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## About Taxpayers Against Fraud Education Fund

The TAF Education Fund (TAFEF) is a non-profit charitable organization dedicated to combating fraud against the Federal Government through the promotion and use of the *qui tam* provisions of the False Claims Act (FCA). *Qui tam* is a unique mechanism in the Act that allows persons and entities with evidence of fraud against federal programs or contracts to bring suit on behalf of the government. Based in Washington, DC, TAFEF informs and educates the general public, the legal community, and other interested groups about the FCA and its *qui tam* provisions. In furtherance of its mission, TAFEF provides information and other assistance to *qui tam* plaintiffs and their counsel, publishes the *False Claims Act and Qui Tam Quarterly Review* and other educational materials, and files *amicus curiae* briefs on important legal and policy issues affecting the Act. TAFEF maintains a comprehensive FCA library for public use and a staff of lawyers and other professionals who are available to assist anyone interested in the False Claims Act and *qui tam*. For more information see [www.taf.org](http://www.taf.org).

## Acknowledgments

This report would not have been possible without the support of TAFEF and the cooperation of the Civil Division of the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and Timothy Terry, Director of the Nevada Medicaid Fraud Control Unit. The author received valuable substantive and editorial guidance from Jim Moorman, TAFEF's President and CEO; Amy Wilken, TAFEF's Associate Director; and Patrick Burns, TAFEF's Director of Communications. The findings and analysis in this report are, however, solely the responsibility of the author.



## Summary

In November 2003, Taxpayers Against Fraud Education Fund issued a report highlighting the emergence of the False Claims Act and its whistleblower provisions as the federal government's most important weapon in protecting the Medicare and Medicaid programs against fraud by drug manufacturers. The report found that as of September 2003, six pharmaceutical manufacturers, including three of the top five U.S. drug companies by sales volume, had settled cases with the Department of Justice (DOJ) involving allegations by whistleblowers of pricing or marketing fraud against Medicare and Medicaid. The settlements resulted in total recoveries of nearly \$1.66 billion, including criminal fines of \$360 million, about \$1.1 billion in civil penalties and damages to the Federal government, and over \$200 million to state governments to compensate them for losses incurred by their Medicaid programs. The November 2003 report speculated that additional settlements would follow.<sup>1</sup>

This report is the next chapter in an unfolding story. During FY 2004—that is, between October 1, 2003 and September 30, 2004—three more whistleblower cases against drug manufacturers were settled for a total of just over \$800 million, raising the total recoveries in such cases by nearly 50 percent to \$2.46 billion (Figure 1). The recoveries in the most recent settlements included \$290 million in criminal fines, \$275 million in penalties and damages to the Federal treasury and Federal grantees, and nearly \$235 million to state governments. All three of these settlements involved allegations of fraud against Medicaid, the federal-state health care program for low-income Americans. None of these settlements involved allegations of fraud against Medicare, the federal health care program for elderly and disabled Americans (as discussed in the November 2003 report, two of the prior settlements involved allegations of Medicare fraud).

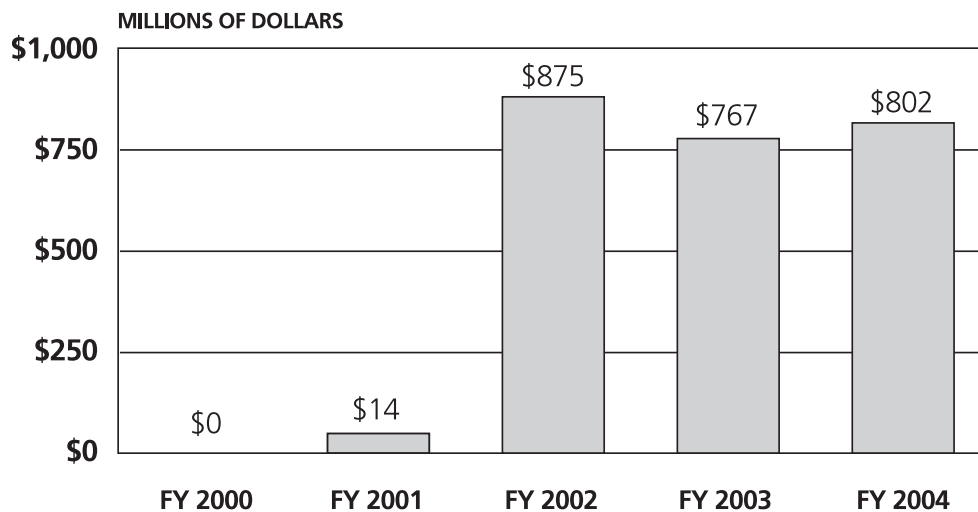
There is no question as to whether there will be more such settlements. The only questions are when these settlements will be announced and how large they will be. According to the Assistant Attorney General for the Civil Division, there are currently under seal in the neighborhood of 100 whistleblower cases involving allegations against over 200 drug manufacturers with respect to 500 different products.<sup>2</sup> If one out of 10 of these cases settles during this fiscal year at the same average amount as the settlements to date, FY 2005 recoveries alone will be about \$2.4 billion.

This update focuses on the three cases settled in FY 2004. It assumes familiarity with the basic mechanics of the federal False Claims Act (FCA), the operation of the Medicaid drug rebate program, corporate integrity agreements (CIAs), and the types of marketing and pricing conduct at issue in the previous settlements, all of which are discussed in the November 2003 report. This update also presents some previously unavailable data on state-by-state recoveries under a number of the pre-FY 2004 settlements.

<sup>1</sup> A. Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (November 2003), [www.taf.org](http://www.taf.org).

<sup>2</sup> Remarks of Peter Keisler, Assistant Attorney General, Civil Division, Department of Justice, to the TAFEF Conference for Relators' Counsel, Washington, D.C., October 14, 2004.

