Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015

March 31, 2016

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Executive Summary

Background

In September 2012, Public Citizen published an updated analysis of all major financial settlements and court judgments[1] between pharmaceutical manufacturers and the federal and state governments from 1991 through July 18, 2012. At the time of the report's publication, over $30 billion had been paid 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.

The following study was undertaken to assess the level of settlement activity from the time period studied in the previous report through 2015, an additional 3½ years thereby providing collective data for the entire 25 years from 1991 through 2015.

Methods

Methodology from the 2012 report was replicated, the sole exception being that unlike the previous studies, this study includes federal and state settlements totaling less than $1 million. Therefore, the study includes all federal and state government settlements reached with pharmaceutical manufacturers from July 19, 2012, through 2015, but only settlements of at least $1 million for the period prior to July 19, 2012. In addition, the totals presented in this report for the period prior to July 19, 2012, are different from those listed in the previous report for several reasons, most notably the overturning on appeal of two previous state court judgments against Johnson & Johnson totaling $1.5 billion in fines. As in the prior report, 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.

Main Findings

From 1991 through 2015, a total of 373 settlements were reached between the federal and state governments and pharmaceutical manufacturers, for a total of $35.7 billion. Of these, 140 were federal settlements, for $31.9 billion, and 233 were state settlements, for $3.8 billion. Other key findings include the following:

- Financial penalties declined sharply since 2013. Just $2.4 billion in federal financial penalties were recovered in the most recent two-year period (2014-2015), less than one-third of the $8.7 billion in federal penalties in 2012-2013 and the lowest two-year total since 2004-2005. In contrast, the number of these federal settlements decreased only slightly, from 22 to 19, from 2012-2013 to 2014-2015. Thus, the average size of federal settlements declined from $395 million per settlement — $8.7 billion for the 22 settlements — in 2012-2013 to $126 million per settlement — $2.4 billion for 19 settlements — in 2014-2015, less than one-third of the average amount in the earlier interval.

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

- There were just 20 state settlements in the final two years of the study period (2014-2015), a nearly 80% drop from the 95 settlements in 2012-2013 and the lowest two-year total since 2006-2007. State financial penalties totaled just $424 million during these two most recent years — compared with $1.2 billion in 2012-2013 — a lower total than in any two-year period since 2007-2008.

- From 1991 through 2015, overcharging of government health insurance programs, mainly drug pricing fraud against state Medicaid programs, was the most common violation, while the unlawful promotion of drugs was the single violation that resulted in the largest financial penalties.

- Almost all of the decrease in the total number of settlements in 2014 and 2015 was attributable to the sharp decrease in the number of single-state settlements involving overcharging government health programs, from a combined 73 settlements in 2012 and 2013 to just five in 2014 and 2015, a 93% drop.

- The decline in total financial penalties in 2014 and 2015 was primarily due to a decrease in the size of federal settlements involving unlawful promotion, with federal financial penalties that could be attributed to unlawful promotion declining by 90% from nearly $2.8 billion in 2012-2013 to $263 million in 2014-2015. The combined total for these latter two years was lower than that for any single year since 2006. As was the case with overall federal financial penalties, this reflects a sharp decrease in the amount of the average penalty paid for unlawful promotion, since the number of federal unlawful promotion violations had declined only slightly, from 11 to eight.

- The most striking decrease in financial penalties involved criminal penalties (all of which, from 1991 through 2015, were federal). For 2012 and 2013 combined, criminal penalties totaled $2.7 billion, but by 2014-2015, the total had fallen to $44 million, a decrease of more than 98%.

- Qui tam (whistleblower) revelations, brought mostly under the False Claims Act, were responsible, at least in part, for 81 of 140 (58%) federal settlements, and $22.8 billion of $31.9 billion (71%) in federal penalties, from 1991 through 2015. By contrast, just 17 of 233 (7%) state settlements and $793 million of $3.8 billion (21%) in state financial penalties originated from qui tam actions. Of all state settlements originating from qui tam actions from 1991 through 2015, a single state, Texas, accounted for nine of 17 (53%) settlements and $409 million of $793 million (52%) in financial penalties.

- From 1991 through 2015, 29 states and the District of Columbia[2] reached at least one single-state settlement with a pharmaceutical company. Hawaii recovered the

[2] The District of Columbia is hereafter considered a "state" for the purposes of this report.

most money as a proportion of Medicaid drug expenditures (15%), South Carolina recouped the most money per enforcement dollar spent ($12.25), Louisiana had the most single-state settlements (55), and Texas finalized, by far, the most whistleblower-initiated settlements (nine). Overall, 17 of the 30 states with at least one single-state settlement from 1991 through 2015 attained a return on investment of $1 or greater for every dollar spent on enforcement of all (both pharmaceutical- and non-pharmaceutical-related) Medicaid fraud.

- From 1991 through 2015, GlaxoSmithKline and Pfizer reached the most settlements (31 each) and paid the most in financial penalties — $7.9 billion and $3.9 billion, respectively —to the federal and state governments. Johnson & Johnson, Merck, Abbott, Eli Lilly, Teva, Schering-Plough, Novartis, and AstraZeneca also paid more than $1 billion in financial penalties. Thirty-one companies entered into repeat settlements with the federal government from 1991 through 2015, with Pfizer (11), Merck (nine), GlaxoSmithKline, Novartis, and Bristol-Myers Squibb (eight each) finalizing the most federal settlements.

Conclusion

The number and size of federal and state settlements against the pharmaceutical industry decreased significantly in 2014 and 2015. It remains to be seen whether this decline represents a longer-term trend. Financial penalties continued to pale in comparison to company profits, with the $35.7 billion in penalties from 1991 through 2015 amounting to only 5% of the $711 billion in net profits made by the 11 largest global drug companies during just 10 of those 25 years (2003-2012). To our knowledge, a parent company has never been excluded from participation in Medicare and Medicaid for illegal activities, which endanger the public health and deplete taxpayer-funded programs. Nor has almost any senior executive been given a jail sentence for leading companies engaged in these illegal activities. Much larger penalties and successful prosecutions of company executives that oversee systemic fraud, including jail sentences if appropriate, are necessary to deter future unlawful behavior. Otherwise, these illegal but profitable activities will continue to be part of companies' business model.

Introduction

Public Citizen has published two previous reports, in 2010[3] and 2012[4], documenting the number and size of settlements and court judgments reached between the federal and state[5] governments and the pharmaceutical industry. The 2012 report revealed that the pace of settlement activity had increased considerably in the previous five-year period. The current report analyzes settlements announced since the data cutoff date for the last report (July 18, 2012) through 2015, an additional 3½ years, thereby providing collective data for the 25 years from 1991 through 2015.

Methods

Methodology was identical to that employed for the 2012 report (see Appendix 2 for more details and updated URLs), with the following exception: The previous reports included only settlements of $1 million or greater. For the period from July 19, 2012, through 2015, all settlements, including those for less than $1 million, were included. This was primarily to ensure that totals for smaller states (which are more likely to have smaller settlements) do not underrepresent those states' efforts in prosecuting Medicaid fraud. However, we did not retroactively search for, nor add, settlements of less than $1 million that were announced prior to the current study period (July 19, 2012). Therefore, for the period prior to July 19, 2012, this report still includes only settlements of $1 million or greater.

Of note, a few of the data corresponding to settlements included in the 2012 report's study period (1991 through July 18, 2012) have changed, as explained in Appendix 3. Finally, subtotals across the different parts of the "Results" section may not add up precisely to overall totals due to rounding.

Results

Overall trends

From 1991 through 2015, a total of 373 settlements were reached between the federal and state governments and pharmaceutical companies, for $35.7 billion (**Figures 1 and 2**).

A decline in the number and size of settlements was evident over the most recent two-year period (2014-2015). Thirty-nine settlements for $2.9 billion were announced during these two years, comprising, respectively, just 29% of the 135 settlements and 37% of the $7.8 billion in financial penalties announced during the 3 ½-year period since the cutoff date (July 18, 2012) of the last report. The most recent two-year period (2014 to 2015) had the

[3] Public Citizen. Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010. December 16, 2010. http://www.citizen.org/hrg1924. Accessed February 7, 2016.
[4] Public Citizen. Pharmaceutical Industry Criminal and Civil Penalties: An Update. September 27, 2012. http://www.citizen.org/hrg2073. Accessed February 7, 2016.
[5] The District of Columbia is considered a "state" for the purposes of this report.

fewest settlements and financial penalties of any two-year period since 2006-2007 and 2004-2005, respectively.

Per the new methodology, the current totals include 21 settlements under $1 million, worth a collective $9.7 million and announced from July 19, 2012, through 2015. Two of these settlements, for $500,000, were federal and 19, for $9.2 million, were state.

Federal settlements

From 1991 through 2015, a total of 140 federal settlements were reached, for $31.9 billion (**Figures 3 and 4**). Just $2.4 billion in federal financial penalties was recovered in the most recent two-year period (2014-2015), less than one-third of the $8.7 billion in federal penalties in 2012-2013 and the lowest two-year total since 2004-2005. In contrast, the number of these federal settlements decreased only slightly, from 22 to 19, between the 2012-2013 and 2014-2015 periods. Thus, the average size of federal settlements declined from $395 million per settlement — $8.7 billion for the 22 settlements — in 2012-2013 to $126 million per settlement — $2.4 billion for 19 settlements — in 2014-2015, less than one-third of the average amount in the earlier interval. Moreover, half ($1.2 billion) of the 2014-2015 total was due to a single, non-DOJ settlement of $1.2 billion in 2015 between the Federal Trade Commission (FTC) and Teva over alleged monopoly practices.

State settlements

From 1991 through 2015, 233 state settlements were reached for $3.8 billion (**Figures 3 and 4**). There were just 20 state settlements in the final two years of the study period (2014-2015), the lowest two-year total since 2006-2007. State financial penalties totaled just $424 million — lower than any two-year period since 2007-2008 — during these two most recent years, compared with $1.2 billion in 2012-2013.

Single-state settlements

From 1991 through 2015, 199 (85%) of the 233 state settlements were single-state settlements and $2.3 billion (60%) of the $3.8 billion in state financial penalties were recovered from single-state settlements. The number of single-state settlements decreased precipitously beginning in 2014, with just 17 reached by nine different states (for $213 million) in 2014 and 2015 (**Figures 5 and 6**).

From 1991 through 2015, 30 states reached at least one single-state settlement with a pharmaceutical company (**Table 1**). Hawaii, New Mexico, South Carolina, and Louisiana, from 1991 through 2015, recovered the most in financial penalties as a proportion of state Medicaid prescription drug expenditures from fiscal year (FY) 2001 to FY 2013, with recoveries of 4% to 15% of the total of each state Medicaid program's spending on drugs over that period (percentages presented as dollars per $1,000 in **Table 1**). The 30 states with at least one single-state settlement recouped a median of approximately 1% ($9.50 per $1,000) and a mean of 2% ($21.64 per $1,000) of their total FY 2001-2013 Medicaid drug expenditures through these settlements. Of the 10 states with the highest Medicaid

prescription drug expenditures from FY 2001 to FY 2013, seven (California, Missouri, North Carolina, Ohio, Illinois, Florida, and New York) all had recoveries from single-state settlements less than the median $9.50 per $1,000, while another (Tennessee) apparently had no single-state settlements.

Twenty-three (77%) of the 30 states with at least one single-state settlement had a False Claims Act (FCA) enacted as of 2015. The seven states without an FCA recouped a far higher median of approximately 2.7% ($27.38 per $1,000) of their total FY 2001-2013 Medicaid drug expenditures than the 23 with an FCA, including the nine with a Deficit Reduction Act (DRA)-compliant FCA (0.7%, or $7.34 per $1,000 for each of these two latter categories of states; see **Appendix 2**, "State FCA status and settlement activity", for an explanation of DRA-compliant FCAs). However, single-state settlements tended to be larger in states with an FCA ($12.9 million average per settlement) than in those without an FCA ($8.7 million average per settlement). States with a DRA-compliant FCA had the largest settlements, averaging $21.8 million per settlement. Notably, 18 of 41 states with an FCA by 2015 had not yet had a single-state settlement.

Seventeen of the 30 states with at least one single-state settlement attained a return on investment (ROI) of $1 or greater per enforcement dollar spent, meaning they recouped enough money through financial penalties from these settlements alone to offset their entire Medicaid fraud enforcement budgets from FY 2006 to FY 2015 (**Table 1**). South Carolina, Alabama, Hawaii, and Idaho had the highest ROIs, returning between $6 and $12 to the state for every $1 spent on enforcement of pharmaceutical- and non-pharmaceutical-related Medicaid fraud.

Overall, from 1991 through 2015, the $1.2 billion recovered in single-state settlements by just the top four states (Texas, Louisiana, South Carolina, and Pennsylvania) represented over one-half (53%) of all single-state penalties and nearly one-third (32%) of all state financial penalties. Louisiana had the most single-state settlements (55), followed by Kentucky (20) and Texas (19).

Multi-state settlements

From 1991 through 2015, there were 34 multi-state settlements totaling approximately $1.5 billion, representing 15% of state settlements and 40% of state financial penalties, respectively. Every state participated in at least one multi-state settlement from 1991 through 2015, with two of the 34 multi-state settlements involving all 50 states and the District of Columbia. States participated in a median of 21 multi-state settlements from 1991 through 2015. Arizona, Florida, and Texas participated in the most multi-state settlements (28 each), followed by California, Massachusetts, North Carolina, and Vermont with 27 each (**Table 2**). Just $790 million (52%) of the $1.52 billion in multi-state settlement financial penalties were attributable as individual states' shares of those settlements.

Overall (single- and multi-state combined) state settlement totals and state FCA status

Table 3 lists the overall state settlement tallies (single- and multi-state combined) for all 51 states from 1991 through 2015. Louisiana (65 settlements), Texas (47), Idaho (38), and Kentucky (37) participated in the most settlements, while New Hampshire (eight settlements), Georgia (seven), and Wyoming (six) participated in the fewest.

Civil versus criminal settlements

From 1991 through 2015, there were 329 civil settlements, 35 civil-criminal settlements, and nine criminal settlements, with $28 billion in civil penalties and $7.8 billion in criminal penalties (**Figures 7 and 8**). Criminal penalties (all of which, from 1991 through 2015, were federal) decreased precipitously over the past two years. For 2012-2013 combined, criminal penalties totaled $2.7 billion, but by 2014-2015, the total had fallen to $44 million, a decrease of more than 98%. There were just two civil-criminal settlements in 2014-2015, down from nine in 2012-2013, and there have been no criminal settlements since 2012.

Among federal settlements, the FCA was the most commonly invoked law in civil settlements, while the Food, Drug, and Cosmetic Act (FDCA) was the most commonly invoked law in criminal cases. All civil-criminal and criminal settlements were federal. In civil-criminal settlements, the violation most commonly resulting in a criminal fine under the FDCA was unlawful promotion (mainly off-label marketing), while violations of the Foreign Corrupt Practices Act (FCPA) were the focus of four of the six criminal settlements since 2009 (although only one FCPA settlement was announced from 2013 to 2015).

FCA and qui tam (whistleblower) settlements

From FY 1991 through FY 2015, at least $10.5 billion in financial penalties were paid by the pharmaceutical industry to the federal government under the FCA, nearly twice the $5.6 billion paid by the defense industry for FCA fraud over the same period.[6] The pharmaceutical industry continued to outpace the defense industry in such payouts from FY 2013 to FY 2015 (**Figure 9**), with $2.2 billion, compared with $1.0 billion paid by the defense industry. While pharmaceutical FCA penalties declined precipitously in FY 2015 to $36 million, they increased again to $401 million through the first three months of FY 2016 (results not shown in figure).

Qui tam (whistleblower) revelations, brought mostly under the FCA, were responsible, at least in part, for 81 of 140 (58%) federal settlements, and $22.8 billion of $31.9 billion (71%) in federal penalties, from 1991 through 2015. This trend continued in recent years, with qui tam settlements responsible, at least in part, for 20 of 29 (69%) federal settlements and $4.1 billion of $5.6 billion (73%) in federal penalties from 2013 through 2015 (**Figures 10 and 11**).

By contrast, from 1991 through 2015, a much lower proportion of state settlements (17 of 233; 7%) and state financial penalties ($793 million of $3.8 billion; 21%) originated from

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

qui tam actions (**Figures 12 and 13**). No state settlements in 2014 and 2015 involved qui tam revelations. Of the 17 state settlements for $793 million originating from qui tam actions from 1991 through 2015, nine (53%) of the settlements and $409 million (52%) of the financial penalties resulted from investigations undertaken by a single state: Texas.

Worst offenders, repeat offenders, and largest settlements

Table 4 presents the 20 companies responsible for having paid the most in financial penalties to the federal and state governments from 1991 through 2015. GlaxoSmithKline and Pfizer top this list with $7.9 billion and $3.9 billion, respectively, and also reached more settlements (31 each) with the federal and state governments than any other companies. Johnson & Johnson, Merck, Abbott, Eli Lilly, Teva, Schering-Plough, Novartis, and AstraZeneca were the other companies that paid more than $1 billion in financial penalties from 1991 through 2015. Thirty-one companies entered into repeat settlements with the federal government from 1991 through 2015, with Pfizer (11), Merck (nine), GlaxoSmithKline, Novartis, and Bristol-Myers Squibb (eight each) finalizing the most federal settlements (**Table 5**). Thirty companies were forced to settle more than once with the federal government from 2000 through 2015. **Table 6** presents the 20 companies responsible for paying the most in financial penalties from July 19, 2012, through 2015.

Table 7 lists the 20 largest settlements (all federal) from 1991 through 2015, with seven settlements involving more than $1 billion in penalties. Three companies had more than one settlement among the Top 20 list (GlaxoSmithKline with three, Pfizer with two, and Merck with two). **Table 8** presents the 20 largest settlements from July 19, 2012, through 2015.

Types of violations (violation categories defined in Table 9)

Overcharging of government health programs and unlawful promotion were the most cited violations in settlements from 1991 through 2015, with 201 (48% of all violations) and 105 (25%) occurrences, respectively (**Figure 14**). These were also the two violations resulting in the most financial penalties from 1991 through 2015, with $11.1 billion (31% of all financial penalties) paid for unlawful promotion and $5.1 billion (14%) for overcharging government health programs. (**Figure 15**). **Figures 16 and 17** present the total number of violations, and financial penalties per violation, respectively, from July 19, 2012, through 2015.

The decrease in the number of single-state settlements in 2014 and 2015 was attributable almost entirely to the decline in cases involving overcharging government health programs (mainly Medicaid pricing fraud), from 44 such settlements in 2010-2011 and 73 in 2012-2013 to just five in 2014-2015 (results not shown in figures). The decline in federal financial penalties in the two-year period from 2014 to 2015 was due to a decrease in the size of settlements involving unlawful promotion,[7] with discernable financial penalties for

[7] The slight resurgence in financial penalties in 2015 was largely due to a single $1.2 billion Federal Trade Commission settlement with Teva's Cephalon subsidiary over monopoly practices. This settlement made up

unlawful promotion decreasing from $2.8 billion in 2012-2013 to just $263 million in 2014-2015 (figures not shown). As was the case with overall federal financial penalties, this reflects a sharp decrease in the amount of the average penalty paid for unlawful promotion, since the number of federal unlawful-promotion violations had declined only slightly, from 11 to eight.

Discussion

This report demonstrates that the number and size of federal and state settlements against the pharmaceutical industry decreased significantly over the 3½-year period following our last report. The decrease was due to the last two years (2014-2015) of the study period. The two-year period from 2014 to 2015 had the fewest settlements and financial penalties of any two-year period since 2006-2007 and 2004-2005, respectively.

The decline in the number of settlements was largely due to a dramatic drop in single-state settlements for overcharging government health programs, while the decrease in the amount of financial penalties resulted mainly from markedly smaller federal settlements, particularly those reached by DOJ over unlawful promotion. It remains to be seen whether this dropoff in settlement activity represents a longer-term trend of declining federal and state enforcement of pharmaceutical industry fraud and, in particular, of off-label promotion.

The largest settlement announced since the last report, and the third-largest health fraud settlement in history, was reached with Johnson & Johnson. The company paid $2.0 billion in a federal settlement in which it pleaded guilty to off-label promotion of its blockbuster antipsychotic drug Risperdal for use in elderly patients with dementia.[8] Johnson & Johnson was also the focus of the largest state settlement during the study period, a multi-state settlement for $181 million that resolved the same allegations of off-label promotion of Risperdal, as well as the unlawful marketing of Johnson & Johnson's other atypical antipsychotic drug, Invega.[9]

Federal settlements

Decline in federal financial penalties for unlawful promotion in 2014 and 2015

58% of federal financial penalties in 2015: Federal Trade Commission. FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics. May 28, 2015. https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill. Accessed February 1, 2016.

[8] Department of Justice. Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations. November 4, 2013. http://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations. Accessed January 29, 2016.

[9] State of Connecticut. Office of the Attorney General. Connecticut Joins $181 Million Settlement With Janssen Pharmaceuticals, Inc. Subsidiary of Johnson & Johnson. August 30, 2012. http://www.ct.gov/ag/cwp/view.asp?A=2341&Q=510130. Accessed January 30, 2016.

Of the nine different violation categories documented in settlements from 1991 through 2015, unlawful promotion (primarily off-label marketing) resulted in the most federal financial penalties. However, the financial penalties from such settlements, initiated by DOJ, have declined dramatically since 2013. The reason for this sudden decline is not entirely clear and several factors may be at play.

