Pharmaceutical Industry Criminal and Civil Penalties: An Update

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Executive Summary

Background

In December 2010, Public Citizen published a report that, for the first time, documented all major financial settlements and court judgments[1] between pharmaceutical manufacturers and the federal and state governments since 1991. At the time of the report's publication, almost $20 billion had been paid out by the pharmaceutical industry to settle allegations of numerous violations, including illegal, off-label marketing and the deliberate overcharging of taxpayer-funded health programs, such as Medicare and Medicaid.

Three-fourths of the settlements and accompanying financial penalties had occurred in just the five-year period prior to 2010. At the time of the report's publication, there was no indication that this upward trend was subsiding. The following study was undertaken to assess the level of settlement activity from the previous report through the first half of 2012 – an additional 1 ½ years – and to conduct, for the first time, an analysis of the results of individual state enforcement efforts since 1991.

Methods

Methodology from the 2010 report was largely replicated, with all federal and state government settlements, of $1 million or greater, reached with pharmaceutical manufacturers from November 2, 2010 through July 18, 2012 included in the current study. In addition, a 50-state analysis of settlement activity, going back to 1991, was conducted for the first time on state settlements that did not involve the federal government. State settlements were classified as single-state settlements (those in which only one state was a party to the final settlement) or multi-state settlements (all other state settlements).

Main Findings

A total of 74 additional settlements, totaling $10.2 billion in financial penalties, were reached between the federal and state governments and pharmaceutical manufacturers between November 2, 2010 and July 18, 2012, with the first half of 2012 alone already representing a record year for both federal ($5.0 billion) and state ($1.6 billion) financial recoveries. Since 1991, a total of 239 settlements, for $30.2 billion, have now been reached (through July 18, 2012) between federal and state governments and pharmaceutical companies. Other key findings included:

- Single-state settlements have been responsible for most of the recent increase in settlement activity, comprising almost three-fifths (59%) of all settlements since the beginning of 2009, compared to only one-fourth (25%) of settlements prior to 2009.

[1] Settlements and court judgments are hereafter referred to collectively as "settlements".

- Since 1991, 27 states have reached at least one single-state settlement with a pharmaceutical company. Kentucky has had the most single-state settlements (17) while Texas has had the highest number of single-state settlements resulting from actions initiated by private whistleblowers (6).

- Seventeen of the 27 states with at least one single-state settlement since 1991 have attained a return on investment of $1 or greater for every dollar spent on enforcement of all (both pharmaceutical-related and non-pharmaceutical) Medicaid fraud.

- Since 2009, the federal government has concluded almost as many settlements and recovered more in financial penalties as it had in the previous 18 years combined.

- Whistleblower-initiated investigations were responsible for most federal settlements (75%) and financial penalties (78%) during the current study period.

- As in the previous study, overcharging government health insurance programs, mainly drug pricing fraud against state Medicaid programs, was the most common violation, while the unlawful promotion of drugs was associated with the largest penalties.

Conclusion

The past two years have seen a continuation of the recent trend of record settlements between the federal and state governments and pharmaceutical manufacturers. A much larger proportion of these recent settlements have been brought about by individual state investigations than in previous years which, in most states involved in such litigation, has resulted in financial recoveries that more than offset enforcement expenses. However, despite the scale of the fraud against their Medicaid programs and the potential recoveries at stake, most states, including some with the highest prescription drug expenditures, have yet to pursue investigations on their own.

On a federal level, financial penalties still continue to pale in comparison to company profits and a parent company is only rarely excluded from participation in Medicare and Medicaid for the illegal activities, which endanger the public health and deplete already overstretched taxpayer-funded programs. In what will hopefully represent an emerging trend, the federal government has recently pursued criminal charges against key company employees and executives, but the cases so far have either been thrown out or resulted in minor sentences. Stronger legislation and more robust enforcement are needed on a federal and state level to deter future unlawful behavior.

Introduction

In December 2010, Public Citizen published a report that was the first to document the scale of illegal pharmaceutical industry activity over the past 20 years.[2] The study analyzed all major financial settlements and court judgments[3] between pharmaceutical manufacturers and the federal and state governments from 1991 through November 1, 2010 and found that almost $20 billion had been paid out by the pharmaceutical industry to settle allegations including, among other violations, illegal promotional activities and the deliberate overcharging of taxpayer-funded health programs, such as Medicare and Medicaid. Three-fourths of the settlements and the accompanying financial penalties had occurred in just the five-year period prior to 2010.

At the time of the report's publication, there was no indication that this upward trend in settlement activity was subsiding. Indeed, this past summer, GlaxoSmithKline (GSK) agreed to pay $3 billion to settle civil and criminal charges in what was the largest health fraud settlement in U.S. history.[4]

The following study was undertaken to assess the level of overall settlement activity from November 2, 2010 through the first half of 2012 and, for the first time, to conduct an analysis of the results of individual state enforcement efforts since 1991.

Methods

Methodology from the 2010 report was largely replicated, with slight modifications to account for outdated websites (see **Appendix 1**).[5] All federal and state government settlements and court judgments reached with pharmaceutical manufacturers from November 2, 2010, through July 18, 2012, were included (the last search conducted for the 2010 report was on November 1, 2010). Analyses correspond to the current study period (November 2, 2010, through July 18, 2012), the previous study period (1991 to November 1, 2010), overall (1991 through July 18, 2012), and annual totals. For each analysis in the "Results" section, the time period examined is clearly described. In this update, a state-level

[2] Public Citizen's Health Research Group. Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010. December 16, 2010. Accessed on July 3, 2012. www.citizen.org/hrg1924.

[3] Most of the cases included in this report are settlements reached between the federal and state governments and pharmaceutical companies, but some represent court judgments resulting from federal or state investigations against the companies. In this report, the term "settlements" refers to both categories.

[4] U.S. Department of Justice. GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data. July 2, 2012. Accessed on July 3, 2012. http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

[5] In cases where there is a discrepancy between methodologies from the previous report and the current report (such as updated source documents), the methodology presented in the current report is the accurate version.

analysis and comparison of state settlements that did not involve the federal government was conducted for the first time, for all settlements dating back to 1991, and the methods for this analysis are described below.

Individual state comparison (Tables 1-3)

Public Citizen's 2010 report on pharmaceutical industry penalties did not include an analysis of settlement activity by individual state. Therefore, all state settlements (those without any federal involvement[6]) comprising the previous (1991 to November 1, 2010) and current (November 2, 2010, to July 18, 2012) reports were reviewed to classify the cases as single-state or multi-state settlements. Single-state settlements were those in which only one state was a party to the final settlement, as gleaned from the information provided in the press release. All other state settlements were classified as multi-state.

Single-state settlements

Complete data on financial penalties were available for single-state settlements (not the case for multi-state settlements). Therefore, two specific analyses were possible for the single-state settlement data: financial recoveries as a proportion of state Medicaid prescription drug expenditures and a return on investment (ROI) analysis (**Table 1**). Both the numerator (financial penalties) and the denominators (Medicaid prescription drug expenditures and Medicaid Fraud Control Unit [MFCU] budgets for the expenditure and ROI analyses, respectively) represent combined federal and state totals, because data were not sufficiently available in the press releases to delineate state shares of financial penalties. The federal government funds Medicaid prescription drug expenditures approximately at the same proportion of each state Medicaid program's Federal Medical Assistance Percentage (FMAP),[7] and it shoulders 75% of the costs of every state's MFCU, with the states funding the remaining 25%.[8]

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[6] State settlements refer to those in which the federal government was neither significantly involved in the investigation or negotiation phase of the settlement, nor was a party to the final settlement, as determined through a review of the press release and, when available, the official settlement document. The latter criterion (whether the federal government was a party to the final settlement) was added to the federal/state definition since the last report (see the "Methods" section of the 2010 report), with no resulting change to any settlement's federal/state status. Ten settlements from the 2010 report were, however, reclassified from "state" to "federal" status, mainly after further review of a database from the National Association of Attorneys General (NAAG). See **Appendix 1** for details.

[7] Personal communication with the U.S. Department of Justice, Civil Division on 8/23/2012. This was confirmed by comparing FMAPs with the federal/state share of prescription drug expenditures in a sample of Centers for Medicare and Medicaid Services data from several states over multiple years.

[8] National Association of Medicaid Fraud Control Units (NAMFCU). Frequently Asked Questions. "How are MFCUs funded? MFCUs receive annual grants (Federal Financial Participation or "FFP") from the U.S. Department of Health and Human Services. Grant amounts must be matched with state funding. Initially, a Unit receives federal funding at a 90 percent level. After its first three years, the FFP is reduced to 75 percent." As all states with MFCUs have had the programs for over three years (as confirmed by the NAMFCU MFCU budgetary data from FY2006-2011), the 75 percent figure now applies to all states. Accessed on August 28, 2012. http://www.namfcu.net/faq/frequently-asked-questions#Q4.

For the first analysis, annual Medicaid prescription drug expenditures were obtained from the Centers for Medicare and Medicaid Services (CMS) for all 50 states and the District of Columbia (D.C.).[9] The sum of all prescription drug expenditures from fiscal year (FY) 2001 (corresponding to the fiscal year of the earliest single-state settlement) through the first two quarters of FY 2011 (the most recent year for which data were available) was used as the denominator, with total single-state financial penalties from FY2001 through July 18, 2012 as the numerator. States were ranked in **Table 1** by the total recoveries per $1,000 of Medicaid prescription drug expenditures.

In the second analysis, ROI values in **Table 1** represent the financial return from single-state settlements relative to each state's Medicaid fraud enforcement expenses. It was assumed that each state's MFCU was the primary agency responsible for investigating pharmaceutical fraud.[10] MFCU annual budgetary data were obtained from National Association of Medicaid Fraud Control Units (NAMFCU) annual state surveys.[11] The sum of all state MFCU budgets from FY 2006 (the earliest year for which data were available) through FY 2011 (the most recent year for which data were available at the time the analysis was conducted) was used as the denominator, with total single-state financial penalties from 2000 (the year of the earliest single-state settlement) through July 18, 2012 as the numerator. All single-state settlement financial recoveries were obtained on or after FY 2006, with only three exceptions (one settlement in California for $85 million in 2000, and two for $2.5 million each in New York and Connecticut in 2004 and 2005, respectively). Because the total MFCU budget, rather than the portion devoted to prosecuting pharmaceutical fraud, was used as the denominator (potentially underestimating true ROIs), while the financial penalties used for the numerator represent both federal and state settlement shares (potentially overestimating true ROIs), the ROIs presented here are merely approximations of states' efficiency in pursuing pharmaceutical fraud.

Multi-state and overall (multi- and single-state combined) settlements

The number of multi-state settlements and accompanying financial penalties was determined through a search of every state's attorney general website (and through the site www.archive.org when necessary to retrieve earlier iterations of the website) for press releases from each state involved in a multi-state settlement. A complete list of participating states was available (from a participating state's press release) for only 29 of

[9] Centers for Medicare and Medicaid Services (CMS). CMS-64 Quarterly Expense Report. Financial Management Reports from FY2001 through the first two quarters of FY2011 were downloaded. Accessed on August 17, 2012. http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/MedicaidBudgetExpendSystem/CMS-64-Quarterly-Expense-Report.html.

[10] There are at least two exceptions to this rule. North Dakota has no MFCU, while Texas' MFCU is not the primary agency responsible for prosecuting civil pharmaceutical fraud cases (in that state, all pharmaceutical fraud cases tend to be civil).

[11] National Association of Medicaid Fraud Control Units (NAMFCU). Statistical Survey: Medicaid Fraud Control Units. 2011 survey, pages 12-13. Accessed on July 20, 2012. http://www.namfcu.net/publications/annual-state-surveys/.

the 35 multi-state settlements. Therefore, the final settlement tallies for some states in **Table 2** may be underestimates.

However, the financial penalties from multi-state settlements presented in this report are certainly underestimates, as many states often did not specify their financial share of the settlement monies. Only $437 million (44%) of the $1.0 billion in multi-state penalties were attributable to individual states and are included in **Table 2**. Therefore, for both the multi-state and total state settlement tables (**Tables 2 and 3**, respectively), states were ranked by the number of settlements in which they participated, rather than the financial return from those settlements.

State False Claims Act (FCA) status and settlement activity

State FCAs were not invoked explicitly in almost all state press releases, thus precluding any calculation of the proportion of settlements brought under state FCA laws. Therefore, a rough, indirect analysis was performed, comparing state FCA status (i.e., whether an FCA was enacted as of 2011) with that state's single- and multi-state settlement activity. A similar analysis was also performed limited to those states with FCAs meeting higher federal standards (e.g., those with strong whistleblower provisions) as defined by the Deficit Reduction Act (DRA) of 2005 (hereafter referred to as DRA-compliant FCAs).[12] As state FCA status was based on 2011 FCA data, in some cases, settlements attributed to states with an FCA may have, in fact, preceded the enactment of an FCA in those states. Thus, this analysis may be underestimating the proportion of states without an FCA that finalized settlements. In addition, all states — with two exceptions, Maine and New York — have specific statutes related to Medicaid fraud, which were likely the laws invoked to prosecute Medicaid fraud in the absence of a state FCA (or even in the presence of an FCA). Maine and New York both have had state FCAs since 2006.

Results

Overall trends: Current study period (November 2, 2010, to July 18, 2012), previous study period (1991 to November 1, 2010), and overall totals (1991 to July 18, 2012)

From November 2, 2010, to July 18, 2012, 74 settlements of $1 million or greater were reached between the federal and state governments and pharmaceutical manufacturers, totaling $10.2 billion in financial penalties. Eleven (for $1.1 billion) were announced during the last two months of 2010, 44 (for $2.5 billion) were announced in 2011, and 19 were announced (for a record $6.6 billion) in the first 6½ months of 2012. Combining the

[12] 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. Arguably, the most important provision emphasized in the DRA was whistleblower protection, with states encouraged to increase rewards for whistleblowers in Medicaid fraud settlements to 15-25% of the financial penalties awarded. See House Report 109-362 – Deficit Reduction Act of 2005. Sec. 6032. Accessed on March 2, 2012. http://thomas.loc.gov/cgi-bin/cpquery/?&sid=cp109Zqrb4&refer=&r_n=hr362.109&db_id=109&item=&sel=TOC_227784&.

previous report's results with the current study, a total of 239 settlements have been reached between federal and state governments and pharmaceutical companies, for $30.2 billion, since 1991 (**Figures 1 and 2**).

During the 21 months of the current study period,[13] there was an average of 3.5 settlements announced per month, higher than that of the previous five years (2.1 settlements per month) and well above the average of the previous 20 years covered by the 2010 report (0.7 settlements per month). Financial penalties have also increased considerably since the last report, with an average of $486 million per month recovered during the current study period, significantly greater than that of the previous five years ($256 million per month) and the previous 20 years ($84 million per month). Average financial penalties per settlement have similarly risen from an average of $124 million over the previous five years to $138 million for the current study period.

Federal settlements: Current study period (November 2, 2010, to July 18, 2012) and overall totals (1991 to July 18, 2012)

Twenty-eight federal settlements, totaling $7.7 billion, were announced during the current study period. Seven (totaling $957 million) were reached in the last two months of 2010, 16 (totaling $1.7 billion) in 2011, and five (totaling $5 billion, up to mid-July) so far in 2012, already a record year in terms of financial penalties. Combining the previous report's results with the current study, 104 federal settlements have been reached (and amounted to $25.9 billion) since 1991 (**Figures 3 and 4**). In the three and a half years since the beginning of 2009, the federal government has concluded almost as many settlements and recovered more in financial penalties (49 settlements, totaling $14.5 billion, respectively) as it has in the previous 18 years combined (55 settlements, totaling $11.3 billion).

State settlements: Current study period (November 2, 2010, to July 18, 2012) and overall totals (1991 to July 18, 2012)

Forty-six state settlements, amounting to $2.5 billion, were announced during the current study period. Four (totaling $123 million) were announced during the last two months of 2010, a joint all-time high of 28 (totaling $828 million) were announced in 2011, and 14 (totaling $1.6 billion, up to mid-July) have been reached so far in 2012. Combining the previous report's results with the current study, 135 state settlements have been reached for $4.3 billion since 1991 (**Figures 3 and 4**). As is the case on the federal level, 2012 already represents a record year for state financial recoveries.[14] In the three and a half

[13] The entire month of July 2012 was included in the denominator for all calculations, even though only part of that month's settlements was included in the numerator. In addition, the previous "20-year" and "five-year" periods refer to the (slightly less than) 20- and five-year periods from 1991 and 2006, respectively, through October 2010.

[14] This sum was largely due to a single court judgment in Arkansas in 2012 that required Johnson & Johnson to pay the state $1.2 billion for the unlawful promotion of the antipsychotic Risperdal. To our knowledge, as of the publication of this report, the company has not yet paid the fine and plans to appeal the judgment.

years since the beginning of 2009, state governments have finalized over twice as many settlements (94 versus 41, respectively) for almost six times more money ($3.7 billion versus $660 million) than the previous 18 years combined.

Single-state settlements: Overall totals (1991 to July 18, 2012)

Of the 135 state settlements occurring since 1991, 108 (80%) were single-state settlements, and of the $4.3 billion in state financial penalties since 1991, $3.3 billion (77%) was recovered from single-state settlements. In addition, single-state settlements have been primarily responsible for the dramatic increase in state settlement activity in recent years. From 1991 through 2007, only 10 of 22 state settlements were finalized by a single state, but since 2008, single-state settlements have become, by far, the predominant type of state settlement, with 98 such settlements compared with 15 multi-state settlements (**Figure 5**).