Figure 1 Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid (FY 2000–FY 2004)



Source: DOJ press releases and settlement agreements

## The FY 2004 Settlements

DOJ announced three settlements with drug manufacturers in FY 2004 involving allegations by whistleblowers of fraud against Medicaid. Two of the three settlements announced in FY 2004 began as lawsuits filed under the federal False Claims Act (FCA) by a whistleblower. The third began as a case under a state false claims act, the Texas Medicaid Fraud Prevention Act. The defendant in one of these cases is the nation's largest drug manufacturer, Pfizer, with annual U.S. sales of \$30 billion, representing over 13% of the U.S. market.<sup>3</sup> (The conduct at issue concerned a subsidiary, the Parke-Davis Division of Warner-Lambert, prior to acquisition of Warner-Lambert by Pfizer). The defendant in the other two cases is Schering-Plough, which ranks 16th with annual U.S. sales of \$3.2 billion.<sup>4</sup> Two of the settlements—Pfizer and one of the Schering-Plough matters—involve criminal fines as well as civil penalties and damages. And one of the settlements—Pfizer—breaks new legal ground by recovering losses to Medicaid alleged to have resulting from the aggressive promotion of a drug for uses other than the use for which the drug was approved by the FDA as safe and effective.

As shown in Table 1, government recoveries in the Pfizer settlement were \$430 million, and in the two Schering-Plough settlements were \$345 million and \$27 million, for a total of \$802 million. These three settlements were among the top 10 settlements

<sup>3</sup> IMS Health, "Leading 20 Corporations by U.S. Sales, Moving Annual Total, June 2004," [www.imshealth.com](http://www.imshealth.com) (Press Room, Top-Line Industry Data).

<sup>4</sup> *Ibid.*

of all FCA cases involving all federal contractors (not just health care providers) in FY 2004.<sup>5</sup> The larger of the Schering-Plough settlements represents the single largest total (federal and state) Medicaid recovery to date in an FCA case (\$282.4 million); the Pfizer settlement is the third largest (\$152 million). Of the 10 largest Medicaid FCA recoveries to date, six (including the top five) are whistleblower cases against drug manufacturers summarized in Table 1: Schering-Plough II (\$282.4 million); Bayer II (\$242.1 million); Pfizer II (\$152 million); GlaxoSmithKline (\$85.1 million); TAP Pharmaceuticals (\$56.7 million); and Pfizer II (\$49 million).<sup>6</sup>

Of the total recoveries in the three FY 2004 settlements, \$557 million, including \$292 million in criminal fines, was returned to the Federal treasury. A total of \$197 million was returned to state treasuries (states pay on average 43 percent of the cost of prescription drugs covered by Medicaid). Whistleblowers received nearly \$62 million. To put this \$802 million in context, in FY 2004 the federal government spent \$749 million for the AIDS Drug Assistance Program (ADAP) to purchase needed drug therapies for about 94,000 persons living with HIV/AIDS.

## **Pfizer II**

The Pfizer II case involved allegations of the illegal marketing of Neurontin, an anti-seizure drug, by the Parke-Davis Division of Warner-Lambert, a Pfizer subsidiary acquired in June 2000.<sup>7</sup> Neurontin ranks ninth among all drugs sold in the U.S., with annual sales of \$2.7 billion.<sup>8</sup> As shown in Table 1, this is the second settlement entered into by Pfizer in response to whistleblower allegations under the FCA. It is also the second largest of the drug manufacturer FCA settlements to date when measured by total recoveries (\$430 million) and by the size of the criminal fine (\$240 million). (The largest recovery and largest criminal fine to date occurred in the TAP Pharmaceuticals case). The whistleblower was David Franklin, a former medical liaison for Parke-Davis, who filed his FCA complaint in 1996. Under the settlement, Mr. Franklin received a relator's share of \$24.6 million.

The Food, Drug & Cosmetic Act (FD&C Act) prohibits the sale of a drug to U.S. consumers unless it is approved as safe and effective by the Food and Drug Administration (FDA).<sup>9</sup> When a manufacturer of a new drug applies for FDA approval, it must specify the use(s) for which the drug is safe and effective. In most cases, once the FDA has approved a drug, physicians may prescribe it for the approved use as well as for other

<sup>5</sup> *Schering-Plough II* ranked 1st, *Pfizer II* ranked 2nd, and *Schering-Plough I* ranked 7th. TAFEF, "False Claims Act Settlements & Judgments Fiscal Year 2004" (October, 2004).

<sup>6</sup> *Schering-Plough II* (\$282.4 million); *Bayer II* (\$242.1 million); *Pfizer II* (\$152 million); *GlaxoSmithKline* (\$85.1 million); *TAP Pharmaceuticals* (\$56.7 million); *Abbott Laboratories* (\$50.2 million); *Pfizer I* (\$49 million); *Caremark* (\$44.5 million) *Columbia HCA I* (2000) (\$36.3 million); *SmithKlineBeecham* (\$35.3 million). Source: TAFEF database and National Association of Medicaid Fraud Control Units spreadsheet, "Medicaid Settlements by State" (July 2004).

<sup>7</sup> The global settlement agreement in this case is between the United States, the 50 States and the District of Columbia, and Warner-Lambert Company LLC. The Corporate Integrity Agreement included in the settlement is between the Office of Inspector General of HHS and Pfizer, Inc., Warner-Lambert's parent company. The government's sentencing memorandum states: "The inclusion of Pfizer in the Corporate Integrity Agreement is not intended by the parties to suggest wrongdoing by Pfizer separate from Warner-Lambert, but is a reflection of Pfizer's ownership of Warner-Lambert and the integration of former Warner-Lambert units and personnel into Pfizer." Sentencing Memorandum of the United States, *U.S. v. Warner-Lambert Company LLC*, Criminal No. 04-10150 RGS (D. Mass., June 2, 2004), p. 3. The same applies to the designation of this settlement as *Pfizer II*.