The 2012 *United States v. Caronia* decision is widely regarded as pivotal in determining the permissible boundaries of off-label marketing.[10] The government brought the case against Alfred Caronia, a former sales representative for Orphan Medical who was charged with marketing the company's drug, Xyrem, for an unapproved use. Although Xyrem was approved only for narcolepsy, Caronia was accused of promoting the drug to physicians for a number of other conditions, including insomnia and fibromyalgia. After his conviction in 2008, Caronia appealed, arguing that the federal government's prosecution violated his right to free speech. The United States Court of Appeals for the Second Circuit agreed with Caronia and overturned the conviction, ruling "that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."[11]

It is difficult to determine whether this decision had any impact on the federal government's willingness to initiate investigations of pharmaceutical companies for off-label promotional activities. Previously, large federal off-label marketing investigations had focused on particularly egregious cases (both admitted and alleged) involving downplaying the side effects of dangerous drugs, systematic (rather than lone-employee) efforts to deceive physicians and the FDA regarding the safety or effectiveness of drugs, and kickbacks.[12] In addition, even before the *Caronia* decision in December 2012, DOJ officials were claiming, in January 2012, that that the era of "really big, corporate-wide, off-label" promotional activity had ended and that large off-label marketing cases were already on the decline.[13] According to *The Pink Sheet*, the officials alluded to a shift in the focus of DOJ

[10] Thomas K. Ruling Is Victory for Drug Companies in Promoting Medicine for Other Uses. The New York Times. December 3, 2012. http://www.nytimes.com/2012/12/04/business/ruling-backs-drug-industry-on-off-label-marketing.html. Accessed March 9, 2016.
[11] United States Court of Appeals for the Second Circuit. Docket No. 09-5006-cr. Decision in United States of America v. Alfred Caronia. http://www.ca2.uscourts.gov/decisions/isysquery/134617f8-8631-47b7-8046-70e82cb22508/1/doc/09-5006_complete_opn.pdf. Accessed March 9, 2016.
[12] See e.g. Department of Justice. GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data. July 2, 2012. https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report; Department of Justice. Justice Department Announces Largest Health Care Fraud Settlement in Its History. September 2, 2009. https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history; Department of Justice. Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations. November 4, 2013. https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations; Department of Justice. Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote. May 7, 2012. https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote. All links accessed March 10, 2016.
[13] Sutter S. Economic Superiority Claims, Manufacturer/Payer Relationships Ripe for Enforcement Scrutiny. The Pink Sheet. February 2012.

enforcement to "false and misleading claims" regarding drugs' safety, effectiveness, and economic superiority outside the context of off-label marketing.[14]

Although it is possible that, in spite of miniscule fines and virtually no executive accountability, drug companies decided to increase their compliance with federal laws regarding off-label marketing, to our knowledge no evidence verifies any such change. For one, annual compliance reports submitted to the federal government by companies that have entered into previous federal settlements (required under corporate integrity agreements, or CIAs) are not publicly disclosed, with litigation thus far unsuccessful in obtaining the full reports.[15] Furthermore, we are not aware of data showing a decline in the number of qui tam complaints related to off-label marketing and the number of qui tam lawsuits submitted to DOJ for alleged wrongdoing on the part of all (pharmaceutical and non-pharmaceutical combined) HHS-contracting industries has remained constant since the latest upsurge in FY 2011.[16]

Finally, the decrease in government enforcement action against off-label marketing to physicians may indicate that drug companies have shifted to other tactics in order to maximize off-label uses of their most lucrative drugs. Previous federal settlements have often involved sensational cases of marketing and kickbacks directed at individual physicians.[17] Increasing restrictions by academic medical centers on drug detailing and other drug company-faculty ties,[18] the implementation of the Open Payments database that has made public all payments from drugmakers to physicians,[19] and a shifting pharmaceutical marketing landscape[20] may have prompted companies to move towards other, perhaps as-yet undetected ways of promoting off-label uses. The pressure to maximize off-label uses of medications has, if anything, increased in recent years due to a sharp spike in approvals[21] of high-priced[22] drugs for rare diseases with small approved

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https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet/75/1/Economic_claims.pdf. Accessed March 10, 2016.

[14] *Ibid*.

[15] Public Citizen. Public Citizen v. Department of Health and Human Services http://www.citizen.org/litigation/forms/cases/getlinkforcase.cfm?cID=752. Accessed March 10, 2016.

[16] Department of Justice, Civil Division. Fraud Statistics – Health and Human Services. October 1, 1987 – September 30, 2015. http://www.justice.gov/opa/file/796866/download. Accessed March 8, 2016.

[17] See footnote 12.

[18] Policy and Medicine. AMSA Expanding Anti-Industry Scorecard to 400 Teaching Hospitals. April 16, 2013. http://www.policymed.com/academic-detailing/. Accessed March 10, 2016.

[19] Center for Medicare and Medicaid Services. Open Payments. https://openpaymentsdata.cms.gov/. Accessed March 10, 2016.

[20] Sullivan, Charles A. and Boozang, Kathleen and Greenwood, Kate, The False Claims Act and the Policing of Promotion Claims About Drugs: A Call for Increased Transparency (September 15, 2015). Available at SSRN: http://ssrn.com/abstract=2674670. Accessed March 15, 2016. This white paper, authored by the Seton Hall University School of Law's Center for Health & Pharmaceutical Law & Policy, extensively reviewed and discussed the enforcement landscape pertaining to off-label promotion. The Center is partly funded by the pharmaceutical industry (See e.g. Appendix B, p. 69 of the report).

[21] Karst KR. Orphan Drug Approvals Dipped in 2015, While Designations and Designation Requests Continue Upward Trend. FDA Law Blog. February 9, 2016. http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/02/orphan-drug-approvals-dipped-in-2015-while-designations-and-designation-requests-continue-upward-tre.html. Accessed March 10, 2016.

patient populations. According to The Seattle Times, from 2005 to 2013, drugmakers and the federal government settled at least 13 cases involving the unlawful marketing of orphan drugs, including off-label marketing.[23]

Unlawful promotion: recent developments, possible factors for future trends

The 1997 Food and Drug Administration Modernization Act outlined conditions under which pharmaceutical and medical device companies would be allowed to disseminate information to physicians that discussed unapproved uses of drugs and devices.[24] The Food and Drug Administration (FDA) implemented this legislation through regulations that specifically permitted, under certain conditions, the distribution of medical journal articles and scientific reference texts describing off-label uses.[25] After this legislation and its implementing regulations expired in 2006, the FDA reaffirmed its position in a 2009 guidance.[26]

In 2014, the FDA released two draft guidances further expanding the scope of permissible off-label promotion to physicians. The first guidance, released in February, added clinical practice guidelines to the list of materials discussing unapproved uses that drugmakers could distribute to physicians during promotional visits.[27] The second guidance, released in June, informed drug companies that the FDA "does not intend to object to the distribution [to physicians] of new risk information that rebuts, mitigates, or refines risk information in the approved labeling" and that has not been reviewed by the agency.[28] This latter guidance

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[22] EvaluatePharma. Orphan Drug Report 2014. October 2014. http://info.evaluategroup.com/rs/evaluatepharmaltd/images/2014OD.pdf. Accessed March 10, 2016.
[23] Armstrong K, Berens JM. How a drug for few patients was turned into $81 million in sales. The Seattle Times.
November 16, 2013. http://apps.seattletimes.com/reports/pharma-windfall/2013/nov/9/seattle-biotech-orphan-drug/.
Accessed March 10, 2016.
[24] Food and Drug Administration. Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices. February 2014. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf. Accessed January 29, 2016. The legislation and its implementing regulations subsequently survived a constitutional challenge from the Washington Legal Foundation (see next footnote).
[25] Food and Drug Administration. Notice: Decision in Washington Legal Foundation v. Henney. 65 Fed. Reg. 14286, March 16, 2000. http://www.fda.gov/OHRMS/DOCKETS/98fr/031600b.pdf. Accessed February 7, 2016.
[26] Food and Drug Administration. Guidance for Industry — Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. January 2009. http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm. Accessed January 29, 2016.
[27] Food and Drug Administration. Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices. February 2014. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf. Accessed January 28, 2016.
[28] Food and Drug Administration. Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products — Recommended

elicited a sharp public response, with more than 1,700 physicians, consumers, and others opposing the guidance in comments submitted to the agency.[29]

In May 2015, the drugmaker Amarin sued the FDA, claiming that the agency's restrictions on off-label promotion impinged on its First Amendment right to relay truthful and non-misleading information to physicians about an unapproved use of its drug Vascepa.[30] The FDA responded to the lawsuit with a letter to the company pointing out that "virtually all of the communications" at issue in the lawsuit fall within the scope of off-label promotion already permitted by the agency in various guidance documents.[31] Despite the FDA's letter, the company did not withdraw its suit and a U.S. district court subsequently ruled in Amarin's favor on its motion seeking a preliminary injunction.[32] The FDA and Amarin reached a settlement on March 8, 2016, which allowed Amarin to promote Vascepa for the off-label treatment of persistently high trigylcerides.[33,34]

Practices. June 2014. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm400104.pdf. Accessed January 30, 2016.

[29] Public Citizen. Press Release: 99 Percent of Commenters Agree: FDA Proposed Guidance Is a Bad Idea, Undermines Purpose of FDA and Puts Patients at Risk. March 11, 2015. http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5437. Accessed March 8, 2016.

[30] Thomas K. Drugmaker Sues F.D.A. Over Right to Discuss Off-Label Uses. *New York Times*. May 7, 2015. http://www.nytimes.com/2015/05/08/business/drugmaker-sues-fda-over-right-to-discuss-off-label-uses.html. Accessed January 30, 2016. The FDA had approved Vascepa only for use in patients with very high triglyceride levels. Amarin had conducted a clinical trial (known as the ANCHOR trial) in patients with less severe triglyceride elevations, which showed that the drug reduced triglyceride levels. However, the FDA concluded that the trial results were inadequate to support approval of the new use, given the absence of evidence from other trials that reducing triglycerides in patients with less severe elevations was effective in reducing the risk of heart disease. Amarin's suit challenged FDA restrictions on what information it could distribute to physicians about the ANCHOR trial. Source: U.S. Food and Drug Administration. Letter to Amarin Pharma, Inc. June 5, 2015. http://freepdfhosting.com/702316334b.pdf. Accessed January 30, 2016.

[31] Food and Drug Administration. Letter to Amarin Pharma, Inc. June 5, 2015. http://freepdfhosting.com/702316334b.pdf. Accessed January 30, 2016.

[32] Amarin Pharma Inc. v. United States Food and Drug Administration. Opinion & Order. Filed August 7, 2015. http://www.fdalawblog.net/Amarin%20Decision%208-2015%20Off-Label.pdf. Accessed March 13, 2016.

[33] [Proposed] Stipulation and Order of Settlement, Amarin v. FDA, No. 15 Civ 3588 (S.D.N.Y. Mar. 8, 2016), http://files.shareholder.com/downloads/AMRN/1666903329x0x879932/A9BE5FCE-A228-429F-8394-DE4D76DAFACF/AMRN.pdf. Accessed March 14, 2016.

[34] In December 2015, the agency settled another lawsuit filed by the drugmaker Pacira Pharmaceuticals in response to a 2014 warning letter from the FDA that claimed that the company was marketing its pain drug Exparel for off-label surgical procedures. In that case, the FDA withdrew its warning letter and acknowledged that the original FDA-approved indication was broad and encompassed the additional surgical procedures for which Pacira had been marketing Exparel. See: Thavaseelan VE. FDA Settles Exparel Marketing Lawsuit, Signaling Change for Off-Label FCA Cases. *FCA Update* (McDermott, Will & Emery). January 11, 2016. http://www.fcaupdate.com/2016/01/fda-settles-exparel-marketing-lawsuit-signaling-change-for-off-label-fca-cases/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=View-Original; and Food and Drug Administration. Letter to Pacira. December 14, 2015. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM477250.pdf. Both links accessed March 16, 2016.

It is not clear to what extent the Caronia and Amarin decisions, as well as the 2014 guidance documents that eased FDA restrictions on off-label promotion, will compromise the success of future federal and state investigations into marketing practices that violate the FDCA and FDA regulations.

Globalized fraud: Criminal and civil penalties not limited to U.S.-based violations

In June 2013, the Chinese government announced that it had begun an investigation into a suspected bribery ring orchestrated by GlaxoSmithKline's subsidiary in China.[35] The company's local subsidiary was eventually found guilty and fined nearly $500 million by the Chinese government for the misconduct. GlaxoSmithKline now faces an ongoing investigation by DOJ and the Securities and Exchange Commission over the bribery charges.[36]

The investigation is emblematic of a recent federal focus, under the FCPA, on pharmaceutical company bribery of foreign public officials, such as government-employed physicians and health officials in poor countries in Eastern Europe and Asia.[37] From 1991 through 2015, five pharmaceutical companies (Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Novo Nordisk, and Pfizer) paid a total of $183 million in seven separate criminal and civil settlements over FCPA violations. All of these settlements have occurred since 2009. And according to The FCPA Blog, at least 11 pharmaceutical manufacturers were under investigation for potential FCPA violations as of December 2015.[38] It may be that drugmakers have shifted resources towards burgeoning and ever more lucrative developing-world markets where fraud may be more difficult for the federal government to detect and, if prosecuted, has thus far resulted in far smaller penalties than previous settlements for domestic off-label marketing violations.

Monopoly practices, increasing generic industry consolidation, and responses

[35] Plumridge H, Burkitt L. GlaxoSmithKline Found Guilty of Bribery in China. *Wall Street Journal*. September 19, 2014. http://www.wsj.com/articles/glaxosmithkline-found-guilty-of-bribery-in-china-1411114817. Accessed January 22, 2016.

[36] Ward A. Bristol-Myers Squibb shakes up China operations to combat bribery. *Financial Times*. March 8, 2016. http://www.ft.com/intl/cms/s/0/79d2c1d8-e542-11e5-bc31-138df2ae9ee6.html#axzz43jsh2RPd. Accessed March 23, 2016. In July 2015, a company whistleblower revealed further allegations of bribery of foreign physicians, this time in Romania. The company is reportedly also looking into alleged bribery in Poland, the United Arab Emirates, Lebanon, Jordan, Syria and Iraq. (Hirschler B. Exclusive: GSK faces new corruption allegations, this time in Romania. Reuters. July 29, 2015. http://www.reuters.com/article/us-gsk-romania-corruption-exclusive-idUSKCN0Q32A920150729. Accessed January 22, 2016.)

[37] Ceresney A, Director, Division of Enforcement, Securities and Exchange Commission. FCPA, Disclosure, and Internal Controls Issues Arising in the Pharmaceutical Industry: Remarks at CBI's Pharmaceutical Compliance Congress in Washington D.C. March 3, 2015. https://www.sec.gov/news/speech/2015-spch030315ajc.html. Accessed March 8, 2016.

[38] Cassin R. The Corporate Investigations List (January 2016). The FCPA Blog. January 5, 2016. http://www.fcpablog.com/blog/2016/1/5/the-corporate-investigations-list-january-2016.html. Accessed March 8, 2016. All entries are based solely on filings to the Securities and Exchange Commission.

For many years, branded and generic drug manufacturers have entered into what are known as "pay-for-delay" deals, in which the brand-name manufacturer pays the generic manufacturer to delay entry of a generic drug into the market.[39] The FTC has estimated that such deals between brand-name and generic pharmaceutical companies have cost consumers and taxpayers $3.5 billion per year in higher drug costs.[40] The FTC has challenged some of these deals as violating antitrust laws. The manufacturer-defendants in some of these lawsuits argued that the FTC lacked the authority to do so. In 2013, the U.S. Supreme Court held that these settlement agreements may be, but are not necessarily, unlawful, allowing such FTC challenges to continue.[41]

The FTC reported that pay-for-delay settlements in FY2014, the first complete fiscal year since the Supreme Court's decision, had declined to 21, a decrease of roughly one half from a record high of 40 in FY 2012, the year prior to the decision.[42] And in 2015, the agency finalized a $1.2 billion settlement (the largest federal settlement with a drugmaker since 2013) with Teva's Cephalon subsidiary for allegedly paying four different generics makers a total of $300 million to delay introducing generic versions of its Provigil sleep medication until 2012.[43] The agency cited the 2013 Supreme Court decision in support of its allegations that such actions could violate antitrust law.

Despite seeming progress in limiting anticompetitive pay-for-delay deals, recently consumer groups have raised concerns[44] about the increasing consolidation of the generic drug industry, with fewer major generics makers and thus less of the competition that has historically resulted in lower drug prices. In 2007, the top 10 generic drug companies had just 28.5% of global market share,[45] but by 2014, had captured 64% of that market.[46] And

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[39] Federal Trade Commission. Pay-for delay: When Drug Companies Agree Not to Compete. https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay. Accessed March 8, 2016.

[40] *Ibid*.

[41] Wyatt E. Supreme Court Lets Regulators Sue Over Generic Drug Deals. *New York Times*. June 17, 2013. http://www.nytimes.com/2013/06/18/business/supreme-court-says-drug-makers-can-be-sued-over-pay-for-delay-deals.html. Accessed February 1, 2016.

[42] Federal Trade Commission. Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2014. January 2016. https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf. Accessed February 2, 2016.

[43] Federal Trade Commission. FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics. May 28, 2015. https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill. Accessed February 1, 2016.

[44] Consumers Union, Consumer Federation of America, U.S. PIRG, Public Citizen, et al. et al . Generic drug manufacturer consolidation is problematic for consumers. Letter to the Federal Trade Commission. July 14, 2015. http://consumersunion.org/research/generic-drug-manufacturer-consolidation-is-problematic-for-consumers/. Accessed February 2, 2016.

[45] Business Insights. The Top 10 Generic Pharmaceutical Companies. http://www.emballagedigest.fr/dotclear/images/BONUS%202008/septembre_08/Top%20Genericspdf.pdf. Accessed March 8, 2016.

[46] EvaluatePharma®. World Preview 2015, Outlook to 2020. June 2015. Page 48. http://info.evaluategroup.com/rs/607-YGS-364/images/wp15.pdf. Accessed March 8, 2016.

in July 2015, just two months after its $1.2 billion FTC settlement, Teva, already the world's largest generic drug company, announced that it was acquiring the third-largest manufacturer, Allergan's generics unit, for $40.5 billion.[47]

Such mergers have likely been a key factor in the recent dramatic price hikes of many generic drugs.[48] Because nearly eight in 10 prescriptions filled in the U.S. are generics,[49] such rising prices have a large impact on the costs of taxpayer-supported healthcare. The recent generic price hikes have therefore prompted lawmakers to respond. Sen. Bernie Sanders (I-Vt.) and Rep. Elijah Cummings (D-Md.) implored the Department of Health and Human Services' Office of Inspector General (OIG) to look into the issue of rising generics prices[50] and introduced a bill that would require all generics makers to pay an additional rebate to Medicaid programs when the prices of their generic drugs rise beyond inflation.[51] Their bill was eventually incorporated as a provision in the Bipartisan Budget Act of 2015 (P.L. 114-74).[52] And in response to Sanders' and Cummings' request for an analysis of the impact of such a provision, OIG released a report in December 2015 that calculated that the provision would have saved Medicaid a total of $1.4 billion during the previous decade (2005-2014) on the top 200 generic drugs reimbursed each year under the program.[53]

State settlements

Pricing fraud: response and consequences

While unlawful promotion was the most commonly cited violation in multi-state settlements from 1991 through 2015, the overcharging of government health programs was, by far, the most common violation cited in single-state settlements to date. Virtually all cases involving the overcharging of government health programs concerned the inflation by drug companies of their drugs' reported average wholesale prices (AWPs),

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[47] Rockoff JD, Mattioli D, Hoffman L. Teva to Buy Allergan Generics for $40.5 Billion. *Wall Street Journal*. July 27, 2015. http://www.wsj.com/articles/teva-to-buy-allergan-generics-for-40-5-billion-1437988044. Accessed February 2, 2016.

[48] Elsevier Clinical Solutions. Generic Drug Price Increases: Causes and Impact. 2015. http://www.goldstandard.com/wp-content/uploads/Elsevier_WP_GenericPriceIncrease2_12_15WEB.pdf. Accessed February 2, 2016.

[49] Food and Drug Administration. Facts about Generic Drugs. June 19, 2015. http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm. Accessed February 2, 2015.

[50] U.S. House of Representatives Committee on Oversight & Government Reform. HHS to Probe Skyrocketing Generic Drug Prices. April 14, 2015. http://democrats.oversight.house.gov/news/press-releases/hhs-to-probe-skyrocketing-generic-drug-prices. Accessed February 2, 2016.

[51] U.S. House of Representatives Committee on Oversight & Government Reform. Sanders, Cummings File Bill on Rising Rx Prices. May 18, 2015. http://democrats.oversight.house.gov/news/press-releases/sanders-cummings-file-bill-on-rising-rx-prices-taxpayers-would-save-1-billion-in. Accessed February 2, 2016.

[52] Congress.gov. Public Law No: 114-74 (November 2, 2015). Sec. 602. Applying the Medicaid Additional Rebate Requirement to Generic Drugs. https://www.congress.gov/bill/114th-congress/house-bill/1314/text. Accessed March 8, 2016.

[53] Department of Health and Human Services, Office of Inspector General. Average Manufacturer Prices Increased Faster Than Inflation for Many Generic Drugs. December 2015. http://oig.hhs.gov/oas/reports/region6/61500030.pdf. Accessed February 2, 2016.

which have traditionally been relied upon by most state Medicaid programs as a basis for determining reimbursement to pharmacies.[54]

However, the number of single-state settlements involving overcharging violations dropped dramatically during the last two years of the study period (2014-2015). This decline is chiefly due to the likely resolution of remaining litigation concerning revelations of alleged AWP fraud by the Ven-a-Care pharmacy whistleblower.[55] And changes in the way Medicaid reimburses for pharmaceuticals may continue the decline in pricing fraud settlements.

In part as a response to the discovery of the systematic fraud involving the AWPs, both state and federal authorities have long been exploring alternative payment schemes less vulnerable to manipulation. In February 2012, the Centers for Medicare and Medicaid Services published a proposed rule that outlined potential changes in the rules for reimbursing outpatient drugs under state Medicaid programs.[56] The proposed rule, which was finalized on February 1, 2016 and will be effective on April 1,[57] will require that state Medicaid programs replace the current system of reimbursing pharmacies for drugs based on their estimated acquisition cost (represented by the AWP and the wholesale acquisition cost, or WAC) with one based on their actual acquisition costs (AACs).[58]

Even before the rule was finalized, states have been free to replace the AWP reimbursement system with AACs or other, more accurate measures of drug acquisition costs. So far, only 12 states have opted to base their reimbursement for most drugs at least in part on AACs.[59] Five of these 12 states (Alabama, Idaho, Iowa, Louisiana, and Texas) have

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[54] Department of Health and Human Services, Office of Inspector General. Replacing Average Wholesale Price; Medicaid Drug Payment Policy. July 2011. http://www.oig.hhs.gov/oei/reports/oei-03-11-00060.pdf. Accessed March 8, 2016.

[55] There has not been a federal settlement since 2011, or state settlement since 2013, based on Ven-a-Care revelations.

[56] 77 *Federal Register* 5318 (2012). Medicaid Program; Covered Outpatient Drugs. Proposed Rule. http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf. Accessed March 8, 2016.

[57] 81 *Federal Register* 5170 (2016). Medicaid Program; Covered Outpatient Drugs. Final Rule With Comment Period. https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf. Accessed March 8, 2016.

[58] The 2010 Affordable Care Act mandated the proposed change in reimbursement from estimated to actual acquisition costs, in addition to increasing the mandatory rebates provided by drug manufacturers to state Medicaid programs. 77 *Federal Register* 5318 (2012). Medicaid Program; Covered Outpatient Drugs. Proposed Rule. http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf. Accessed January 30, 2016. In order to arrive at accurate estimates for drugs' AACs, CMS has been conducting national monthly surveys of retail pharmacies and publishing the reported costs for reimbursed drugs (referred to as National Average Drug Acquisition Costs, or NADACs) online: Centers for Medicare and Medicaid Services. Medicaid: Survey of Retail Prices. Centers for Medicare and Medicaid Services. Survey of Retail Prices. http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html. Accessed March 8, 2016.

[59] Centers for Medicare and Medicaid Services. Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State. Quarter Ending December 2015. http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf. Accessed January 22, 2016.

successfully pursued, and recovered money from, drug manufacturers for falsely inflated AWPs in the past.