Twenty-seven states have reached at least one single-state settlement with a pharmaceutical company between 1991 and July 18, 2012 (**Table 1**). Just four states (Arkansas,[15] Louisiana, South Carolina, and Texas) recovered $2.3 billion in single-state penalties, representing over two-thirds (70%) of single-state, and over one-half (54%) of overall, state financial penalties. Kentucky had the most single-state settlements (17), followed by Idaho (12).

Arkansas, Hawaii, South Carolina, and Louisiana recovered the most in financial penalties as a proportion of state Medicaid prescription drug expenditures over the past decade, with recoveries of 6% to 51% of each state Medicaid program's spending on drugs since FY 2001 (percentages presented as dollars per $1,000 in **Table 1**). On average, the 27 states with at least one single-state settlement recouped approximately 2% ($20.31 per $1,000) of FYs 2001-2011 drug expenditures through these settlements. Of the 10 states with the highest Medicaid prescription-drug expenditures over the past decade, six (New York, California, Florida, Illinois, Ohio, and Missouri) have all had recoveries from single-state settlements less than this $20.31 per $1,000 average, while two others (Tennessee and North Carolina) apparently had no single-state settlements.

Seventeen of the 27 states with at least one single-state settlement attained an ROI of $1 or greater, meaning they recouped enough money through financial penalties from these settlements alone to offset their entire Medicaid fraud enforcement budgets from FYs 2006-2011 (**Table 1**). Arkansas, South Carolina, Alabama, and Hawaii had the highest ROIs, returning between $12 and $84 to the state for every $1 spent on enforcement of Medicaid fraud. Smaller states tended to be the most efficient, as nine of the 10 states with the highest ROIs have a population of less than 5 million.

Multi-state settlements: Overall totals (1991 to July 18, 2012)

[15] Arkansas's large recoveries were due to a single court judgment in 2012 worth $1.2 billion, part or all of which may be appealed by the company.

There have been 27 multi-state settlements (totaling $1 billion, 23% of all state financial penalties and 20% of all state settlements) since 1991. Every state, and D.C., has participated in at least one multi-state settlement over the past two decades, with two of the 27 multi-state settlements involving all 50 states and D.C. States participated in a median of 14 multi-state settlements since 1991. Texas (22 settlements), Arizona (21), California (21), and Massachusetts (21) participated in the most multi-state settlements, while Wyoming participated in the fewest at 2 (**Table 2**).

State settlement totals (single- and multi-state combined) and state FCA status: Overall totals (1991 to July 18, 2012)

Table 3 lists the settlement tallies (single- and multi-state combined) for all 50 states since 1991. Kentucky (30 settlements), Texas (29), and Idaho (28) participated in the most settlements, while New Hampshire (4 settlements), Georgia (3), and Wyoming (2) participated in the fewest.

There was no appreciable difference in the average number of total settlements (single- and multi-state combined) between states with and without an FCA (as of 2011), or with and without a DRA-compliant FCA. States without an FCA actually had slightly more total settlements (mean 17.6) than states with an FCA (mean 15.0). Notably, only half (20 of 40) of the states with an FCA had at least one single-state settlement, with more than half of all single-state settlements (56 of 108) finalized by just 11 states without an FCA. Twenty (74%) of the 27 states with at least one single-state settlement had an FCA, while 20 (83%) of the 24 states without a single-state settlement had an FCA.

Among states with an FCA as of 2011, those with a DRA-compliant FCA had a slightly higher number of total settlements (mean 16.3) than states with an FCA that was not DRA-compliant (mean 14.4).

Civil versus criminal settlements: Current study period (November 2, 2010, to July 18, 2012), previous study period (1991 to November 1, 2010), and overall totals (1991 to July 18, 2012)

Civil settlements made up the majority (65, or 88%) of settlements during the current study period, with combined civil-criminal settlements (6, or 8%) and criminal settlements (3, or 4%) constituting the rest. Since 1991, there have been 205 civil settlements, 27 civil-criminal settlements, and 7 criminal settlements, with $23.5 billion in civil penalties and $6.7 billion in criminal penalties (**Figures 6 and 7**).

Among federal settlements, during the current study period, the FCA remained the most common law invoked in civil settlements, while the Food, Drug, and Cosmetic Act (FDCA) has been the most common law in criminal cases. There has been no appreciable change in the proportion of settlements with a criminal component, with 9 of 74 cases (12%) involving a criminal fine or forfeiture during the current study period, compared with 25 of 165 (15%) cases during the preceding 20-year period.

FCA and qui tam (whistleblower) settlements: Current study period (November 2, 2010, to July 18, 2012) and overall totals (1991 to July 18, 2012)

The pharmaceutical industry continued to outpace the defense industry in settlement payouts to the federal government under the FCA in FY 2011, and FY 2012 has already far surpassed any previous year in federal FCA financial penalties paid by the pharmaceutical industry (**Figure 8**).[16]

As in the previous study, federal qui tam settlements and penalties brought under the FCA (21, totaling $6 billion) outnumbered non-whistleblower federal settlements (7, totaling $1.7 billion) during the current study period.[17] 2010 represented a record year for the number of federal qui tam settlements (16), while 2012 has already surpassed any previous year in terms of financial penalties from such settlements, at $4.5 billion (see **Figures 9 and 10**).

By contrast, over the entire 1991 – July 18, 2012, period, a much lower proportion of state settlements (10%) have originated from qui tam actions than have federal settlements (55%), a trend that has persisted during the current study period, with only five of 46 (11%) state settlements arising from qui tam actions (see **Figures 11 and 12**). However, state qui tam settlements have yielded more in financial penalties per settlement ($54 million) than non-qui tam settlements ($29 million). Of the 14 state settlements for $753 million originating from a qui tam action since 1991, six (43%) of the settlements and $354 million (47%) of the financial penalties have resulted from investigations undertaken by a single state: Texas.

Worst offenders and largest settlements: Current study period (November 2, 2010, to July 18, 2012) and overall totals (1991 to July 18, 2012)

Three companies (GSK, Johnson & Johnson, and Abbott) were responsible for approximately two-thirds (66%) of financial penalties during the current study period. GSK, once again, topped the list with $3.1 billion alone in settlement monies (**Table 4**).

Three of the 10 largest cases during the current study period were state court judgments (Arkansas and South Carolina) or settlements (Texas) with Johnson & Johnson over the unlawful promotion of its antipsychotic Risperdal (**Table 6**).[18] Two of the 10 largest

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[16] These represent underestimates of the FCA totals for the pharmaceutical industry. Many settlement press releases did not permit adjudication of the federal portion of penalties, thus excluding those settlements from this analysis.

[17] Financial penalties in qui tam settlements presented here include both the civil portion under the FCA and the criminal portion, if applicable.

[18] A federal settlement with the company over these practices is pending, with preliminary announcements suggesting the total federal settlement could be as much as $2.2 billion. Bloomberg Businessweek (Associated Press story). Report: J&J will pay $2.2B in Risperdal settlement. July 19, 2012. Accessed on August 2, 2012. http://www.businessweek.com/ap/2012-07-19/report-j-and-j-will-pay-2-dot-2b-in-risperdal-settlement.

settlements resulted from federal investigations initiated by the Ven-A-Care whistleblower (see the "Discussion" section).

Tables 5 and 7 list the worst offending companies and largest settlements, respectively, over the entire 1991 – July 18, 2012, period.

Types of violations: Current study period (November 2, 2010, to July 18, 2012) and overall totals (1991 to July 18, 2012)

The general pattern of violation frequency and concomitant penalties remained consistent during the current study period (**Figures 13 and 15**). Overcharging government health programs remained the most common violation (48 violations, 38 of which were from state settlements), while unlawful promotion was still associated with the largest financial penalties ($4.5 billion). Overall violation frequency and concomitant penalties since 1991 are presented in **Figures 14 and 16**, respectively. **Table 8** lists the definitions for each violation type.

Discussion

The past two years have seen a continuation of the recent trend of record settlement activity between the federal and state governments and pharmaceutical manufacturers. The first seven months of 2012 have already set a record for the most monies recovered in a single year on both federal and state levels. This period also saw the largest health fraud settlement ever reached between a pharmaceutical company and the federal government. GSK agreed to pay $3 billion to resolve allegations that it had illegally marketed multiple medications, including the dangerous diabetes drug Avandia, for off-label uses and had paid kickbacks to physicians to induce them to prescribe the drugs.[19]

The GSK settlement followed closely on the heels of a $1.5 billion settlement with Abbott this past May,[20] while an agreement has been reached in principle this year with Johnson & Johnson for $2.2 billion to resolve allegations that it paid illegal kickbacks to increase sales of its antipsychotic medication, Risperdal.[21] The three largest state cases, all concerning Johnson & Johnson's unlawful marketing of Risperdal, were also finalized within the past two years (**Table 6**). The Taxpayers Against Fraud (TAF) watchdog group predicts that by

[19] U.S. Department of Justice. GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data. July 2, 2012. Accessed on July 9, 2012. http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

[20] U.S. Department of Justice. Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote. May 7, 2012. Accessed on August 2, 2012. http://www.justice.gov/opa/pr/2012/May/12-civ-585.html.

[21] Bloomberg Businessweek (Associated Press story). Report: J&J will pay $2.2B in Risperdal settlement. July 19, 2012. Accessed on August 2, 2012. http://www.businessweek.com/ap/2012-07-19/report-j-and-j-will-pay-2-dot-2b-in-risperdal-settlement.

the end of 2012, a record $8.3 billion will have been paid by pharmaceutical companies in settlements and court judgments.[22]

Single-state settlements: More states going it alone, but many lag far behind

Much of this recent enforcement activity is due to individual state attorneys general taking the initiative to pursue Medicaid fraud by the pharmaceutical industry. Although collaboration with federal or other state agencies brings more human and financial resources to these investigations, those advantages are clearly not essential. For one, states acting alone may be able to recover money more quickly than would be the case if they waited for other states or the federal government to lead the way.

Single-state settlements may also be more lucrative to the individual states involved. A prime example is provided by the cases concerning the alleged unlawful promotion of Zyprexa, Eli Lilly's blockbuster antipsychotic drug. In 2008, the allegations were resolved through a multi-state settlement that awarded the 33 participating states a total of $62 million.[23] However, several states that chose to pursue their own cases against Eli Lilly recovered far more in single-state settlements than they would have otherwise received from the multi-state agreement, including Idaho ($13 million)[24] and South Carolina ($45 million).[25]

Furthermore, prosecuting pharmaceutical fraud through single-state investigations can be exceedingly cost-effective. As this study demonstrated, 17 states recouped the equivalent of their entire Medicaid fraud enforcement budgets with money from single-state settlements alone. And states need not invest a large sum in enforcement through MFCUs to combat pharmaceutical fraud within their Medicaid programs, as the federal government covers 75% of state MFCU budgets. States with the smallest per capita MFCU budgets have had some of the highest ROIs, recovering $3 to $48 in single-state pharmaceutical settlements alone for every dollar (federal and state) invested in the MFCU (**Table 1**).

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[22] Taxpayers Against Fraud (TAF) Education Fund. False Claims Act Update and Alert. Our Amazing 2012 Prediction: $9 Billion to be Recovered in False Claims Act Cases in 2012. Only estimates pertaining to pharmaceutical manufacturers were included for the $8.3 billion figure. Dec. 15, 2011. Accessed on August 15, 2012. http://www.taf.org/whistle334.htm.

[23] Florida Office of the Attorney General. Florida, 32 States Reach Landmark $62 Million Settlement with Eli Lilly. October 7, 2008. Accessed on August 27, 2012. http://www.myfloridalegal.com/newsrel.nsf/newsreleases/160ED91F903304BA852574DB004BB3CD.

[24] Office of the Attorney General, State of Idaho. Idaho Reaches $13 Million Settlement with Eli Lilly. October 13, 2009. Accessed on August 27, 2012. http://www.ag.idaho.gov/media/newsReleases/2009/nr_10132009.html.

[25] Office of Attorney General Henry McMaster, State of South Carolina. $45 Million Eli Lilly Settlement Nation's Largest. October 23, 2009. Accessed on August 27, 2012. http://media.charleston.net/2009/pdf/elililly_102309.pdf.

However, it appears that most states have not successfully leveraged their MFCUs to prosecute pharmaceutical fraud through single-state investigations, including many states with high prescription drug expenditures and well-funded MFCUs. These states may be focusing their limited enforcement resources on non-pharmaceutical Medicaid fraud. However, pharmaceutical companies are the biggest defrauders of the federal government,[26] and this is also likely true at the state level, given the size of recent state settlements. Therefore, pharmaceutical fraud should be the highest priority for states concerned with evermore stretched Medicaid budgets,[27] especially as budgetary pressures increase with the coming Medicaid expansion mandated in the Patient Protection and Affordable Care Act (PPACA).[28]

The future of state enforcement efforts

States' continued ability to pursue fraud investigations may hinge on the outcomes of several ongoing lawsuits filed by drug manufacturers against litigating states. The companies contend that their due process rights are violated by the states' enforcement tactics.[29] Individual states with limited resources often hire a private law firm to prosecute pharmaceutical companies, using a contingency-fee arrangement in which the firm is paid a percentage of settlement proceeds if the case results in a successful outcome for the state. In the pending lawsuits, the pharmaceutical companies are arguing that this introduces a conflict of interest on the part of the law firm and may result in "overzealous prosecution."[30]

The suits represent a novel tactic employed by the pharmaceutical industry to stymie state enforcement efforts and, if successful, would severely undermine individual states' ability to prosecute pharmaceutical fraud. Many attorneys general, particularly in smaller states, do not have sufficient staff in-house to undertake such demanding investigations and consequently depend on these contracts with private law firms to continue their enforcement efforts.

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[26] U.S. Department of Justice. Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011. December 19, 2011. Accessed on July 26, 2012. http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html.

[27] Kaiser Family Foundation. Moving Ahead Amid Fiscal Challenges: A Look at Medicaid Spending, Coverage and Policy Trends. October 2011. Accessed on July 20, 2012. http://www.kff.org/medicaid/8248.cfm.

[28] Kaiser Family Foundation. Focus on Health Reform. Accessed on August 17, 2012. http://www.kff.org/healthreform/upload/8061.pdf.

[29] Pharmalot. AstraZeneca Pays $26M To Settle Seroquel Suit. August 27, 2012. Accessed on August 27, 2012. http://www.pharmalot.com/2012/08/astrazeneca-pays-26m-to-settle-seroquel-suit/.

[30] Pharmalot. Merck Can Sue State For Outsourcing Vioxx Lawsuits. July 26, 2012. Accessed on August 27, 2012. http://www.pharmalot.com/2012/04/merck-can-sue-state-for-outsourcing-vioxx-lawsuits/.

The changing landscape of how Medicaid pays for prescription drugs may also alter the focus of state enforcement actions. Currently, single-state settlements revolve mostly around the fraudulent overcharging of Medicaid programs, with states cracking down on industry manipulation of the ubiquitous average wholesale price (AWP) reimbursement method for pharmaceuticals. Under this arrangement, many Medicaid programs reimburse pharmacies and other intermediaries based on the AWPs reported by the manufacturer. The manufacturers routinely inflate the AWPs and then highlight the difference (known as the "spread", which pharmacies pocket) between these AWPs and the drugs' actual price to entice pharmacies to purchase the drug, with the goal of increasing the manufacturer's market share.[31]

As this fraud has come under public scrutiny over the past decade (and partially in response to recent court challenges against the AWP system, along with the exit from the market of a major AWP publisher[32]), states are increasingly switching to alternative reimbursement schemes to more accurately identify the price paid by intermediate suppliers for drugs. To what extent this will mitigate the pricing fraud and re-direct state enforcement efforts to other forms of pharmaceutical fraud remains to be seen.

Continued importance of whistleblowers in combating pharmaceutical fraud

The whistleblower provisions of the FCA constitute the most important factor spurring the recent wave of federal settlements, as the pharmaceutical industry continues to be the largest defrauder of the federal government under the FCA.[33] Enacted in 1863 during the Civil War to combat defense contractor fraud, the FCA has been amended numerous times over the past 26 years, in part to increase financial rewards for private whistleblowers who reveal fraudulent activities by government contractors.[34] Almost half of the qui tam settlements during the current study period were made possible by a single whistleblower: the Ven-A-Care pharmacy, which has been called "…the most successful — and least well-known — whistleblower operation of all time."[35] Housed in a nondescript building on a

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[31] U.S. Department of Health and Human Services, Office of Inspector General. Compliance Program Guidance for Pharmaceutical Manufacturers. Pages 26-27. April 2003. http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.

[32] Kaiser Family Foundation. Moving Ahead Amid Fiscal Challenges: A Look at Medicaid Spending, Coverage and Policy Trends. Page 55. October 2011. Accessed on July 27, 2012. http://www.kff.org/medicaid/upload/8248.pdf.

[33] U.S. Department of Justice. Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011. December 19, 2011. Accessed on July 26, 2012. http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html.

[34] Gersh J. Saying What They Mean: The False Claims Act Amendments in the Wake of Allison Engine. Journal of Business & Technology Law, Vol 5(1), 125-142. 2010. Accessed on August 2, 2012. http://www.law.umaryland.edu/academics/journals/jbtl/issues/5_1/5_1_125_Gersh.pdf.

[35] Javers E. How Four Men Got Rich Exposing Pharma Fraud. CNBC. February 10, 2011. Accessed on July 26, 2012. http://www.cnbc.com/id/41491563/How_Four_Men_Got_Rich_Exposing_Pharma_Fraud.

side street in Key West, Florida, Ven-A-Care has been responsible for recovering at least $1.3 billion for the federal government from the pharmaceutical industry since 2001.[36]

Partly due to the absence of strong FCA qui tam provisions in 38 states (22 of which have no qui tam provisions at all),[37] states have apparently not taken similar advantage of whistleblower revelations to enforce pharmaceutical fraud.[38] In this study, the existence of neither an FCA nor a DRA-compliant FCA seemed to predict states' level of enforcement of pharmaceutical fraud, at least as measured by the number of settlements.

