November

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