Single-state settlements more fruitful, prompt industry pushback

During the study period, single-state settlements were far more common, and larger in terms of per-state financial penalties, than multi-state settlements. The average financial return in single-state settlements was $11.4 million, compared with a per-state average share of $1.5 million for multi-state settlements. Louisiana Attorney General Buddy Caldwell alluded to this greater return in announcing two single-state settlements that generated four to 20 times the likely funds that would have gone to the state had it opted to participate in multi-state settlements over the same allegations.[60,61]

Given certain states' limited funding and staffing, many of these single-state settlements were achieved with the help of private law firms, contracted on a contingency fee basis. A contingency fee is a percentage of settlement proceeds paid to the law firm if the case results in a successful outcome for the state.[62] In our previous report, we noted that certain pharmaceutical companies had sued some states over this practice, contending that their due process rights were violated and that the civil penalties sought were excessive, due to the private firms' financial incentives to prosecute the companies.[63]

Since then, at least three states — West Virginia, Kentucky,[64] and Pennsylvania[65] — have prevailed in court against lawsuits brought by pharmaceutical and other health care companies attempting to force the states to discontinue the practice. As of December 2014, no company had yet been successful in such a suit against a state.[66] This likely prompted the pharmaceutical and other industries to lobby for state legislation to curb the practice. The American Legislative Exchange Council developed model legislation, the Private

[60] Louisiana Attorney General. Louisiana to Receive $2.9 Million From Shire Pharmaceuticals. October 3, 2014. https://www.ag.state.la.us/Article.aspx?articleID=907&catID=5. Accessed March 8, 2016.
[61] Louisiana Attorney General. AG Recovers $45 Million for Louisiana in Litigation with GSK. July 26, 2013. http://www.ag.state.la.us/Article.aspx?articleID=749&catID=5. Accessed January 30, 2016.
[62] Taylor AL. Walking a Tightrope: AG Enforcement Authority and Private Counsel Contingency Fee Arrangements. State & Local Law News (American Bar Association). Vol. 36, No. 3. Spring 2013. http://www.americanbar.org/publications/state_local_law_news/2012_13/spring_2013/walking_a_tightrope.html. Accessed March 8, 2016.
[63] Anderson C, Hoidal J. Three Courts Weigh in on AGs Authority to Retain Outside Counsel. *State & Local Law News.* 2013;37(1).
[64] *Ibid*.
[65] GGNSC Clarion LP et al. v. Kane. (Commonwealth Court of Pennsylvania, 2015). http://www.pacourts.us/assets/opinions/Commonwealth/out/165MD15_1-11-16.pdf?cb=1. Accessed February 8, 2016.
[66] Lipton E. Lawyers Create Big Paydays by Coaxing Attorneys General to Sue. *New York Times*. December 18, 2014. http://www.nytimes.com/2014/12/19/us/politics/lawyers-create-big-paydays-by-coaxing-attorneys-general-to-sue-.html. Accessed January 26, 2016.

Attorney Retention Sunshine Act,[67] and notes that 18 states have enacted some form of legislation placing restrictions on the hiring of outside counsel by state attorneys general.[68]

The influence of the pharmaceutical lobby was critical in pushing through such legislation in Louisiana, as highlighted in an in-depth analysis by *The New York Times*.[69] Between 2010 and 2014, Louisiana had settled 55 cases for $299 million with drug manufacturers (**Table 1**), virtually all of which were achieved with the assistance of private law firms.[70] Following a lobbying campaign by the Pharmaceutical Research and Manufacturers Association (PhRMA and a partly drug-industry-supported[71] advocacy group, Coalition for Common Sense, the Louisiana state legislature passed a law in 2014 restricting such arrangements, particularly those based on contingency fees.[72] Louisiana did not finalize any single-state settlements in 2015, but we are unable to determine if the new law was responsible for this decline in settlement activity.

States still largely not utilizing whistleblower revelations

Unlike federal settlements, the majority of which have resulted, at least in part, from private whistleblower revelations (**Figure 10**),[73] most states have not benefited from such revelations, despite limited resources to uncover fraud within their Medicaid programs. Of

[67] American Legislative Exchange Council. Private Attorney Retention Sunshine Act. Model Policy. https://www.alec.org/model-policy/private-attorney-retention-sunshine-act/. Accessed March 8, 2016.
[68] Anderson AK. Arkansas Becomes 16th State to Pass Sunshine Legislation for State-Hired Private Attorneys. American Legislative Exchange Council. April 17, 2015. http://www.alec.org/article/arkansas-becomes-16th-state-to-pass-sunshine-legislation-for-state-hired-private-attorneys/. Accessed February 9, 2016. In a subsequent personal communication on February 9, 2016, with the American Legislative Exchange Council's Amy Kjose Anderson, it was brought to our attention that two other states, Ohio and Louisiana, had passed such legislation since her article was published in April 2015.
[69] Louisiana and the Fight Over Outside Lawyers. *New York Times*. December 18, 2014. http://www.nytimes.com/interactive/2014/12/19/us/politics/2-Louisiana-and-the-Fight-Over-Outside-Lawyers.html. Accessed January 30, 2016.
[70] *Ibid*.
[71] Coalition for Common Sense. Supporters. http://coalitionforcommonsense.com/index.php?option=com_content&view=article&id=3&Itemid=3. Accessed January 27, 2016.
[72] Louisiana and the Fight Over Outside Lawyers. *New York Times*. December 18, 2014. http://www.nytimes.com/interactive/2014/12/19/us/politics/2-Louisiana-and-the-Fight-Over-Outside-Lawyers.html. Accessed January 26, 2016.
[73] Such whistleblower-initiated lawsuits, filed under the FCA for matters under the purview of the Department of Health and Human Services (which includes both pharmaceutical and non-pharmaceutical matters), continue to increase in number. In a December 2015 press release, DOJ released updated figures showing that the number of such lawsuits (classified in the data file as "New Matters: Qui tam") increased from 3 in FY 1987 to more than 100 a year from FYs 1996 to 2010 to more than 400 in each fiscal year from 2011 to the present. Department of Justice. Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015. December 3, 2015. http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015; which, in turn, links to the following statistics: Department of Justice, Civil Division. Fraud Statistics – Health and Human Services. October 1, 1987 – September 30, 2015. http://www.justice.gov/opa/file/796866/download. Both links accessed March 8, 2016. The U.S. Department of Justice confirmed to us, in a personal communication, that these totals represent all lawsuits, including those not joined by the federal government. Personal communication with Dan Anderson, Deputy Director of the Civil Law Division, U.S. Department of Justice, on August 1, 2015.

the 30 states with qui tam provisions in their FCAs as of 2015,[74] only four (California, Florida, New Jersey, and Texas) had successfully concluded any whistleblower-initiated single-state settlements with pharmaceutical manufacturers. And Texas alone accounted for nine of 17 (53%) such settlements and $409 million of $793 million (52%) in financial penalties recovered through the help of whistleblowers from 1991 through 2015. Texas' experience should serve as a model for the 26 other states that have not yet benefited from the critical knowledge about prescription drug fraud from former company employees and other insiders.

More aggressive enforcement urgently needed

This report found that 31 companies had entered into two or more settlements with the federal government from 1991 through 2015, with 30 companies having done so in just the 16 years since 2000. In a 2015 paper, Marc A. Rodwin, professor at the Suffolk University School of Law, noted that despite a long-standing "epidemic of pharmaceutical firm illegal conduct," federal officials have to date "sh[ied] away from making use of the stronger sanctions currently available to them."[75] This has likely been a major factor responsible for the drugmaker recidivism identified in this report. Rodwin's paper provided an extensive overview of current enforcement strategies, centering on two themes: stronger sanctions and greater federal oversight of pharmaceutical manufacturers' activities to prevent wrongdoing before it occurs.

Insufficient — and declining — penalties

While it may seem like a large sum, the $35.7 billion paid by the pharmaceutical industry from 1991 through 2015 represents a miniscule fraction of drug company profits – just 5% of the $711 billion in net profits made by the 11 largest global drug companies during only 10 of those 25 years (2003-2012).[76] This contrast is especially striking in light of the sales figures for the specific drugs involved in fraudulent activity. In the largest health fraud settlement in history, GlaxoSmithKline paid $3 billion for violations involving multiple

[74] National Association of Medicaid Fraud Control Units. Statistical Survey: State Medicaid Fraud Control Units. 2015. http://www.namfcu.net/publications/annual-state-surveys/Statistics%202015%20-%20expanded.pdf. Accessed March 8, 2016.

[75] Rodwin MA. Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms? *Food and Drug Law Journal*. 2015; 70(3). The paper also included a tally of federal settlements from July 18, 2012 to December 31, 2014. However, there are discrepancies, due to slightly differing methodologies, between that paper's list of federal settlements and our own database of federal settlements with pharmaceutical manufacturers announced during that time period. The paper lists seven settlements totaling $370 million in financial penalties that were not included in our database as these cases concerned fraud involving medical devices or nonpharmaceutical manufacturers, both of which we have excluded from every iteration of our report. Of the remaining settlements, violation categories were often discrepant due to differing methodologies in classifying violations to the nine categories outlined in our three reports to date (see **Table 9** for our definitions of the nine categories of violations used in this report).

[76] Healthcare for America Now. Big Pharma Pockets $711 Billion in Profits by Price-Gouging Taxpayers and Seniors. April 8, 2013. http://healthcareforamericanow.org/2013/04/08/pharma-711-billion-profits-price-gouging-seniors/. Accessed January 30, 2016.

drugs.[77] On just the three drugs involved in the criminal plea agreement — Paxil, Wellbutrin SR, and Avandia — GlaxoSmithKline made $28 billion in sales,[78] or nine times the total fine for all implicated products in the settlement, during the years covered by the settlement.[79]

The third-largest-ever health fraud settlement, in 2013, forced Johnson & Johnson to pay $2 billion for violations involving, among other drugs, Risperdal.[80] Risperdal alone brought in $11.7 billion in sales for the company, or almost six times the total settlement amount, in just the first 12 years after its approval (1994-2005).[81] In two of the years (2002-2003) during which the criminal off-label promotion occurred,[82] DOJ noted that 75-84% of Risperdal use in elderly patients was off-label, with approximately 50% of this use in elderly patients with dementia.[83]

Legislation introduced in September 2015 by Sen. Sanders[84] and Rep. Cummings[85] (a previous version of which Sen. Sanders introduced in May 2012[86]) seeks to prevent companies that have admitted to, or been found guilty of committing, illegal activity

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[77] Thomas K, Schmidt M. Glaxo Agrees to Pay $3 Billion in Fraud Settlement. *New York Times*. July 2, 2012. http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html. Accessed January 26, 2016.

[78] For brand-name medicines still within their exclusivity periods and/or patent lives, a category to which the drugs in the GlaxoSmithKline and Johnson & Johnson settlements discussed in this and the following paragraph belonged for at least part of the periods during which the violations occurred, sales closely approximate profits because the marginal cost of producing and distributing the pills is far lower than their monopoly sales prices. (See, e.g., Nordrum A. Why Are Prescription Drugs So Expensive? Big Pharma Points To The Cost Of Research And Development, Critics Say That's No Excuse. *International Business Times*. May 19, 2015. http://www.ibtimes.com/why-are-prescription-drugs-so-expensive-big-pharma-points-cost-research-development-1928263. Accessed January 26, 2016.)

[79] Thomas K, Schmidt M. Glaxo Agrees to Pay $3 Billion in Fraud Settlement. *New York Times*. July 2, 2012. http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html. Accessed January 16, 2016.

[80] Department of Justice. Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations. November 4, 2013. http://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations. Accessed January 30, 2016.

[81] U.S. District Court, Eastern District of Pennsylvania. United States of America v. Janssen Pharmaceuticals, Inc. Filed November 4, 2013. http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-info.pdf. Accessed January 26, 2016.

[82] Department of Justice. Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations. November 4, 2013. http://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations. Accessed January 30, 2016.

[83] U.S. District Court, Eastern District of Pennsylvania. United States of America v. Janssen Pharmaceuticals, Inc. Filed November 4, 2013. http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-info.pdf. Accessed January 30, 2016.

[84] Congress.gov. S. 2023 — Prescription Drug Affordability Act of 2015. Introduced September 10, 2015. https://www.congress.gov/bill/114th-congress/senate-bill/2023/text#toc-id949AFDF5ED7747CA94B46DFDA34D7130. Accessed February 2, 2016.

[85] Congress.gov. H.R.3513 - Prescription Drug Affordability Act of 2015. Introduced September 16, 2015. https://www.congress.gov/bill/114th-congress/house-bill/3513/text. Accessed March 24, 2016.

[86] Sen. Bernie Sanders. Press release: Sanders: Crack Down on Pharmaceutical Fraud. May 23, 2012. http://www.sanders.senate.gov/newsroom/press-releases/sanders-crack-down-on-pharmaceutical-fraud. Accessed March 24, 2016.

involving drugs with remaining FDA-granted exclusivity periods from continuing to generate astronomical profits off of the drugs. The two bills would mandate that such companies lose FDA-granted marketing exclusivity for the specific drugs involved in illegal activity.[87,88] These measures would serve as far more effective deterrents against fraud involving expensive brand-name drugs than current settlement penalties, while increasing access to cheaper generics for U.S. patients.

Executive impunity

The inability of paltry financial penalties to serve as a deterrent to further wrongdoing heightens the importance of other enforcement avenues. However, despite the plethora of settlements reached with the pharmaceutical industry under the FCA, DOJ has, with a few exceptions,[89] not held company heads accountable for overseeing the fraudulent activities at issue in the settlements. In his 2015 paper, Rodwin argues for legislation that would extend financial penalties to individuals within an offending firm, requiring those responsible for wrongdoing to "forfeit bonuses, stock options and other incentive compensation" to the federal and state governments.[90] Financial sanctions against

[87] Congress.gov. S. 2023 — Prescription Drug Affordability Act of 2015. Introduced September 10, 2015. https://www.congress.gov/bill/114th-congress/senate-bill/2023/text#toc-id949AFDF5ED7747CA94B46DFDA34D7130. Accessed February 2, 2016.
[88] Congress.gov. H.R.3513 - Prescription Drug Affordability Act of 2015. Introduced September 16, 2015. https://www.congress.gov/bill/114th-congress/house-bill/3513/text. Accessed March 24, 2016.
[89] To our knowledge, through 2014, the following cases had resulted in guilty pleas by, or convictions of, executives of pharmaceutical manufacturers: 1) 2007: Three executives from Purdue Pharma pleaded guilty to deceiving doctors and patients about the risks of the lucrative painkiller Oxycontin and paid a total of $34.5 million in fines. 2) 2009: Former InterMune CEO Scott Harkonen was convicted for approving a press release that advertised one of the company's drugs, Actimmune, for off-label uses, for which he was sentenced to six months of home confinement and forced to pay a $20,000 fine; 3) 2009: Thomas Farina and Mary Holloway, both sales representatives at Pfizer, were convicted for promoting the painkiller Bextra for off-label uses, for which Farina was sentenced to six months of home confinement and Holloway to two years' probation and a $75,000 fine; 4) 2011: Former KV Pharmaceuticals CEO Marc Hermelin pleaded guilty to two misdemeanors under the FDCA and was ordered to pay $1.9 million in fines and forfeitures and sentenced to 30 days (of which he served 15) in prison for failing to report that some of his company's tablets were oversized and possibly dangerous. Sources, respectively: Meier B. In Guilty Plea, OxyContin Maker to Pay $600 Million. *New York Times*. May 10, 2007. http://www.nytimes.com/2007/05/10/business/11drug-web.html; Stohr G. Ex-InterMune CEO Harkonen's Conviction Let Stand by Court. Bloomberg Business. December 16, 2013. http://www.bloomberg.com/news/articles/2013-12-16/ex-intermune-ceo-harkonen-s-conviction-let-stand-by-court; Edwards J. Pfizer Exec Gets 6 Months' Home Confinement for Off-Label Bextra Sales. CBS. July 20, 2009. http://www.cbsnews.com/news/pfizer-exec-gets-6-months-home-confinement-for-off-label-bextra-sales/; Department of Justice. News Release: Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case. March 10, 2011. http://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case; and: In the Court of Chancery of the State of Delaware. Marc S. Hermelin vs. K-V Pharmaceutical Company. Civil Action No. 6936-VCG. Opinion decided February 7, 2012. http://courts.delaware.gov/opinions/download.aspx?ID=168260. The following source listed no other "recent" cases against executives of pharmaceutical manufacturers that had been brought, presumably as of April 2014, under the Park Doctrine: Kelly J.E. (Bass Berry & Sims). Recent Enforcement Actions Under the Park Doctrine. Presentation at the Food, Drug, and Law Institute. April 24, 2014. http://www.fdli.org/docs/ac2014/kelly.pdf?sfvrsn=0. All sources accessed January 30, 2016.
[90] Rodwin MA. Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms? *Food and Drug Law Journal*, 2015;70(3).

executives have been meted out only rarely and, with the exception of the 2007 Purdue settlement and the 2011 conviction of former KV Pharmaceuticals Chairman and Chief Executive Officer Marc Hermelin, have involved minuscule fines.[91]

Criminal prosecution of individual company executives and other employees resulting in prison sentences for egregious misconduct has similarly been rare.[92] In September 2015, DOJ, under the new leadership of Attorney General Loretta Lynch, issued a memorandum to federal prosecutors announcing its intention to hold accountable individual employees, including corporate executives, who engage in criminal activities.[93] The next month, DOJ announced that three former district managers and the former president of Warner Chilcott (now a subsidiary of Actavis[94]) had been criminally charged with conspiring to submit fraudulent prior authorization forms for the company's drugs and paying kickbacks to physicians.[95] Two of the former district managers pleaded guilty to, among other charges, "conspiracy to commit health care fraud," while the former president, Carl Reichel, was arrested on the same day that DOJ announced a $125 million settlement with the company over the allegations.[96] The sentences have not yet been announced, but the charges against one of the former district managers carries a maximum jail term of 10 years.[97]

These recent indictments and arrests of senior company employees, and most importantly, of a former executive, are a welcome — but long overdue — development.[98] Criminal

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[91] See footnote 89.
[92] See footnote 89.
[93] Apuzzo A, Protess, B. Justice Department Sets Sights on Wall Street Executives. *New York Times.* September 9, 2015. http://www.nytimes.com/2015/09/10/us/politics/new-justice-dept-rules-aimed-at-prosecuting-corporate-executives.html. Accessed January 26, 2016.
[94] Actavis says Warner Chilcott unit held talks to settle U.S. probe. Reuters. May 14, 2015. http://www.reuters.com/article/2015/05/15/us-actavis-ie-walter-chilott-idUSKBN0O004O20150515. Accessed January 26, 2016.
[95] Department of Justice. Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations. October 29, 2015. http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million. Accessed January 26, 2016.
[96] *Ibid.*
[97] U.S. Attorney's Office, District of Massachusetts. Former Warner Chilcott Sales Manager Pleads Guilty to Conspiracy to Commit Health Care Fraud. July 7, 2015. http://www.justice.gov/usao-ma/pr/former-warner-chilcott-sales-manager-pleads-guilty-conspiracy-commit-health-care-fraud. Accessed January 30, 2016.
[98] It is worth noting that, in the Warner Chilcott case, the former employees were charged with participating directly in the illegal activities. The federal government also has the authority to prosecute pharmaceutical executives under the Park Doctrine, a legal precedent that holds company heads responsible for misconduct within their companies, even if they did not have direct knowledge about the specific unlawful acts in question. However, the federal government has been exceedingly reluctant to wield this authority. With the exception of the 2011 case of Marc Hermelin (see footnote 89), we are not aware of any executive of a pharmaceutical manufacturer who has been jailed under the Park Doctrine for overseeing fraudulent activity against the federal government. In 2011, the FDA released criteria it would use in deciding whether to pursue criminal investigations of executives under the Park Doctrine, but, to our knowledge, there have been no further convictions of pharmaceutical executives, under the Park Doctrine, since the Hermelin case . See e.g.: Walsh AK. FDA Finally Releases "Non-binding" Park Doctrine Criteria. FDA Law Blog. February 6, 2011. http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/fda-finally-releases-non-binding-park-

prosecutions of pharmaceutical executives, had they occurred years ago, may have deterred the systemic fraud responsible for the wave of drug industry settlements over the past 25 years. Many more such indictments, as appropriate, are necessary in order to prevent future wrongdoing. Moreover, it is critical that any newfound focus on executive accountability complement, not replace, investigations of parent companies. Unless financial penalties are considerably increased, even the specter of executive prosecutions will not be enough to deter criminal activity.

Toothless corporate integrity agreements

In addition to stronger sanctions, Rodwin argues for more rigorous federal monitoring of pharmaceutical manufacturers in order to identify, and ultimately prevent, the sort of systemic fraud that has long been the norm.[99] Such oversight is ostensibly the purpose of corporate integrity agreements (CIAs), which pharmaceutical companies enter into with the Department of Health and Human Services' OIG as part of civil settlements, in exchange for OIG's agreement not to exclude the companies from federal healthcare programs.[100] The agreements require companies to reform their practices and submit annual reports to OIG documenting their newfound compliance. However, multiple companies, such as Pfizer and GlaxoSmithKline, have had repeat settlements while still under previous CIAs.[101]

Furthermore, the annual reports submitted by companies to OIG are not made public, and despite litigation to force the release of these records, OIG has withheld the bulk of them from public view.[102] Rodwin argues that such reports should be made public and that "firms and the OIG [should] have the burden of proving that release of particular information would result in specific, significant harm to the firm."[103] He also argues for extending the duration of CIAs beyond the current five-year norm.

Such moves would be critical in identifying fraud on a more real-time basis and, if combined with far stronger sanctions when systematic wrongdoing is identified, would go a long way toward changing the cost-benefit calculus that has made fraud effectively a business model within the pharmaceutical industry.

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doctrine-criteria.html; and Food and Drug Administration. Inspections, Compliance, Enforcement, and Criminal Investigations. Recommending Park Doctrine Prosecutions. http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3. Accessed January 30, 2016.

[99] Rodwin MA. Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms? Food and Drug Law Journal, Vol. 70, No. 3, Fall 2015.

[100] Department of Health and Human Services, Office of Inspector General. Corporate Integrity Agreements. http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp. Accessed March 8, 2016.

[101] Wolfe SM. Escalating Criminal and Civil Violations: Pharma has Corporate Integrity? Not Really. *BMJ*. 2013;347:f7507.

[102] See, e.g., Public Citizen v. Department of Health and Human Services. http://www.citizen.org/litigation/forms/cases/getlinkforcase.cfm?cID=752. Accessed January 26, 2016.

[103] Rodwin MA. Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms? Food and Drug Law Journal, Vol. 70, No. 3, Fall 2015.

Limitations and future research

Several factors limit the current study, as was similarly the case in the earlier versions . Due to the reliance on publicly available governmental press releases, this data set may not be complete and therefore possibly 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 state and federal government actions taken against pharmaceutical companies. The lack of such a source 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 and cannot 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 3½ years of data, long-term trends in illegal activity and enforcement actions cannot be gleaned from this report. That said, the sharp decline, during the past two years, in the number and size of settlements, especially criminal penalties and those resulting from DOJ investigations, is worrisome should it represent an emerging trend of reduced federal prosecution of pharmaceutical fraud.