<sup>8</sup> IMS Health, "Leading 20 Products by U.S. Sales, Moving Annual Total, June 2004," [www.imshealth.com](http://www.imshealth.com) (Press Room, Top-Line Industry Data).

<sup>9</sup> 21 U.S.C. §301 *et seq.*

**Table 1 Whistleblower Cases Under Federal and State FCAs Settled with Prescription Drug Manufacturers as of September 30, 2004**

Company	Settlement Date	Product	Total Recovery	Type of Alleged Fraud	Whistleblower
<b>AstraZeneca</b>	6/20/03	Zoladex (prostate cancer)	\$355 million	Marketing the spread Concealment of "Best Price"	Sales executive of competitor TAP Pharmaceuticals
<b>Bayer I</b>	1/23/01	Kogenate, Koate-HP (hemophilia) Gamimmune (immune deficiency)	\$14 million	Marketing the spread Concealment of "Best Price"	Specialty pharmacy (same as Dey, Schering-Plough I)
<b>Bayer II</b>	4/16/03	Adalat CC (blood pressure) Cipro (antibiotic)	\$257 million	Concealment of "Best Price"	Bayer marketing executive
<b>Dey*</b>	6/11/03	Albuterol Sulfate and Ipratropium Bromide (asthma inhalants)	\$18.5 million	Marketing the spread	Independent pharmacy (same as Bayer, Schering-Plough I)
<b>GlaxoSmithKline</b>	4/16/03	Paxil (anti-depressant) Flonase (nasal allergy spray)	\$88 million	Concealment of "Best Price"	(derived from Bayer marketing executive allegations)
<b>Pfizer I</b>	10/28/02	Lipitor (cholesterol)	\$49 million	Concealment of "Best Price"	National account manager for Pfizer subsidiary
<b>Pfizer II</b>	5/13/04	Neurontin (anti-seizure for epilepsy)	\$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
<b>Schering-Plough I*</b>	5/3/04	Albuterol drugs (asthma inhalants)	\$27 million	Marketing the spread	Specialty pharmacy (same as Bayer, Dey)
<b>Schering-Plough II</b>	7/29/04	Claritin family of products (non-sedating antihistamines)	\$345 million	Concealment of "Best Price"	Three employees at Schering-Plough subsidiary
<b>TAP Pharmaceuticals</b>	10/3/01	Lupron (prostate cancer)	\$875 million	Marketing the spread Concealment of "Best Price"	HMO physician and TAP sales executive

\* Settled under the False Claims Act and the Texas Medicaid Fraud Prevention Act

unapproved or “off-label” uses. In general, the Medicaid program purchases drugs on behalf of its low-income beneficiaries if the drugs are prescribed by physicians as medically necessary, whether or not the use is specifically approved by the FDA or off-label.<sup>10</sup> However, the FD&C Act prohibits a manufacturer from marketing or promoting its product among physicians for any unapproved or “off-label” uses.<sup>11</sup> If the manufacturer wants to market or promote a drug for an unapproved use, it must demonstrate to the FDA that the drug is safe and effective for that use. The OIG has identified certain promotional activities as areas of “potential risk” for drug manufacturers in regard to compliance with anti-kickback prohibitions.<sup>12</sup>

The FDA approved Neurontin in December 1993 for use by epilepsy patients as a supplement to another drug to prevent seizures. Mr. Franklin alleged that Warner-Lambert illegally marketed the drug for a number of off-label uses, including the treatment of bipolar mental disorder, Amyotrophic Lateral Sclerosis (ALS, commonly known as Lou Gehrig’s Disease), attention deficit disorder, migraine headaches, and drug and alcohol withdrawal seizures, among others. The firm’s marketing techniques allegedly included misleading sales presentations by medical liaisons to prescribing physicians; free tickets to the Atlanta Olympics and trips to resorts in Palm Beach, Florida and Maui, Hawaii for prescribing physicians; and ostensibly “independent medical education” events on off-label uses of Neurontin. The marketing and promotion activities were effective: off-label uses of Neurontin grew from 15% of prescriptions in 1994 to 94% in 2002. Warner-Lambert, which had previously been convicted of violating the FD&C Act,<sup>13</sup> pleaded guilty to two new counts of violating the Act.<sup>14</sup> It agreed to pay a fine of \$240 million, which DOJ characterizes as “the second largest criminal fine ever imposed in a health care fraud prosecution.”<sup>15</sup>

The civil claims in Pfizer II focused primarily on Medicaid, which spent an estimated \$422 million on off-label uses of Neurontin over the period 1994 to mid-2000.<sup>16</sup> To settle allegations under the FCA of losses incurred by Medicaid due to its illegal drug promotion and marketing, Pfizer’s Warner-Lambert subsidiary agreed to pay \$83.6 million to the federal government and \$68.4 million to the 50 states and the District of Columbia. In addition, Warner-Lambert agreed to pay the states a total of \$38 million to settle its civil liabilities under state consumer protection laws arising out of its improper marketing conduct.

Pfizer entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of HHS that covers the parent company, not just its Warner-Lambert sub-

<sup>10</sup> A Medicaid “covered outpatient drug” includes a drug used for a “medically accepted indication,” which includes a use supported by one or more citations in certain drug use compendia. Sections 1927(k)(3), (k)(6), and (g)(1)(B)(i) of the Social Security Act, 42 U.S.C. §1396r-8(k)(3), (k)(6), and (g)(1)(B)(i).

<sup>11</sup> 21 U.S.C. §331(d), §355.

<sup>12</sup> OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 FR at 23734-23739 (May 5, 2003).

<sup>13</sup> Warner-Lambert was convicted of a felony offense under the FD&C Act in November 1995 for “fraudulently failing to report to the FDA drug stability failure concerning Dilantin and other drugs.” Sentencing Memorandum of the United States, *U.S. v. Warner-Lambert Company LLC*, Criminal No. 04-10150 RGS (D. Mass., filed June 2, 2004), p. 9.