Texas is one prominent exception that has leveraged its DRA-compliant FCA to recover money through whistleblower-initiated investigations. The state's law awards whistleblowers 15-25% of the financial penalties of a settlement.[39] Texas has successfully invoked these provisions more than any other state, recovering at least $354 million through qui tam settlements and demonstrating the potential of a strong FCA to combat fraud if fully utilized.

Increasing globalization of pharmaceutical fraud

On the federal level, "at least a dozen" investigations are reportedly ongoing against pharmaceutical and medical device manufacturers for alleged bribery of government-employed physicians in foreign countries.[40] Until recently, federal prosecution of these violations under the Foreign Corrupt Practices Act (FCPA) had been rare,[41] but these latest cases may represent a growing trend.

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[36] *Ibid.*

[37] The federal incentive, through the 2005 DRA, for states to enact stronger FCAs has had some additional impact over the past two years. Thirty-nine states (and D.C.) have now enacted FCAs (up from 34 two years earlier), but only 13 are DRA-compliant (up from 10 in 2009). Source: National Association of Medicaid Fraud Control Units (NAMFCU). Statistical Survey: State Medicaid Fraud Control Units. 2009 and 2011 surveys. Pages 9-11. Accessed on July 23, 2012. http://www.namfcu.net/publications/annual-state-surveys/. The 2009 figures are slightly different than those presented in the 2010 report, as we used NAMFCU data this time, as opposed to the use of Taxpayers Against Fraud figures in 2010, which listed only FCAs with qui tam provisions.

[38] The study's reliance on press releases likely lead to an underestimation of the number of states invoking a specific law, such as an FCA, to bring charges against the companies.

[39] Taxpayers Against Fraud (TAF). Texas Human Resources Code. Chapter 36.110(a). Accessed on September 24, 2012. http://www.taf.org/resources/statefca/texas.

[40] Harris G, Singer N. Drug Companies Face Federal Inquiries. New York Times. August 13, 2010. Accessed on August 13, 2012. http://prescriptions.blogs.nytimes.com/2010/08/13/drug-companies-face-federal-inquiries/.

[41] According to our data, only three settlements, for a combined $79 million, were reached between pharmaceutical manufacturers and the federal government to resolve allegations of FCPA violations from 1991 through July 18, 2012.

According to the *New York Times*, the pharmaceutical companies involved in the investigations are suspected of paying kickbacks to induce doctors to use their products and of paying large sums to physicians running clinical trials, ostensibly to influence trial results in the company's favor.[42] Two such settlements with Johnson & Johnson in 2011 — totaling $70 million (the largest-ever FCPA settlements involving a pharmaceutical manufacturer) —resolved allegations that the company paid kickbacks to government-employed doctors in several eastern European countries and to Iraqi governmental officials for contracts in violation of the United Nations' Oil for Food Program.[43]

The scope of the FCPA, and thus the federal government's reach, is limited to cases involving bribery of government employees, but foreign governments are beginning to crack down on other forms of pharmaceutical fraud in their countries. One such case in 2011 involved allegations that GSK conspired with a South Korean company, Dong-A, to prevent the sale of generic versions of two GSK drugs — Zofran (an anti-nausea medicine) and Valtrex (an antiviral) — in that country. GSK was fined $2.6 million by the South Korean government for these monopoly practices.[44]

More aggressive prosecution still necessary

Although the upward trend in settlement activity and accompanying financial penalties has continued over the past two years, the penalties are still far too low to deter future violations. The $30 billion in settlements paid out by pharmaceutical companies since 1991 represents just over two-thirds of the profits made by the 10 largest companies in a single year (2010).[45] Although this is primarily due to unwillingness on the part of the executive branch to hold companies more financially accountable, stronger legislation could help in this regard. For one, the FCA could be amended to allow for increased civil penalties for each fraudulent transaction.

In addition, parent companies (as opposed to subsidiaries) have only rarely been excluded from participation in federal health programs, such as Medicare and Medicaid, as a result of criminal convictions or guilty pleas under the FDCA. The federal government has

[42] *Ibid.*

[43] U.S. Securities and Exchange Commission. SEC Charges Johnson & Johnson With Foreign Bribery. April 7, 2011. Accessed on August 31, 2012. http://www.sec.gov/news/press/2011/2011-87.htm; and U.S. Department of Justice. Office of Public Affairs. Johnson & Johnson Agrees to Pay $21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations. April 8, 2011. Accessed on August 31, 2012. http://www.justice.gov/opa/pr/2011/April/11-crm-446.html.

[44] Project on Government Oversight. Federal Contractor Misconduct Database. GlaxoSmithKline South Korea Antitrust Fine. October 27, 2011. Accessed on August 13, 2012. http://www.contractormisconduct.org/index.cfm/1,73,222,html?CaseID=1716.

[45] CNN Money: Fortune 500 Pharmaceuticals. Issue Date: May 23, 2011. Profits of the 10 largest companies totaled $43.1 billion. I assumed the figures were 2010 totals, based on the both the Issue date and the column "% change from 2009". Accessed on August 13, 2012. http://money.cnn.com/magazines/fortune/fortune500/2011/industries/21/index.html.

presumably avoided this scenario because even a single large company's removal from the programs may result in a loss of access to critical drugs for federally insured patients.

Legislation introduced by Sen. Bernie Sanders (I-Vt.) in May 2012 addressed this concern by mandating that companies lose Food and Drug Administration (FDA) granted data exclusivity only for the specific drugs involved in criminal activity, rather than for their entire repositories.[46] The Sanders amendment, which was defeated, would have more effectively targeted companies' bottom lines, while increasing access to cheaper generics for Medicare and Medicaid patients.

Targeting company executives with felony charges also poses no drug-access dilemma, yet this strategy has only rarely been pursued. The federal government has the authority to prosecute executives under the Park Doctrine, a legal precedent that holds executives responsible for misconduct within their companies, even if they did not know about the specific unlawful acts in question.[47]

There are some indications that the federal government may finally be moving in this direction. In 2011, the FDA issued a final guidance outlining its position on the Park doctrine, listing several criteria it will consider when weighing whether to prosecute corporate officers for misconduct committed by their companies.[48] Around the same time, a former KV Pharmaceutical chairman of the board and chief executive officer, Marc S. Hermelin, became the fourth pharmaceutical executive successfully prosecuted under the Park Doctrine,[49] and the first to be sentenced to prison (albeit for only 30 days).[50] Hermelin pleaded guilty to two misdemeanors under the FDCA for failing to report that some of his company's tablets were oversized and possibly dangerous.

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[46] Maxmen A. Vital prescription-drug bill plods though Senate. Nature Newsblog. May 23, 2012. Accessed on August 16, 2012. http://blogs.nature.com/news/2012/05/vital-fda-bill-plods-though-senate.html.

[47] Andrews C. FDA Guidance Sheds Little Light On Criminal Liability From Park Doctrine Plea. Forbes. February 2, 2011. Accessed on August 21, 2012. http://www.forbes.com/sites/docket/2011/02/08/fda-guidance-sheds-little-light-on-criminal-liability-from-park-doctrine-plea/print/; and: Food and Drug Administration. Inspections, Compliance, Enforcement, and Criminal Investigations. Recommending Park Doctrine Prosecutions. Accessed on August 21, 2012. http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3.

[48] *Ibid.*

[49] Five years ago, three Purdue Pharma executives pleaded guilty under the Park Doctrine to misleading federal investigators regarding the off-label promotion of the addictive pain medicine OxyContin but received no jail time. See: Meier B. In Guilty Plea, OxyContin Maker to Pay $600 Million. The New York Times. May 10, 2007. Accessed on August 28, 2012. http://www.nytimes.com/2007/05/10/business/11drug-web.html?_r=1&hp&oref=slogin. In both this and the KV Pharmaceutical case, the executives pleaded guilty to misdemeanor rather than felony offenses.

[50] U.S. Department of Justice, Office of Public Affairs. Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case. March 10, 2011. Accessed on August 29, 2012. http://www.justice.gov/opa/pr/2011/March/11-civ-306.html.

In another recent case (not under the Park Doctrine), the U.S. Department of Justice (DOJ) charged a former GSK lawyer for obstructing an FDA investigation into suspected off-label marketing practices, but the case was subsequently thrown out mid-trial.[51] These initial steps, although not having much direct impact, sent a strong signal of the government's intent to hold executives accountable. The DOJ must now follow through with more substantive prosecutions.

On a state level, more states need to follow the successful examples of Texas, Kentucky, and others that have acted alone in prosecuting pharmaceutical fraud. Enacting strong, DRA-compliant state FCAs would enable states to pursue whistleblower-initiated lawsuits, a critical avenue given the tight state budgets and inadequate staff that make it difficult for states to uncover fraudulent activity on their own. However, enacting an FCA is not enough. State governments must also be willing to act on that legislation, as Texas has, to prosecute fraud. Adequate funding of state MFCUs and targeting scarce resources toward what is likely the largest perpetrator of state Medicaid fraud — the pharmaceutical industry — can, as this study has shown, pay for itself in the long run.

Limitations and future research

Several factors — as was similarly the case in the 2010 study — limited the current study. Due to the reliance on publicly available press releases, this data set may not be complete and likely understates the extent of criminal and civil violations by the pharmaceutical industry. To our knowledge, there is still no official, comprehensive, publicly available source for all government actions taken against pharmaceutical companies. This is especially important at the state level as certain states that did not publicize settlements online, or that did not have adequate websites to review, may have been underrepresented in individual state tallies. In addition, the study does not reflect real-time trends in unlawful behavior by companies, as alleged violations typically precede a settlement's conclusion by several years. Given this lag time, and the fact that the current study encompassed only a year and a half of data, meaningful trends in enforcement activity cannot be deduced from this report.

Future research could expand the scope of the current study to other healthcare industries, in particular medical device companies, which have been the subject of increased discussion in the past year with the renewal of the Medical Device User Fee Act (MDUFA).[52] In a particularly egregious case in December 2011, Medtronic, the world's largest medical

[51] Kolker C. and Pelofsky J. Reuters. Judge throws out case vs ex-Glaxo lawyer. May 10, 2011. Accessed on July 17, 2012. http://www.reuters.com/article/2011/05/10/us-glaxosmithkline-lawyer-idUSTRE7496NA20110510.

[52] Public Citizen. Substantially Unsafe: Medical Devices Pose Great Threat to Patients; Safeguards Must be Strengthened, Not Weakened. February 2012. Accessed on August 30, 2012. http://www.citizen.org/documents/substantially-unsafe-medical-device-report.pdf.

device manufacturer,[53] agreed to pay $23.5 million to the federal government to resolve allegations that it paid $1,000-$2,000 kickbacks to physicians to induce them to implant the company's pacemakers and defibrillators in patients.[54] It remains to be seen what effect, if any, the renewal of MDUFA and the increased legislative and regulatory focus on the woefully deficient medical device approval and oversight process, will have on federal efforts to combat medical device fraud.

Conclusion

The past two years have seen a continuation of the recent trend of record settlements between the federal and state governments and pharmaceutical manufacturers. A much larger proportion of these recent settlements have been brought about by individual state investigations than in previous years which, in most states involved in such litigation, has resulted in financial recoveries that more than offset enforcement expenses. However, despite the scale of the fraud against their Medicaid programs and the potential recoveries at stake, most states, including some with the highest prescription drug expenditures, have yet to pursue investigations on their own.

On a federal level, financial penalties still continue to pale in comparison to company profits and a parent company is only rarely excluded from participation in Medicare and Medicaid for the illegal activities, which endanger the public health and deplete already overstretched taxpayer-funded programs. In what will hopefully represent an emerging trend, the federal government has recently pursued criminal charges against key company employees and executives, but the cases so far have either been thrown out or resulted in minor sentences. Stronger legislation and more robust enforcement are needed on a federal and state level to deter future unlawful behavior.

[53] Medtronic. Overview. Accessed on August 3, 2012. http://phx.corporate-ir.net/phoenix.zhtml?c=76126&p=irol-irhome.

[54] U.S. Department of Justice, Office of Public Affairs. Minnesota-Based Medtronic Inc. Pays US $23.5 Million to Settle Claims That Company Paid Kickbacks to Physicians. December 12, 2011. Accessed on August 3, 2012. http://www.justice.gov/opa/pr/2011/December/11-civ-1623.html.

Appendix 1. Updated methodology

Inclusion and exclusion criteria

As with the 2010 report, only settlements of $1 million or greater involving companies that were predominantly pharmaceutical manufacturers (e.g., not pharmacy chains or medical device manufacturers) were included. Cases were excluded if the wrongdoing concerned a product that was not a pharmaceutical (e.g., medical devices were excluded; intravenous solutions, on the other hand, were considered pharmaceuticals).

Data sources

The following data sources were accessed from January through July 2012. All searches were updated through July 18, 2012.

For federal cases, the following sources were accessed: 1) the U.S. DOJ website,[55] 2) the Securities and Exchange Commission (SEC) website,[56] and 3) the Project on Government Oversight's (POGO) Federal Contractor Misconduct Database.[57] Press releases from the DOJ website were found by going to the "Justice News" part of the website. Almost all federal settlements were found in DOJ press releases. To search the SEC website, the link to "Press Releases" was used. On the Federal Contractor Misconduct Database, the search tool "Sort the Data" was used to access all settlements between November 2, 2010, and July 18, 2012. In addition, for the updated comparison of annual federal FCA payouts by the defense and pharmaceutical industries (**Figure 8**), data on financial penalties recovered by the Department of Defense through FY 2011 were obtained online.[58] Figures for FY 2012 were not yet available at the time of the report's publication.

State cases were found through a search of press releases from all 50 state and D.C. attorney general websites. For sites that did not display press releases during part, or all, of the relevant time period (November 2, 2010 through July 18, 2012), the website www.archive.org was accessed (as it was in 2010) to recover past releases, using the most current URL (or a variant) for the state attorney general website (explained in detail in the 2010 report) as the search term. This method was necessary to obtain data from seven states (AL, DC, KS, NE, OH, RI, and SC), all having a gap in time (ranging from seven days to 16 months) during which press releases were unavailable on either the current or archived

[55] U.S. Department of Justice, Office of Public Affairs. Justice News. Last accessed on July 18, 2012. http://www.justice.gov/opa/pr/2012/January/index.html.

[56] Securities and Exchange Commission. Recent Press Releases. Last accessed on July 18, 2012. http://www.sec.gov/news/press.shtml.

[57] Project on Government Oversight. Federal Contractor Misconduct Database. Last accessed on July 18, 2012. http://www.contractormisconduct.org/index.cfm/.

[58] Fraud Statistics – Overview. Civil Division, U.S. Department of Justice. October 1, 1987 – September 30, 2011. Accessed on July 10, 2012. http://www.crowell.com/pdf/FalseClaimStat.pdf.

state attorney general websites. Two other states (MN and PA) did not have any centralized listing of press releases. Both had a search function, which was utilized to find settlements under the search terms "pharmaceutical" and "settlement." Several state cases involved court judgments rather than settlement agreements. These court judgments were included in the database with the original court-ordered financial penalty. Some of these penalties may have been (or may be in the future) overturned on appeal or negotiated down from the original mandated penalties, but records were not always available to verify these subsequent modifications.

For both federal and state websites in which press releases were available, all press release titles were read individually for announcements of settlements between the federal and state governments and pharmaceutical manufacturers. Data from these releases were then cross-checked with several nongovernmental online databases, all of which (or previous versions of which) were also used to verify the data from the 2010 report.[59, 60,61] The rest of the databases used in the 2010 report were out of date, with no updated versions available online.

