Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015 (Chart Book)

March 31, 2016

Sammy Almashat, M.D., M.P.H. Sidney M. Wolfe, M.D. Michael Carome, M.D.



www.citizen.org

About Public Citizen

Public Citizen is a national nonprofit organization with more than 400,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues, including consumer rights in the marketplace, product safety, financial regulation, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.

About this Document

On March 31, 2016, Public Citizen published a report that catalogs and analyzes all major financial settlements, with accompanying criminal and civil penalties, reached between pharmaceutical manufacturers and federal and state governments. This document contains all charts presented in that report. The full report is available at: www.citizen.org/hrg2311.

See Appendix 2 of that report for the methodology used in compiling the data presented in these charts. See Appendix 3 for an explanation of changes made to some of the pre-2013 data presented in the previous 2012 iteration (available at www.citizen.org/hrg2073) of this report.

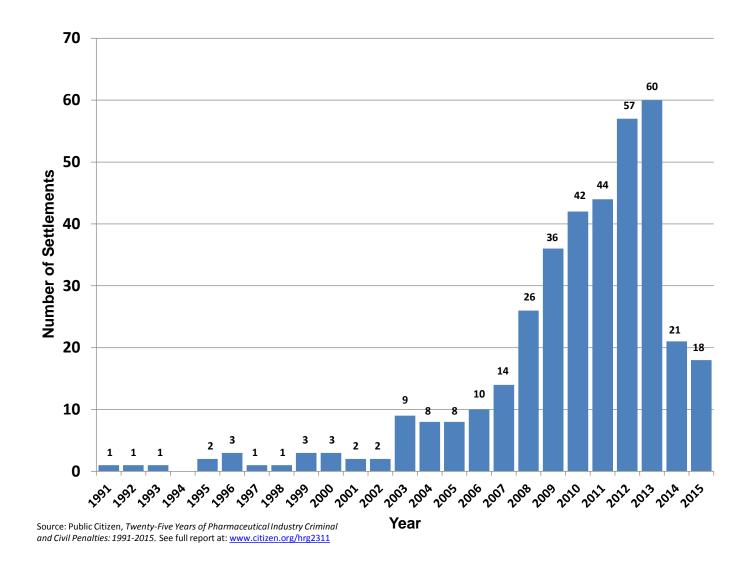
This chart book has been updated since its original posting, as follows: a) Tables 4, 5, 7, and 8 presenting settlement totals by company have been updated with corrected totals for Merck. The previous versions of these tables in both the current and previous iterations of the report lumped together all settlements involving either the American company Merck & Co. (aka Merck Sharp & Dohme) or the German company Merck KGaA under the single entity "Merck". However, we subsequently learned that Merck & Co. and Merck KGaA are, in fact, two entirely separate parent companies. Therefore, the updated company totals present, separately, the totals for the two companies. The term "Merck" now includes only the settlements involving the American Merck & Co. (Merck Sharp & Dohme), with all settlements involving the German company listed under "Merck KGaA"; b) slight changes have been made to the order in which some tables appear; and c) in the first footnote in Table 9, "2009" has been replaced with "2012".

Table of Contents

- Figure 1. Number of Pharmaceutical Industry Settlements, 1991 2015
- Figure 2. Pharmaceutical Industry Financial Penalties, 1991 2015
- Figure 3. Number of Pharmaceutical Industry Settlements, 1991 2015: Federal vs. State
- Figure 4. Pharmaceutical Industry Financial Penalties, 1991 2015: Federal vs. State
- <u>Figure 5</u>. Number of State Pharmaceutical Industry Settlements, 1991 2015: Multi-State vs. Single-State
- <u>Figure 6</u>. State Pharmaceutical Industry Financial Penalties, 1991 2015: Multi-State vs. Single-State
- <u>Figure 7</u>. Number of Pharmaceutical Industry Settlements, 1991 2015: Civil vs. Criminal
- Figure 8. Pharmaceutical Industry Financial Penalties, 1991 2015: Civil vs. Criminal
- Figure 9. Federal False Claims Act (FCA): Financial Penalties by Industry, Fiscal Year (FY) 1991 2015
- <u>Figure 10</u>. Federal Pharmaceutical Industry Settlements, 1991 2015: Qui Tam (Whistleblower) vs. Non-Qui Tam
- <u>Figure 11</u>. Federal Pharmaceutical Industry Financial Penalties, 1991 2015: Qui Tam (Whistleblower) vs. Non-Qui Tam
- <u>Figure 12</u>. State Pharmaceutical Industry Settlements, 1991 2015: Qui Tam (Whistleblower) vs. Non-Qui Tam
- <u>Figure 13</u>. State Pharmaceutical Industry Financial Penalties, 1991 2015: Qui Tam (Whistleblower) vs. Non-Qui Tam
- Figure 14. Types of Pharmaceutical Industry Violations, 1991 2015
- Figure 15. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991 2015
- Figure 16. Types of Pharmaceutical Industry Violations, Jul. 19, 2012 Dec. 31, 2015
- <u>Figure 17</u>. Pharmaceutical Industry Financial Penalties by Type of Violation, Jul. 19, 2012 Dec. 31, 2015
- <u>Table 1</u>. Single-state Settlement Totals, 1991 2015
- <u>Table 2</u>. Multi-state Settlement Totals, 1991 2015