<sup>14</sup> Specifically, Warner-Lambert pleaded guilty to: (1) introducing a misbranded drug into interstate commerce which did not have adequate directions on the label for the intended uses of the drug” in violation of 21 C.F.R. §201.5 and §201.128; and (2) the introduction of an unapproved new drug into interstate commerce in violation of 21 U.S.C. §§331(d), 355(a). Sentencing Memorandum of the United States, *U.S. v. Warner-Lambert Company LLC*, Criminal No. 04-10150 RGS (D. Mass., June 2, 2004), pp. 5-8.

<sup>15</sup> DOJ Press Release, “Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion” (May 13, 2004), [www.usdoj.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm).

<sup>16</sup> D. Armstrong and R. Zimmerman, “Pfizer to Settle Medicaid Fraud Case,” *Wall Street Journal* (May 13, 2004), page A3.

subsidiary. Under the CIA, which extends through May 2009, Pfizer agrees, among other things, to maintain a corporate compliance program meeting certain specifications and to notify the OIG within 30 days of any “reportable event”—i.e., a probable violation of criminal, civil, or administrative laws applicable to Medicare, Medicaid, or any other Federal health care program. Pfizer also will retain an Independent Review Organization (IRO) that periodically analyzes and reports to the OIG on Pfizer’s compliance with the Medicaid rebate program with respect to all of its products, its product promotional activities vis-à-vis managed care customers, and its marketing activities with respect to off-label uses of all of its products.<sup>17</sup>

## **Schering-Plough I**

Two of the three FY 2004 settlements involved Schering-Plough Corporation. While both settlements resolve allegations of Medicaid fraud, they involve different products, different types of conduct, and different types of liability.

In May 2004, Schering-Plough entered into an agreement with the Texas Attorney General and DOJ to settle allegations of fraudulent pricing practices with respect to generic inhalant drugs prescribed to treat asthma and other lung conditions that were purchased by the Texas Medicaid program on behalf of its beneficiaries.<sup>18</sup> The case was filed under the Texas false claims act in March 2000 by a specialty pharmacy, Ven-a-Care of the Florida Keys, which has also been a relator in two other settlements involving drug manufacturers, the *Bayer* and *Dey* cases (Table 1). The complaint named a number of manufacturers as defendants, including Schering-Plough and its subsidiary, Warrick Pharmaceuticals. In June 2003, another of the defendants, Dey, Inc., settled the allegations against it for a total of \$18.5 million.<sup>19</sup>

The complaint alleged fraud by Schering-Plough and Warrick against the Texas Medicaid program for false price reporting designed to enable the manufacturers to “market the spread” for albuterol sulfate, prescribed to treat asthma, and other generic inhalants. The state Medicaid program’s payment for a drug is based upon the price information reported by manufacturers to the Texas Vendor Drug Program (TVDP). Participating manufacturers are required to certify to the TVDP the “price to wholesaler and/or distributor.” The complaint alleged that, among other things, Schering-Plough and Warrick reported inflated prices to TVDP on which the state then based its Medicaid payment for the drug to the dispensing pharmacist. To induce pharmacists to purchase their products, Schering-Plough and Warrick allegedly “marketed the spread,” selling the products to pharmacists at steep discounts off of the inflated prices reported to TVDP. The pharmacist could then keep the difference between the inflated price paid by the state Medicaid program and the discounted price at which he or she bought the drug from Schering-Plough or Warrick.

<sup>17</sup> *Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc.* (May 11, 2004), [www.oig.hhs.gov](http://www.oig.hhs.gov).

<sup>18</sup> *State of Texas ex rel. Ven-a-Care of the Florida Keys v. Warrick Pharmaceuticals Corp.*, No. GV002327 (District Court Travis County, 53<sup>rd</sup> Judicial District, May 2004).

<sup>19</sup> *State of Texas ex rel. Ven-a-Care of the Florida Keys v. Dey, Inc.* No. GV002327 (District Court Travis County, 53<sup>rd</sup> Judicial District, June 11, 2003).

Under the settlement, Schering-Plough agreed to pay \$12.4 million to the U.S. for the federal government's share of the losses sustained by the Texas Medicaid program and \$9,238,000 to the State for its share. Ven-a-Care received \$5,362,000 for the relator's share and attorneys' fees and costs. Schering-Plough remains a defendant in one other state FCA case out from under seal.<sup>20</sup> The Ven-a-Care complaint in Texas is pending against the remaining defendants. A motion by two of these, Roxane Laboratories and Boehringer Ingelheim Pharmaceuticals, to remove the case to a federal district court in Boston, has been denied. In May 2004, the Texas Attorney General filed an amended complaint against three defendants that had been severed from the original complaint (Abbott Laboratories Inc. Baxter Healthcare Corp., B. Braun Medical Inc.) alleging false reporting of prices to the Texas Medicaid program for intravenous fluids.<sup>21</sup>

## **Schering-Plough II**

On July 30, 2004, Schering-Plough agreed to settle an FCA case alleging fraud against the Medicaid rebate program arising from the marketing of Claritin, a non-sedating anti-histamine, and related drug products.<sup>22</sup> The complaint was initially filed in 1998 by Charles Alcorn, Beatrice Manning, and Raymond Pironti, Jr., former employees of ITG, Inc. and Schering Plough subsidiary. The company paid a total of \$345 million to settle its criminal and civil liabilities to federal and state governments. The three relators received a total of \$31,662,173.