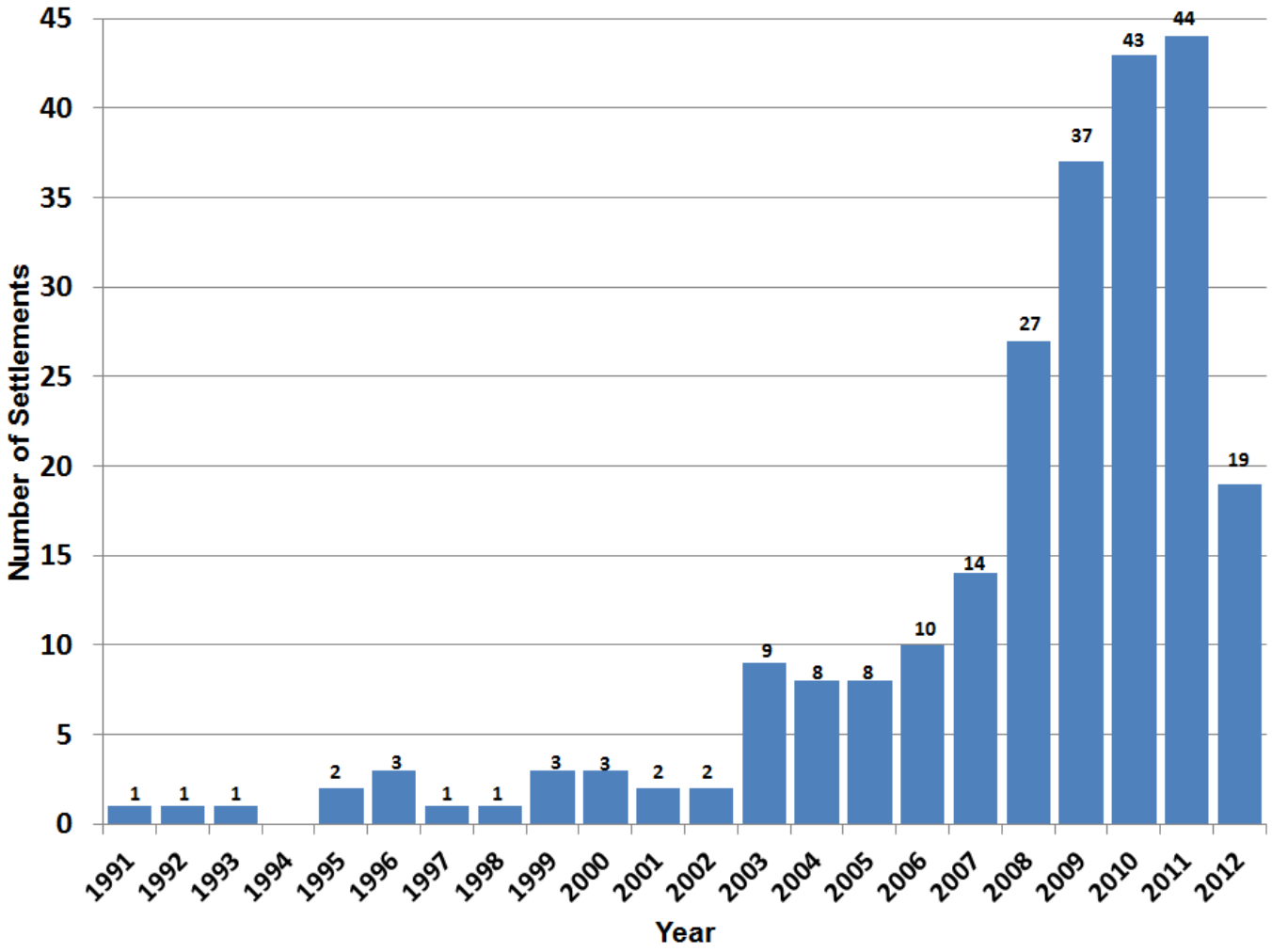
[59] Taxpayers Against Fraud (TAF). Top 100 FCA Cases. Accessed on August 2, 2012. http://taf.org/general-resources/top-100-fca-cases; and TAF Blog. Last accessed on August 2, 2012. http://www.taf.org/blog.

[60] Elmer, B. False Claims Act Settlements 2000-2012. Crowell & Moring LLP. Updated on April 30, 2012. Last accessed on July 19, 2012. http://www.crowell.com/files/False-Claims-Act-FCA-Settlements-Crowell-Moring.pdf.

[61] National Association of Attorneys General. Last accessed on July 19, 2012. http://naag.org; 1) For antitrust cases, the following URL was accessed: http://naag.org/antitrust.php. As in 2010, "Multistate Litigation Database" was selected, followed by "Search Civil only". Titles were searched individually for cases related to the pharmaceutical industry. In addition, unlike in 2010, individual company names from all multi-state settlements were also inputted into the database to further determine whether there was any federal involvement in these cases. Using this new method, eight cases classified as "state" settlements in the 2010 report were reclassified as "federal" settlements. Finally, "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. Within each bimonthly report, the word "pharmaceutical" was typed into the full-text search box and relevant cases were found.

Appendix 2. Figures and tables[62]

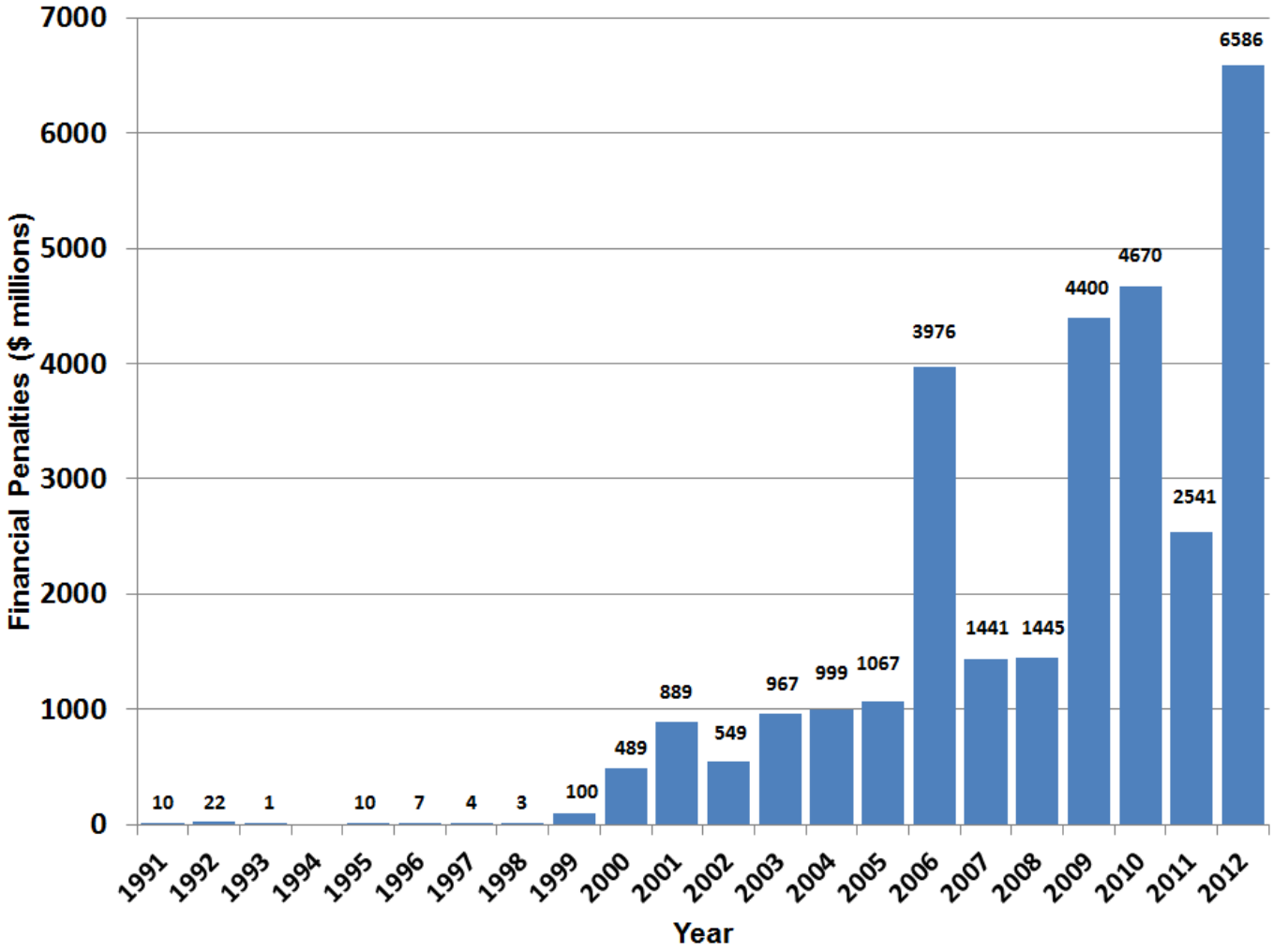
Figure 1. Number of Pharmaceutical Industry Settlements, 1991 – July 18, 2012*



*Totals for two years, 2000 and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state case in CA in 2000 has been found and added and another state case in WV in 2009 has since been successfully appealed by the company and removed from the database.

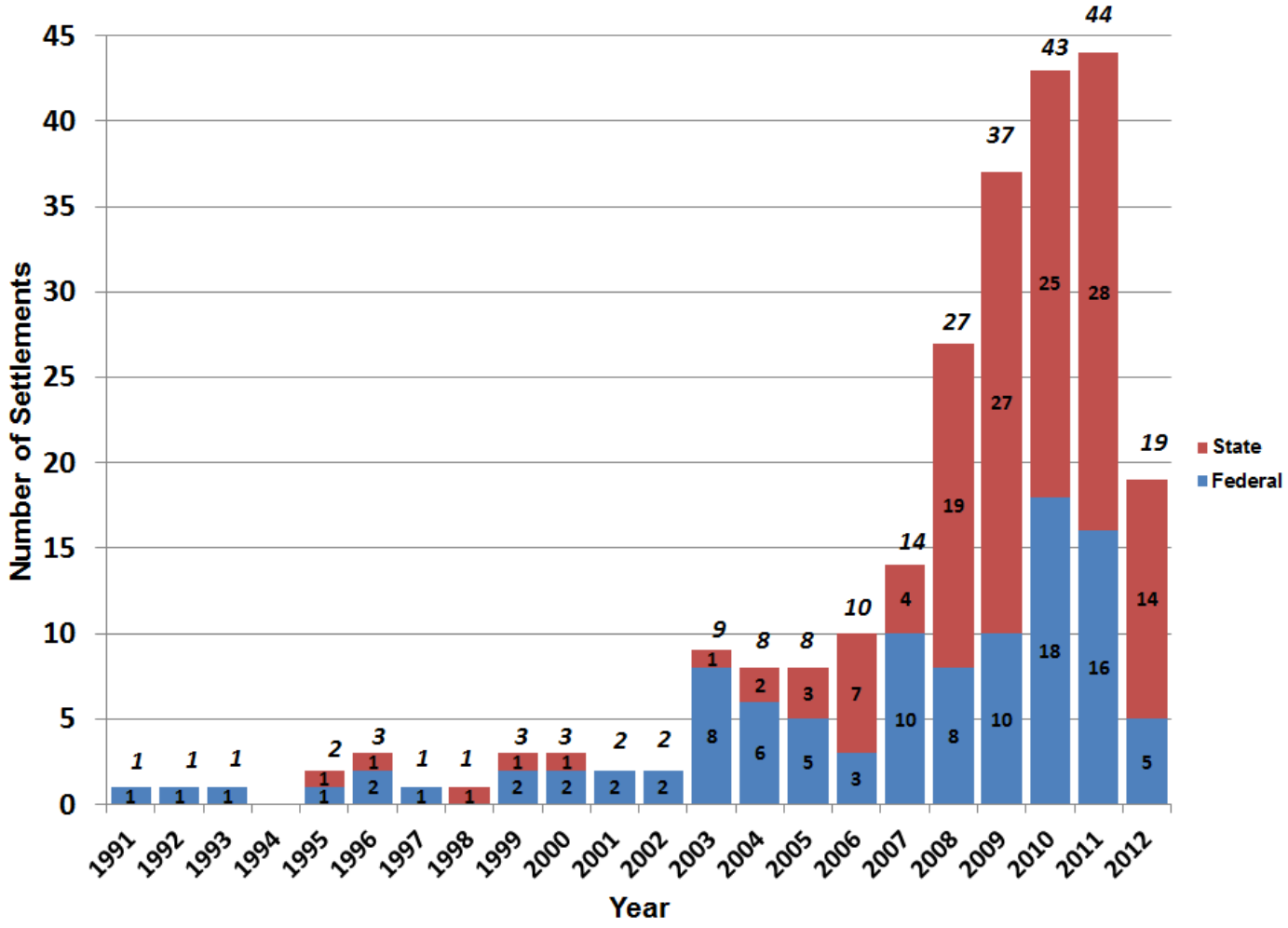
[62] Totals across different figures may vary by $1-2 million due to rounding.

Figure 2. Pharmaceutical Industry Financial Penalties, 1991 – July 18, 2012*



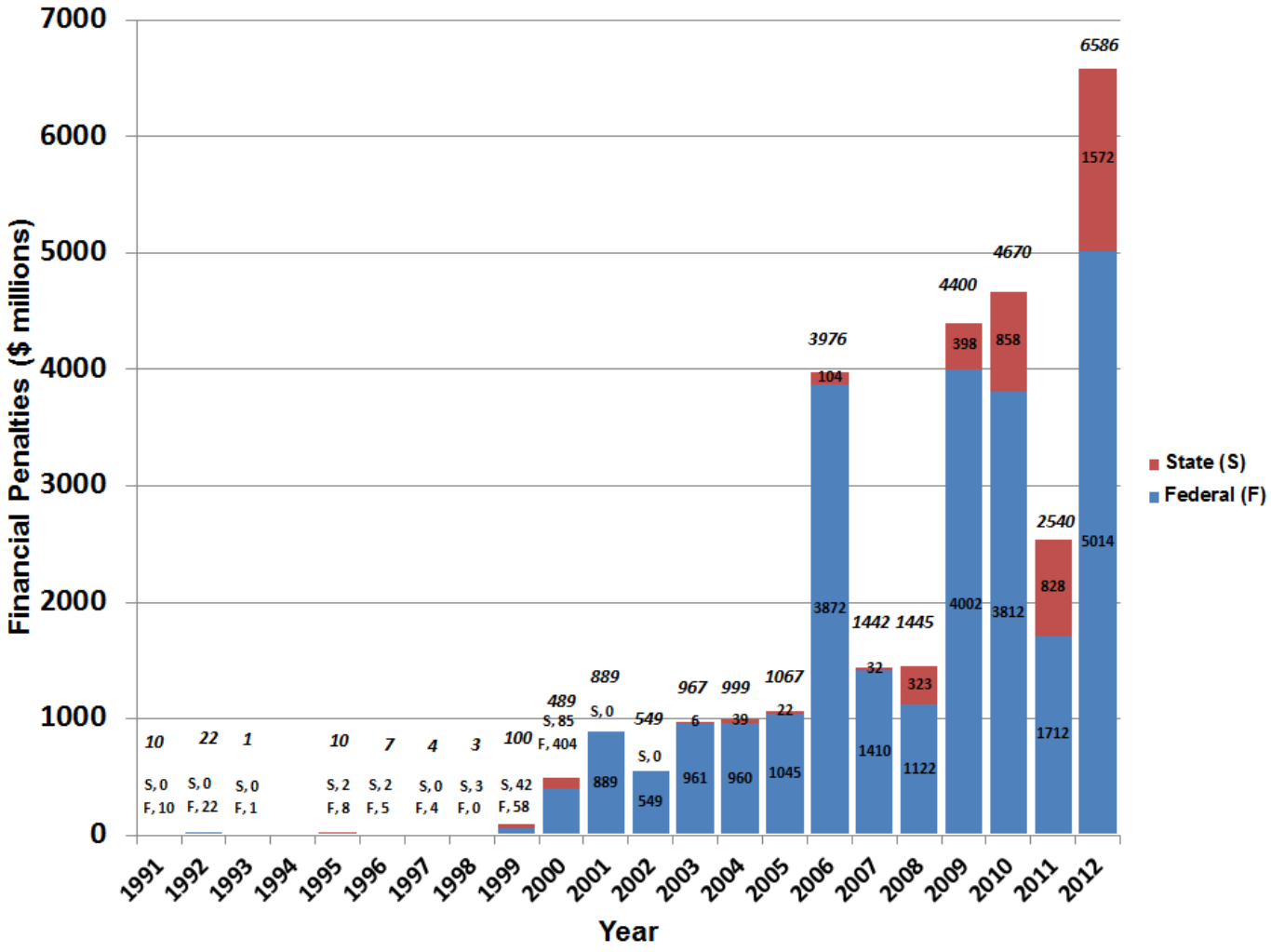
*Totals for two years, 2000 and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state case in CA in 2000 (for $85 million) has been found and added and another state case in WV in 2009 (for $4.5 million) has since been successfully appealed by the company and removed from the database.

Figure 3. Number of Pharmaceutical Industry Settlements, 1991 – July 18, 2012*: State vs. Federal



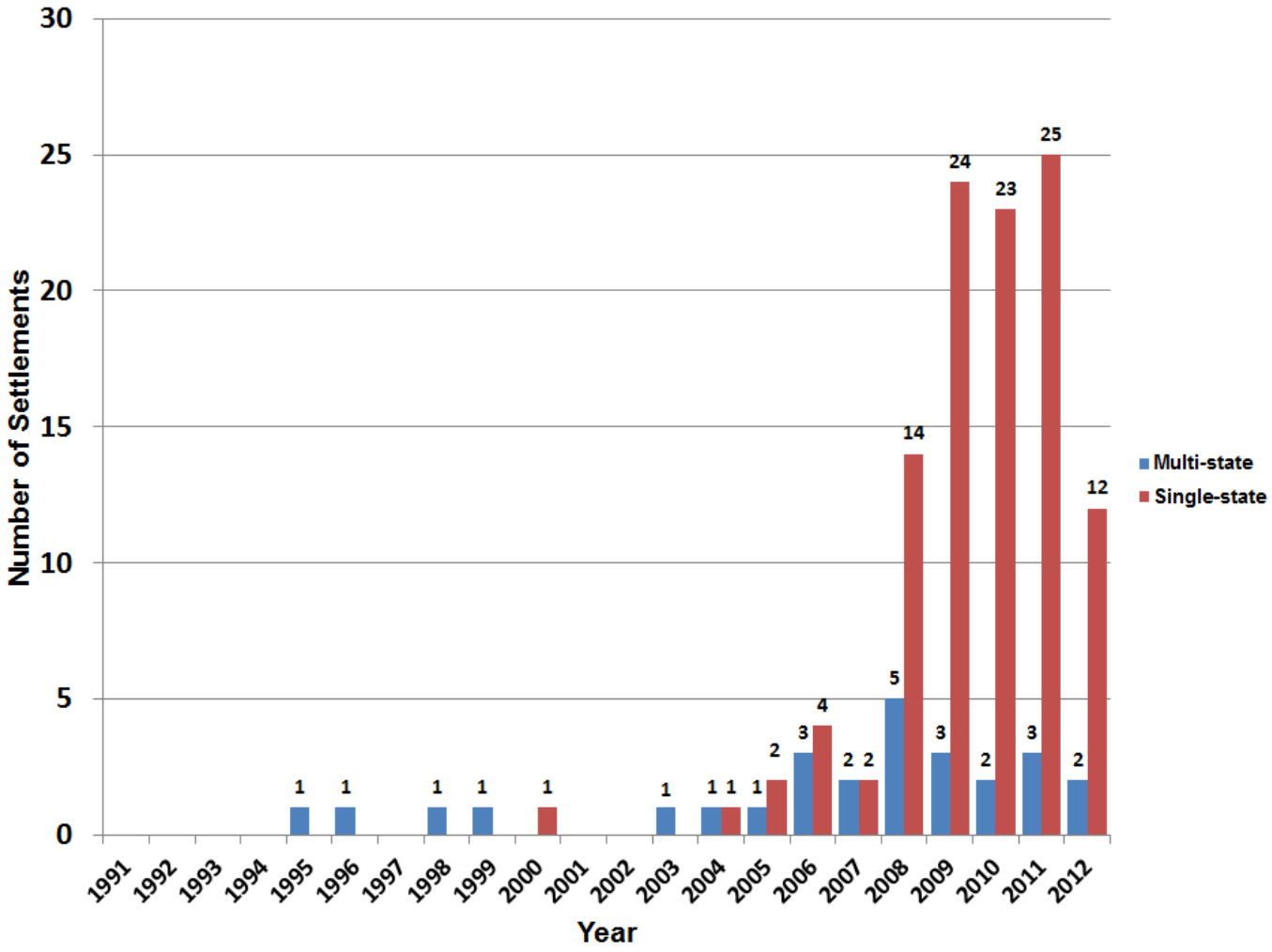
*Totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state case in CA in 2000 has been found and added and another state case in WV in 2009 has since been successfully appealed by the company and removed from the database. Ten cases (one in 1992, two in 2000, two in 2003, one in 2004, one in 2005, one in 2007, one in 2008, and one in 2009) that were classified as state settlements in the 2010 report were reclassified upon further review as federal settlements (see **Appendix 1**).