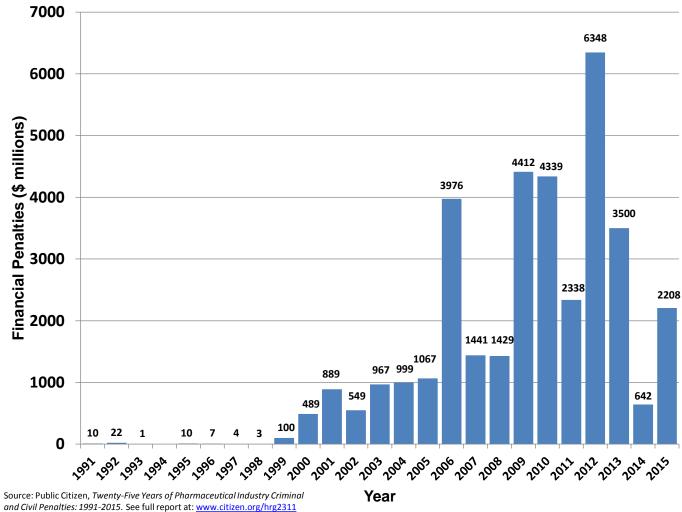
- <u>Table 3</u>. Overall State Settlement Totals, 1991 2015
- <u>Table 4</u>. Pharmaceutical Company Penalties: Worst Offenders, 1991-2015
- <u>Table 5</u>. Pharmaceutical Company Penalties: Repeat Offenders, 1991-2015
- Table 6. Pharmaceutical Company Penalties: Worst Offenders, Jul. 19, 2012 Dec. 31, 2015
- <u>Table 7</u>. Pharmaceutical Company Penalties: Worst Offenders, 2006-2015
- Table 8. Pharmaceutical Company Penalties: Repeat Offenders, 2006-2015
- <u>Table 9</u>. Twenty Largest Settlements and Judgments, 1991 2015
- Table 10. Twenty Largest Settlements and Judgments, Jul. 19, 2012 Dec. 31, 2015
- <u>Table 11</u>. Definitions of the Types of Violations by Pharmaceutical Companies

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



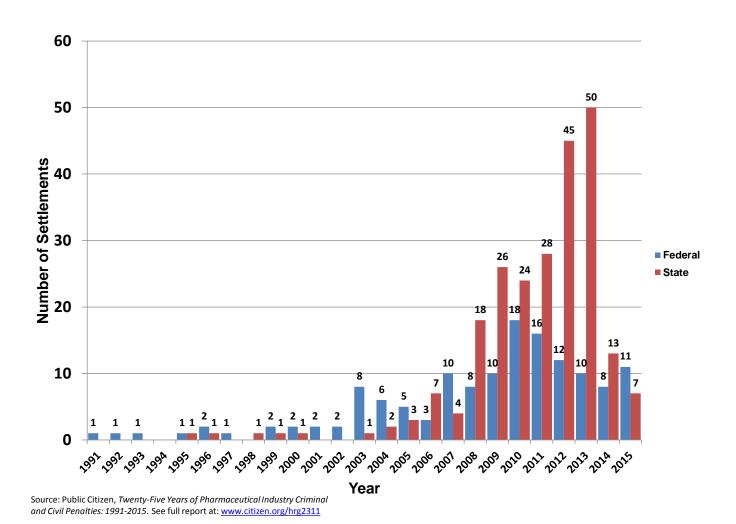
5

Figure 2. Pharmaceutical Industry Financial Penalties, 1991 – 2015



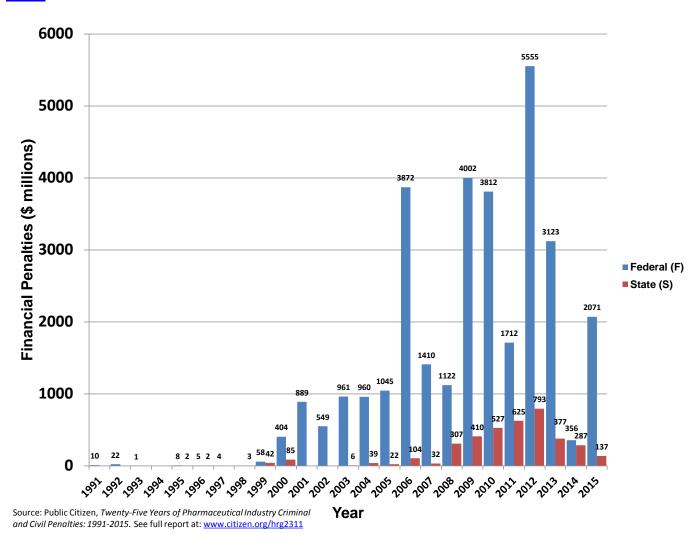
and Civil Penalties: 1991-2015. See full report at: www.citizen.org/hrg2311

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



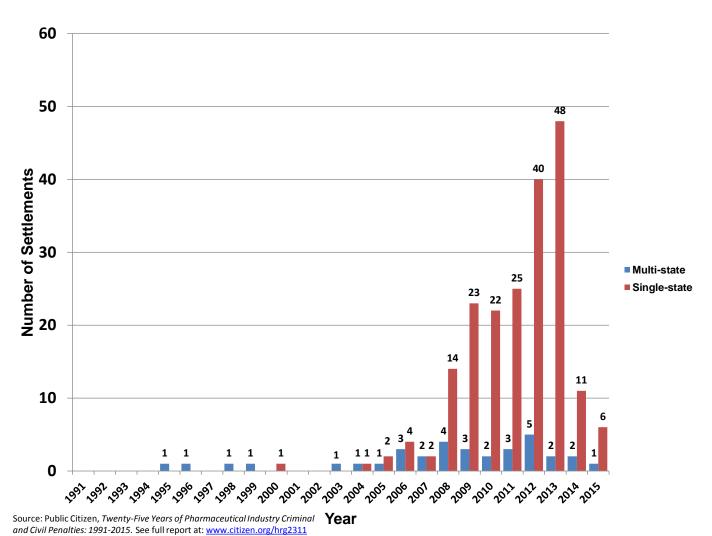
*State settlements refer to those in which the federal government neither was involved in the investigation responsible for the settlement nor was a party to the final settlement, as determined through a review of the press release and, when available, the official settlement document. All other cases were classified as federal, including joint federal-state cases (e.g., those involving Medicaid).