In connection with the settlement, Schering Sales Corporation, a subsidiary of Schering-Plough, pleaded guilty to one count of violating the federal anti-kickback statute and paid a \$52.5 million criminal fine. According to the criminal information,<sup>23</sup> Claritin was Schering-Plough's best-selling and most profitable product. Its main competitor was Allegra, a therapeutically equivalent but less expensive drug. Among Schering-Plough's markets were large national managed care plans like Cigna, which use formularies to limit the drugs they will cover for their enrollees. In order to induce Cigna to keep Claritin on its formulary, Schering-Plough agreed to pay Cigna (among other things) a kickback disguised as a "data fee" of 2% of the value of Schering-Plough drugs purchased by Cigna. (The 2000 "fee" was \$1.8 million). The effect of the criminal plea is to bar Schering Sales Corporation from doing business with Medicare, Medicaid, or any other federal health program; this bar does not extend to Schering-Plough Corporation or any of its other subsidiaries.<sup>24</sup>

Schering-Plough's marketing efforts also gave rise to civil liability under the FCA. In a variation on its arrangement with Cigna, Schering-Plough also entered into a "risk share" agreement with PacifiCare, another large managed care plan. Under this agree-

<sup>20</sup> *State of Florida ex rel. Ven-a-Care of the Florida Keys v. Boehringer Ingelheim Corp.*, No. 98-3032A (Second Judicial Circuit Court Leon County, July 9, 2003).

<sup>21</sup> *State of Texas ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, GV000146- A (District Court of Travis County, May 26, 2004) Attorney General Abbott sues Three More Drug Makers in Multimillion Dollar Whistleblower Fraud Case (May 26, 2004) <http://www.oag.state.tx.us/oagnews>.

<sup>22</sup> *U.S. ex rel. Charles Alcorn, Beatrice Manning, G. Raymond Pironti v. Schering-Plough Corp.*, CA 98-5688 (E.D. PA, July 29, 2004), [www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm](http://www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm).

<sup>23</sup> [www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm](http://www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm).

<sup>24</sup> J. Schmit, "Drug Companies Dodge Ban from Medicare, Medicaid," *USA Today* (August 16, 2004), [www.kaisernetwork.org/daily\\_reports](http://www.kaisernetwork.org/daily_reports).

ment, Schering-Plough effectively lowered the price of Claritin to PacifiCare by paying a portion of PacifiCare's costs for covering anti-histamine drugs; over 3 years, Schering-Plough's payments to PacifiCare "risk share" payments totaled \$25 million. Schering-Plough did not directly lower its prices to Cigna or PacifiCare in part because of the Medicaid "best price" rebate law, which requires participating manufacturers to give Medicaid the roughly the same discounts they give to other large customers. When Schering-Plough reported the prices at which it sold Claritin to Cigna and PacifiCare to the federal Medicaid rebate program, it did not report the actual prices these purchasers paid, net of "data fees," "risk share" payments, and other discounts. The effect of reporting prices without these discounts was to lower the amount of the rebate payments that Schering-Plough would owe on the Schering-Plough drugs that Medicaid purchased on behalf of its beneficiaries. This in turn raised Medicaid spending on these prescription drugs by the federal and state governments.

To settle its civil liability resulting from the concealment of "best prices" from Medicaid, Schering-Plough agreed to pay \$165.3 million to the federal government and \$117.1 million to the 50 states for their respective share of Medicaid losses incurred.<sup>25</sup> According to the settlement agreement, this amount has "the effect of equating the price of Claritin to that of Allegra from the first quarter of 1998 to the fourth quarter of 2002."<sup>26</sup> Schering-Plough also agreed to pay \$10.6 million to certain public hospitals and community clinics that were overcharged for Claritin and related drug products as a result of its concealment of the Medicaid "best price."<sup>27</sup>

Although there was no corporate integrity agreement (CIA) in *Schering-Plough I*, there is in this case.<sup>28</sup> Like the CIA in *Pfizer II*, this CIA has a five-year term, and includes requirements that Schering-Plough maintain a compliance program, file annual compliance reports with OIG, and engage an IRO to review its compliance with Medicaid rebate law, its promotional activities vis-à-vis managed care customers, and its sales and marketing processes and policies. Unlike the *Pfizer II* CIA, however, the *Schering-Plough II* CIA requires that the company report, on a quarterly basis, Average Sales Prices (ASP) of Claritin and other specified products.<sup>29</sup> The ASPs for these products must be certified as accurate by a "high managerial agent" of the company, and must be reported to the OIG, to state Medicaid agencies, and to First DataBank Inc., a commercial drug price reporting service.<sup>30</sup>

<sup>25</sup> Schering-Plough was credited for amounts previously received by the federal government (\$31.3 million) and the states (\$22.3 million) through a prior refund to the Medicaid rebate program.

<sup>26</sup> Settlement Agreement, p. 14, [www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm](http://www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.htm).

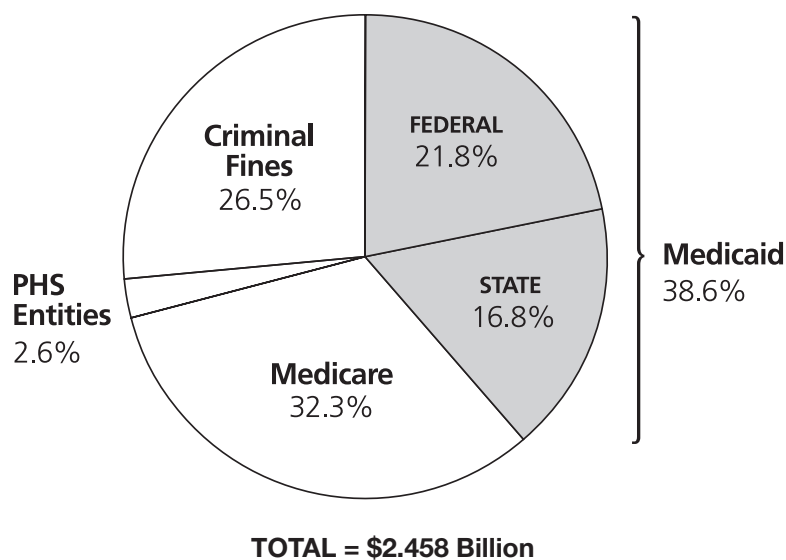
<sup>27</sup> These entities are referred to in the settlement documents as "Public Health Service (PHS) entities." They are the safety net clinics and hospitals specified in section 340B of the Public Health Service Act, 42 U.S.C. § 256b. Under this "340B Program," <http://bphc.hrsa.gov/opa>, manufacturers that want to participate in Medicaid must not only enter into a Medicaid rebate agreement with the Secretary of HHS but also sign a separate contract with the Secretary under which they agree to provide a discounted price for outpatient drugs purchased by these clinics and hospitals for their non-Medicaid patients. The discounted price is tied to the Medicaid rebate for the drug; the greater the rebate amount, the greater the discounted price.