Figure 4. Pharmaceutical Industry Financial Penalties, 1991 – July 18, 2012*: State vs. Federal



*Totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state case in CA in 2000 (for $85 million) has been found and added and another state case in WV in 2009 ($4.5 million) has since been successfully appealed by the company and removed from the database. Ten cases (one in 1992 [$22 million], two in 2000 [$149 and $255 million], two in 2003 [$62 and $80 million], one in 2004 [$1.5 million], one in 2005 [$30.7 million], one in 2007 [$5.5 million], one in 2008 [$1.1 million], and one in 2009 [$20 million]) that were classified as state settlements in the 2010 report were reclassified upon further review as federal settlements (see **Appendix 1**).

Figure 5. Number of State Pharmaceutical Industry Settlements, 1991 – July 18, 2012: Multi-State vs. Single-State Settlements*



*Single-state settlements were those in which only one state was a party to the final settlement, as gleaned from the information provided in the press release. All other state settlements were multi-state. Overall totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, one additional single-state case in CA in 2000 has been found and added and another single-state case in WV in 2009 has since been successfully appealed by the company and removed from the database. Ten cases (one in 1992, two in 2000, two in 2003, one in 2004, one in 2005, one in 2007, one in 2008, and one in 2009) listed as state settlements in the 2010 report were reclassified upon further review as federal settlements (see **Appendix 1**).

Table 1. Single-state Settlement Totals, 1991 – July 18, 2012

State	Recoveries per $1,000 Medicaid prescription drug expenditures*	Total Financial Penalties ($ millions)**	Number of Settlements and Judgments	ROI (dollars recovered per enforcement dollar spent)***	FCA****
Arkansas	$511.85	$1,201	1	$83.99	Y
Hawaii	$148.89	$84	2	$12.50	Y
South Carolina	$115.90	$372	2	$47.69	Y
Louisiana	$56.87	$376	3	$12.38	Y
Idaho	$37.10	$33	12	$10.52	
Pennsylvania	$33.09	$156	7	$4.69	
Alabama	$32.86	$124	8	$19.04	
Texas	$25.08	$356	7	$2.98	Y
Mississippi	$24.29	$87	9	$6.32	
Alaska	$23.66	$15	1	$3.26	
Utah	$23.17	$29	3	$3.48	Y
New Mexico	$22.08	$10	1	$0.82	Y
Kentucky	$20.15	$94	17	$6.98	
West Virginia	$9.76	$23	1	$3.63	Y
Connecticut	$9.48	$28	2	$4.38	Y
California	$7.01	$163	3	$0.90	Y
Wisconsin	$6.45	$30	7	$3.49	Y
Massachusetts	$6.24	$34	5	$1.56	Y
Missouri	$5.69	$37	3	$2.98	Y
Kansas	$4.00	$6	2	$0.80	Y
Oregon	$2.12	$3	1	$0.38	Y
Iowa	$2.07	$4	2	$0.65	Y
Illinois	$1.46	$14	2	$0.23	Y
Ohio	$1.39	$12	2	$0.46	
Florida	$1.36	$15	2	$0.12	Y
New Jersey	$0.23	$1	1	$0.05	Y
New York	$0.16	$5	2	$0.02	Y
Total	**$20.31†**	**$3,311**	**108**	**$3.08‡**	**20/27**

*Calculated by dividing single-state financial penalties ("Total Financial Penalties" column) from October 10, 2000 (FY 2001; the earliest single-state settlement) through July 18, 2012 by each state's Medicaid prescription drug expenditures from FY2001 through the first two quarters of FY2011 (the most recent year for which data were available from the Centers for Medicare and Medicaid Services [CMS]). These figures are merely an approximation, as there is usually a several-year lag between any prescription drug expenditures involved in the fraudulent activity alleged in the settlement and when that settlement is finalized.

**Values rounded to nearest million. Unlike the case of multi-state settlements, financial penalties obtained through single-state settlements presented in this table represent, to our knowledge, a comprehensive list of such penalties.

***Return on Investment (ROI) was calculated by dividing single-state financial penalties ("Total Financial Penalties" column) from October 10, 2000 (the earliest single-state settlement) through July 18, 2012, by the

state's total Medicaid Fraud Control Unit (MFCU) budgets from FY 2006-2011 as obtained from the National Association of Medicaid Fraud Control Units (NAMFCU) 2011 survey at http://www.namfcu.net/publications/annual-state-surveys/. Only three single-state settlements were finalized prior to FY 2006 (one in CA for $85 million, and two in NY and CT, each for $2.5 million). These ROIs are merely an approximation, as all enforcement activities may not have been conducted by state MFCUs, and there is usually a several-year lag between the time an investigation is initiated and a settlement is finalized.

****False Claims Act (FCA) as of 2011. Obtained from NAMFCU 2011 survey. Values in red signify that the FCA is Deficit Reduction Act (DRA)-compliant, with strong qui-tam provisions. In some cases, settlements may have been finalized prior to the enactment of an FCA.

†Final average recoveries per $1,000 Medicaid dollars spent (from FY2001 through the first two quarters of FY2011) on prescription drugs across all states weighted for Medicaid prescription drug expenditures: sum total of financial penalties ($3.31 billion) divided by total Medicaid prescription drug expenditures of states in table ($163.05 billion from FY2001 through the first two quarters of FY2011).

‡Average ROI across all states in table weighted for MFCU budget size: sum total of financial penalties ($3.31 billion) divided by total MFCU budget across all states ($1.08 billion).

Table 2. Multi-state Settlement Totals, 1991 – July 18, 2012

State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)*	FCA**	State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)*	FCA**
Texas	22	$87.32	Y	Kentucky	13	$5.46	
Arizona	21	$13.79		South Carolina	13	$0	Y
California	21	$35.29	Y	Delaware	12	$3.79	Y
Massachusetts	21	$13.14	Y	District of Columbia	12	$4.46	Y
Florida	20	$40.51	Y	Nebraska	12	$1.89	Y
North Carolina	20	$16.87	Y	New Jersey	12	$12.59	Y
Vermont	20	$8.73		South Dakota	12	$5.71	Y
Illinois	19	$20.62	Y	Hawaii	11	$0	Y
Maryland	19	$6.52	Y	Minnesota	11	$0	Y
Nevada	19	$7.54	Y	Montana	11	$1.06	Y
Wisconsin	19	$7.35	Y	North Dakota	11	$0	
Connecticut	18	$3.86	Y	Colorado	10	$3.35	Y
New York	17	$21.10	Y	Mississippi	9	$0.59	
Oregon	17	$20.14	Y	Oklahoma	9	$0	Y
Pennsylvania	17	$12.21		Rhode Island	9	$2.61	Y
Tennessee	17	$11.03	Y	West Virginia	9	$1.00	Y
Washington	17	$13.07	Y	Louisiana	8	$0.67	Y
Idaho	16	$7.28		Virginia	8	$4.10	Y
Iowa	16	$4.28	Y	Alaska	7	$1.67	
Michigan	16	$4.66	Y	Alabama	6	$0	
Missouri	16	$9.30	Y	Indiana	6	$3.58	Y
Ohio	16	$7.73		Utah	6	$0.10	Y
Arkansas	15	$3.99	Y	New Hampshire	4	$0	Y
Kansas	14	$0.70	Y	Georgia	3	$0	Y
Maine	14	$5.98	Y	Wyoming	2	$0	
New Mexico	14	$1.30	Y				

*Financial penalties represent only individual state settlement shares that were publicly available in press releases, which amounted to only $437 million, or 44% of multi-state settlement financial penalties over the time period. Therefore, state performance in multi-state settlement activity should be driven by the number of settlements, not the financial penalties, attributed to each state in this table. Some states (South Carolina, Hawaii, Minnesota, North Dakota, Oklahoma, Alabama, New Hampshire, Georgia, and Wyoming) had no individual state shares listed in press releases, explaining the "0" value for financial penalties.

**FCA as of 2011. Obtained from NAMFCU 2011 survey. Values in red signify that the FCA is Deficit Reduction Act (DRA)-compliant, with strong qui-tam provisions. In some cases, settlements may have been finalized prior to the enactment of an FCA.

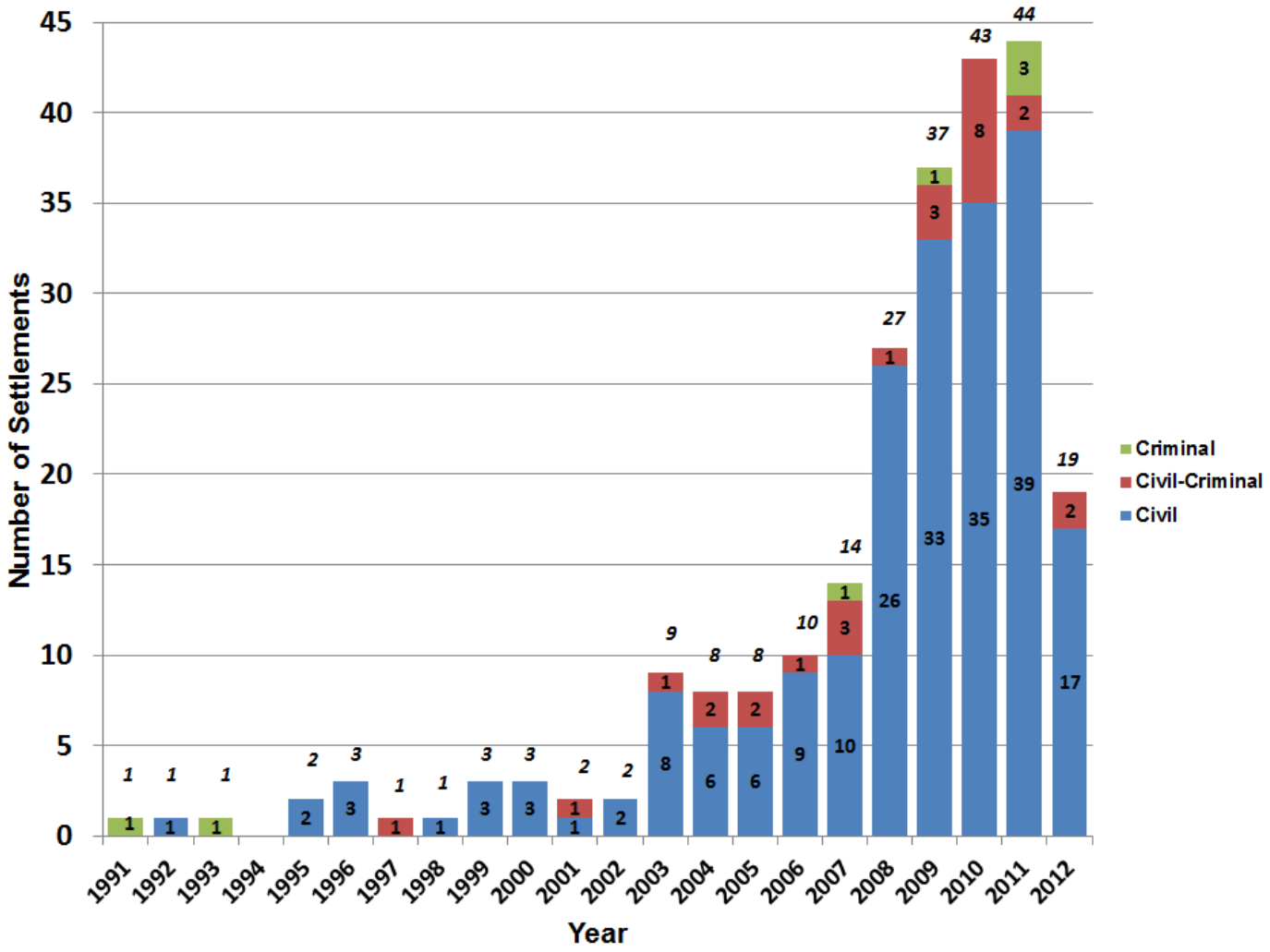
Table 3. Overall State Settlement Totals (single-state and multi-state settlements combined), 1991 – July 18, 2012

State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)*	FCA**	State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)*	FCA**
Kentucky	30	$99.00		New Mexico	15	$11.40	Y
Texas	29	$443.62	Y	South Carolina	15	$372.00	Y
Idaho	28	$39.90		Alabama	14	$123.75	
Massachusetts	26	$47.54	Y	Maine	14	$5.98	Y
Wisconsin	26	$37.75	Y	Hawaii	13	$83.75	Y
California	24	$198.59	Y	New Jersey	13	$13.89	Y
Pennsylvania	24	$167.86		Delaware	12	$3.79	Y
Florida	22	$55.51	Y	District of Columbia	12	$4.46	Y
Arizona	21	$13.79		Nebraska	12	$1.89	Y
Illinois	21	$34.62	Y	South Dakota	12	$5.71	Y
Connecticut	20	$31.46	Y	Louisiana	11	$376.87	Y
North Carolina	20	$16.87	Y	Minnesota	11	$0	Y
Vermont	20	$8.73		Montana	11	$1.06	Y
Maryland	19	$6.52	Y	North Dakota	11	$0	
Missouri	19	$46.30	Y	Colorado	10	$3.35	Y
Nevada	19	$7.54	Y	West Virginia	10	$23.50	Y
New York	19	$26.10	Y	Oklahoma	9	$0	Y
Iowa	18	$8.58	Y	Rhode Island	9	$2.61	Y
Mississippi	18	$87.19		Utah	9	$28.60	Y
Ohio	18	$20.17		Alaska	8	$16.67	
Oregon	18	$23.48	Y	Virginia	8	$4.10	Y
Tennessee	17	$11.03	Y	Indiana	6	$3.58	Y
Washington	17	$13.07	Y	New Hampshire	4	$0	Y
Arkansas	16	$1,204.99	Y	Georgia	3	$0	Y
Kansas	16	$6.40	Y	Wyoming	2	$0	
Michigan	16	$4.66	Y				

*Financial penalties include an incomplete sample ($437 million, or 44%) of financial penalties from multi-state settlements i.e. only individual state settlement shares that were publicly available in press releases over the time period. Therefore, state performance in overall settlement activity should be driven by the number of settlements, not the financial penalties, attributed to each state in this table. Some states (Minnesota, North Dakota, Oklahoma, New Hampshire, Georgia, and Wyoming) had neither individual state shares listed in press releases, nor any single-state settlements or judgments, explaining the "0" value for financial penalties.

**FCA as of 2011. Obtained from NAMFCU 2011 survey. Values in red signify that the FCA is Deficit Reduction Act (DRA)-compliant, with strong qui-tam provisions. In some cases, settlements may have been finalized prior to the enactment of an FCA.