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



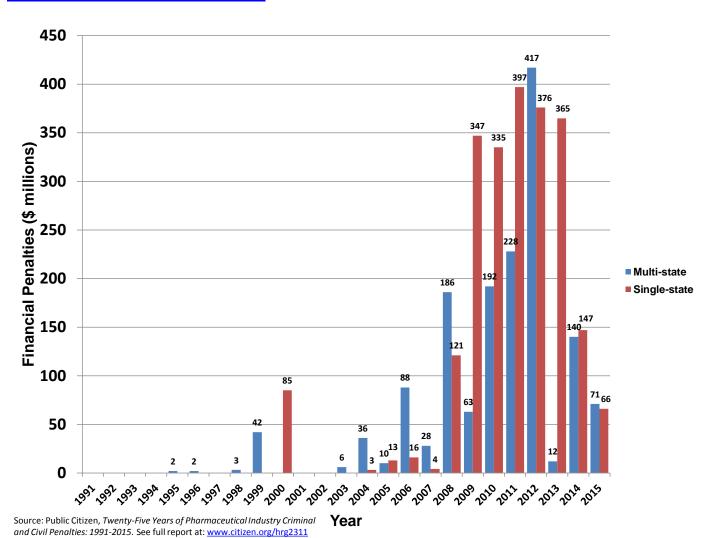
*State settlements refer to those in which the federal government neither was involved in the investigation responsible for the settlement nor was a party to the final settlement, as determined through a review of the press release and, when available, the official settlement document. All other cases were classified as federal, including joint federal-state cases (e.g., those involving Medicaid).

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



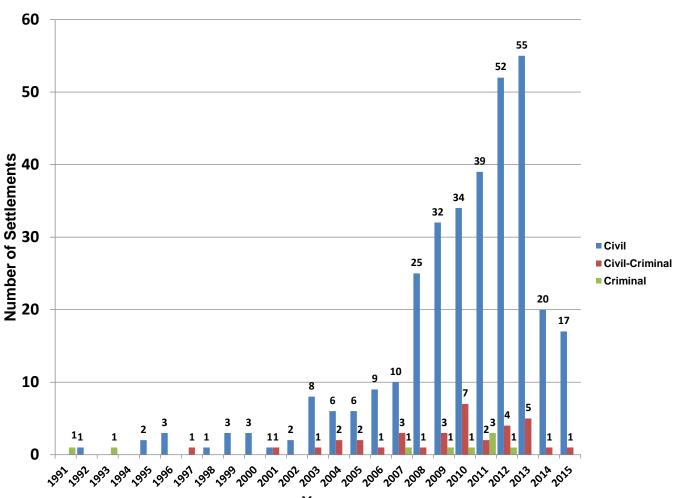
*Single-state settlements were those in which only one state was a party to the final settlement, as gleaned from the information provided in the press release. All other state settlements were classified as multi-state.

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



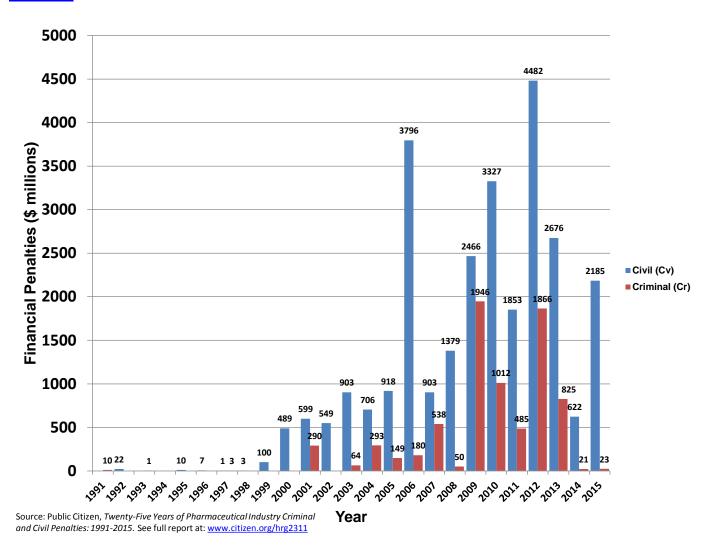
^{*}Single-state settlements were those in which only one state was a party to the final settlement, as gleaned from the information provided in the press release. All other state settlements were classified as multi-state.

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



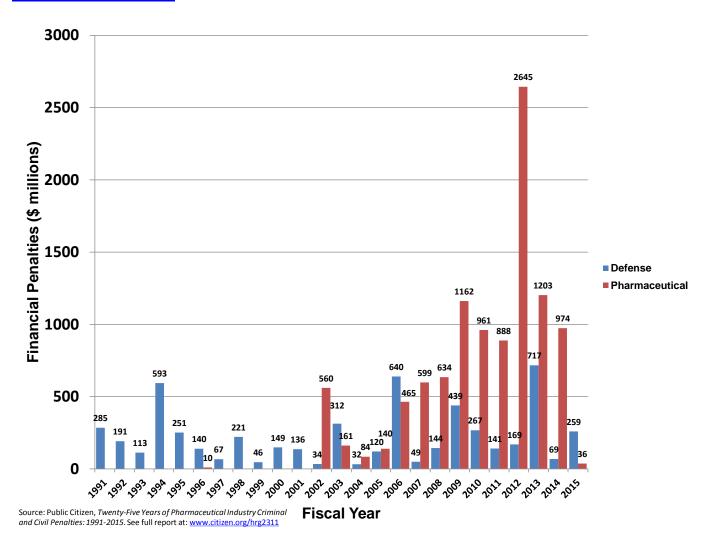
*"Civil" refers to all solely civil settlements. "Civil-Criminal" refers to settlements with both a civil and criminal financial penalty. "Criminal" refers to cases with only a criminal component. All criminal and civil-criminal settlements were federal. All state settlements were civil.