<sup>28</sup> Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation, (July 29, 2004), [www.oig.hhs.gov/fraud/cias.html](http://www.oig.hhs.gov/fraud/cias.html).

<sup>29</sup> Under the CIA, *op. cit.*, the ASP for this purpose has the same meaning as the term under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173. That definition, codified at section 1847A(c) of the Social Security Act, 42 USC 1395w-3(c), is the price of a drug for a calendar quarter determined by dividing (1) the manufacturer's sales of the drug to all purchasers in the U.S. (except Medicaid and sales at nominal charge) by (2) the total number of units of the drug sold by the manufacturer in the quarter. The manufacturer's sales price must include volume discounts, prompt pay discounts, cash discounts, chargebacks, rebates, and may at the Secretary's discretion include any other price concessions identified by the Office of Inspector General.

<sup>30</sup> CIA, *op. cit.* at p. 16. The CIA uses as its definition of ASP that established in section 303(c) of the Medicare Modernization Act, P.L. 108-173, and codified at section 1847A(c) of the Social Security Act, 42 U.S.C. 1395w-3(c).

**Figure 2** Disposition of Recoveries in Cases for Drug Pricing Fraud in Medicare and Medicaid (FY 2001 – FY 2004)



Source: Settlement agreements on file at TAF Education Fund library.

## Disposition of Recoveries Since FY 2001

The three settlements announced over the past year bring to ten the number of federal or state FCA settlements with drug manufacturers, with recoveries totaling over \$2.4 billion. As shown in Figure 2, most of this amount was returned to the federal government. About one third of the total (\$794 million) was returned to the Medicare Trust Fund, about one fourth (\$652 million) went to the Crime Victims Fund, and about one fifth (\$535 million) went to the general fund for the federal share of Medicaid. From these federal recoveries, whistleblowers received \$249 million; this represents 18.7 percent of the federal civil recoveries (Medicare and Medicaid) and 12.6 percent of federal civil recoveries and related criminal fines. Recoveries by states for their share of Medicaid amounted to \$413 million, or about one sixth of the total recoveries. A case-by-case breakdown of recoveries appears in Table 2.

## Corporate Integrity Agreements Since FY 2001

Most of the public attention on the settlements to date has focused on the monetary recoveries, whether civil or criminal. Clearly, these recoveries have not only helped the federal and state governments recoup some of their losses, but they are also highly likely to deter similar marketing and pricing conduct in the future. However, it may be that,

**Table 2 Recoveries in Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2004)**

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Relator's Share
<b>AstraZeneca</b> (6/20/03)	\$355 million	\$63.9 million	\$266.1 million <sup>31</sup>	\$24.9 million	\$13.7 million	\$11.2 million	\$47.6 million
<b>Bayer I</b> (1/23/01)	\$14 million	None	None	\$14 million	\$7.8 million	\$6.2 million	\$1.6 million
<b>Bayer II</b> (4/16/03)	\$257 million <sup>32</sup>	\$5.6 million	None	\$242.1 million	\$133.2 million	\$108.9 million	\$34.2 million
<b>Dey</b> (6/11/03)	\$18 million <sup>33</sup>	None	None	\$14.8 million	\$9.2 million	\$5.6 million	\$3.2 million
<b>GlaxoSmithKline</b> (4/16/03)	\$88 million <sup>34</sup>	None	None	\$85.1 million	\$46.8 million	\$38.3 million	None
<b>Pfizer I</b> (10/28/02)	\$49 million	None	None	\$49 million	\$27.9 million	\$21.1 million	\$5.9 million
<b>Pfizer II</b> (May 13, 2004)	\$430 million <sup>35</sup>	\$240 million	None	\$152 million	\$83.6 million	\$68.4 million	\$24.6 million
<b>Schering-Plough I</b> (5/3/04)	\$27 million <sup>36</sup>	None	None	\$27 million	\$12.4 million	\$9.2 million	\$5.4 million
<b>Schering-Plough II</b> (7/29/04)	\$345.5 million <sup>37</sup>	\$52.5 million	None	\$282.4 million	\$165.3 million	\$117.1 million	\$31.7 million
<b>TAP Pharmaceuticals</b> (10/3/01)	\$875 million	\$290 million	\$528.3 million	\$56.7 million	\$31.2 million	\$25.5 million	\$95.1 million
<b>Totals</b>	<b>\$2.458 billion</b>	<b>\$652 million</b>	<b>\$794.4 million</b>	<b>\$948 million</b>	<b>\$534.9 million</b>	<b>\$413.1 million</b>	<b>\$249.3 million</b>

**Source:** Settlement agreements on file at TAF Education Fund library

**Note:** Totals for Federal and State Medicaid Recovery columns adjusted by allocating \$5.4 million relator's share in proportion to Texas federal matching rate of 60 percent.

over time, the corporate integrity agreements (CIAs) entered into between the manufacturers and the Office of Inspector General of HHS will have an equal if not greater impact on the way in which drug manufacturers do business with the federal and state governments.