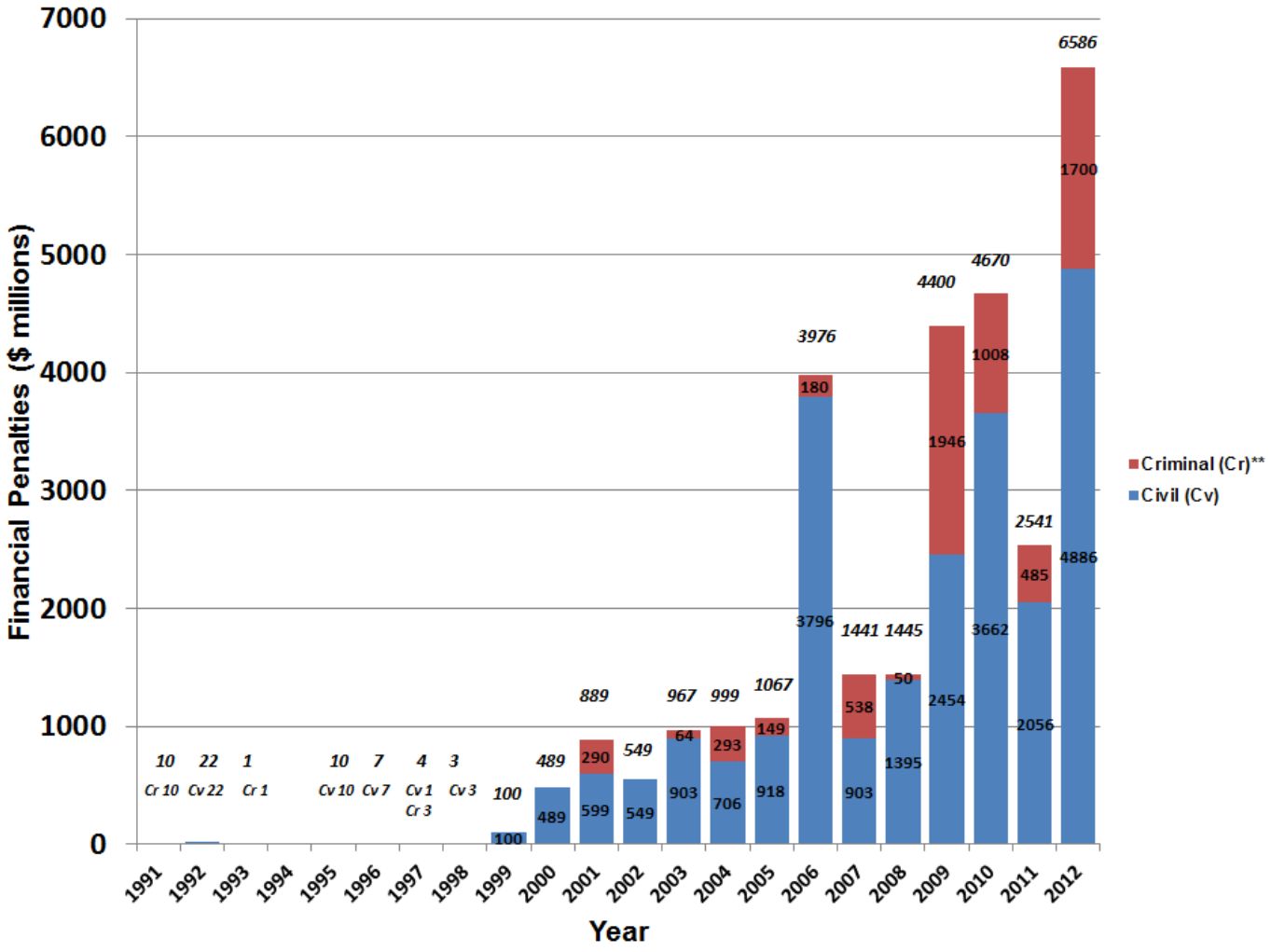
Figure 6. Number of Pharmaceutical Industry Settlements, 1991 – July 18, 2012*: Civil vs. Criminal



*Totals are slightly discrepant from the five-year values listed in the 2010 report. One additional "civil" case in 2000 has been found and added since the last report and one 2009 "civil" case has since been successfully appealed by the company and removed from the database. One 1997 settlement has since been reclassified after further review from "civil" to "civil-criminal". One 2007 settlement has since been reclassified after further review from "civil-criminal" to "civil". Two 2009 settlements and one 2010 settlement have been reclassified after further review from "criminal" to "civil".

"Civil" refers to all solely civil settlements. "Civil-Criminal" refers to settlements with both a civil and criminal financial penalty. "Criminal" refers to cases with only a criminal component.

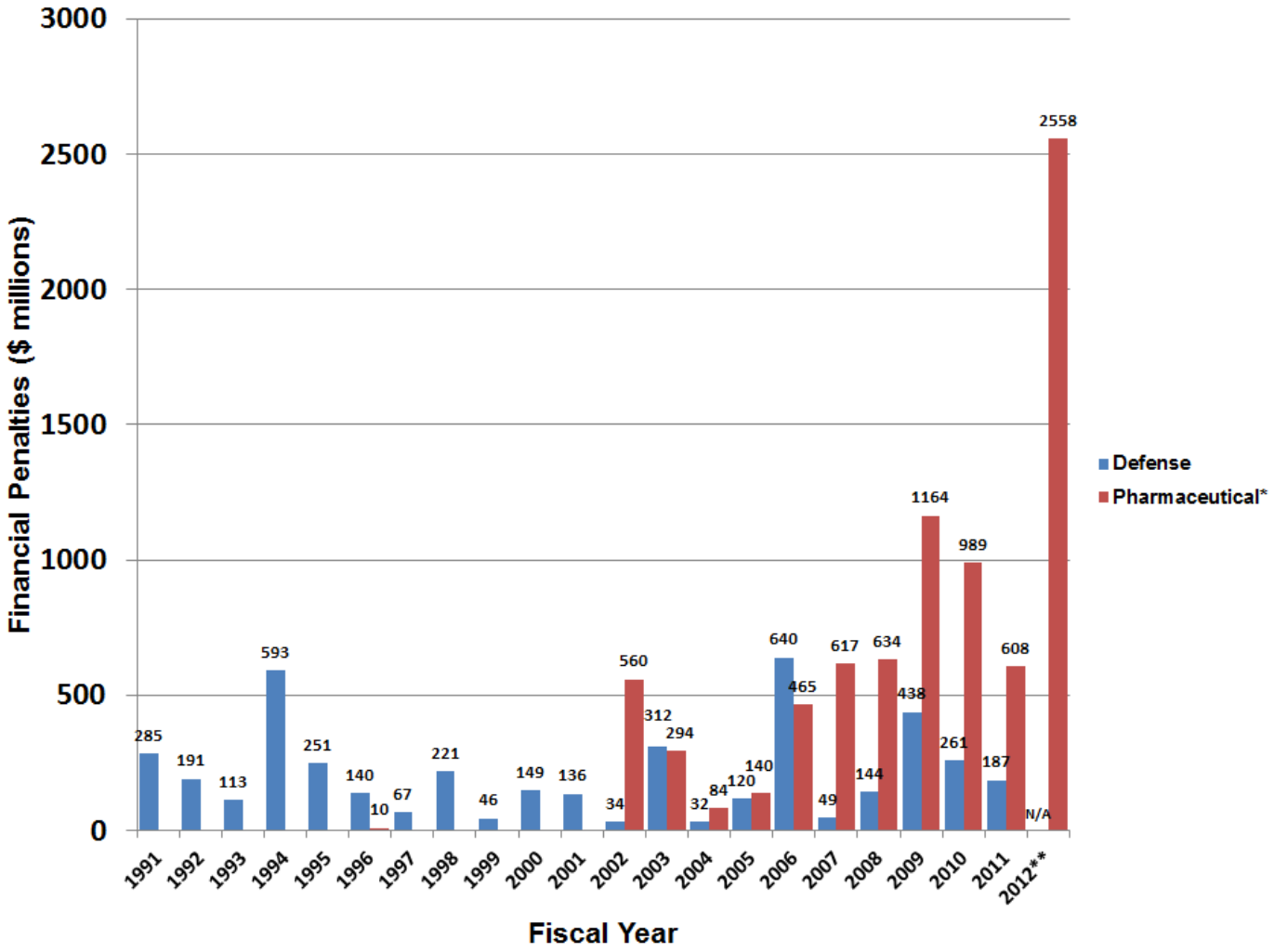
Figure 7. Pharmaceutical Industry Financial Penalties, 1991 – July 18, 2012*: Civil vs. Criminal



*Totals are slightly discrepant from the five-year values listed in the 2010 report. One $3 million criminal fine in a 1997 settlement has since been added and one additional civil settlement in 2000 worth $85 million has been found and added since the last report. One 2009 civil case worth $4.5 million has since been successfully appealed by the company and removed from the database. One $25 million criminal fine in 2007 has since been reclassified after further review as civil. Two criminal fines worth a combined $25 million from two 2009 settlements and one criminal fine of $28 million in 2010 have since been reclassified as civil penalties.

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

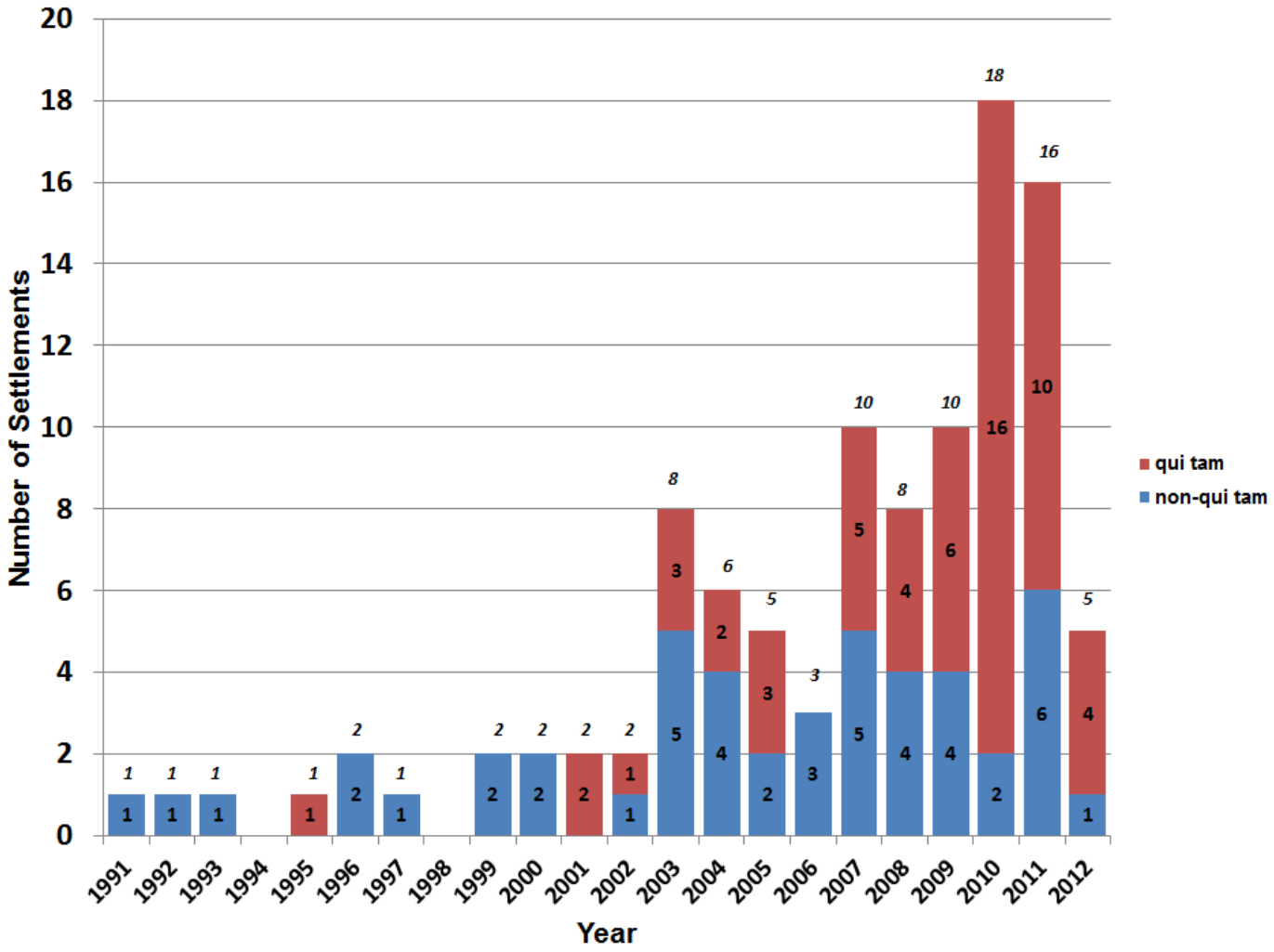
Figure 8. Federal False Claims Act (FCA): Financial Penalties by Industry, Fiscal Year (FY) 1991 – 2012



*Pharmaceutical totals include only those cases in which the federal portion of the FCA penalty was specified in the press release. All other FCA penalties were excluded from the totals.

**Pharmaceutical totals through July 18, 2012. Defense totals not yet available for FY 2012.

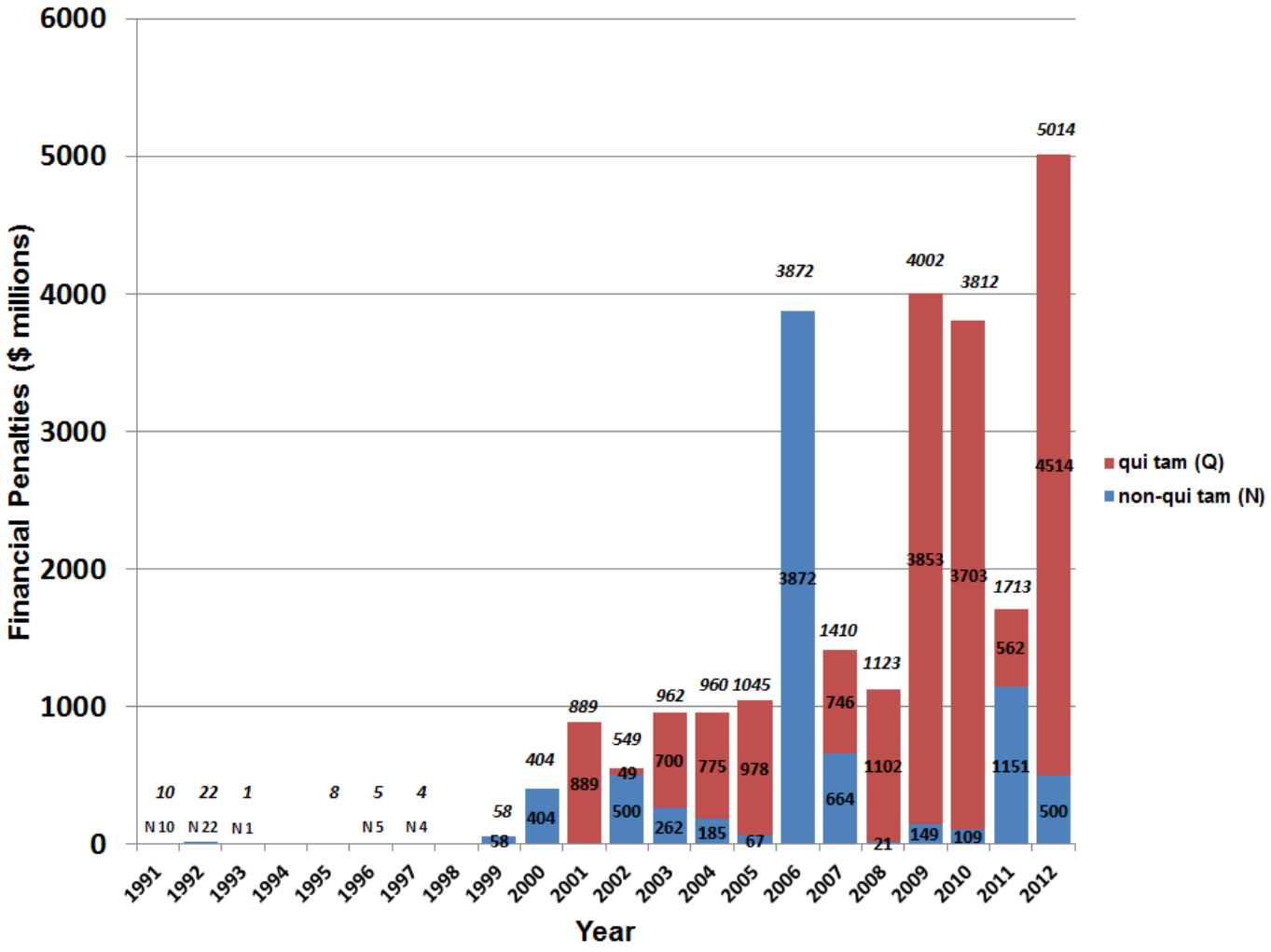
Figure 9. Qui Tam* ("Whistleblower") Federal Pharmaceutical Industry Settlements, 1991 – July 18, 2012**



*qui tam cases are those in which any part of the settlement was triggered by a qui tam action.

Overall federal totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, ten non-qui tam cases (one in 1992, two in 2000, two in 2003, one in 2004, one in 2005, one in 2007, one in 2008, and one in 2009) that were classified as state cases in that report were reclassified upon further review as federal non-qui tam cases (see **Appendix 1). Additionally, one non-qui tam federal case in 2005 was reclassified as a qui tam case.