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



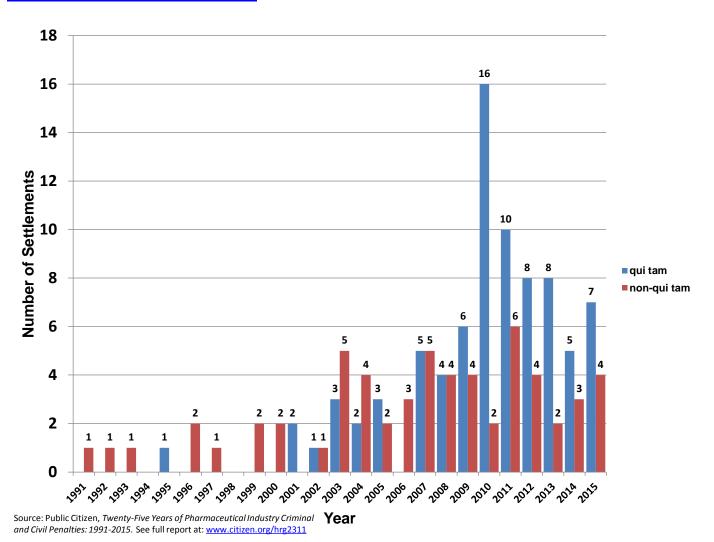
*All criminal penalties were federal. All state penalties were civil. In mixed civil-criminal settlements, the civil and criminal portions were separated out and added to their corresponding categories here.

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



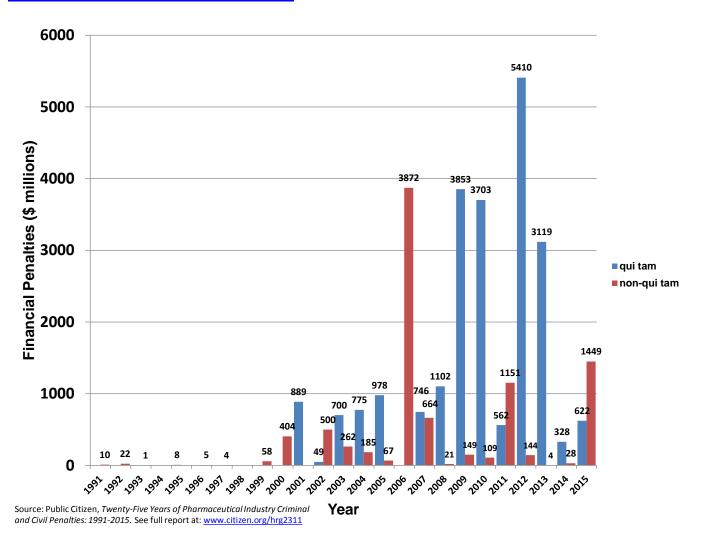
*Defense totals for FY2009, FY2010, and FY2011 have been revised by the U.S. Department of Justice since the 2012 report. Pharmaceutical totals include only those cases in which the federal portion of the FCA penalty was specified in the press release or, during a subsequent search performed since the 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.

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



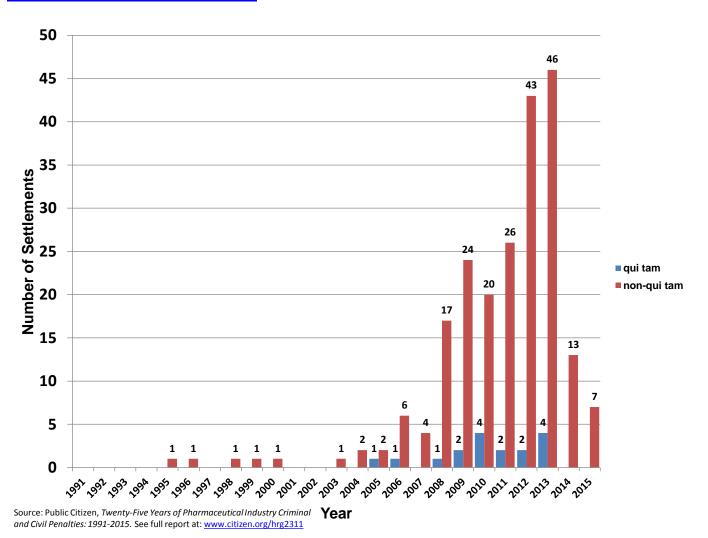
*qui tam cases are those in which any part of the settlement was triggered by a qui tam action.

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



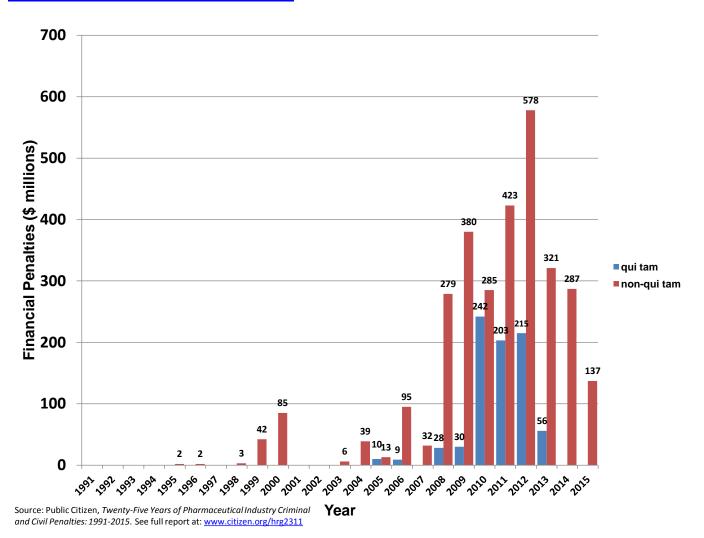
*qui tam cases are those in which any part of the settlement was triggered by a qui tam action. Financial penalties in qui tam settlements presented here include all penalties, including any penalties that may not have been obtained as a result of a qui tam action.