As shown in Table 3, two of the settlements over the past year, and eight of the ten settlements to date, have involved CIAs. One of these expires in 2007; the rest expire in 2008 or 2009. Thus, it will be several years before the full impact of these CIAs can

<sup>31</sup> This amount includes payments to settle claims by TRICARE and Department of Defense.

<sup>32</sup> This amount includes Bayer payments to PHS entities of \$9.5 million.

<sup>33</sup> This amount includes \$2.3 million in attorneys' fees and costs to relator and to state of Texas.

<sup>34</sup> This amount includes GSK payments to PHS entities of \$2.6 million.

<sup>35</sup> This amount includes Pfizer payments of \$38 million to states for harm to consumers and to fund remediation program.

<sup>36</sup> This amount includes \$5.4 million payment for relator's share and attorneys' fees and costs presented in "Relator's Share" column.

<sup>37</sup> This amount includes Schering-Plough payments to PHS entities of \$10.6 million.

**Table 3 Obligations under Corporate Integrity Agreements (CIAs) in Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2004)**

Manufacturer (CIA effective date)	Term (Expiration Date)	Compliance Program <sup>38</sup>	Average Sales Price (ASP) Reporting	Independent Review Organization Review: Rebates	Independent Review Organization Review: Other	Annual Compliance Report
<b>AstraZeneca</b> (6/4/03)	5 Years (2008)	Yes	Yes (8 products only)	Yes	Yes (sales and marketing; ASP reporting)	Yes
<b>Bayer I</b> (1/23/01)	5 Years (incorporated into Bayer II)	Yes	Yes	Yes	Yes (compliance with CIA)	Yes
<b>Bayer II</b> (1/23/03)	6 Years (2009)	Yes	Yes	Yes	Yes (managed care transactions)	Yes
<b>GlaxoSmithKline</b> (4/15/03)	5 Years (2008)	Yes	No	Yes	Yes (contract pricing)	Yes
<b>Pfizer I</b> (10/24/02)	5 Years (2007)	Yes	No	Yes	Yes (managed care transactions)	Yes
<b>Pfizer II</b> (5/11/04)	5 years (2009)	Yes	No	Yes	Yes (managed care contracting; promotional and product services)	Yes
<b>Schering-Plough</b> (7/29/04)	5 years (2009)	Yes	Yes (9 products)	Yes	Yes (managed care expenditures; promotional and product services)	Yes
<b>TAP</b> (9/28/01)	7 Years (2008)	Yes	Yes	Yes	Yes (sales and marketing; ASP reporting; compliance with CIA)	Yes

**Source:** Text of CIAs as posted on [www.oig.hhs.gov](http://www.oig.hhs.gov)

be assessed. This assessment will be complicated by the implementation, on January 1, 2006, of the new Medicare Part D program, which will give over 40 million elderly or disabled Medicare beneficiaries the option to enroll in private plans to receive outpatient drug coverage. On that same day, Medicaid, which currently pays for outpatient prescription drugs for over 6 million low-income elderly and disabled Medicare beneficiaries, will no longer do so. These dual eligibles will have to obtain their prescription

<sup>38</sup> Compliance Program includes: written standards of conduct; compliance officer and compliance committee; education and training programs for relevant employees; disclosure mechanism (e.g., employee hotline); and required reporting to OIG of probable violations of criminal or civil laws applicable to Federal health care programs.

drug coverage through Medicare Part D plans, not through Medicaid. In addition, the prices at which manufacturers sell their products to Medicare Part D plans will no longer have to be reported to the Secretary of HHS for Medicaid rebate purposes.<sup>39</sup> Finally, the way in which the current Medicare Part B program purchases drugs administered by physicians will change dramatically beginning in 2005, in part as a result of the lessons taken by policymakers from the *TAP Pharmaceuticals* and *AstraZeneca* cases.<sup>40</sup>

As implementation of the Medicare drug law changes the government market for drug manufacturers, the CIAs now in effect will enable OIG to monitor the sales and marketing behavior of five of the top 20 drug manufacturers by U.S. sales, including three of the top five. Vigorous OIG enforcement of the CIAs should not only encourage legal conduct on the part of manufacturers, it could also give the OIG early warning of new trends in product promotion practices. In addition, four of the CIAs—involving AstraZeneca, Bayer, Schering-Plough, and TAP Pharmaceuticals—require quarterly reporting of Average Sales Prices (ASPs) of some or all of the manufacturer's products to the OIG, to state Medicaid programs, and to a commercial price reporting service. This pricing data offers a potential reference point for the OIG to gauge the prices paid by the new Medicare drug plans and program beneficiaries. It will also enable state Medicaid agencies to purchase these products more effectively, potentially yielding additional Medicaid savings to the federal and state governments.

## State Recoveries

Medicaid is financed jointly by federal and state governments. States that elect to participate in Medicaid make payments for covered services like prescription drugs on behalf of eligible individuals. The federal government shares in those costs. The federal share of Medicaid spending on prescription drugs varies from state to state, ranging from a minimum of 50 percent to as much as 77 percent. Because liability under the FCA for a false or fraudulent Medicaid claim is to the United States Government, and not to the state that pays the claim, the civil penalties and damages are calculated on the basis of the federal share of the payments involved. Similarly, the whistleblower's statutory share is determined on the basis of the federal government's recovery, not the portion received by the states.<sup>41</sup> In order to improve the incentive for whistleblowers to come forward with information about fraud against state Medicaid programs, 14 states and the District of Columbia have enacted their own false claims acts authorizing whistleblower actions against individuals or entities defrauding Medicaid and, in most cases, other state-run programs as well.<sup>42</sup>

As shown in Table 2, states have participated in the Medicaid recoveries in each of the 10 settlements with drug manufacturers. The settlements yielded recoveries to

<sup>39</sup> For an overview of the new Medicare drug law, Health Policy Alternatives, *Prescription Drug Coverage for Medicare Beneficiaries: an Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)* (January 14, 2004), [www.kff.org/medicare/6120.cfm](http://www.kff.org/medicare/6120.cfm).