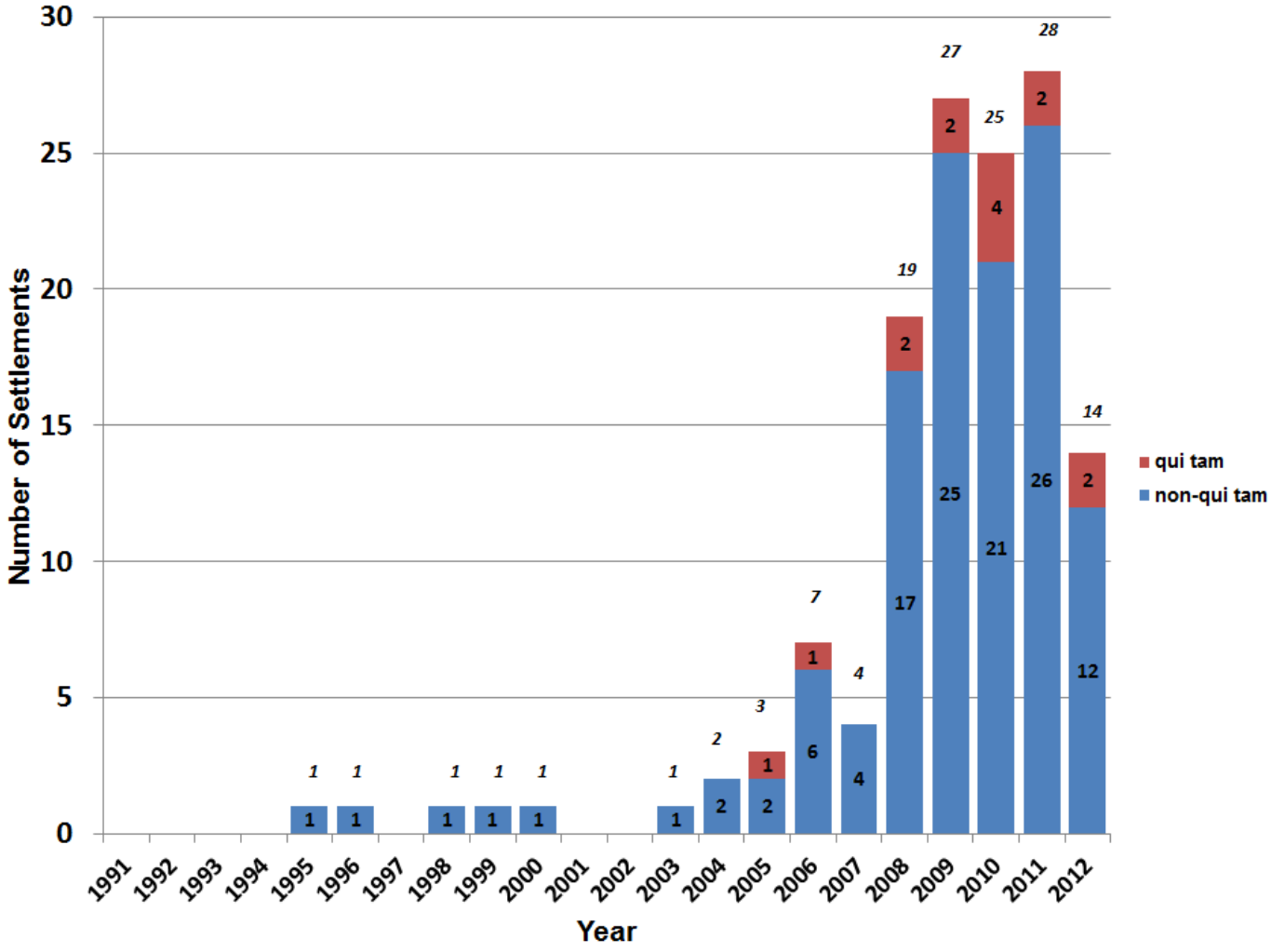
Figure 10. Qui Tam* ("Whistleblower") Federal Pharmaceutical Industry Settlements, 1991 – July 18, 2012**: Financial Penalties ($ millions)



*qui tam cases are those in which any part of the settlement was triggered by a qui tam action. Financial penalties in qui tam settlements presented here include both the civil portion under the FCA and the criminal portion, if applicable.

Overall federal totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, ten state non-qui tam cases (one in 1992 [for $22 million], two in 2000 [$149 and $255 million], two in 2003 [$62 and $80 million], one in 2004 [$1.5 million], one in 2005 [$30.7 million], one in 2007 [$5.5 million], one in 2008 [$1.1 million], and one in 2009 [$20 million]) were reclassified upon further review as federal non-qui tam cases (see **Appendix 1). Additionally, one non-qui tam federal case in 2005 for $124 million was reclassified as a qui tam case.

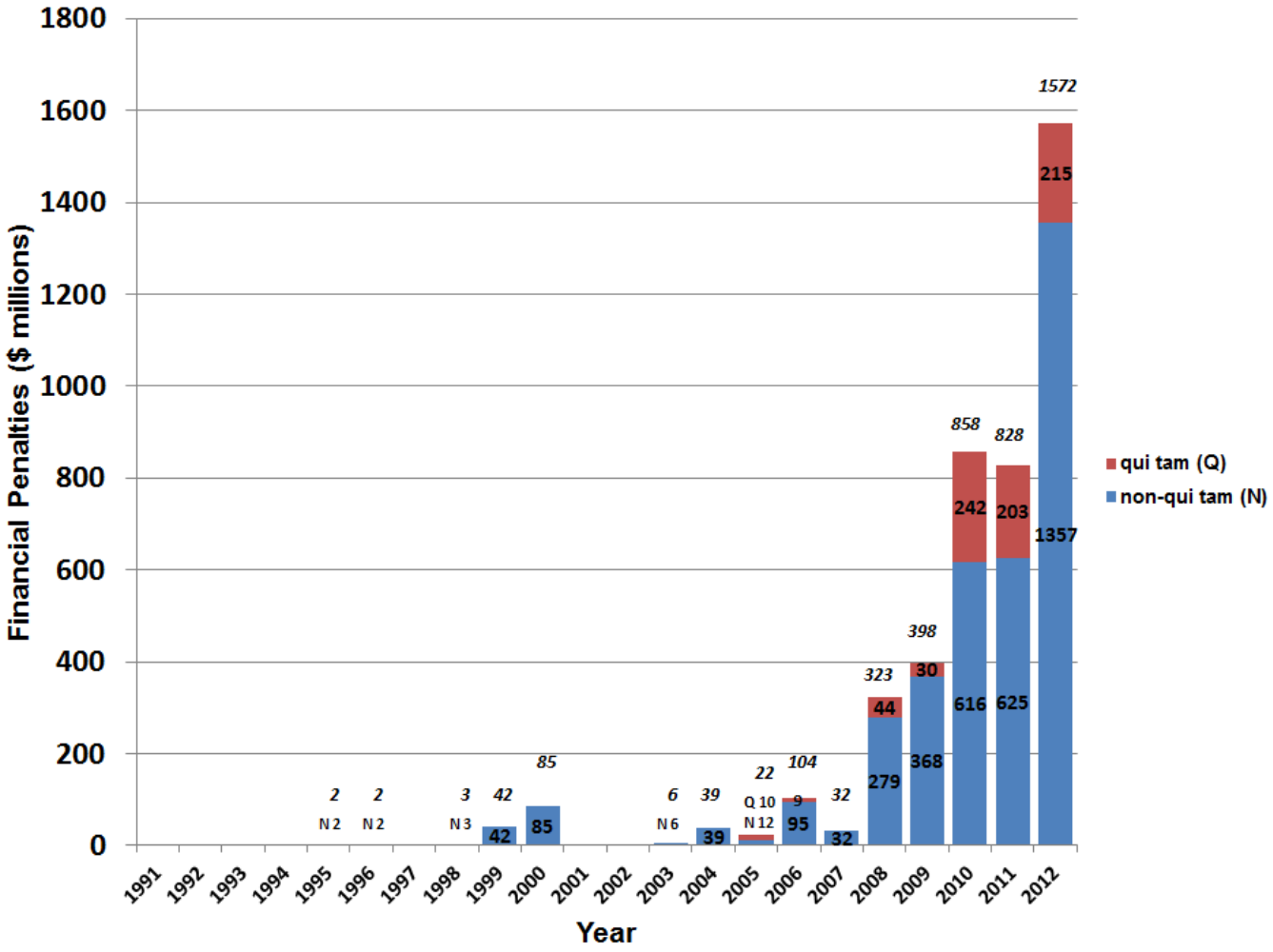
Figure 11. Qui Tam* ("Whistleblower") State Pharmaceutical Industry Settlements, 1991 – July 18, 2012**



*qui tam cases are those in which any part of the settlement was triggered by a qui tam action.

Overall state totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state non-qui tam case in CA in 2000 has been found and added and another state non-qui tam case in WV in 2009 has since been successfully appealed by the company and removed from the database. Ten non-qui tam cases (one in 1992, two in 2000, two in 2003, one in 2004, one in 2005, one in 2007, one in 2008, and one in 2009) that were classified as state settlements in the 2010 report were reclassified upon further review as federal settlements (see **Appendix 1).

Figure 12. Qui Tam* ("Whistleblower") State Pharmaceutical Industry Settlements, 1991 – July 18, 2012: Financial Penalties ($ millions)**



*qui tam cases are those in which any part of the settlement was triggered by a qui tam action.

Overall state totals for years 1992, 2000, 2003, 2004, 2005, 2007, 2008, and 2009, are slightly discrepant from the 2010 report. Since that report, one additional state non-qui tam case in CA in 2000 (for $85 million) has been found and added and another state non-qui tam case in WV in 2009 ($4.5 million) has since been successfully appealed by the company and removed from the database. Ten non-qui tam cases (one in 1992 [$22 million], two in 2000 [$149 and $255 million], two in 2003 [$62 and $80 million], one in 2004 [$1.5 million], one in 2005 [$30.7 million], one in 2007 [$5.5 million], one in 2008 [$1.1 million], and one in 2009 [$20 million]) that were classified as state settlements in the 2010 report were reclassified upon further review as federal settlements (see **Appendix 1).

Table 4. Pharmaceutical Company Penalties: Offending Companies, Nov. 2, 2010 – July 18, 2012

Company*	Total Financial Penalties	Percent of Total**	Number of Settlements†
GlaxoSmithKline	$3.06 billion	29.96%	6
Johnson & Johnson	$1.90 billion	18.63%	9
Abbott	$1.77 billion	17.32%	4
Merck	$1.04 billion	10.16%	11
Daiichi Sankyo	$500 million	4.90%	1
Mylan	$420 million	4.11%	10
Boehringer Ingelheim	$281 million	2.76%	3
Novartis	$257 million	2.52%	4
Actavis	$213 million	2.08%	5
Elan Corporation	$204 million	1.99%	1
Par Pharmaceutical Companies	$160 million	1.57%	4
Watson Pharmaceuticals	$81 million	0.79%	2
AstraZeneca	$71 million	0.70%	2
UCB	$34 million	0.34%	1
Novo Nordisk	$27 million	0.26%	2
Pfizer	$20 million	0.20%	4
Hoffman-La Roche	$20 million	0.20%	1
KV Pharmaceutical	$17 million	0.17%	1
B. Braun Melsungen	$15 million	0.14%	1
Dava Pharmaceuticals	$11 million	0.11%	1
Eisai	$11 million	0.11%	1
Takeda Pharmaceutical Company	$5 million	0.05%	1
Sanofi	$4 million	0.04%	4
Cypress Pharmaceutical	$3 million	0.03%	1
Ferring	$2 million	0.02%	1
Forest Laboratories	$2 million	0.02%	1
Bayer	$0	0.00%	1
Total	**$10.12 billion**	**99.2%**	**83**

*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.

**Percent of $10.207 billion in total penalties. Percentages do not add up to 100% as financial penalties from three settlements (totaling $85 million, or 0.8% of all financial penalties), including one with Bayer, were excluded due to inability to determine individual company share in settlement. These settlements were, however, included in the tabulation of the number of settlements attributable to each company.

† Total (83) listed here is greater than the total number of settlements over the time period (74) due to a number of multi-company settlements.

Table 5. Pharmaceutical Company Penalties: Worst Offenders, 1991 – July 18, 2012

Company*	Total Financial Penalties	Percent of Total†	Number of Settlements‡
GlaxoSmithKline	$7.56 billion	25.1%	20
Pfizer	$2.96 billion	9.8%	15
Johnson & Johnson	$2.33 billion	7.7%	14
Merck***	$1.86 billion	6.2%	27
Abbott	$1.82 billion	6.0%	12
Eli Lilly	$1.71 billion	5.7%	13
Schering-Plough	$1.34 billion	4.4%	7
AstraZeneca	$954 million	3.2%	7
TAP Pharmaceutical Products	$875 million	2.9%	1
Novartis	$793 million	2.6%	12
Bristol-Myers Squibb***	$789 million	2.6%	12
Mylan	$707 million	2.3%	19
Serono	$704 million	2.3%	1
Purdue	$620 million	2.1%	2
Allergan	$600 million	2.0%	1
Daiichi Sankyo	$500 million	1.7%	3
Cephalon	$425 million	1.4%	1
Boehringer Ingelheim	$329 million	1.1%	14
Forest Laboratories	$315 million	1.0%	4
Sanofi	$313 million	1.0%	10
Other**	$1.88 billion	6.2%	108
Total	**$29.35 billion**	**97.4%**	**303**

*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.

†Percent of $30.174 billion in overall penalties. Percentages do not add up to 100% as some cases (totaling $795 million, or 2.6% of all financial penalties) were excluded due to inability to determine individual company share in settlement.

‡Total (303) listed here is greater than the total number of settlements over the 1991-July 18, 2012 time period (239) as some settlements involved more than one company.

**Other companies (in order of total penalties paid): Bayer; Actavis; Elan Corporation; Teva; King Pharmaceuticals; Par Pharmaceutical Companies; Watson Pharmaceuticals; UCB; Genentech; KV Pharmaceutical; BASF; Intermune; AkzoNobel; Novo Nordisk; Biovail Pharmaceuticals; Sandoz; Jazz Pharmaceuticals; Hoffman-La Roche; Baxter; Amgen; B. Braun Melsungen; Geneva Pharmaceuticals; Bolar; Dava Pharmaceuticals; Eisai; Cell Therapeutics; Medicis; Modern Wholesale Drug Midwest; Takeda Pharmaceutical Company; Barr Pharmaceuticals; Warner Chilcott; Otsuka; Perrigo; Warner-Lambert; Cypress Pharmaceutical; Circa Pharmaceuticals; Alpharma; Ferring; Andrx; Aventis; Chinook; Evonik; Solvay; Lonza; Mitsubishi Tanabe; Mitsui; Nepera; Sumitomo; Vertellus

***The totals for two companies, Merck and Bristol-Myers Squibb, are discrepant from those obtained by adding the two companies' totals from the prior report (1991 – Nov. 1, 2010) and the current report (Nov. 2, 2010 – July 18, 2012; Table 4) for the following reasons. In the case of Bristol-Myers Squibb, one settlement for $100 million was erroneously assigned solely to Bristol-Myers Squibb in the previous report, but after review of additional sources, it was determined that another company, Watson Pharma, was also a party to the settlement, with no indication as to each company's share of financial penalties. In the case of Merck, five settlements with Dey for $11.6 million and one settlement with Schering-Plough/MSP Singapore Company for 5.4 million were all attributed to Merck after a review of additional sources showed that all companies were actually subsidiaries of Merck at the time of the settlements.

Table 6. Ten Largest Settlements and Judgments, Nov. 2, 2010 – July 18, 2012

Company	Total Penalty	Federal/ State	Year	Violation(s)*	Major Drug Products Involved (if applicable)**	Laws Violated (if known)***	Qui Tam†
GlaxoSmithKline	$3.0 billion	Federal	2012	unlawful promotion; kickbacks; concealing study findings; overcharging govt health programs	Paxil, Wellbutrin, Avandia	FCA; FDCA	Y
Abbott	$1.5 billion	Federal	2012	unlawful promotion; kickbacks	Depakote	FCA; FDCA; Anti-Kickback Statute	Y
Johnson & Johnson	$1.2 billion	State (AR)	2012	unlawful promotion	Risperdal		
Merck	$950 million	Federal	2011	unlawful promotion	Vioxx	FCA; FDCA	
Daiichi Sankyo	$500 million	Federal	2012	poor manufacturing practices; concealing study findings	Multiple	FDCA	
Johnson & Johnson	$327 million	State (SC)	2011	unlawful promotion	Risperdal		
Boehringer Ingelheim	$280 million	Federal	2010	overcharging govt health programs	Multiple	FCA	Y (Ven-a-Care)
Mylan	$280 million	Federal	2010	overcharging govt health programs	Albuterol, Cromolyn Sodium, Ipratropium	FCA	Y (Ven-a-Care)
Elan Corporation	$204 million	Federal	2010	unlawful promotion; kickbacks	Zonegran	FCA; FDCA	Y
Johnson & Johnson	$158 million	State (TX)	2012	unlawful promotion	Risperdal		Y

*Violations include those alleged in civil settlements, as well as violations for which companies were convicted, or to which companies pled guilty, in criminal settlements.

**If known from the press release; not necessarily a comprehensive list.

***Laws allegedly violated in civil settlements, or those under which companies were convicted or pled guilty in criminal settlements; not necessarily a comprehensive list. FCA (False Claims Act); FDCA (Food, Drug, and Cosmetic Act).