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



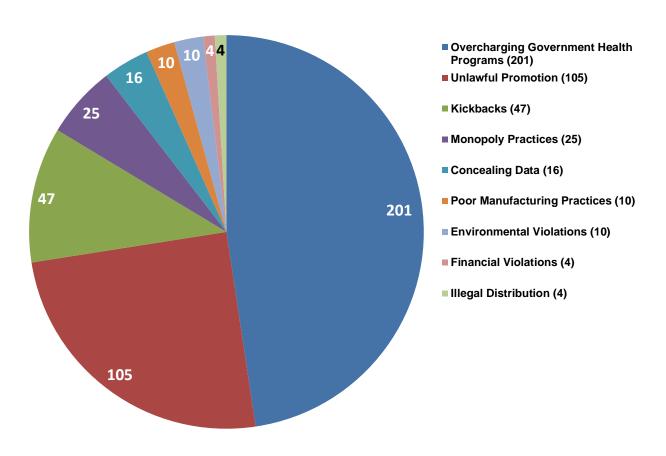
*qui tam cases are those in which any part of the settlement was triggered by a qui tam action.

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



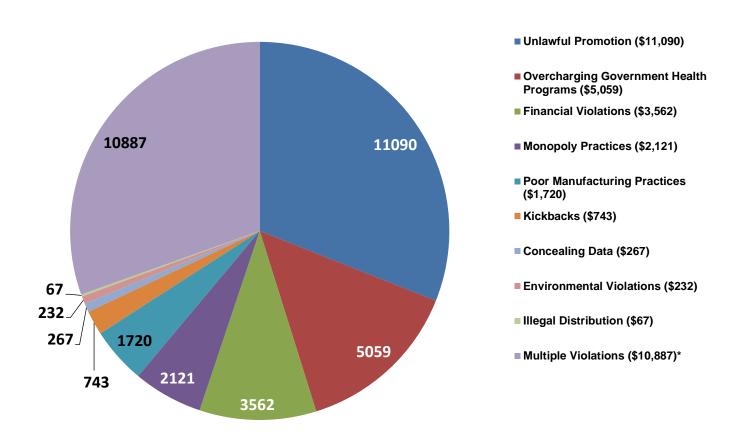
*qui tam cases are those in which any part of the settlement was triggered by a qui tam action. Financial penalties in qui tam settlements presented here include all penalties, including any penalties that may not have been obtained as a result of a qui tam action.

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



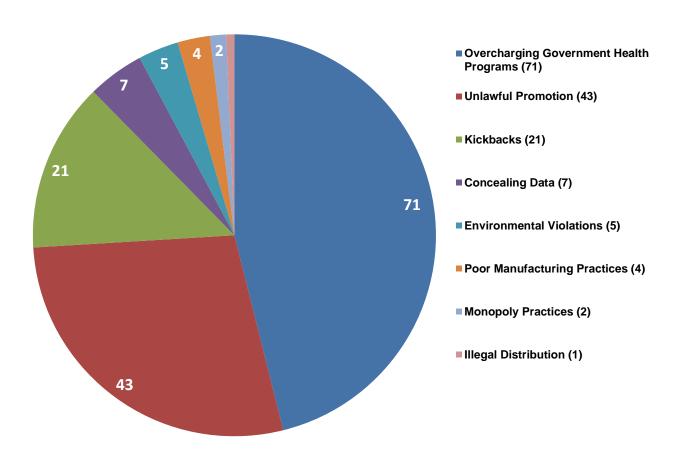
^{*}Total number of violations (422) exceeds number of settlements (373) as some settlements involved more than one type of violation.

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



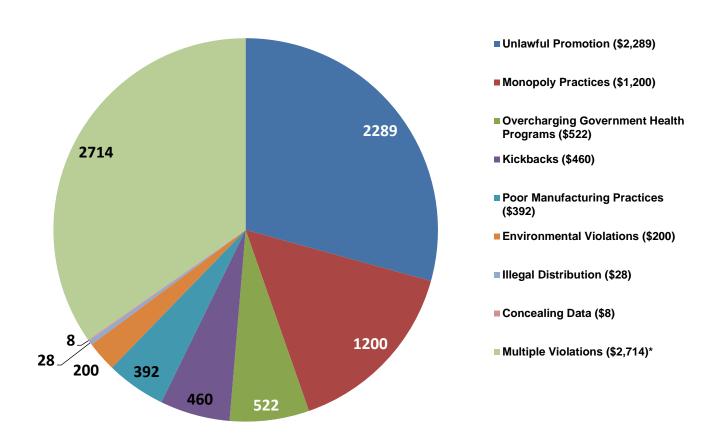
^{*}Settlements that involved more than one type of violation were reviewed and, where possible, individual penalties for each type of violation were determined and added to the totals for that violation. The final total for "multiple violations" represents the sum total that could not be attributed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

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



^{*}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 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	Υ
New Mexico	\$88.15	\$34.10	2	\$1.60	Υ
South Carolina	\$48.59	\$169.00	2	\$12.25	Υ
Louisiana	\$37.96	\$298.84	55	\$5.49	Υ
Texas	\$37.40	\$584.10	19	\$2.92	Υ
daho	\$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	Υ
West Virginia	\$16.84	\$44.50	2	\$3.22	Υ
Nevada	\$10.57	\$9.50	1	\$0.56	Υ
Visconsin	\$9.97	\$46.25	6	\$2.98	Υ
Montana	\$9.02	\$5.90	1	\$0.84	Υ
Massachusetts	\$8.35	\$50.13	8	\$1.12	Υ
Connecticut	\$7.34	\$27.60	2	\$2.16	Υ
California	\$6.27	\$163.30	3	\$0.53	Υ
Maryland	\$4.86	\$15.00	1	\$0.51	Υ
Missouri	\$4.54	\$37.00	3	\$1.82	Υ
Oregon	\$4.52	\$7.99	5	\$0.48	Υ
Kansas	\$3.71	\$5.70	2	\$0.47	Υ
North Carolina	\$2.39	\$25.93	2	\$0.50	Υ
owa	\$1.80	\$4.30	2	\$0.39	Υ
Ohio	\$1.29	\$12.44	2	\$0.21	
llinois	\$1.26	\$14.00	2	\$0.13	Υ
Florida	\$1.18	\$15.00	2	\$0.07	Υ
New Jersey	\$0.22	\$1.30	1	\$0.03	Υ
New York	\$0.18	\$5.38	4	\$0.01	Υ
Total / Median	\$9.50 [median]	\$2,274.64	199	\$1.57 [median]	23/30