Future research could begin to quantify the harm to patients resulting from the fraudulent activities described in the settlements. Off-label promotion and concealing vital study data, in particular, expose patients to the risks of drugs that may have little to no benefit for their condition. To take just one recent example, in its 2013 settlement, Johnson & Johnson pleaded guilty to promoting Risperdal for off-label use in elderly patients with dementia, even though the government alleged that the company knew, from its own, concealed study findings, that the drug may cause strokes in those patients.[104] The government further alleged that the illegal marketing continued even after the FDA required, in April 2005, a black-box warning that atypical antipsychotics, including Risperdal, increased the risk of death in patients with dementia-related psychosis.[105,106]

Conclusion

The number and size of federal and state settlements against the pharmaceutical industry decreased significantly in 2014 and 2015. It remains to be seen whether this decline represents a longer-term trend. Financial penalties continued to pale in comparison to

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[104] The company also allegedly ignored repeated FDA warnings that its promotional practices were "misleading": Department of Justice. Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations. November 4, 2013. http://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations. Accessed January 30, 2016.

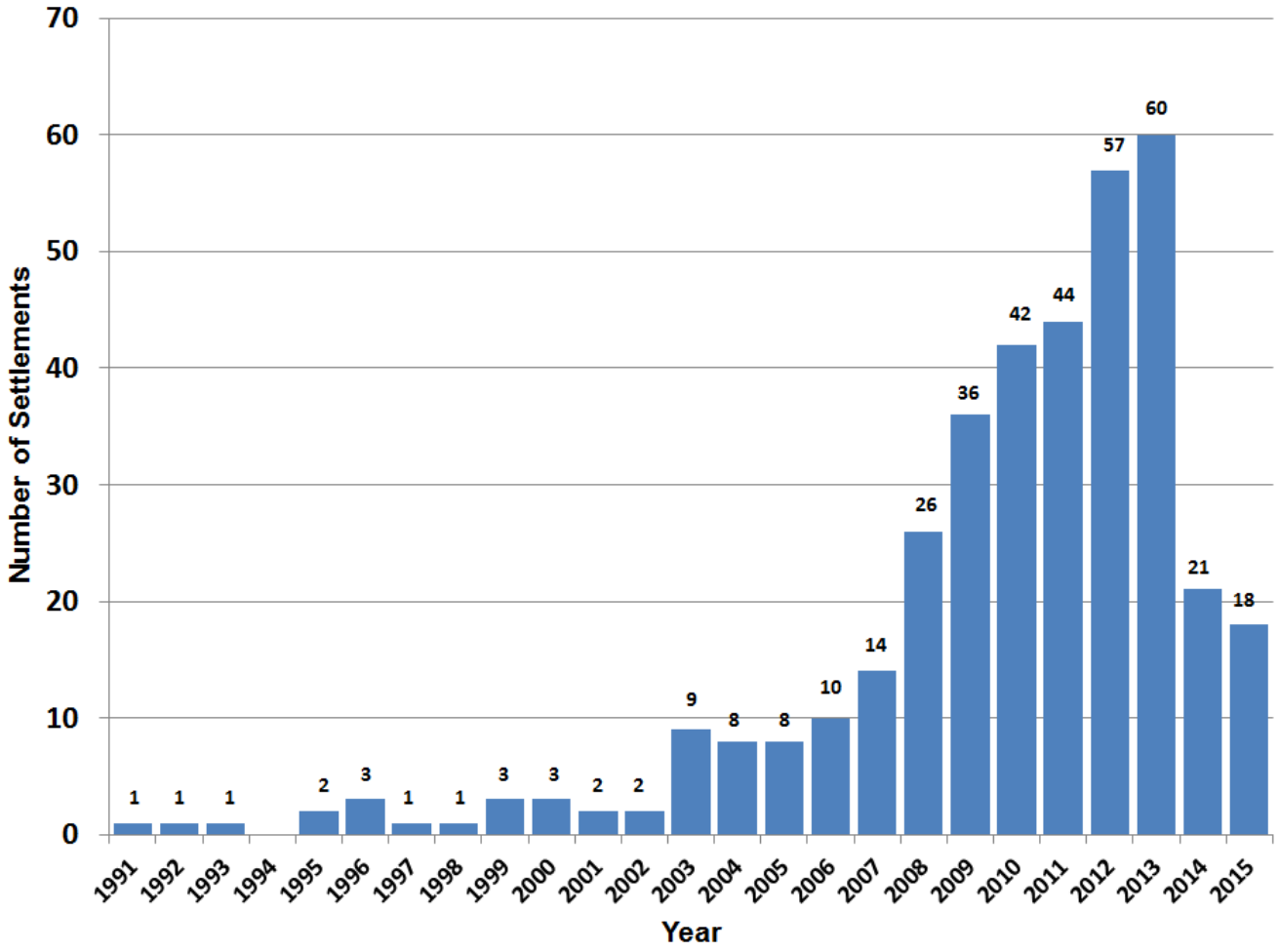
[105] U.S. District Court, Eastern District of Pennsylvania. United States of America v. Janssen Pharmaceuticals. Criminal Information. http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-info.pdf. Accessed January 26, 2016.

[106] For an in-depth look at Johnson & Johnson's wrongdoing in the marketing of Risperdal, see "America's Most Admired Lawbreaker" by Steven Brill in the Huffington Post. Brill S. America's Most Admired Lawbreaker. The Huffington Post. http://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/. Accessed January 30, 2016.

company profits, with the $35.7 billion in penalties from 1991 through 2015 amounting to only 5% of the $711 billion in net profits made by the 11 largest global drug companies during just 10 of those 25 years (2003-2012). To our knowledge, a parent company has never been excluded from participation in Medicare and Medicaid for illegal activities, which endanger the public health and deplete taxpayer-funded programs. Nor has almost any senior executive been given a jail sentence for leading companies engaged in these illegal activities. Much larger penalties and successful prosecutions of company executives that oversee systemic fraud, including jail sentences if appropriate, are necessary to deter future unlawful behavior. Otherwise, these illegal but profitable activities will continue to be part of companies' business model.

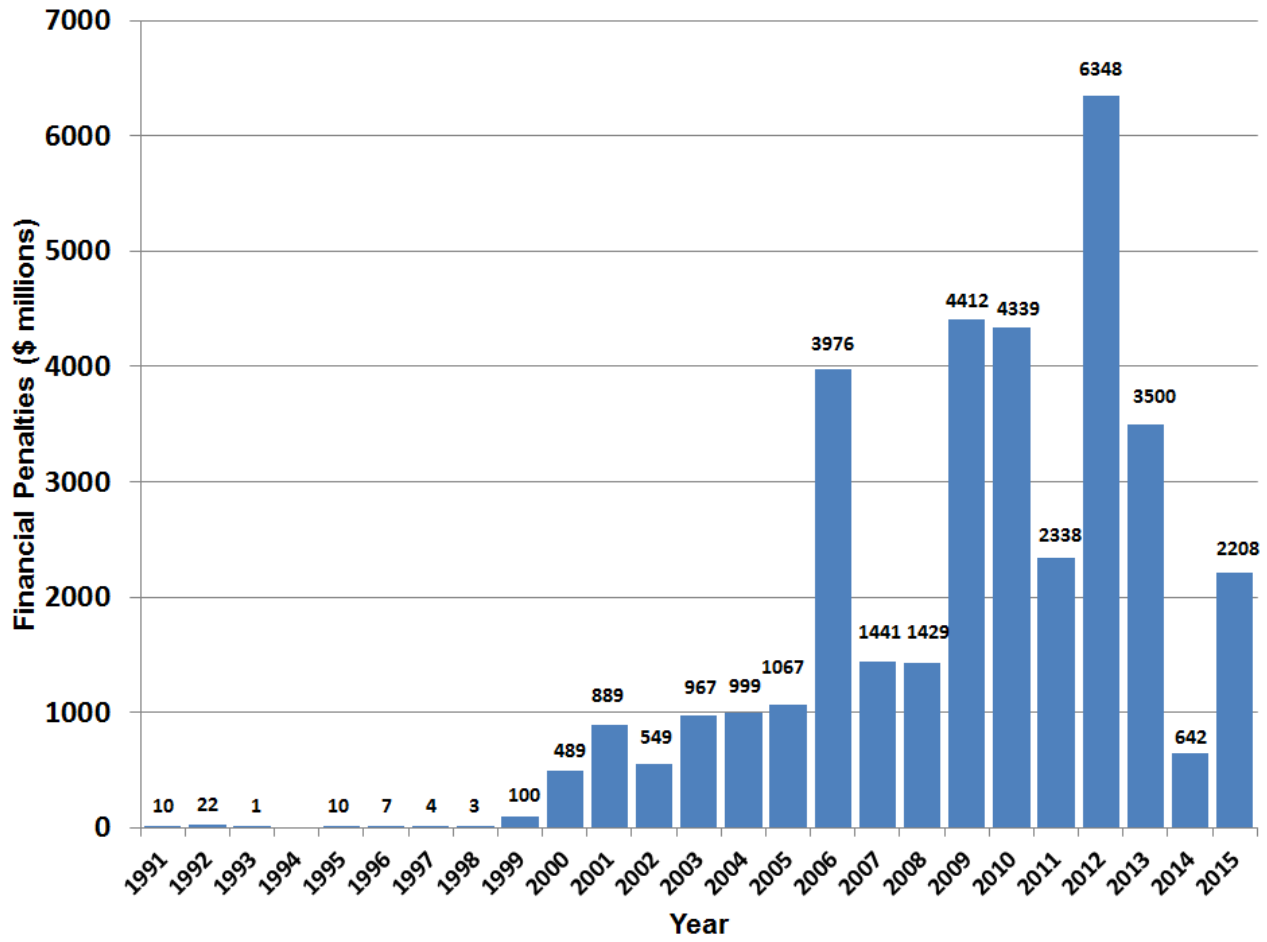
Appendix 1: Figures and Tables

Figure 1. Number of Pharmaceutical Industry Settlements, 1991 – 2015*



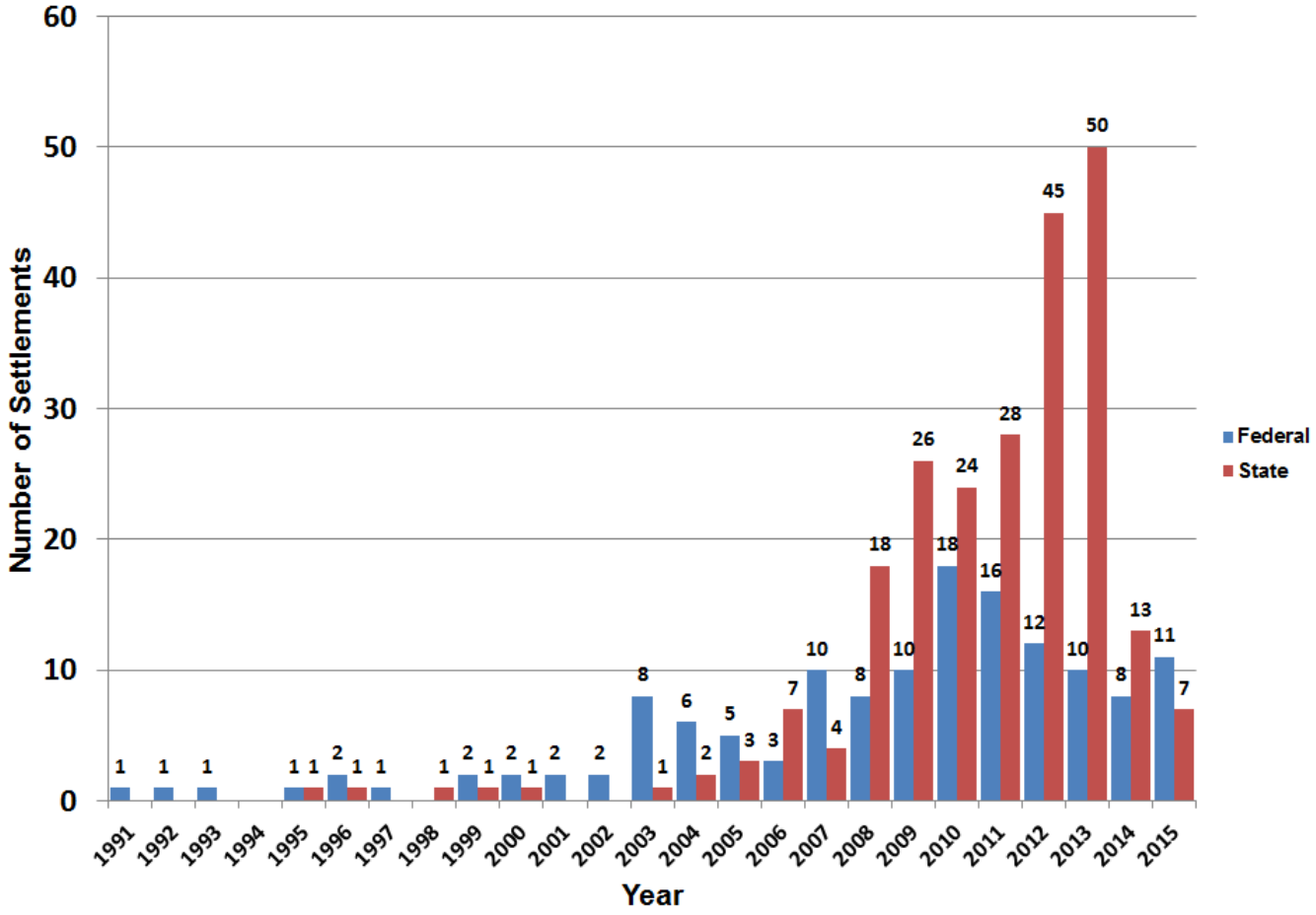
*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Figure 2. Pharmaceutical Industry Financial Penalties, 1991 – 2015*



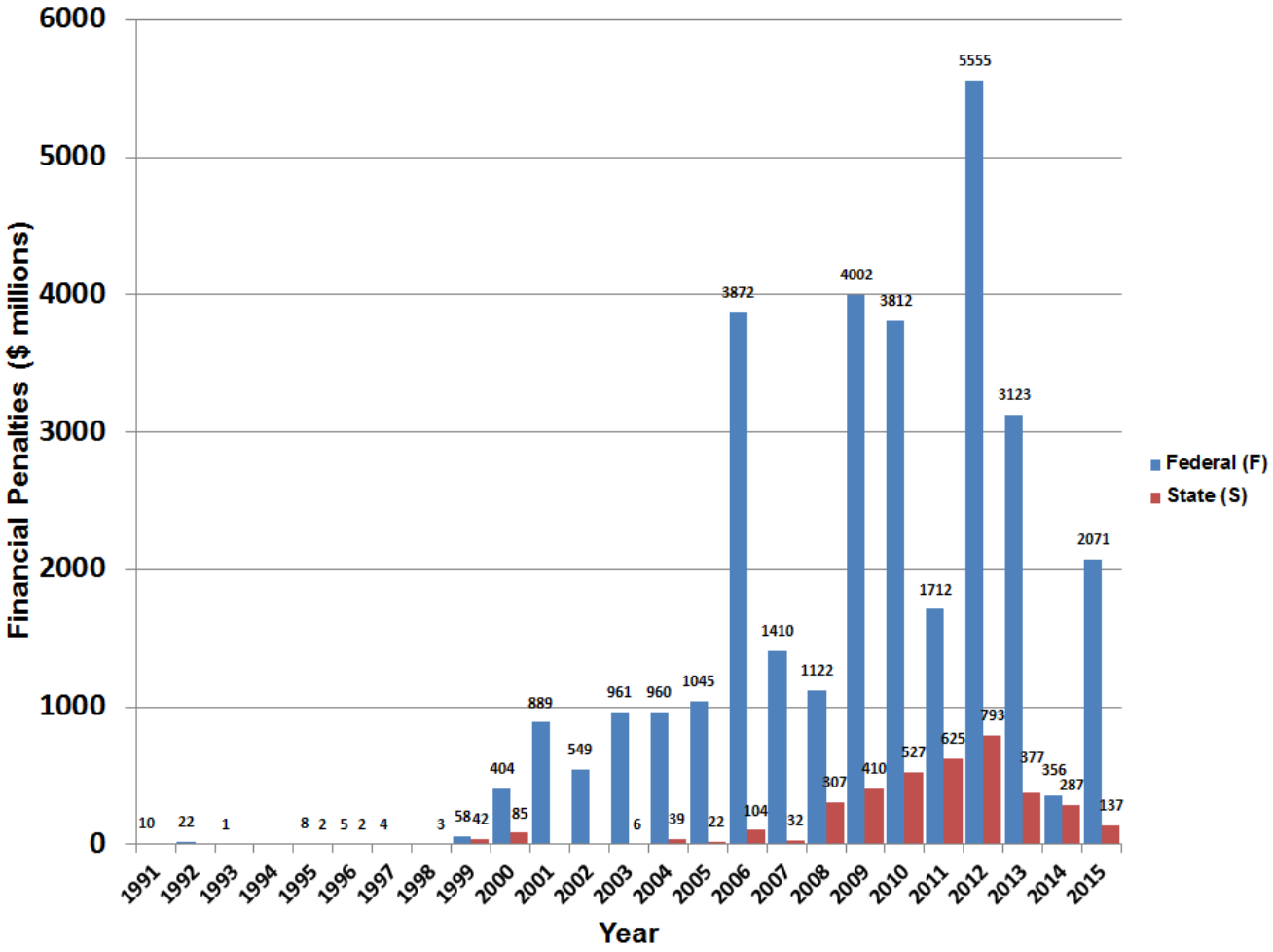
*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Figure 3. Number of Pharmaceutical Industry Settlements, 1991 – 2015: Federal vs. State*



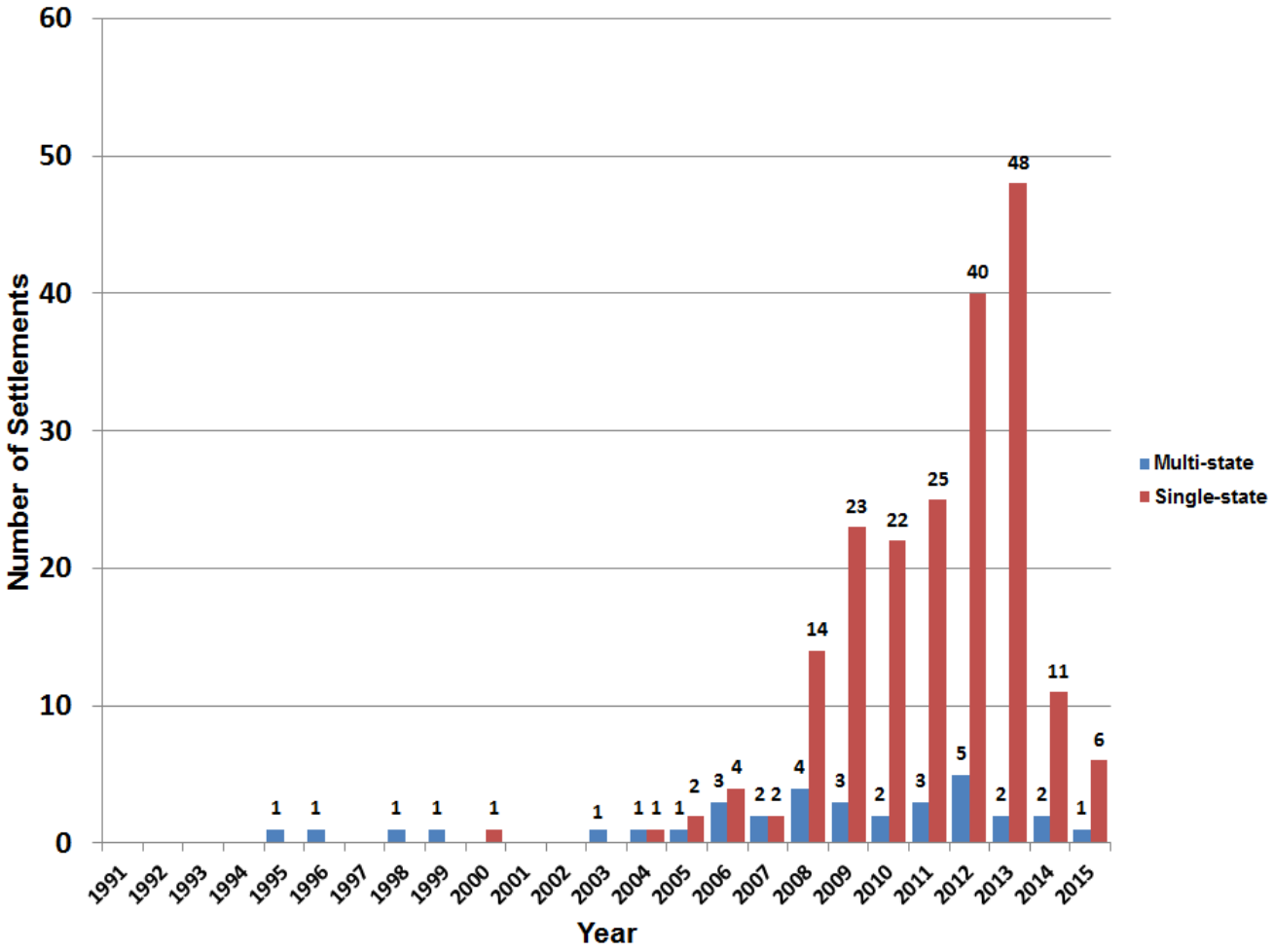
*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Figure 4. Pharmaceutical Industry Financial Penalties, 1991 – 2015: Federal vs. State*