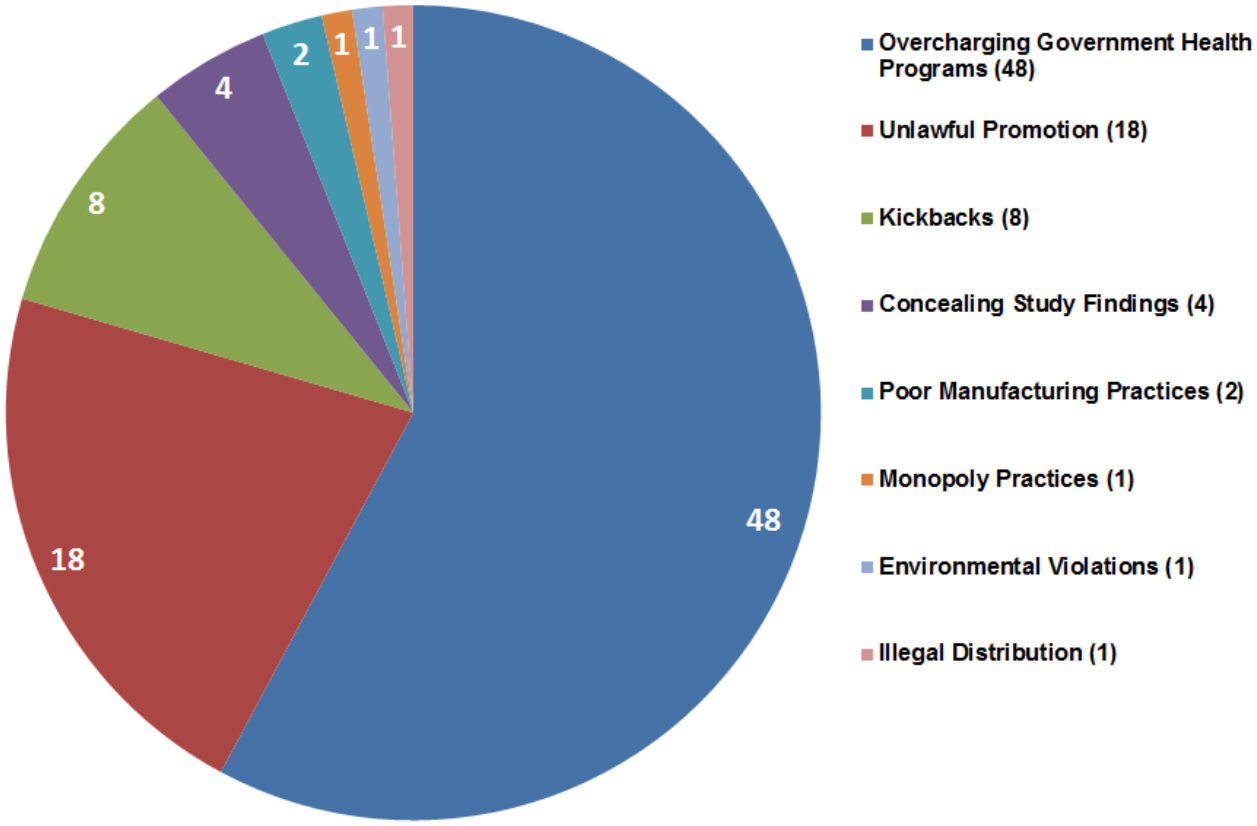
†Qui tam refers to settlements initiated by whistleblowers. Ven-a-Care is the small pharmacy in the Florida Keys responsible for initiating some of the largest settlements against the pharmaceutical industry.

Table 7. Twenty Largest Settlements and Judgments, 1991 – July 18, 2012

Company	Total Penalty	Federal/ State	Year	Violation(s)*	Major Drug Products Involved (if applicable)**	Laws Violated (if known)***	Qui tam†
GlaxoSmithKline	$3.4 billion	Federal	2006	Financial violation	N/A		
GlaxoSmithKline	$3.0 billion	Federal	2012	unlawful promotion; kickbacks; concealing study findings; overcharging govt health programs	Paxil, Wellbutrin, Avandia	FCA; FDCA	Y
Pfizer	$2.3 billion	Federal	2009	unlawful promotion; kickbacks	Bextra, Geodon, Zyvox, Lyrica	FCA; FDCA	Y
Abbott	$1.5 billion	Federal	2012	unlawful promotion; kickbacks	Depakote	FCA; FDCA; Anti-Kickback Statute	Y
Eli Lilly	$1.4 billion	Federal	2009	unlawful promotion	Zyprexa	FCA; FDCA	Y
Johnson & Johnson	$1.2 billion	State (AR)	2012	unlawful promotion	Risperdal		
Merck	$950 million	Federal	2011	unlawful promotion	Vioxx	FCA; FDCA	
TAP Pharmaceutical Products	$875 million	Federal	2001	overcharging govt health programs; kickbacks	Lupron	FCA; Prescription Drug Marketing Act	Y
GlaxoSmithKline	$750 million	Federal	2010	poor manufacturing practices	Kytril, Bactroban, Paxil CR, Avandamet	FCA; FDCA	Y
Serono	$704 million	Federal	2005	unlawful promotion; kickbacks; monopoly practices	Serostim	FCA	Y
Merck	$650 million	Federal	2008	overcharging govt health programs; kickbacks	Vioxx, Zocor, Pepcid	FCA; Medicaid Rebate Statute	Y
Purdue	$600 million	Federal	2007	unlawful promotion	Oxycontin	FCA	
Allergan	$600 million	Federal	2010	unlawful promotion	Botox	FCA; FDCA	Y
AstraZeneca	$520 million	Federal	2010	unlawful promotion; kickbacks	Seroquel	FCA; Anti-Kickback Statute	Y
Bristol-Myers Squibb	$515 million	Federal	2007	kickbacks; unlawful promotion; overcharging govt health programs	Abilify; Serzone	FCA; FDCA	Y (Ven-a-Care)
Schering Plough	$500 million	Federal	2002	poor manufacturing practices	Multiple		
Daichii Sankyo	$500 million	Federal	2012	poor manufacturing practices; concealing study findings	Multiple	FDCA	
Schering Plough	$435 million	Federal	2006	unlawful promotion; kickbacks; overcharging govt health programs	Temodar, Intron A, Claritin	FCA; FDCA	
Pfizer	$430 million	Federal	2004	unlawful promotion	Neurontin	FCA; FDCA	Y
Cephalon	$425 million	Federal	2008	unlawful promotion	Actiq, Gabitril, Provigil	FCA; FDCA	Y

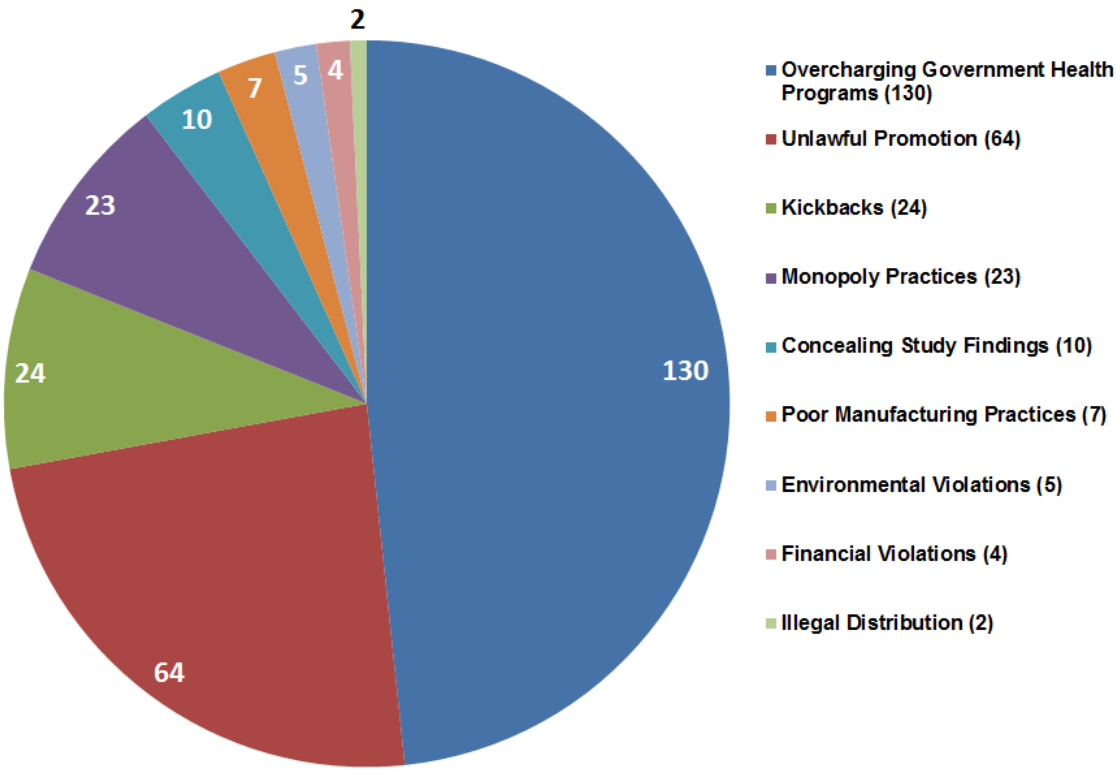
*Violations include those alleged in civil settlements, as well as violations for which companies were convicted, or to which companies pled guilty, in criminal settlements.
**If known from the press release; not necessarily a comprehensive list.
***Laws allegedly violated in civil settlements, or those under which companies were convicted or pled guilty in criminal settlements; not necessarily a comprehensive list. FCA (False Claims Act); FDCA (Food, Drug, and Cosmetic Act).
†Qui tam refers to settlements initiated by whistleblowers. Ven-a-Care is the small pharmacy in the Florida Keys responsible for initiating some of the largest settlements against the pharmaceutical industry.

Figure 13. Types of Pharmaceutical Industry Violations, Nov. 2, 2010 – July 18, 2012*



*Total number of violations (83) exceeds number of settlements (74) as some settlements involved more than one type of violation.

Figure 14. Types of Pharmaceutical Industry Violations, 1991 – July 18, 2012*

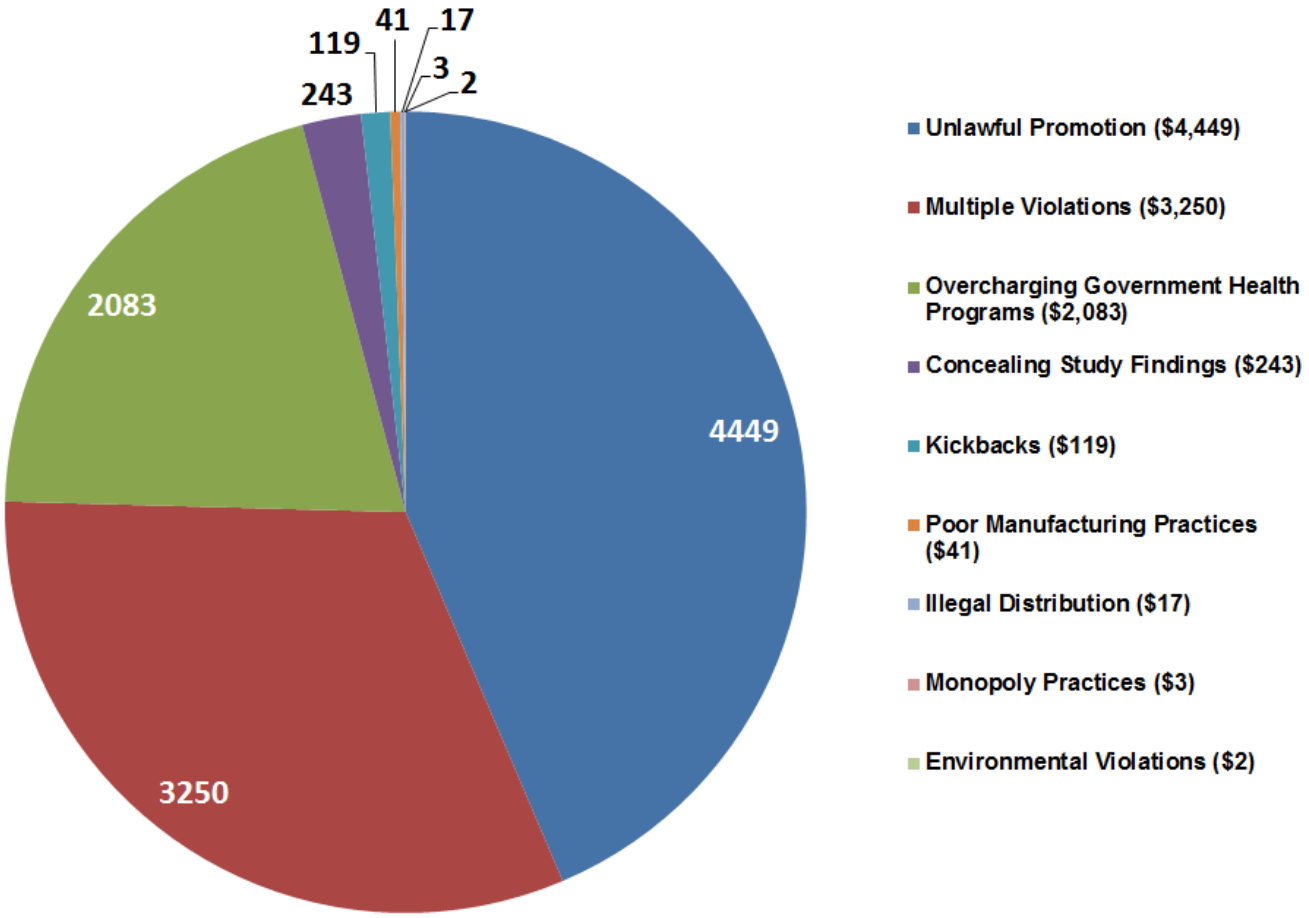


*Total number of violations (269) exceeds number of settlements (239) as some settlements involved more than one type of violation.

Totals presented here for each violation may be slightly discrepant from those obtained by adding the totals from the last report (1991 – Nov. 1, 2010) and the current report (Nov. 2, 2010 – July 18, 2012: **Figure 13) due to three errata in, and two modifications since, the previous report:

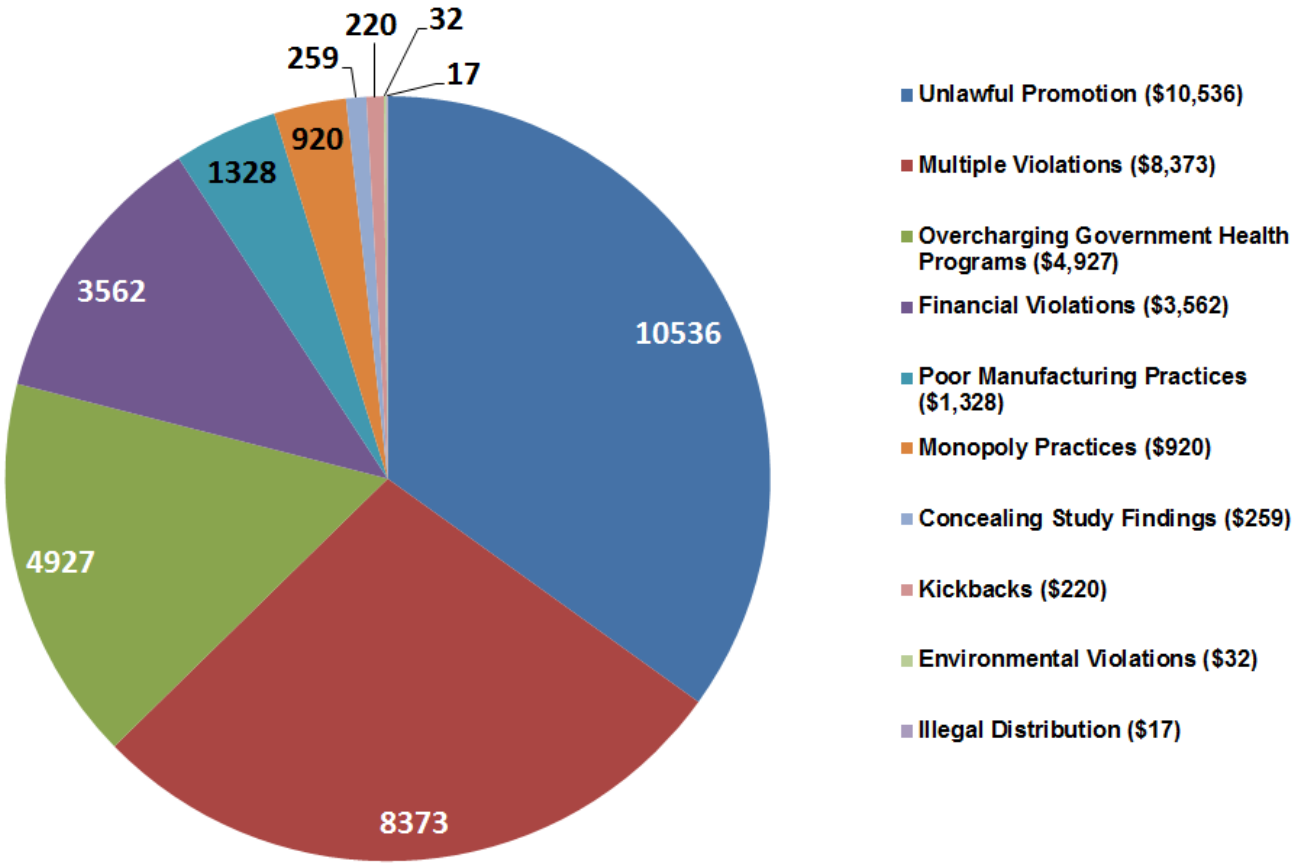
- Overcharging government health programs: the 2010 figure presented the total number of violations as 80 when it was actually 82
- Unlawful promotion: one unlawful promotion settlement in 2009 was removed from the database due to a successful appeal of the court judgment by the company
- Kickbacks: the 2010 figure presented the total number of violations as 17 when it was actually 16
- Monopoly practices: the 2010 figure presented the total number of violations as 20 when it was actually 21; in addition, a settlement involving monopoly practices in 2000 was found and added to the database since the last report.

Figure 15. Pharmaceutical Industry Financial Penalties by Type of Violation, Nov. 2, 2010 – July 18, 2012* ($ millions)



*In a revised methodology not used in the 2010 report, the settlements that involved more than one type of violation were reviewed and, where data was available in the press releases, individual penalties for each type of violation were determined and added to the violation total here.

Figure 16. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991 – July 18, 2012* ($ millions)



*In a revised methodology not used in the 2010 report, all settlements from 1991 through July 18, 2012 that involved more than one type of violation were reviewed and, where data was available in the press releases, individual penalties for each type of violation were determined and added to that violation's total. This new methodology resulted in discrepancies between the totals for some violations presented here and those obtained when adding the previous report's totals with the current totals in **Figure 15**.

Table 8. 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 the federal or state governments or the general public, or falsifying data submitted to the federal government
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

*This definition presented in Table 1 of the last report was incomplete, as it failed to include the additional elements presented in this, expanded definition. However, all older settlements had already been classified according to this expanded definition – only the table in the prior report was incorrect.