*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	Υ	New Jersey	20	\$27.41 Y	
Florida	28	\$60.77	Υ	South Dakota	20	\$12.47 Y	
Arizona	28	\$22.85		Delaware	19	\$11.27 Y	
California	27	\$46.99	Υ	Nebraska	19	\$1.89 Y	
North Carolina	27	\$34.19	Υ	Hawaii	19	\$0.00 Y	
Massachusetts	27	\$19.37	Υ	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	Υ	Kentucky	17	\$8.74	
Washington	25	\$25.21	Y	Rhode Island	16	\$9.19 <mark>Y</mark>	
Tennessee	25	\$23.33	Υ	Montana	15	\$3.02 <mark>Y</mark>	
Nevada	25	\$16.12	Υ	Oklahoma	15	\$0.00 Y	
New York	24	\$42.36	Υ	South Carolina	15	\$0.00 Y	
Ohio	24	\$25.76		Indiana	13	\$12.58 <mark>Y</mark>	
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	Υ	Mississippi	10	\$1.12	
Missouri	22	\$19.65	Υ	Utah	10	\$0.10 Y	
Idaho	22	\$14.31		Alaska	9	\$2.86	
lowa	22	\$12.23	Υ	New Hampshire	8	\$3.55 Y	
Maine	21	\$9.88	Υ	Georgia	7	\$2.59 Y	
Arkansas	21	\$7.46	Υ	Wyoming	6	\$0.00 Y	
Kansas	21	\$0.70	Υ				

^{*}Financial penalties include an incomplete sample (\$790 million, or 52%) of financial penalties from multistate settlements i.e. only individual state settlement shares that were publicly available in press releases over the time period. Therefore, state performance in multi-state 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.

<u>Table 3. Overall State Settlement Totals (single-state and multi-state settlements combined), 1991 – 2015</u>

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	Υ	Kansas	23	\$6.40 Y	
Texas	47	\$690.08	Υ	Alabama	22	\$124.25	
Idaho	38	\$52.41		Hawaii	21	\$83.75 <mark>Y</mark>	
Kentucky	37	\$147.28		New Jersey	21	\$28.71 Y	
Massachusetts	35	\$69.50	Υ	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	Υ	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	Υ	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	Υ	Colorado	17	\$12.90 <mark>Y</mark>	
Maryland	27	\$23.52	Υ	Rhode Island	16	\$9.19 Y	
Vermont	27	\$16.73		Montana	16	\$8.92 <mark>Y</mark>	
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	Υ	Indiana	13	\$12.58 <mark>Y</mark>	
Washington	25	\$25.21	Υ	Virginia	12	\$9.17 Y	
Tennessee	25	\$23.33	Υ	Alaska	10	\$17.86	
lowa	24	\$16.53	Υ	New Hampshire	8	\$3.55 Y	
District of Columbia	24	\$13.58	Υ	Georgia	7	\$3 Y	
Michigan	24	\$4.66	Υ	Wyoming	6	\$0 Y	
Mississippi	23	\$106.46					

^{*}Financial penalties include an incomplete sample (\$790 million, or 52%) of financial penalties from multistate 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.

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†	\$1,841	5.1%	22
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***	\$3,160	8.8%	170
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: Merck KGaA: 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. † This table has been updated with corrected totals for Merck. The previous versions of these tables in both the current and previous iterations of the report lumped together all settlements involving either the American company Merck & Co. (aka Merck Sharp & Dohme) or the German company Merck KGaA under the single entity "Merck". However, we subsequently learned that Merck & Co. and Merck KGaA are, in fact, two entirely separate parent companies. Therefore, the updated company totals present, separately, the totals for the two companies. The term "Merck" now includes only the settlements involving the American Merck & Co. (Merck Sharp & Dohme), with all settlements involving the German company listed under "Merck KGaA".

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

Company**	Number of Federal Settlements	Total Federal Financial Penalties (\$ millions)	Percent of Total***
Pfizer	11	\$3,631	11.4%
GlaxoSmithKline	8	\$7,393	23.1%
Novartis	8	\$1,125	3.5%
Bristol-Myers Squibb	8	\$747	2.3%
Merck [†]	7	\$1,662	5.2%
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****	24 (12 different companies)	\$493	1.5%
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; Merck KGaA; UCB; KV; Biovail; Hoffman-La Roche; Bolar; Eisai; Perrigo; Alpharma; Aventis.

[†] This table has been updated with corrected totals for Merck. The previous versions of these tables in both the current and previous iterations of the report lumped together all settlements involving either the American company Merck & Co. (aka Merck Sharp & Dohme) or the German company Merck KGaA under the single entity "Merck". However, we subsequently learned that Merck & Co. and Merck KGaA are, in fact, two entirely separate parent companies. Therefore, the updated company totals present, separately, the totals for the two companies. The term "Merck" now includes only the settlements involving the American Merck & Co. (Merck Sharp & Dohme), with all settlements involving the German company listed under "Merck KGaA".