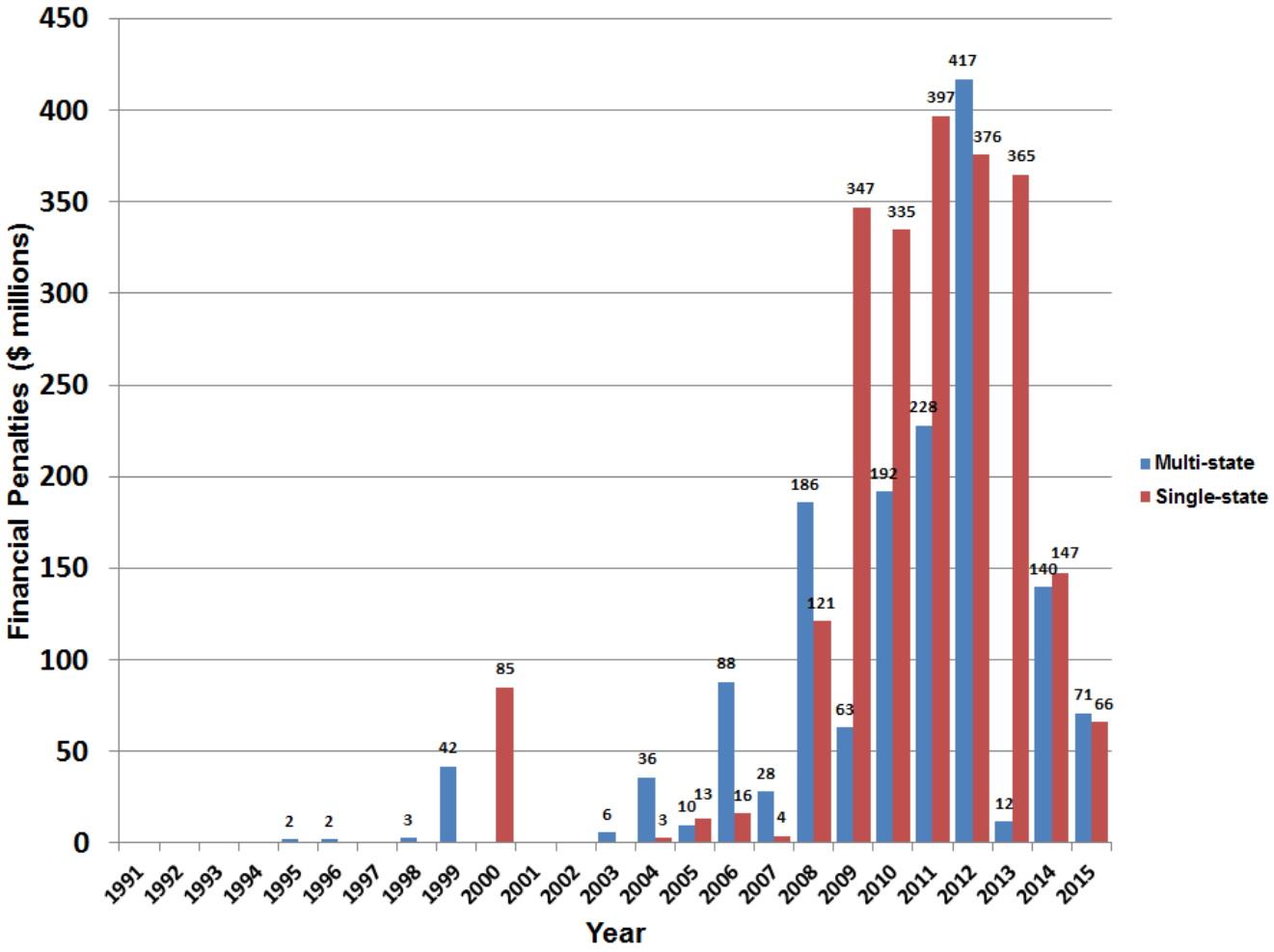
*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Figure 5. Number of State Pharmaceutical Industry Settlements, 1991 – 2015: Multi-State vs. Single-State Settlements*



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Figure 6. State Pharmaceutical Industry Financial Penalties, 1991 – 2015: Multi-State vs. Single-State Settlements*



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

Table 1. Single-state Settlement Totals, 1991 – 2015*

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 as of 2015****
Hawaii	$148.20	$83.75	2	$6.86	Y
New Mexico	$88.15	$34.10	2	$1.60	Y
South Carolina	$48.59	$169.00	2	$12.25	Y
Louisiana	$37.96	$298.84	55	$5.49	Y
Texas	$37.40	$584.10	19	$2.92	Y
Idaho	$37.19	$38.10	16	$5.86	
Pennsylvania	$34.18	$163.90	8	$2.80	
Kentucky	$28.86	$138.54	20	$5.52	
Alabama	$27.38	$124.25	9	$12.06	
Mississippi	$26.48	$105.34	13	$3.98	
Alaska	$20.85	$15.00	1	$1.53	
Utah	$19.74	$28.50	3	$1.64	Y
West Virginia	$16.84	$44.50	2	$3.22	Y
Nevada	$10.57	$9.50	1	$0.56	Y
Wisconsin	$9.97	$46.25	6	$2.98	Y
Montana	$9.02	$5.90	1	$0.84	Y
Massachusetts	$8.35	$50.13	8	$1.12	Y
Connecticut	$7.34	$27.60	2	$2.16	Y
California	$6.27	$163.30	3	$0.53	Y
Maryland	$4.86	$15.00	1	$0.51	Y
Missouri	$4.54	$37.00	3	$1.82	Y
Oregon	$4.52	$7.99	5	$0.48	Y
Kansas	$3.71	$5.70	2	$0.47	Y
North Carolina	$2.39	$25.93	2	$0.50	Y
Iowa	$1.80	$4.30	2	$0.39	Y
Ohio	$1.29	$12.44	2	$0.21	
Illinois	$1.26	$14.00	2	$0.13	Y
Florida	$1.18	$15.00	2	$0.07	Y
New Jersey	$0.22	$1.30	1	$0.03	Y
New York	$0.18	$5.38	4	$0.01	Y
Total / Median	**$9.50 [median]**	**$2,274.64**	**199**	**$1.57 [median]**	**23/30**

*Sums presented here are discrepant from those obtained by adding the previous, 2012 report's totals with new violation totals since that report, for the reasons outlined in Appendix 3.

**Calculated by dividing single-state financial penalties ("Total Financial Penalties" column) from October 10, 2000 (FY 2001; the earliest single-state settlement) through 2015 by each state's Medicaid prescription drug expenditures from FY 2001 through FY 2013 (the most recent year for which data were available from Medicaid's website with Form 64 data). 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 the date on which that settlement is finalized.

***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 2015, by the state's total Medicaid Fraud Control Unit (MFCU) budgets from FY 2006 (the earliest year for which data are available) through FY 2015 as obtained from the National Association of Medicaid Fraud Control

Units (NAMFCU) 2006-2015 surveys 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 FY 2015, as determined from the NAMFCU 2015 survey (see Appendix 2). Values in red signify that the FCA is Deficit Reduction Act (DRA)-compliant, with strong qui-tam provisions. Note that settlements may have been finalized prior to the enactment of the state's FCA.

Table 2. Multi-state Settlement Totals, 1991 – 2015*

State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)**	FCA***	State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)**	FCA***
Texas	28	$105.98	Y	New Jersey	20	$27.41	Y
Florida	28	$60.77	Y	South Dakota	20	$12.47	Y
Arizona	28	$22.85		Delaware	19	$11.27	Y
California	27	$46.99	Y	Nebraska	19	$1.89	Y
North Carolina	27	$34.19	Y	Hawaii	19	$0.00	Y
Massachusetts	27	$19.37	Y	New Mexico	18	$3.33	Y
Vermont	27	$16.73		Minnesota	18	$0.00	Y
Wisconsin	26	$17.46	Y	North Dakota	18	$0.00	
Maryland	26	$8.52	Y	Colorado	17	$12.90	Y
Illinois	25	$45.42	Y	Kentucky	17	$8.74	
Washington	25	$25.21	Y	Rhode Island	16	$9.19	Y
Tennessee	25	$23.33	Y	Montana	15	$3.02	Y
Nevada	25	$16.12	Y	Oklahoma	15	$0.00	Y
New York	24	$42.36	Y	South Carolina	15	$0.00	Y
Ohio	24	$25.76		Indiana	13	$12.58	Y
District of Columbia	24	$13.58	Y	Alabama	13	$0.00	
Michigan	24	$4.66	Y	Virginia	12	$9.17	Y
Oregon	23	$33.21	Y	West Virginia	12	$1.85	Y
Pennsylvania	23	$26.01		Louisiana	10	$1.80	Y
Connecticut	23	$11.72	Y	Mississippi	10	$1.12	
Missouri	22	$19.65	Y	Utah	10	$0.10	Y
Idaho	22	$14.31		Alaska	9	$2.86	
Iowa	22	$12.23	Y	New Hampshire	8	$3.55	Y
Maine	21	$9.88	Y	Georgia	7	$2.59	Y
Arkansas	21	$7.46	Y	Wyoming	6	$0.00	Y
Kansas	21	$0.70	Y				

*Sums presented here are discrepant from those obtained by adding the previous, 2012 report's totals with new violation totals since that report, for the reasons outlined in Appendix 3.

**Financial penalties include an incomplete sample ($790 million, or 52%) 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 is driven by the number of settlements, not the financial penalties, attributed to each state in this table. Some states (Hawaii, Minnesota, North Dakota, South Carolina, Oklahoma, Alabama, and Wyoming) had no individual state shares listed in press releases, explaining the "0" value for financial penalties.

***FCA as of FY 2015, as determined from the NAMFCU 2015 survey (see Appendix 2). 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 – 2015*

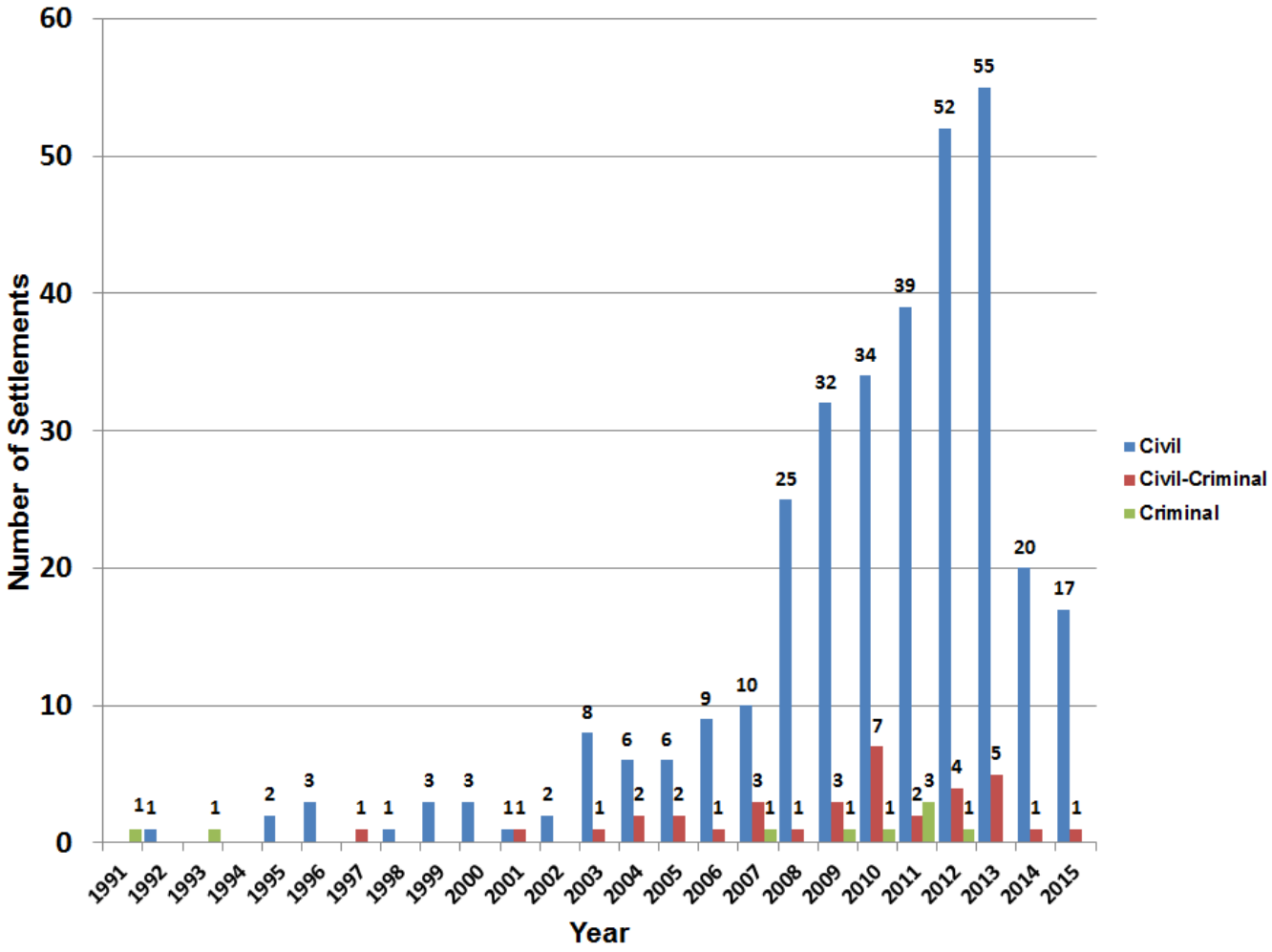
State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)**	FCA***	State	Number of Settlements and Judgments	Verifiable Financial Penalties ($ millions)**	FCA***
Louisiana	65	$300.64	Y	Kansas	23	$6.40	Y
Texas	47	$690.08	Y	Alabama	22	$124.25	
Idaho	38	$52.41		Hawaii	21	$83.75	Y
Kentucky	37	$147.28		New Jersey	21	$28.71	Y
Massachusetts	35	$69.50	Y	Maine	21	$9.88	Y
Wisconsin	32	$63.71	Y	Arkansas	21	$7.46	Y
Pennsylvania	31	$189.91		New Mexico	20	$37.43	Y
California	30	$210.29	Y	South Dakota	20	$12.47	Y
Florida	30	$75.77	Y	Delaware	19	$11.27	Y
North Carolina	29	$60.12	Y	Nebraska	19	$1.89	Y
New York	28	$47.74	Y	Minnesota	18	$0	Y
Oregon	28	$41.20	Y	North Dakota	18	$0	
Arizona	28	$22.85		South Carolina	17	$169.00	Y
Illinois	27	$59.42	Y	Colorado	17	$12.90	Y
Maryland	27	$23.52	Y	Rhode Island	16	$9.19	Y
Vermont	27	$16.73		Montana	16	$8.92	Y
Ohio	26	$38.20		Oklahoma	15	$0	Y
Nevada	26	$25.62	Y	West Virginia	14	$46.35	Y
Missouri	25	$56.65	Y	Utah	13	$28.60	Y
Connecticut	25	$39.32	Y	Indiana	13	$12.58	Y
Washington	25	$25.21	Y	Virginia	12	$9.17	Y
Tennessee	25	$23.33	Y	Alaska	10	$17.86	
Iowa	24	$16.53	Y	New Hampshire	8	$3.55	Y
District of Columbia	24	$13.58	Y	Georgia	7	$3	Y
Michigan	24	$4.66	Y	Wyoming	6	$0	Y
Mississippi	23	$106.46					

*Sums presented here are discrepant from those obtained by adding the previous, 2012 report's totals with new violation totals since that report, for the reasons outlined in Appendix 3.

**Financial penalties include an incomplete sample ($790 million, or 52%) 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 is driven by the number of settlements, not the financial penalties, attributed to each state in this table. Some states (Minnesota, North Dakota, Oklahoma, 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.

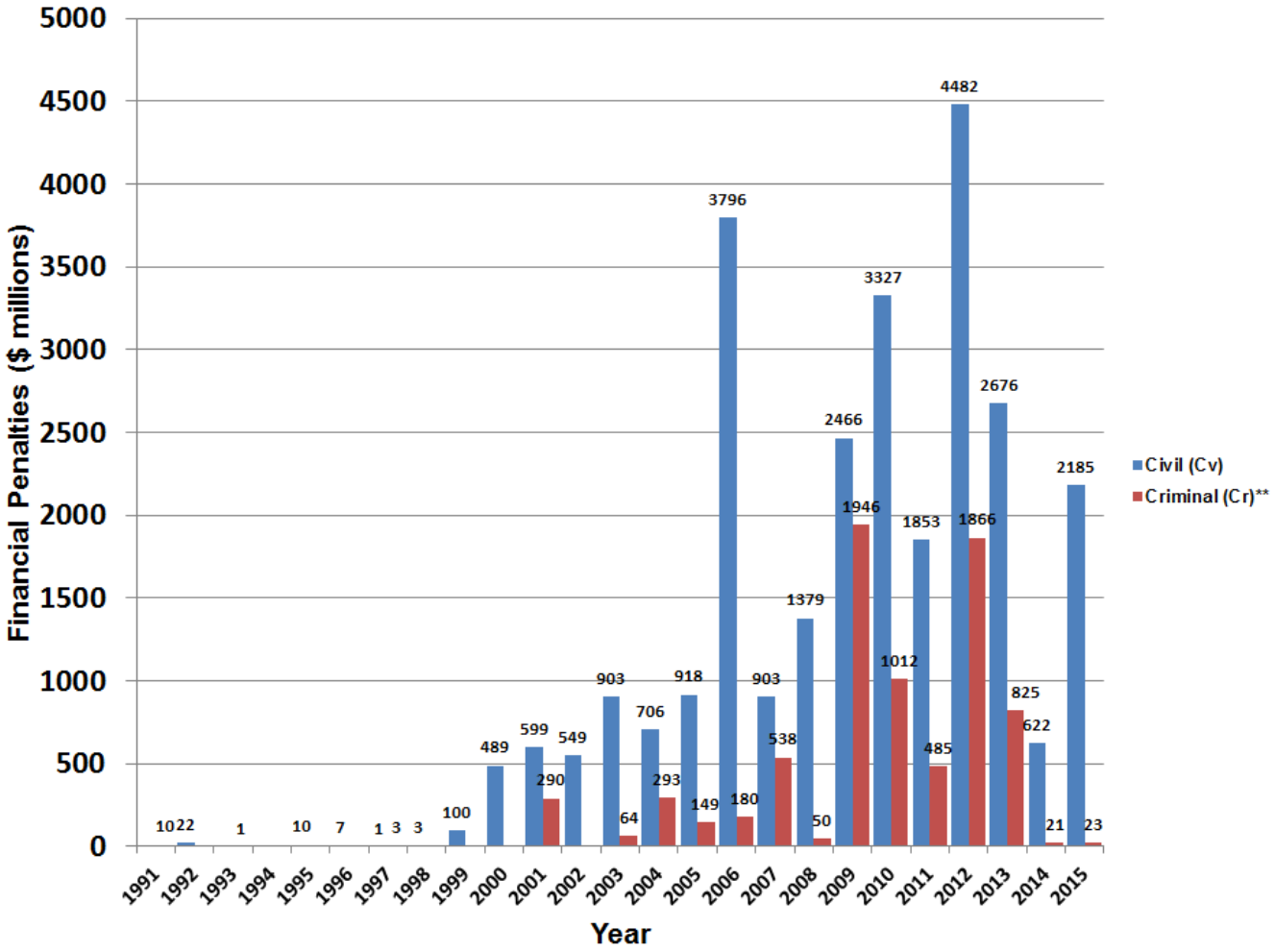
***FCA as of FY 2015, as determined from the NAMFCU 2015 survey (see Appendix 2). Values in red signify that the FCA is Deficit Reduction Act (DRA)-compliant, with strong qui-tam provisions. In some cases, settlements may have been finalized prior to the enactment of an FCA.

Figure 7. Number of Pharmaceutical Industry Settlements, 1991 – 2015: Civil vs. Criminal*



*"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. All criminal and civil-criminal settlements were federal. All state settlements were civil. Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

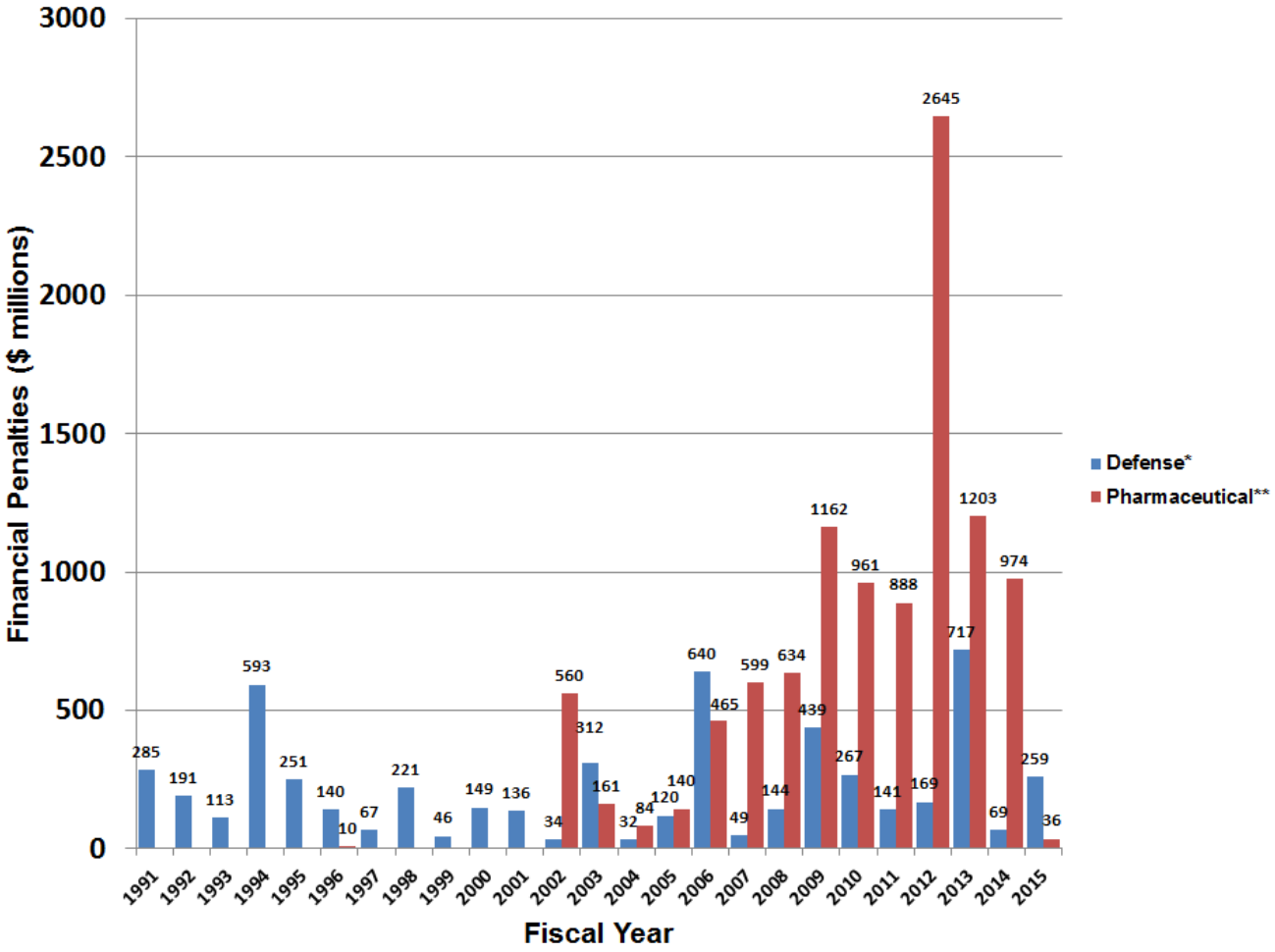
Figure 8. Pharmaceutical Industry Financial Penalties, 1991 – 2015: Civil vs. Criminal*



*All criminal penalties were federal. All state penalties were civil. Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

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

Figure 9. Federal False Claims Act (FCA): Financial Penalties by Industry, Fiscal Year (FY) 1991 – 2015*