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

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. Pharmaceutical Company Penalties: Worst Offenders, 2006-2015

Company*	Total Penalties, 2006-2015 (\$ millions)	Percent of Total Penalties, 2006-2015**	Number of Settlements, 2006-2015***	Penalties, 2014-2015 (\$ millions) [†]	Penalties in 2014- 2015 as a Proportion of Total Penalties from 2006-2015
GlaxoSmithKline	\$7,628	24.9%	26	\$127	1.7%
Pfizer	\$3,458	11.3%	28	\$240	6.9%
Johnson & Johnson	\$2,822	9.2%	18	\$22	0.8%
Merck [‡]	\$1,837	6.0%	20	\$37	2.0%
Abbott	\$1,822	5.9%	15	\$10	0.5%
Eli Lilly	\$1,706	5.6%	14		
Teva	\$1,471	4.8%	13	\$1,235	84.0%
Novartis	\$1,230	4.0%	18	\$390	31.7%
Amgen	\$901	2.9%	12	\$71	7.9%
AstraZeneca	\$669	2.2%	10	\$54	8.1%
Purdue	\$646	2.1%	5	\$24	3.7%
Allergan	\$601	2.0%	2		
Daiichi Sankyo	\$586	1.9%	6	\$81	13.8%
Bristol-Myers Squibb	\$583	1.9%	10	\$15	2.5%
Mylan	\$566	1.8%	20		
Schering-Plough	\$466	1.5%	2		
Cephalon	\$425	1.4%	1		
Boehringer Ingelheim	\$417	1.4%	14		
Actavis	\$355	1.2%	9	\$125	35.2%
Sanofi	\$322	1.1%	12		
Other***	\$1,880	6.1%	119	\$419	22.3%
Total	\$30,391	99.2%	374	\$2,850	9.4%

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

^{**}Percent of \$30.633 billion in overall penalties.

^{***}Total (374) listed here is greater than the total number of settlements over the 2006 - 2015 time period (328) as several settlements involved more than one company.

[†]Just 22 of the 81 companies who reached at least one settlement with the federal or state governments from 2006-2015 paid any financial penalties in 2014-2015.

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

[‡] This table has been updated with corrected totals for Merck. The previous versions of these tables in both the current and previous iterations of the report lumped together all settlements involving either the American company Merck & Co. (aka Merck Sharp & Dohme) or the German company Merck KGaA under the single entity "Merck". However, we subsequently learned that Merck & Co. and Merck KGaA are, in fact, two entirely separate parent companies. Therefore, the updated company totals present, separately, the totals for the two companies. The term "Merck" now includes only the settlements involving the American Merck & Co. (Merck Sharp & Dohme), with all settlements involving the German company listed under "Merck KGaA".

Table 8. Pharmaceutical Company Penalties: Repeat Offenders, 2006-2015*

Company**	Number of Federal Settlements, 2006-2015	Total Federal Penalties, 2006-2015 (\$ millions)	Percent of Total Federal Penalties, 2006-2015***	Federal Penalties, 2014-2015 (\$ millions)****	Federal Penalties in 2014-2015 as a Proportion of Total Federal Penalties from 2006-2015
Pfizer	9	\$3,152	11.7%	\$195	6.2%
GlaxoSmithKline	6	\$7,155	26.5%	\$0.5	0.0%
Johnson & Johnson	6	\$2,246	8.3%		
Merck [†]	6	\$1,660	6.1%	\$37	2.2%
Novartis	6	\$1,105	4.1%	\$390	35.3%
Teva	5	\$1,251	4.6%	\$1,235	98.7%
Bristol-Myers Squibb	5	\$535	2.0%	\$15	2.7%
AstraZeneca	4	\$577	2.1%	\$54	9.4%
Abbott	3	\$1,668	6.2%		
Amgen	3	\$802	3.0%		
Sanofi	3	\$308	1.1%		
Novo Nordisk	3	\$36	0.1%		
Eli Lilly	2	\$1,444	5.3%		
Daiichi Sankyo	2	\$539	2.0%	\$39	7.2%
Mylan	2	\$398	1.5%		
Boehringer Ingelheim	2	\$375	1.4%		
Endo	2	\$232	0.9%	\$232	100.0%
Par	2	\$199	0.7%		
UCB	2	\$56	0.2%		
KV	2	\$45	0.2%		
Biovail	2	\$36	0.1%		
Total	77	\$23,819	88.1%	\$2,197	9.2%

^{*}Companies with at least two federal settlements from 2006-2015. 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 \$27.035 billion in overall federal penalties, for all companies, including those with only one federal settlement, from 2006-2015.

^{****}Just 13 of the 50 companies who reached at least one settlement (i.e. including non-repeat offenders) with the federal government from 2006-2015 paid any financial penalties in 2014-2015.

[†] This table has been updated with corrected totals for Merck. The previous versions of these tables in both the current and previous iterations of the report lumped together all settlements involving either the American company Merck & Co. (aka Merck Sharp & Dohme) or the German company Merck KGaA under the single entity "Merck". However, we subsequently learned that Merck & Co. and Merck KGaA are, in fact, two entirely separate parent companies. Therefore, the updated company totals present, separately, the totals for the two companies. The term "Merck" now includes only the settlements involving the American Merck & Co. (Merck Sharp & Dohme), with all settlements involving the German company listed under "Merck KGaA".

Table 9. 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	Υ
Johnson & Johnson	\$2,006	2013	Unlawful promotion; Kickbacks; Concealing data	Risperdal; Invega; Natrecor	FCA; FDCA	Υ
Abbott	\$1,500	2012	Unlawful promotion; Kickbacks; Concealing data****	Depakote	FCA; FDCA; Anti- Kickback Statute	Υ
Eli Lilly	\$1,415	2009	Unlawful promotion	Zyprexa	FCA; FDCA	Υ
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 Kytril; Bactroban; Paxil CR;	FCA; FDCA	Υ
GlaxoSmithKline	\$750	2010	Poor manufacturing practices	Avandamet	FCA; FDCA	Υ
Serono	\$704	2005	Unlawful promotion; Kickbacks; Monopoly practices	Serostim	FCA	Υ
Merck	\$650	2008	Overcharging govt. health programs; Kickbacks	Zocor; Vioxx; Pepcid	FCA; Medicaid Rebate Statute	Υ
Purdue	\$600	2007	Unlawful promotion	Oxycontin	FCA	
Allergan	\$600	2010	Unlawful promotion	Botox	FCA; FDCA	Υ
AstraZeneca	\$520	2010	Unlawful promotion; Kickbacks	Seroquel	FCA; Anti-Kickback Statute	Υ
Bristol-Myers Squibb		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	Υ
Pfizer	\$491	2013	Unlawful promotion	Rapamune	FCA; FDCA	Υ
			'	•		

^{*}An AR state court judgment against Johnson and Johnson in 2012 for \$1.2 billion has since been overturned on appeal.

‡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.

^{**}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).

<u>Table 10. Twenty Largest Settlements and Judgments, Jul. 19, 2012 – Dec. 31, 2015</u>

Total Penalty (\$ millions)	Federal/ State	Year	Violation(s)*	Major Drug Products Involved (if applicable and known)**	Laws Violated (if known)†	Qui tam‡
\$2,006	Federal	2013	Unlawful promotion; Kickbacks; Concealing data	Risperdal; Invega; Natrecor	FCA; FDCA	Y
\$1,200	Federal	2015	Monopoly practices		Federal Trade Commission Act	
\$762	Federal	2012	Kickbacks; Overcharging	Aranesp: Enbrel: Neulasta	FCA: FDCA	Y
\$500	Federal	2013	Poor manufacturing practices; Concealing data	Cefaclor; Cefadroxil; Amoxicillin; Sotret; Gabapentin; Ciprofloxacin	FCA; FDCA	Y
\$491	Federal	2013	Unlawful promotion	Rapamune	FCA; FDCA	Υ
\$390	Federal	2015	Unlawful promotion; Kickbacks	Exjade; Myfortic	FCA; Anti- Kickback Statute; federal civil forfeiture statute	
\$195	Federal	2015	Environmental violations			
\$193	Federal	2014	Unlawful promotion	Lidoderm	FCA; FDCA	Υ
\$181	State (mult)	2012	Unlawful promotion	Risperdal; Invega		
\$125	Federal	2015	Unlawful promotion; Kickbacks	Actonel; Asacol; Atelvia; Doryx; Enablex; Estrace; Loestrin	FCA; Anti- Kickback Statute	
\$105	State (mult)	2014	Unlawful promotion	Advair; Paxil; Wellbutrin		
\$95	Federal	2012	Unlawful promotion; Kickbacks	Aggrenox; Combivent; Micardis; Atrovent	FCA	Y
\$90	State (mult)	2012	Unlawful promotion	Avandia		
\$71	State (mult)	2015	Unlawful promotion	Aranesp; Enbrel		
\$57	Federal	2014	Unlawful promotion	Adderall XR; Vyvanse; Daytrana; Pentasa; Lialda	FCA	Y
\$55	Federal	2012	Unlawful promotion	Protonix	FDCA	
\$47	Federal	2015	Overcharging govt. health programs		FCA	Y
\$45	Federal	2012	Kirkharks			
				Megace ES		Υ
\$45		2013	Unlawful promotion	Avandia; Paxil; Wellbutrin; Advair;	ĺ	
	(\$ millions) \$2,006 \$1,200 \$762 \$500 \$491 \$390 \$195 \$193 \$181 \$125 \$105 \$95 \$90 \$71 \$57 \$55 \$47 \$45 \$45	(\$ millions) State \$2,006 Federal \$1,200 Federal \$762 Federal \$500 Federal \$491 Federal \$195 Federal \$193 Federal \$181 State (mult) \$125 Federal \$105 State (mult) \$95 Federal \$90 State (mult) \$71 State (mult) \$57 Federal \$47 Federal \$45 Federal \$45 Federal \$45 Federal	\$2,006 Federal 2013 \$1,200 Federal 2015 \$762 Federal 2012 \$500 Federal 2013 \$491 Federal 2013 \$390 Federal 2015 \$195 Federal 2015 \$193 Federal 2014 \$181 State (mult) 2012 \$125 Federal 2015 \$105 State (mult) 2014 \$95 Federal 2012 \$90 State (mult) 2012 \$71 State (mult) 2015 \$57 Federal 2014 \$55 Federal 2012 \$47 Federal 2015 \$45 Federal 2015 \$45 Federal 2012 \$45 Federal 2015	\$2,006 Federal 2013 Unlawful promotion; Kickbacks; Concealing data \$1,200 Federal 2015 Monopoly practices Unlawful promotion; Kickbacks; Overcharging govt. health programs Poor manufacturing practices; Concealing data \$491 Federal 2013 Unlawful promotion \$390 Federal 2015 Environmental violations \$193 Federal 2015 Environmental violations \$193 Federal 2014 Unlawful promotion \$181 State (mult) 2012 Unlawful promotion \$125 Federal 2015 Kickbacks \$105 State (mult) 2014 Unlawful promotion \$198 Federal 2015 Vickbacks \$105 Vickbacks \$106 Vickbacks \$107 Vickbacks \$108 Vickbacks \$109 Vickbacks \$109 Vickbacks \$109 Vickbacks \$100 Vick	\$2,006 Federal 2015 Monopoly practices Unlawful promotion; Kickbacks; Concealing data Aranesp; Enbrel; Neulasta Cefaclor; Cefadroxil; Amoxicillin; Soto Federal 2015 Unlawful promotion Kickbacks; Overcharging govt. health programs Pederal 2013 Unlawful promotion Rapamune Cefaclor; Cefadroxil; Amoxicillin; Soto Federal 2013 Unlawful promotion Rapamune Cefaclor; Cefadroxil; Amoxicillin; Sotret; Gabapentin; Ciprofloxacin Cefaclor; Cefadroxil; Amoxicillin; Cefaclor; Cefac	Commission Com

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

†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.

^{**}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.

Table 11. Definitions of the 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".