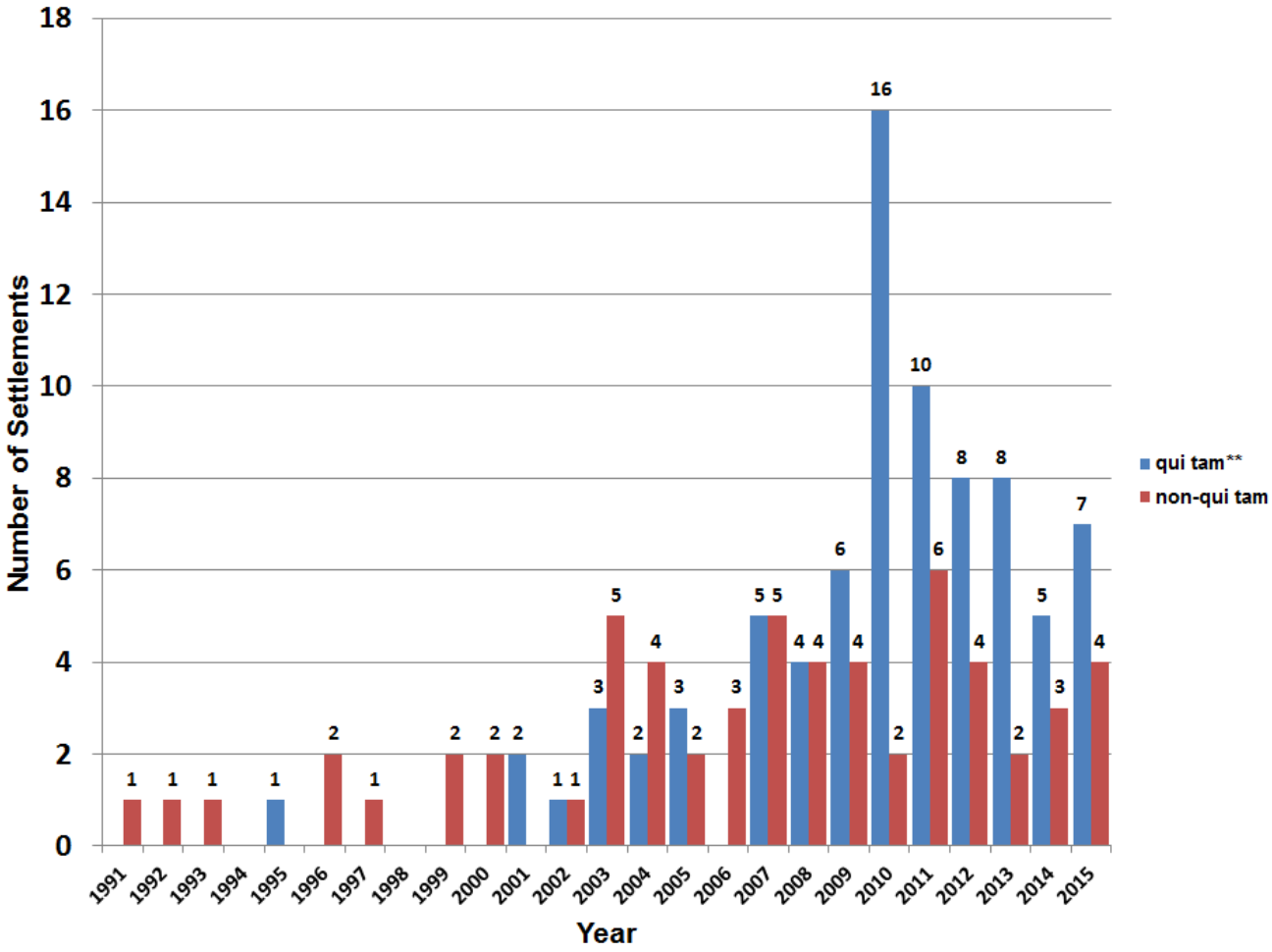


*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

*Defense values for FY2009, FY2010, and FY2011 have been revised by the U.S. Department of Justice since the 2012 report.

**Pharmaceutical totals include only those cases in which the federal portion of the FCA penalty was specified in the press release or, during a subsequent search performed since the 2012 report, in the original settlement document. Since the 2012 report, for all cases in which the federal portion was not specified in the press release, we searched for original settlement documents, which led to a revision of the federal pharmaceutical totals for FY 2003, 2007, 2009, 2010, and 2011. In addition, one settlement (Daiichi Sankyo [Ranbaxy subsidiary] for $500 million), originally dated in FY 2012, the year in which the consent decree was filed against the company, was reclassified as an FY 2013 settlement, the year in which the final monetary settlement was announced by the U.S. Department of Justice.

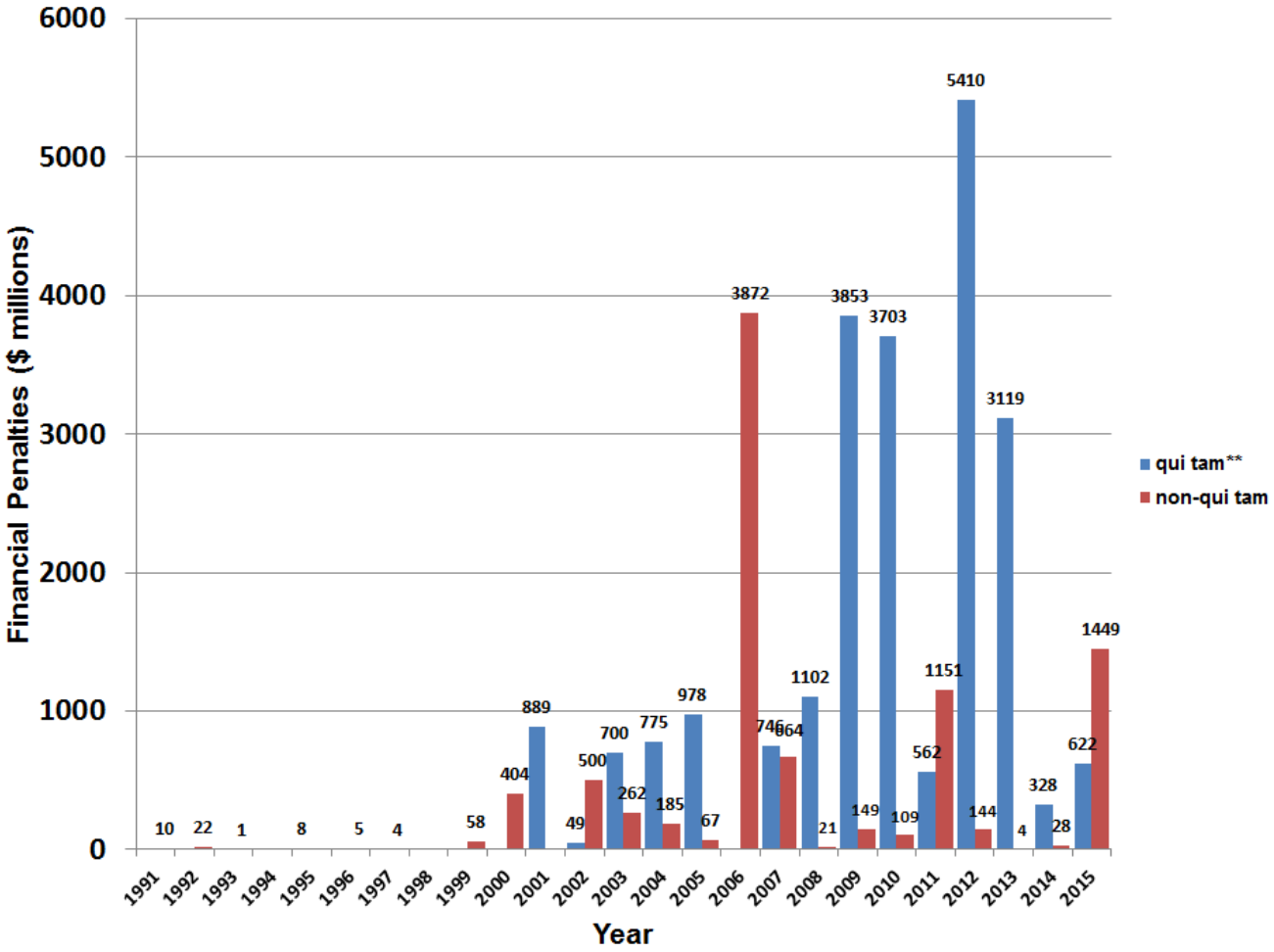
Figure 10. Federal Pharmaceutical Industry Settlements, 1991 – 2015: Qui Tam (Whistleblower) vs. Non-Qui Tam*



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

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

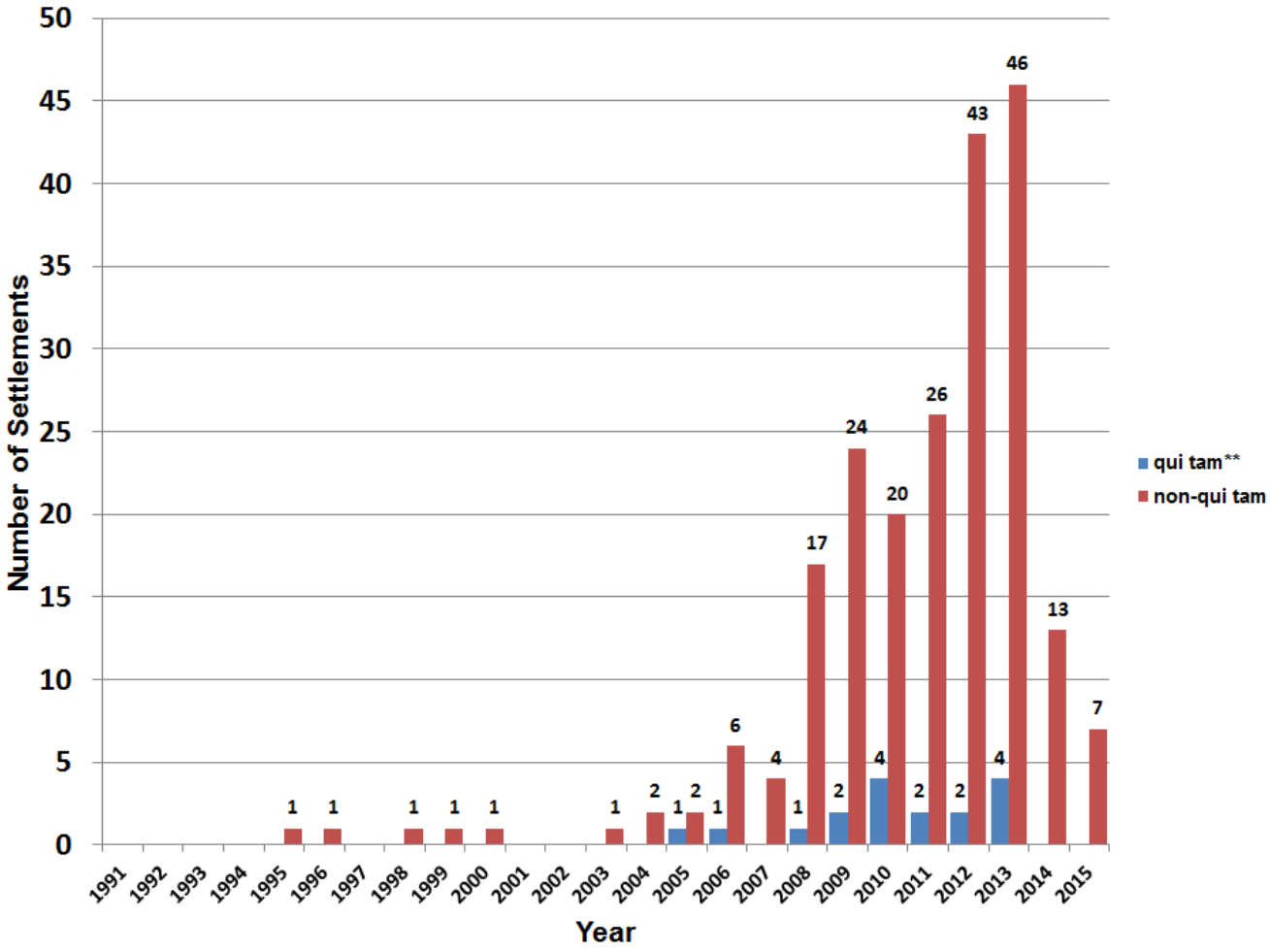
Figure 11. Federal Pharmaceutical Industry Financial Penalties, 1991 – 2015: Qui Tam* (Whistleblower) vs. Non-Qui Tam



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

**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 all penalties, including any penalties not obtained as a result of a qui tam action.

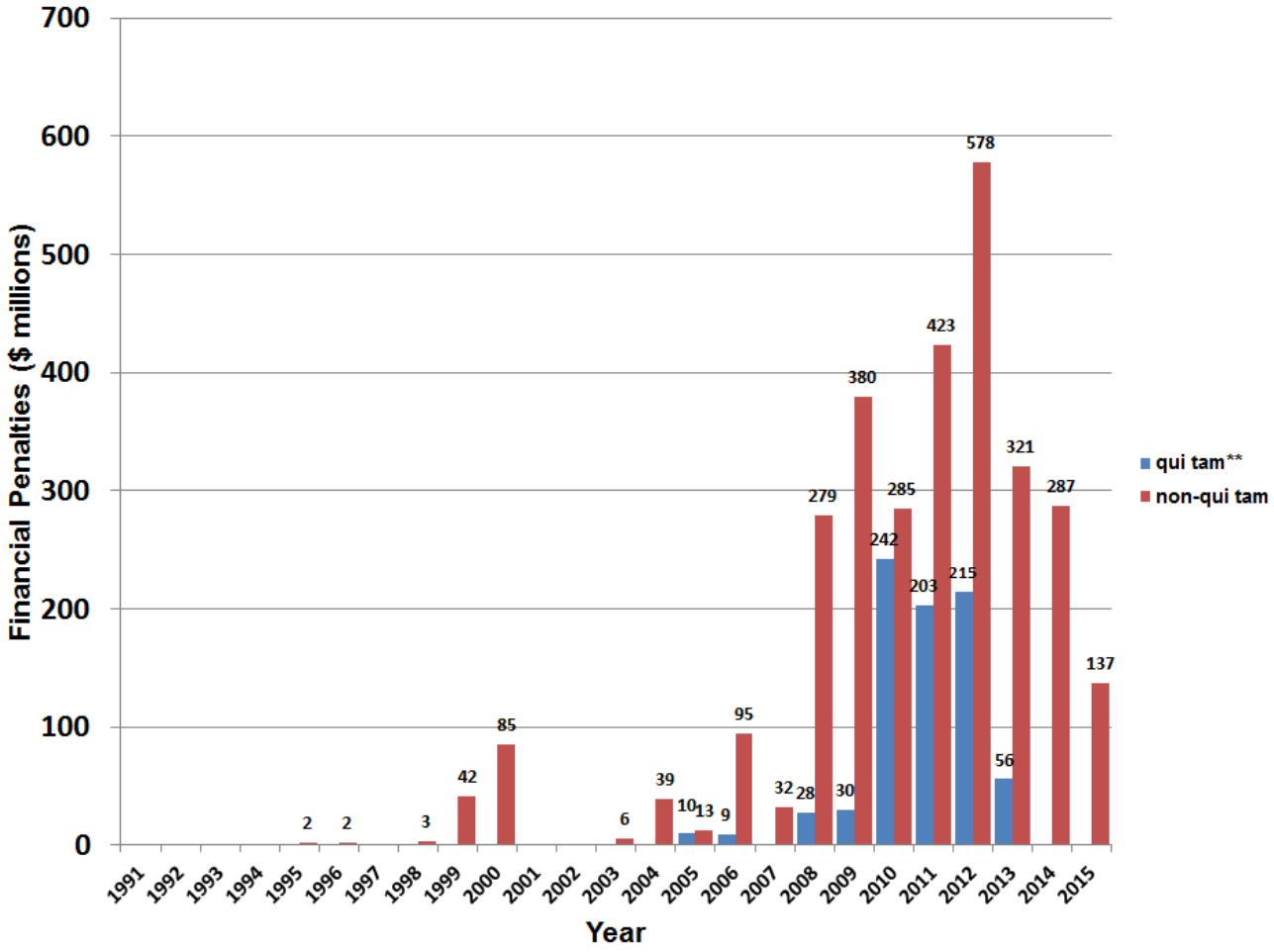
Figure 12. State Pharmaceutical Industry Settlements, 1991 – 2015: Qui Tam* (Whistleblower) vs. Non-Qui Tam



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

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

Figure 13. State Pharmaceutical Industry Financial Penalties, 1991 – 2015: Qui Tam* (Whistleblower) vs. Non-Qui Tam



*Some of the sums for the pre-2013 period are discrepant from those presented in the previous, 2012 report for the reasons outlined in Appendix 3.

**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 all penalties, including any penalties not obtained as a result of a qui tam action.

Table 4. Pharmaceutical Company Penalties: Worst Offenders, 1991-2015

Company*	Total Financial Penalties ($ millions)	Percent of Total**	Number of Settlements***
GlaxoSmithKline	$7,881	22.0%	31
Pfizer	$3,943	11.0%	31
Johnson & Johnson	$2,824	7.9%	19
Merck	$1,915	5.4%	30
Abbott	$1,840	5.1%	16
Eli Lilly	$1,742	4.9%	15
Teva	$1,471	4.1%	13
Schering-Plough	$1,339	3.7%	6
Novartis	$1,250	3.5%	20
AstraZeneca	$1,024	2.9%	11
Amgen	$901	2.5%	12
TAP	$875	2.4%	1
Bristol-Myers Squibb	$795	2.2%	13
Mylan	$715	2.0%	21
Serono	$704	2.0%	1
Purdue	$646	1.8%	5
Allergan	$601	1.7%	2
Daiichi Sankyo	$586	1.6%	8
Boehringer Ingelheim	$427	1.2%	15
Cephalon	$425	1.2%	1
Other****	$3,086	8.6%	162
Total	**$34,990**	**97.9%**	**433**

*Parent company at time of settlement. If company is non-existent now, name at time of most recent settlement was used.

**Percent of $35.748 billion in overall penalties.

***Total (433) listed here is greater than the total number of settlements over the 1991 - 2015 time period (373) as 18 settlements involved more than one company.

****Other companies (in order of total penalties paid): Actavis; Sanofi; Forest; Bayer; Endo; Par; Elan; King; Watson; Shire; UCB; Genentech; KV; BASF; CareFusion; Novo Nordisk; InterMune; AkzoNobel; Biovail; Bausch+Lomb; DFB; Glenmark Generics; Hi-Tech; Pharmacal; Hoffman-La Roche; Sun; Sandoz; Jazz; Baxter; B. Braun Melsungen; Eisai; Victory; Bolar; Dava; Takeda; Cell Therapeutics; Hikma; Medicis; Astellas; Upsher-Smith; Modern Wholesale Drug Midwest; Warner Chilcott; Barr; Perrigo; Taro; The Harvard Drug Group; Otsuka; Apotex; Warner-Lambert; Mallinckrodt; Cypress; Circa; Alpharma; Dainippon Sumitomo; Ferring; Insys; Pernix; Shionogi; Wockhardt; Lupin; Gilead; Valeant; Andrx; Aventis; Chinook; Evonik; Lonza; Mitsubishi Tanabe; Mitsui; Nepera; Solvay; Sumitomo; Vertellus.

Table 5. Pharmaceutical Company Penalties: Repeat Offenders (Federal Settlements Only), 1991-2015*

Company**	Number of Settlements	Total Financial Penalties ($ millions)	Percent of Total***
Pfizer	11	$3,631	11.4%
Merck	9	$1,725	5.4%
GlaxoSmithKline	8	$7,393	23.1%
Novartis	8	$1,125	3.5%
Bristol-Myers Squibb	8	$747	2.3%
Johnson & Johnson	6	$2,246	7.0%
Schering-Plough	5	$1,308	4.1%
Teva	5	$1,251	3.9%
AstraZeneca	5	$932	2.9%
Abbott	4	$1,687	5.3%
Eli Lilly	3	$1,480	4.6%
Amgen	3	$802	2.5%
Mylan	3	$547	1.7%
Daiichi Sankyo	3	$539	1.7%
Sanofi	3	$308	1.0%
Bayer	3	$291	0.9%
Novo Nordisk	3	$36	0.1%
Boehringer Ingelheim	2	$375	1.2%
Endo	2	$232	0.7%
Par	2	$199	0.6%
Others****	22 (11 different companies)	$430	1.3%
Total	**118**	**$27,284**	**85.4%**

*Companies with at least two federal settlements from 1991-2015. Note that this is an underestimate of the number of repeat offenders/offenses, as it excludes state settlements involving separate allegations of fraud than those resolved in federal settlements. State settlements were excluded from these tallies because some state settlements (which could not be consistently distinguished based on the limited information in press releases) resolved the same alleged fraudulent activities as those addressed in one or more federal settlements.

**Parent company at time of settlement. If company is non-existent now, name at time of most recent settlement was used.

***Percent of $31.949 billion in overall federal penalties.

****Other companies with two federal settlements (in order of total penalties paid): King; Watson; UCB; KV; Biovail; Hoffman-La Roche; Bolar; Eisai; Perrigo; Alpharma; Aventis.

Table 6. Pharmaceutical Company Penalties: Worst Offenders, Jul. 19, 2012 – Dec. 31, 2015

Company*	Total Financial Penalties ($ millions)	Percent of Total	Number of Settlements**
Johnson & Johnson	$2,234	28.6%	7
Teva	$1,269	16.2%	7
Pfizer	$976	12.5%	17
Amgen	$886	11.3%	6
Daiichi Sankyo	$586	7.5%	6
Novartis	$457	5.8%	8
GlaxoSmithKline	$301	3.9%	8
Endo	$261	3.3%	5
Actavis	$134	1.7%	2
Boehringer Ingelheim	$95	1.2%	1
AstraZeneca	$70	0.9%	4
Shire	$63	0.8%	3
Merck	$55	0.7%	4
Par	$51	0.7%	3
CareFusion	$40	0.5%	1
Bausch+Lomb	$34	0.4%	1
Eli Lilly	$31	0.4%	2
DFB	$28	0.4%	1
Purdue	$26	0.3%	3
Glenmark Generics	$25	0.3%	1
Other***	$190	2.4%	46
Total	**$7,813**	**100.0%**	**136**

*Parent company at time of settlement. If company is non-existent now, name at time of most recent settlement was used.

**Total (136) listed here is greater than the total number of settlements over the Jul. 19, 2012 – 2015 time period (135) as one settlement involved more than one company.

***Other companies (in order of total penalties paid): Hi-Tech Pharmacal; Sun; Bristol-Myers Squibb; Abbott; Victory; Hikma; Sanofi; Astellas; Upsher-Smith; Forest; Mylan; Taro; The Harvard Drug Group; Hoffman-La Roche; Apotex; Takeda; Mallinckrodt; UCB; Perrigo; Dainippon Sumitomo; Novo Nordisk; Bayer; Baxter; Insys; Warner Chilcott; Pernix; Eisai; Shionogi; Wockhardt; Allergan; Lupin; Gilead; Valeant; Otsuka.

Table 7. Twenty Largest Settlements and Judgments, 1991 – 2015 (all federal*)

Company	Total Penalty ($ millions)	Year	Violation(s)**	Major Drug Products Involved (if applicable and known)***	Laws Violated (if known)†	Qui tam‡
GlaxoSmithKline	$3,400	2006	Financial violations			
GlaxoSmithKline	$3,000	2012	Unlawful promotion; Kickbacks; Concealing data; Overcharging govt. health programs	Paxil; Wellbutrin; Advair; Lamictal; Zofran; Imitrex; Lotronex; Flovent; Valtrex; Avandia	FCA; FDCA	Y
Pfizer	$2,300	2009	Unlawful promotion ; Kickbacks	Bextra; Geodon; Zyvox; Lyrica	FCA; FDCA	Y
Johnson & Johnson	$2,006	2013	Unlawful promotion; Kickbacks; Concealing data	Risperdal; Invega; Natrecor	FCA; FDCA	Y
Abbott	$1,500	2012	Unlawful promotion; Kickbacks; Concealing data****	Depakote	FCA; FDCA; Anti-Kickback Statute	Y
Eli Lilly	$1,415	2009	Unlawful promotion	Zyprexa	FCA; FDCA	Y
Teva	$1,200	2015	Monopoly practices		Federal Trade Commission Act	
Merck	$950	2011	Unlawful promotion	Vioxx	FCA; FDCA	
TAP	$875	2001	Overcharging govt. health programs; Kickbacks	Lupron	FCA; Anti-Kickback Statute; Prescription Drug Marketing Act	Y
Amgen	$762	2012	Unlawful promotion; Kickbacks; Overcharging govt. health programs	Aranesp; Enbrel; Neulasta	FCA; FDCA	Y
GlaxoSmithKline	$750	2010	Poor manufacturing practices	Kytril; Bactroban; Paxil CR; Avandamet	FCA; FDCA	Y
Serono	$704	2005	Unlawful promotion; Kickbacks; Monopoly practices	Serostim	FCA	Y
Merck	$650	2008	Overcharging govt. health programs; Kickbacks	Zocor; Vioxx; Pepcid	FCA; Medicaid Rebate Statute	Y
Purdue	$600	2007	Unlawful promotion	Oxycontin	FCA	
Allergan	$600	2010	Unlawful promotion	Botox	FCA; FDCA	Y
AstraZeneca	$520	2010	Unlawful promotion; Kickbacks	Seroquel	FCA; Anti-Kickback Statute	Y
Bristol-Myers Squibb	$515	2007	Kickbacks; Unlawful promotion; Overcharging govt. health programs	Abilify; Serzone	FCA; FDCA	Y (Ven-a-Care)
Schering Plough	$500	2002	Poor manufacturing practices		FDA Current Good Manufacturing Practices	
Daiichi Sankyo*****	$500	2013	Poor manufacturing practices; Concealing data	Cefaclor; Cefadroxil; Amoxicillin; Amoxicillin/Clavulanate; Sotret; Gabapentin; Ciprofloxacin	FCA; FDCA	Y
Pfizer	$491	2013	Unlawful promotion	Rapamune	FCA; FDCA	Y

*An AR state court judgment against Johnson and Johnson in 2009 for $1.2 billion has since been overturned on appeal.
**Violations include those alleged in civil settlements, as well as violations to which companies pleaded guilty, in criminal settlements.
***If known from the press release; not necessarily a comprehensive list. In some cases dating from the last report, certain drug products were added after further review of the press releases.
****After further review, it was determined that this settlement also involved concealing data, in addition to unlawful promotion and kickbacks, the two violations listed for this settlement in the 2012 report.
*****In the previous report, this settlement was reported to have occurred in 2012, but it has since been determined that the settlement was finalized in May 2013.
†Laws allegedly violated in civil settlements, or those to which companies pleaded guilty to violating 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 8. Twenty Largest Settlements and Judgments, Jul. 19, 2012 – Dec. 31, 2015

Company	Total Penalty ($ millions)	Federal/ State	Year	Violation(s)*	Major Drug Products Involved (if applicable and known)**	Laws Violated (if known)†	Qui tam‡
Johnson & Johnson	$2,006	Federal	2013	Unlawful promotion; Kickbacks; Concealing data	Risperdal; Invega; Natrecor	FCA; FDCA	Y
Teva	$1,200	Federal	2015	Monopoly practices		Federal Trade Commission Act	
Amgen	$762	Federal	2012	Unlawful promotion; Kickbacks; Overcharging govt. health programs	Aranesp; Enbrel; Neulasta	FCA; FDCA	Y
Daiichi Sankyo***	$500	Federal	2013	Poor manufacturing practices; Concealing data	Cefaclor; Cefadroxil; Amoxicillin; Sotret; Gabapentin; Ciprofloxacin	FCA; FDCA	Y
Pfizer	$491	Federal	2013	Unlawful promotion	Rapamune	FCA; FDCA	Y
Novartis	$390	Federal	2015	Unlawful promotion; Kickbacks	Exjade; Myfortic	FCA; Anti-Kickback Statute; federal civil forfeiture statute	
Pfizer (Wyeth)	$195	Federal	2015	Environmental violations			
Endo	$193	Federal	2014	Unlawful promotion	Lidoderm	FCA; FDCA	Y
Johnson & Johnson	$181	State (mult)	2012	Unlawful promotion	Risperdal; Invega		
Actavis (Warner Chilcott)	$125	Federal	2015	Unlawful promotion; Kickbacks	Actonel; Asacol; Atelvia; Doryx; Enablex; Estrace; Loestrin	FCA; Anti-Kickback Statute	
GlaxoSmithKline	$105	State (mult)	2014	Unlawful promotion	Advair; Paxil; Wellbutrin		
Boehringer Ingelheim	$95	Federal	2012	Unlawful promotion; Kickbacks	Aggrenox; Combivent; Micardis; Atrovent	FCA	Y
GlaxoSmithKline	$90	State (mult)	2012	Unlawful promotion	Avandia		
Amgen	$71	State (mult)	2015	Unlawful promotion	Aranesp; Enbrel		
Shire	$57	Federal	2014	Unlawful promotion	Adderall XR; Vyvanse; Daytrana; Pentasa; Lialda	FCA	Y
Pfizer (Wyeth)	$55	Federal	2012	Unlawful promotion	Protonix	FDCA	
AstraZeneca	$47	Federal	2015	Overcharging govt. health programs		FCA	Y
Pfizer (Wyeth)	$45	Federal	2012	Kickbacks		Foreign Corrupt Practices Act	
Par	$45	Federal	2013	Unlawful promotion	Megace ES	FCA; FDCA	Y
GlaxoSmithKline	$45	State (LA)	2013	Unlawful promotion	Avandia; Paxil; Wellbutrin; Advair; Lamictal; Zofran; Imitrex; Lotronex; Flovent; Valtrex		

*Violations include those alleged in civil settlements, as well as violations to which companies pleaded guilty, in criminal settlements.

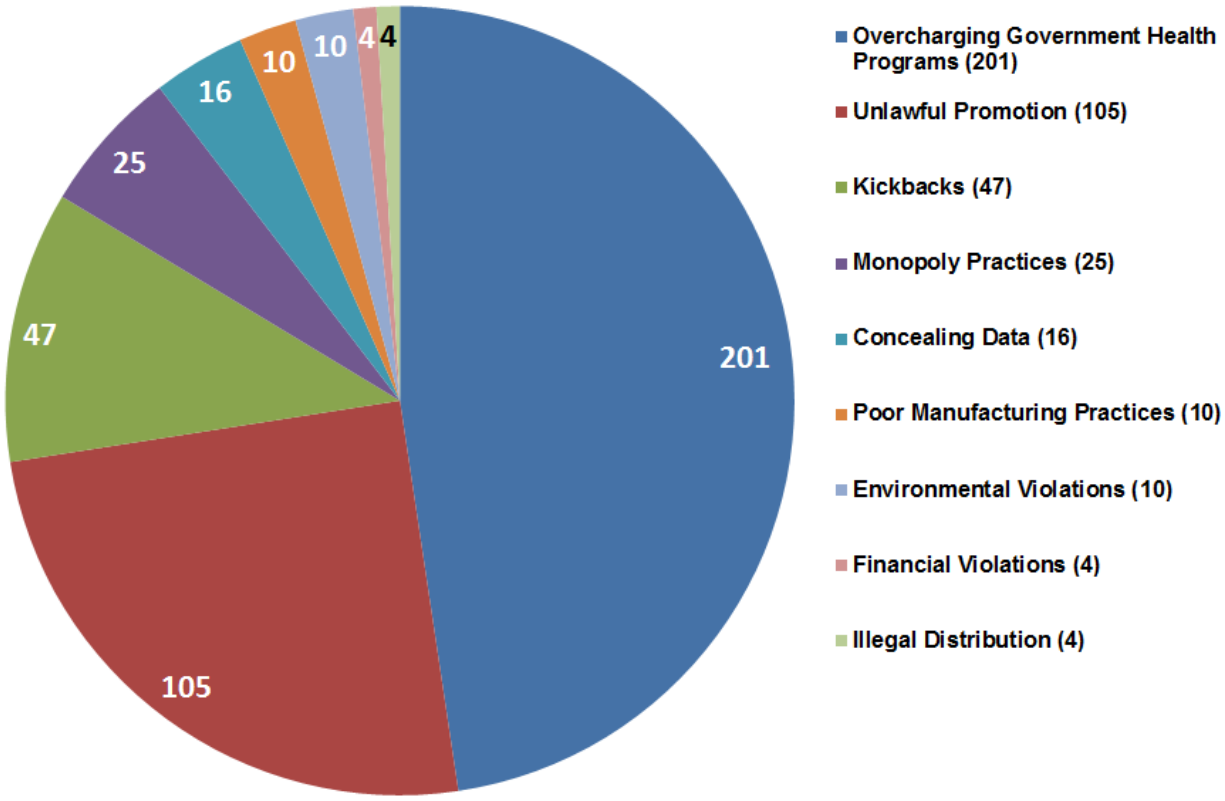
**If known from the press release; not necessarily a comprehensive list.

***This settlement was previously listed in the 2012 report, but it has since been determined that the settlement was not finalized until May 2013. Therefore, it has been included in the new time period.

†Laws allegedly violated in civil settlements, or those to which companies pleaded guilty to violating in criminal settlements; not necessarily a comprehensive list. FCA (False Claims Act); FDCA (Food, Drug, and Cosmetic Act).

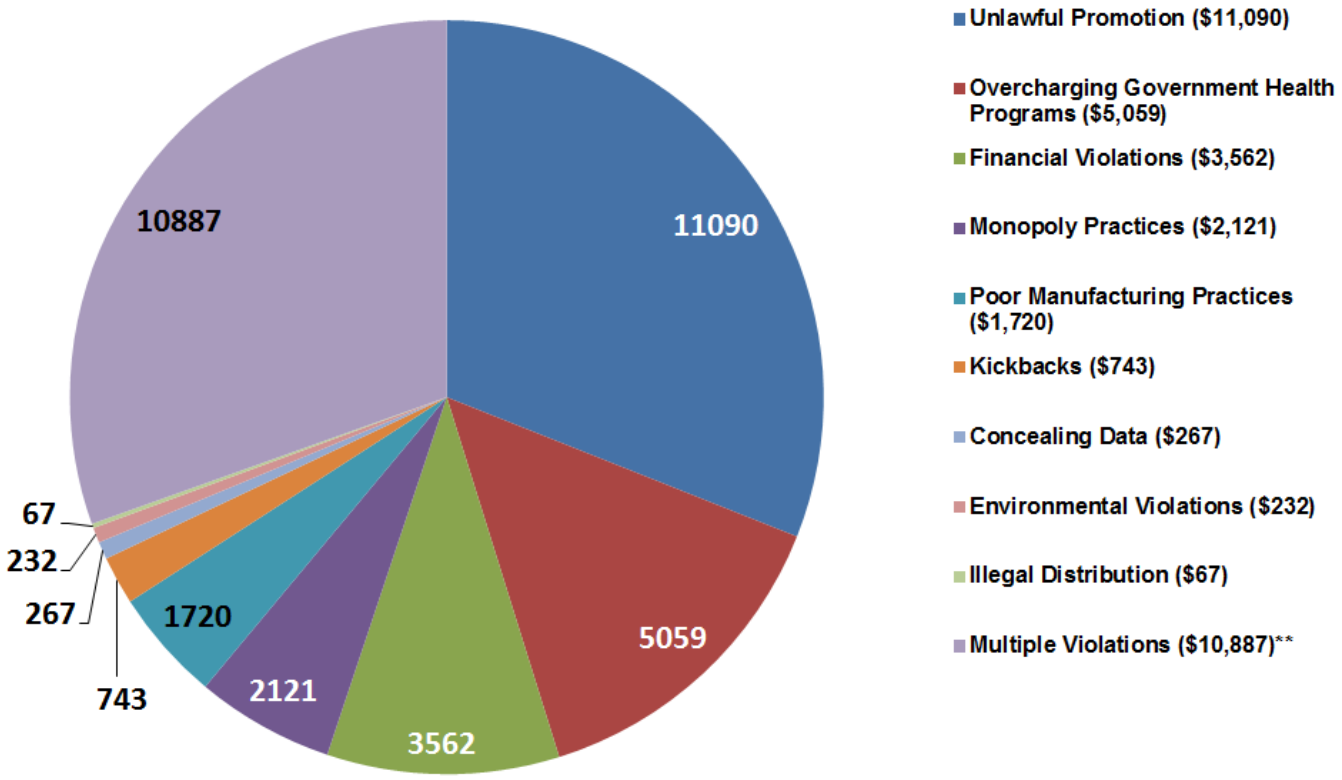
‡Qui tam refers to settlements initiated, at least in part, by whistleblowers.

Figure 14. Types of Pharmaceutical Industry Violations, 1991 – 2015*



*Total number of violations (422) exceeds number of settlements (373) as some settlements involved more than one type of violation. Sums presented here are discrepant from those obtained by adding the previous, 2012 report's totals with new violation totals since that report, for the reasons outlined in Appendix 3.

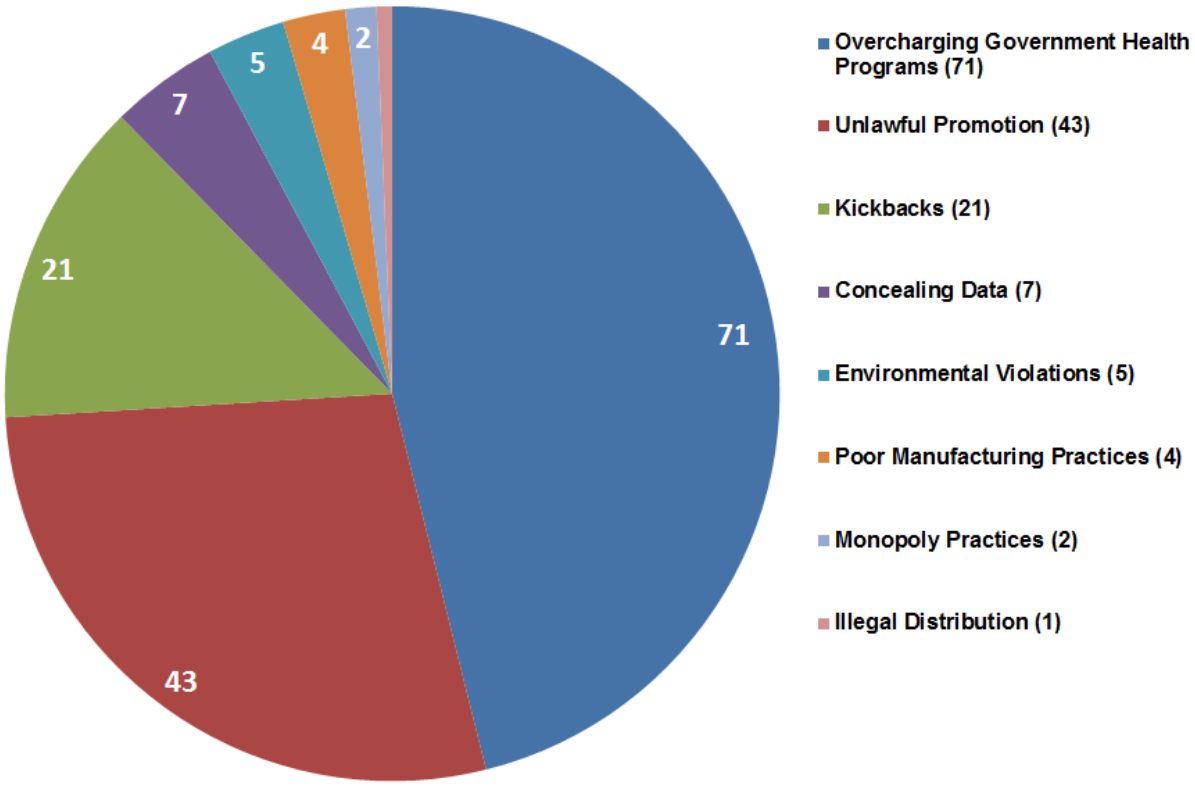
Figure 15. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991 – 2015 ($ millions)*



*Sums presented here are discrepant from those obtained by adding the previous, 2012 report's totals with new violation totals since that report, for the reasons outlined in Appendix 3.

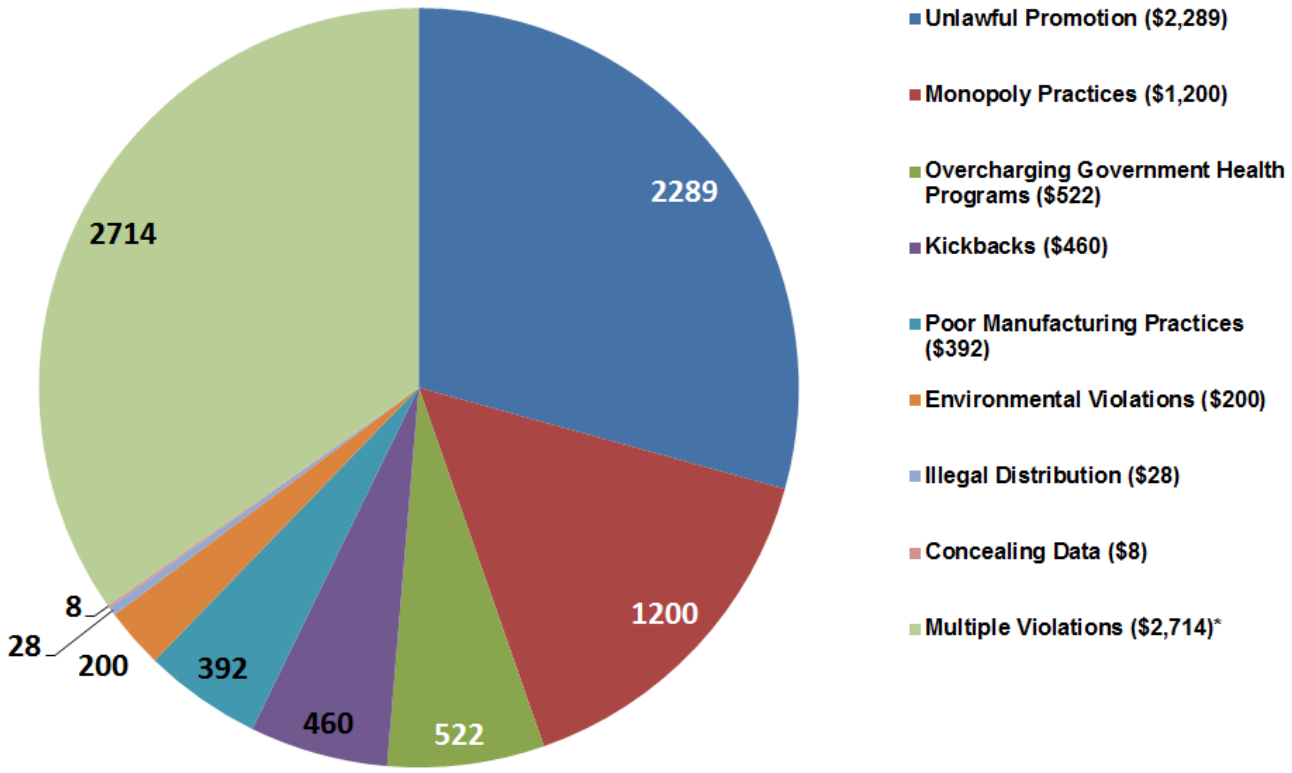
**Settlements that involved more than one type of violation were reviewed and, where possible, individual penalties for each type of violation were determined and added to the totals for that violation. The final total for "multiple violations" represents the sum total that could not be (or was not) attributed to a single violation.

Figure 16. Types of Pharmaceutical Industry Violations, Jul. 19, 2012 – Dec. 31, 2015*



*Total number of violations (154) exceeds number of settlements (135) as some settlements involved more than one type of violation.

Figure 17. Pharmaceutical Industry Financial Penalties by Type of Violation, Jul. 19, 2012 – Dec. 31, 2015 ($ millions)



*Settlements that involved more than one type of violation were reviewed and, where possible, individual penalties for each type of violation were determined and added to the totals for that violation. The final total for "multiple violations" represents the sum total that could not be attributed to a single violation.

Table 9. 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 Data*	Concealing results of company-sponsored studies, or other data, 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

*In the previous reports, this category was labeled “concealing study findings”. However, in some cases, the data did not originate from formal studies but may have come from post-market surveillance or other sources. Therefore, the more accurate term, used in this report (and applying to all settlements, including those in the previous reports), is “concealing data”.

Appendix 2. Detailed Methodology

Inclusion and exclusion criteria

As with the previous reports, only settlements 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).[107] If a release mentioned a singular "settlement," regardless of how many companies or states were involved, it was counted as one settlement in our database. If a release mentioned the plural "settlements" and there was a breakdown of amount paid by company, then each company's settlement was counted as a separate case.

Data sources

For federal cases, the following sources were accessed: 1) the Department of Justice (DOJ) website,[108] 2) the Securities and Exchange Commission (SEC) website,[109] and 3) the Project on Government Oversight's (POGO's) Federal Contractor Misconduct Database.[110] Press

[107] We also excluded the following cases: 1) three enforcement actions taken by Vermont against three different pharmaceutical manufacturers (ALK [$1,250], Angelini Labopharm [$750], and Novartis [$36,000]) on September 18, 2013, for violating the state's law restricting the provision of gifts by manufacturers of prescribed products to physicians and other health care providers; or 2) a $5,000 fine issued in 2014 by the Connecticut state government against Pfizer for allegedly failing to disclose lobbying activities. This was because we did not consider these cases to represent settlements resulting from civil or criminal investigations by the state government, but rather enforcement actions by certain state agencies, with accompanying fines. Sources for each of these cases are, respectively: Vermont Office of the Attorney General. Press Release: Attorney General Settles With Twenty-Five Manufacturers Over Violations of Vermont's Prescribed Product Gift Ban and Disclosure Law. September 23, 2013. http://ago.vermont.gov/focus/news/attorney-general-settles-with-twenty-five-manufacturers-over-violations-of-vermonts-prescribed-product-gift-ban-and-disclosure-law.php. Settlement documents available here: http://ago.vermont.gov/focus/consumer-info/health1/prescribed-products/pprod-settlement-docs.php; and Connecticut Office of State Ethics. Stipulation and Consent Order with Pfizer. June 9, 2014. http://s3.amazonaws.com/fcmd/documents/documents/000/003/890/original/Pfizer_-_CT_Lobbying_Violation_ORDER.pdf?1431023980. All links accessed March 30, 2016.

[108] Department of Justice, Office of Public Affairs. Justice News. http://www.justice.gov/justice-news. Accessed January 4, 2016.

[109] Securities and Exchange Commission. Press Releases. http://www.sec.gov/news/press.shtml. Accessed January 5, 2016.

[110] Project on Government Oversight. Federal Contractor Misconduct Database. http://www.contractormisconduct.org/misconduct. Accessed January 9, 2016. **(No new settlements were found in this database.)** A case found on the Federal Contractor Misconduct Database between eight different states and GlaxoSmithKline, for $229 million, was not included in our database as a multi-state settlement, as a search of all eight states' attorney general websites revealed that two of the three states announcing the settlement reported the case as separate single-state settlements and not a multi-state settlement. We included all three of these states' portions as single-state settlements and, because the remaining five states did not announce their respective settlements, we could not include these states or their settlement amounts in our database. Source: http://www.contractormisconduct.org/misconduct/2146/multistate-avandia-settlement-july-2013. Accessed March 30, 2016.

releases from the DOJ website were found by going to the "Justice News" section of the website. Almost all federal settlements were found in DOJ press releases. (As in the two previous reports, in a few cases, federal settlements were found during searches of state attorneys general websites, with no corresponding federal agency press release located.) To search the SEC website, the link to "Press Releases" was used. In POGO's Federal Contractor Misconduct Database, the "Misconduct Filter" was used to access all settlements between 2012 and 2014 involving the Department of Health and Human Services as the contracting party. In addition, for the updated comparison of annual federal False Claims Act (FCA) payouts by the defense and pharmaceutical industries (**Figure 9**), data on financial penalties recovered by the Department of Defense through FY 2014 were obtained online from DOJ.[111]

State cases were found through a search of press releases from all 50 state and District of Columbia (D.C.) attorney general websites. For sites that did not display press releases during part, or all, of the relevant time period (July 19, 2012-December 31, 2015), the website www.archive.org was accessed to recover past releases, searching for the most current URL (or a variant) for the state attorney general website (explained in detail in the 2010 report). However, four states (Mississippi, Nebraska, Pennsylvania, and West Virginia) all had a gap in time, ranging from one to 30 months, for which press releases were unavailable on either the current or archived state attorney general websites. Another state (Minnesota) did not have a centralized list of press releases but did have a search function, which was used to find settlements under the search terms "pharmaceutical" and "settlement" (no settlements were found).

Data from federal and state press releases were cross-checked with several nongovernmental online databases, previous versions of which were also used to verify the data from the 2012 report.[112,113,114]

Criminal vs. civil settlements

[111] Department of Justice. Fraud Statistics — Overview. October 1, 1987-September 30, 2015. http://www.justice.gov/opa/file/796866/download. Accessed January 17, 2016.
[112] Taxpayers Against Fraud (TAF). Top 100 FCA Cases. http://taf.org/general-resources/top-100-fca-cases. Accessed January 10, 2016. **(No new settlements were found in this list.)**
[113] Elmer B. False Claims Act Settlements 2000-2015. Crowell & Moring LLP. Updated April 23, 2015. http://www.crowell.com/files/False-Claims-Act-FCA-Settlements-Crowell-Moring.pdf. Accessed January 10, 2016. **(One new settlement was identified from this list, referenced in a press release from the U.S. Attorney for the Central District of California: a July 2013 settlement with Amgen for $15 million over alleged kickbacks.** http://www.justice.gov/usao-cdca/pr/ventura-county-based-amgen-inc-pays-over-15-million-resolve-allegations-it-illegally. Accessed January 10, 2016.)
[114] National Association of Attorneys General. http://naag.org. 1) For antitrust cases, the following URL was accessed: http://app3.naag.org/antitrust/search/. "Search Only Civil Litigation Records" was selected and all cases corresponding to the "Related Industry" categories "health care" and "pharmaceuticals" were searched on January 10, 2016. **No new settlements were identified from this database**. 2) For Medicaid fraud cases, the National Association of Medicaid Fraud Control Units Medicaid Fraud Reports were accessed at http://www.namfcu.net/resources/medicaid-fraud-reports-newsletters/. Within each bimonthly report, the word "pharmaceutical" was typed into the full-text search box. **No pharmaceutical settlements were found in a search of these newsletters through the Jan/Feb 2015 issue conducted on January 10, 2016.**

Criminal settlements, or criminal components of civil-criminal settlements, were defined as those in which there was a financial penalty labeled a "criminal" fine for violation of a law or for which a penalty was ordered to be paid as part of a plea agreement or deferred-prosecution agreement. All other financial penalties were defined as civil. Civil-criminal settlements were defined as those containing both civil and criminal financial penalties.

The False Claims Act, including qui tam provisions, and the Food, Drug, and Cosmetic Act

The False Claims Act (FCA) is a commonly used legal tool to prosecute fraud against the government. Originally enacted in 1863 during the Civil War to combat defense contractor fraud, the FCA has been strengthened through various amendments beginning in 1986.[115] These amendments included protection of whistleblowers from employer retaliation and increased financial rewards for coming forward.[116] The qui tam (whistleblower) provisions are a key part of the act, allowing private citizens to bring to light illegal activities that may spur prosecution of the offending companies. The 2005 Deficit Reduction Act (DRA) rewarded states that enacted FCAs with strong qui tam provisions and civil penalties with a 10% increase in financial recoveries resulting from an investigation pursued under the state FCA.[117] As of FY 2015, 16 states had FCAs that were DRA-compliant.[118] Violations of the FCA by pharmaceutical companies have typically resulted in civil, rather than criminal, penalties.

The Food, Drug, and Cosmetic Act (FDCA) is the other major federal law used to prosecute illegal pharmaceutical industry behavior. The FDCA, enacted in 1938 and since amended, forms the basis for the regulation of pharmaceuticals, including the prohibition of making false therapeutic claims about a product, including those made regarding unapproved uses (i.e., off-label promotion).[119] Violations of the FDCA by pharmaceutical companies have

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[115] Department of Justice. The False Claims Act: A Primer. http://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf. Accessed February 6, 2016.

[116] Krause JH. Twenty-five years of Health Law Through the Lens of the Civil False Claims Act. *Ann Health Law.* 2010;19(1 Spec No):13-7.

[117] Department of Health and Human Services, Office of Inspector General. Updated OIG Guidelines for Evaluating State False Claims Acts. March 15, 2013. http://www.oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf. Accessed February 6, 2016.

[118] National Association of Medicaid Fraud Control Units. Statistical Survey: State Medicaid Fraud Control Units, 2015. http://www.namfcu.net/publications/annual-state-surveys/Statistics%202015%20-%20expanded.pdf. Accessed February 6, 2016. In addition to state FCA laws, several states have laws specifically covering Medicaid fraud (e.g., Texas Medicaid Fraud Prevention Act) and consumer protection (e.g., Louisiana Unfair and Deceptive Trade Practices Act) that have been invoked to hold pharmaceutical companies accountable for allegedly defrauding state Medicaid programs. Sources: Attorney General of Texas. Attorney General Abbott Recovers $39.75 Million for State of Texas, U.S. Medicaid Program. October 16, 2014. https://www.texasattorneygeneral.gov/oagnews/release.php?id=4874; and Office of the Attorney General, State of Louisiana. Attorney General Caldwell Announces $20 Million Settlement With Pharmaceutical Company. April 7, 2010. http://www.ag.state.la.us/Article.aspx?articleID=392&catID=1&printer=1. Both accessed February 6, 2016.

[119] Food and Drug Administration. FDA History – Part II: The Food, Drug, and Cosmetic Act. http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm. Accessed February 6, 2016.

typically resulted in criminal penalties. Other federal laws cited to prosecute pharmaceutical companies include the Anti-Kickback Statute, the Foreign Corrupt Practices Act, and the Clean Air Act.

In analyzing FCA violations in the defense and pharmaceutical industries, all totals represent only the portion of the civil settlement paid to the federal government. For pharmaceutical industry totals, settlements in which the federal portion was not specified were excluded. Therefore, the pharmaceutical industry totals by fiscal year in **Figure 9** represent underestimates of the total federal FCA payouts made by the industry during those years.

Qui tam cases were typically brought under federal or state FCAs. Settlements classified as qui tam cases were those in which there was any mention in the press release of a qui tam provision being invoked, or of a whistleblower being responsible for triggering any part of the investigation.

Company totals

We obtained total settlement amounts by company by reviewing the amount paid by each company in each settlement. For some settlements involving multiple companies, the dollar amount paid by each company could not be determined. These cases (representing just 2% of all financial penalties from 1991 through 2015) were therefore excluded when calculating total financial penalties by company. Settlements were recorded in the database under each company's parent company at the time of the final settlement. If a settlement was announced after the offending company had been acquired by, or had merged with, another company, then the settlement was attributed to the new parent company, regardless of when the alleged violations took place. When presenting company totals, we used the most current parent company names; for companies not currently existing independently, we used the parent company's name at the time of the most recent settlement.

Violation types

Violations were classified into nine general categories: concealing data, environmental violations, financial violations, illegal distribution, kickbacks, monopoly practices, overcharging government health programs, poor manufacturing practices, and unlawful promotion. **Table 9** defines each category.

Federal and state settlements

State settlements refer to those in which the federal government neither was involved in the investigation responsible for 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. All other cases were classified as federal, including joint federal-state cases (e.g., those involving Medicaid).

All state settlements 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.

It should be noted that, in both single-state and multi-state settlements involving Medicaid fraud, the federal government generally receives a fraction of the settlement proceeds corresponding to each state's FMAP, even though the federal government is not a party to these settlements.[120]

Single-state settlements

Complete data on financial penalties were available for single-state settlements but not for multi-state settlements. Therefore, two 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 numerators (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 state shares of financial penalties were not consistently disclosed in the press releases. The federal government has historically funded Medicaid prescription drug expenditures at approximately the same proportion of each state Medicaid program's FMAP,[121] and it shoulders 75% of the costs of every state's MFCU, with the states funding the remaining 25%.[122]

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.[123] The sum of all prescription drug expenditures from FY 2001 (corresponding to the fiscal year of the earliest single-state settlement) through FY 2013 (the most recent year for which data were available, as of January 31, 2016[124]) was used as the denominator,

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[120] Social Security Act: Payment adjustment for health care-acquired conditions, 42 U.S. Code § 1396b (2010).
[121] Personal communication with the Department of Justice, Civil Division on August 23, 2012, prior to the publication of the previous report. 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.
[122] 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 FYs 2006-2015), the 75% figure currently applies to all states (except North Dakota, which does not have an MFCU). http://www.namfcu.net/faq/frequently-asked-questions#Q4. Accessed January 31, 2016.
[123] Centers for Medicare and Medicaid Services (CMS). CMS-64 Quarterly Expense Report. Financial Management Reports from FY2001 through FY 2013 were downloaded. http://medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/expenditure-reports-mbes-cbes.html. Accessed January 31, 2016.
[124] As of January 31, 2016, data for FY 2014 were available for adults newly enrolled in Medicaid under the Affordable Care Act, but these totals were not included in calculations of total Medicaid drug expenditures

with total single-state financial penalties from calendar year (CY) 2000 (all of which occurred in FY 2001) through CY 2015 as the numerator. States were ranked in **Table 1** by the total recoveries per $1,000 of Medicaid prescription drug expenditures. However, because settlement penalties beyond FY 2013 were included in the numerator, the figures given for settlement recoveries per $1,000 of Medicaid prescription drug expenditures in **Table 1** represent overestimates.

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.[125] MFCU annual budgetary data were obtained from annual state surveys by the National Association of Medicaid Fraud Control Units (NAMFCU).[126] The sum of all state MFCU budgets from FY 2006 (the earliest year for which data were available) through FY 2015 (the most recent data available) was used as the denominator, with total single-state financial penalties from CYs 2000 (the year of the earliest single-state settlements) through CY 2015 as the numerator. All single-state settlement financial recoveries were obtained during 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.

A third analysis was undertaken to determine whether there exists a rough association between the number of – and financial penalties resulting from – single-state settlements and the presence of a state FCA (as of 2015). A similar analysis was also performed that was limited to those states with FCAs meeting higher federal standards (e.g., those with strong whistleblower provisions) as defined by the 2005 DRA (referred to in this report as DRA-compliant FCAs).[127] As state FCA status was based on 2015 FCA data, in some cases,

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because the federal medical assistance percentages (FMAPs) for these enrollees was 100% at the time. Therefore, states cannot recoup any funds for their own governments through investigations of fraud affecting these new enrollees.

[125] There are at least two exceptions to this rule. North Dakota is the only state without an MFCU (Department of Health and Human Services, Office of Inspector General. MFCU Statistical Data for Fiscal Year 2015. http://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/expenditures_statistics/fy2015-statistical-chart.htm. Accessed March 8, 2016), while Texas' MFCU is not the primary agency responsible for prosecuting civil pharmaceutical fraud cases (as in all other states, pharmaceutical fraud cases in Texas are civil).

[126] National Association of Medicaid Fraud Control Units. Annual Medicaid Fraud Control Unit (MFCU) Surveys. http://www.namfcu.net/publications/annual-state-surveys/. Accessed January 13, 2016.

[127] 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. http://thomas.loc.gov/cgi-

single-state 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 that finalized settlements without an FCA. In addition, even in states with an FCA as of 2015, other state laws may have been invoked to prosecute Medicaid fraud by pharmaceutical manufacturers.

A note on Medicaid prescription drug expenditure data

Medicaid drug expenditures for fiscal years 2011-2013 were obtained from the Centers for Medicare and Medicaid Services.[128] Expenditures for all years represent only those made by the fee-for-service segment of state Medicaid programs and exclude rebates given to Medicaid Managed Care Organizations (MCOs). In addition, expenditures for FYs 2010-2013 exclude the increased prescription drug rebates to Medicaid programs mandated by the Affordable Care Act (ACA), as the entirety of these rebates was remitted to the federal government. (Note that the previous report included both the MCO and ACA rebates for FY 2010 and the first two quarters of FY 2011, but the rebates accounted for just 0.3% and 6.6% of gross drug expenditures during those fiscal years, respectively. Therefore, there is a slight but negligible difference in the net expenditures for all states for those years between the 2012 report and this iteration.)

These two categories of data were excluded for the following reasons, following discussions with an official from the Centers for Medicare and Medicaid Services:[129]

> 1) The two rows containing MCO rebate amounts reflect not only rebates for drugs but also rebates for other expenditure categories in the managed care plans. Therefore, including these rebates would overly deflate the net expenditure totals.
>
> 2) The increased ACA offset rows contain additional rebates mandated by the ACA but paid entirely to the federal government. Therefore, since pharmaceutical settlement penalties are split between the federal and state governments roughly according to the federal/state Medicaid funding split (i.e., the Federal Medical Assistance Percentage [FMAP]), we restricted our prescription drug expenditures and rebates to those categories (i.e., Drug Rebate Offset — National and State) that are, similarly, split roughly along the federal/state FMAP allocations.

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

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bin/cpquery/?&sid=cp109Zqrb4&refer=&r_n=hr362.109&db_id=109&item=&sel=TOC_227784&. Accessed July 30, 2015.

[128] Centers for Medicare and Medicaid Services. Expenditure Reports from MBES/CBES. http://medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/expenditure-reports-mbes-cbes.html. Accessed July 13, 2015. The fee-for-service Medicaid prescription drug net expenditures were obtained by adding up the three rows in the source documents titled "Prescribed Drugs," "Drug Rebate Offset — National," and "Drug Rebate Offset — State Sidebar Agreement." The rows titled "MCO" and "Increased ACA Offset" were excluded.

[129] Personal communication with Meagan Khau, health insurance specialist, Centers for Medicare and Medicaid Services. July 13, 2015.

The number of multi-state settlements and accompanying financial penalties was determined through a search of every state's attorney general website for press releases from each state involved in a multi-state settlement. A complete list of participating states was not found for two of the 34 multi-state settlements. Therefore, the final settlement tallies for some states in **Table 2** may be underestimates.

In addition, the financial penalties from multi-state settlements presented in this report are certainly underestimates, as many states did not always specify their financial share of the settlement amounts. Only $790 million (52%) of the $1.52 billion in multi-state penalties were attributable to individual states and are included in **Table 2**. Therefore, for both the multi-state and overall 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.

Appendix 3. Data Modified Since the 2012 Report

Some of the data corresponding to settlements included in the 2012 report's study period (1991 through July 18, 2012) have changed, as follows:

1) One announcement of a multi-state, qui tam, civil settlement with Bristol-Myers Squibb for $15.7 million, dated July 17, 2008,[130] has since been determined, after consulting additional sources, to have been a part of the 2007 federal settlement in which the company paid $515 million. This multi-state settlement has therefore been deleted from our database.
2) One additional single-state, non-qui tam, civil settlement, between North Carolina and Pfizer for $25.5 million in 2009, was found and added to the database.[131]
3) Two single-state, non-qui tam, civil cases, between Wisconsin and Pfizer for a total of $13.5 million in 2009,[132] have been replaced with a single civil settlement for $29.5 million, in 2013, which represents the year in which final payment (including the original damages, forfeitures, and other costs, as well as calculated interest on these original fines) was made for the allegations underlying the 2009 settlements.[133]
4) Two single-state, non-qui tam, civil court judgments against Johnson & Johnson that were included in the previous totals, one in 2010 (in Louisiana, for $331 million)

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[130] The Attorney General of Texas. Attorney General Abbott Recovers $15.7 Million in Medicaid Costs Under National Settlement. July 17, 2008. https://texasattorneygeneral.gov/oagnews/release.php?id=2557. Accessed March 12, 2016. Two factors entered into our conclusion that Texas' press release was announcing Texas' share in the 2007 federal settlement: 1) similarities between the allegations at issue, and the involvement of the Ven-a-Care whistleblower, in Texas' announcement and those detailed in the 2007 federal settlement with Bristol-Myers Squibb for $515 million (Department of Justice. Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing. September 28, 2007. https://www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html. Accessed March 12, 2016.) and 2) an announcement by the Minnesota Attorney General (just four days after Texas' announcement) which made clear that Minnesota's payment was part of the 2007 federal settlement with Bristol-Myers Squibb for $515 million (Bjorhus J. Minnesota to get $4 million in Bristol-Myers Squibb settlement. TwinCities.com Pioneer Press. July 21, 2008. http://www.twincities.com/2008/07/21/minnesota-to-get-4-million-in-bristol-myers-squibb-settlement/. Accessed March 12, 2016.)

[131] North Carolina Department of Justice. Focus on Medicaid Fraud Yields $53 Million in 2010, Says AG Cooper. January 3, 2011. http://www.ncdoj.gov/News-and-Alerts/News-Releases-and-Advisories/Press-Releases/Focus-on-Medicaid-fraud-yields-$53-million-in-2010.aspx. Accessed March 11, 2016.

[132] Wisconsin Department of Justice. Jury Finds Pharmacia Committed Fraud On Wisconsin Medicaid Program; Van Hollen's Department Of Justice Wins State $9 Million. February 17, 2009. https://www.doj.state.wi.us/news-releases/jury-finds-pharmacia-committed-fraud-wisconsin-medicaid-program-van-hollens-department; and Wisconsin Department of Justice. Court Orders Forfeitures of $4.5 Million Against Pharmacia in Pharmaceutical Pricing Fraud Case. September 30, 2009. https://www.doj.state.wi.us/news-releases/court-orders-forfeitures-45-million-against-pharmacia-pharmaceutical-pricing-fraud. Both links accessed March 16, 2016.

[133] Wisconsin Department of Justice. Drug Company Pharmacia Pays $29 Million Toward Judgment. September 4, 2013. https://www.doj.state.wi.us/news-releases/drug-company-pharmacia-pays-29-million-toward-judgment. Accessed March 11, 2016.

and another in 2012 (in Arkansas, for $1.2 billion), have since been overturned on appeal.[134]

5) The penalty for one single-state, non-qui tam, civil court judgment against Johnson & Johnson in South Carolina in 2011 was subsequently reduced from $327 million to $124 million.[135]
6) One single-state, non-qui tam, civil settlement, between LA and five companies (Actavis, Boehringer Ingelheim, GlaxoSmithKline, Merck [Schering-Plough subsidiary], and Mylan [Dey subsidiary]) for a total of $25.2 million in 2012, has, based on further documentation, been broken into five separate settlements, one for each company, which add up to the same amount in financial penalties.[136]
7) One federal, qui tam, civil-criminal settlement with Daiichi Sankyo's Ranbaxy subsidiary for $500 million, originally dated in 2012, the year in which the consent decree was filed against the company,[137] was reclassified as a 2013 settlement, the year in which the final monetary settlement was announced by the Department of Justice (DOJ).[138]

[134] Thomas K. Arkansas Court Reverses $1.2 Billion Judgment Against Johnson & Johnson. *New York Times*. March 20, 2014. http://www.nytimes.com/2014/03/21/business/arkansas-court-reverses-1-2-billion-judgment-against-johnson-johnson.html?_r=0. Accessed January 30, 2016. The *New York Times* article notes only the original $258 million fine, but, according to an earlier Bloomberg report, a judge later added $73 million to the penalty, for a final total of $331 million: Feeley J, Church S. J&J Ordered to Pay $327 Million Over Deceptive-Marketing Claims. BloombergBusiness. June 4, 2011. http://www.bloomberg.com/news/articles/2011-06-03/j-j-ordered-to-pay-327-million-on-deceptive-marketing-claims. Accessed January 30, 2016.

[135] Supreme Court of South Carolina. State ex rel. Wilson [South Carolina attorney general] v. Ortho-McNeil-Janssen Pharmaceuticals, Inc. Order on petition for rehearing. July 8, 2015. http://www.judicial.state.sc.us/opinions/HTMLFiles/SC/27502.pdf. Accessed January 29, 2016.

[136] Office of the Attorney General. State of Louisiana. Attorney General Recovers $25.2 Million from Drug Companies Charged with Fraud. February 7, 2012. http://s3.amazonaws.com/fcmd/documents/documents/000/002/620/original/glaxo-et-al-defrauding-la-medicaid_laagpr.pdf?1423021174; Separate settlement agreements with five companies: http://s3.amazonaws.com/fcmd/documents/documents/000/002/621/original/glaxo-et-al-defrauding-la-medicaid_settlements.pdf?1423021175. Both links accessed March 12, 2016.

[137] Department of Justice. U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories. January 25, 2012. https://www.justice.gov/opa/pr/us-files-consent-decree-permanent-injunction-against-pharmaceutical-ranbaxy-laboratories. Accessed March 11, 2016.

[138] Department of Justice. Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA. May 13, 2013. https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false. Accessed March 11, 2016.