<sup>40</sup> See *Reducing Medicare and Medicaid Fraud by Drug Manufacturers*, *op. cit.*, at pp. 26-28, p. 46, [www.taf.org](http://www.taf.org); Application of Average Sales Price Methods Beginning in 2005, section 303(c) of P.L. 108-173.

<sup>41</sup> See A. Schneider, *Reducing Medicaid Fraud: The Potential of the False Claims Act* (June 2003), pp. 24-28, [www.taf.org](http://www.taf.org).

<sup>42</sup> Arkansas, California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, New Mexico, Nevada, Tennessee, Texas, Utah, and Virginia. TAFEE, "State False Claims Acts," [www.taf.org/statefca.htm](http://www.taf.org/statefca.htm).

states totaling \$413 million. In two of the cases—*Dey* and *Schering-Plough I*—the state recoveries accrued only to the state under whose false claims act the case was filed (Texas). In the remaining cases, other states participated.

Table 4 presents the recoveries, by state, in each of the 5 national settlements for which data are available (*TAP*, *Bayer I*, *GlaxoSmithKline*, *Pfizer I*, and *Bayer II*).<sup>43</sup> Unfortunately, these data do not include the settlements discussed in this report.<sup>44</sup> The amount of each state’s recovery is determined through settlement negotiations among the federal prosecutors, state Attorneys General, and defendants. In these 5 settlements, the 14 states and the District of Columbia with their own false claims acts received \$171.9 million, or 38 percent of the total state recoveries of \$447.1 million. These 14 states and the District also accounted for 38 percent of Medicaid prescription drug spending (federal and state) in FY 2000.<sup>45</sup> If the recoveries from the two state false claims act cases, *Dey* and *Schering-Plough I*, are included, these 14 states and DC received 40 percent of the total recoveries.

## Conclusion

The past federal fiscal year has yielded three more settlements of FCA whistleblower cases involving allegations of Medicaid fraud against drug manufacturers. The recoveries in these three cases totaled over \$800 million and raised to more than \$2.4 billion the total federal and state recoveries from the ten such settlements over the past three years. If the trend shown in Figure 1 continues over the next two years, total recoveries from drug manufacturers could exceed \$4 billion over 5 years. Since there are in the neighborhood of 100 such cases under seal, this trend is likely to continue, if not accelerate.

It is well worth noting that in seven of the 10 settlements to date, the whistleblower was an employee of the manufacturer (or the manufacturer’s competitor). These seven settlements yielded 98 percent of the total recoveries from all 10 cases. (The remaining 2 percent of recoveries was attributable to three cases brought by a specialty pharmacy doing business with the manufacturers and having access to pricing data not available to federal or state government). It is highly unlikely that, in absence of the information supplied by these employee whistleblowers, federal or state officials administering the Medicaid or Medicare programs would have learned of the non-transparent marketing or pricing practices at issue in these cases, such as the “risk share” and “data fee” arrangements in *Schering-Plough II*.

Finally, while the amount of the actual recoveries is large, it almost certainly understates the amount of savings the FCA and its whistleblower provisions are producing for the federal and state governments with respect to Medicaid spending on prescription drugs. As health economist Jack Meyer has noted in the Medicare context, FCA settle-

<sup>43</sup> In three of the five cases (*TAP*, *Bayer I*, and *GSK*), the settlement totals at the bottom of Table 4 correspond to the State Medicaid Recovery amounts presented in Table 2. In the remaining two cases (*Pfizer I* and *Bayer II*), the state settlement totals at the bottom of Table 4 correspond to the Total Medicaid Recovery totals presented in Table 2, not the State Medicaid Recovery amounts.

<sup>44</sup> For a discussion of Medicaid fraud data limitations, see *Reducing Medicaid Fraud*, *op. cit.*, at pp. 49-51.

<sup>45</sup> Kaiser Commission on Medicaid and the Uninsured, *2000 State and National Medicaid Enrollment and Spending Data (MSIS)*, Table 3: Medicaid Payments by Service, FFY 2000, [www.kff.org/medicaid/kcmu031104bpkg.cfm](http://www.kff.org/medicaid/kcmu031104bpkg.cfm).

**Table 4 Recoveries in Whistleblower Cases Against Pharmaceutical Manufacturers, by State (Settlements as of September 30, 2004)**

State	BAYER I—2001	BAYER II—2004	GSK—2003	PFIZER (LIPITOR)— 2003	TAP—2001	TOTAL MEDICAID SETTLEMENT
AL	\$294,525	\$8,713,129	\$1,511,644	\$665,078	\$726,907	\$11,911,283
AK	\$17,018	\$325,567	\$257,296	\$94,411	\$124,557	\$818,849
AZ	\$0	\$0	\$0	\$0	\$144,229	\$144,229
AR	\$168,564	\$2,590,511	\$1,078,090	\$376,641	\$525,780	\$4,739,586
CA	\$1,248,174	\$27,887,017	\$4,254,660	\$6,876,280	\$4,502,632	\$44,768,763
CO	\$72,965	\$1,578,234	\$746,849	\$279,789	\$271,610	\$2,949,447
CT	\$117,037	\$2,839,815	\$816,558	\$817,188	\$826,385	\$5,416,983
DE	\$1,462	\$665,541	\$341,444	\$172,639	\$334,586	\$1,515,672
DC	\$0	\$791,251	\$250,853	\$108,839	\$197,309	\$1,348,252
FL	\$2,873,474	\$16,213,810	\$5,495,415	\$2,677,404	\$2,838,464	\$30,098,567
GA	\$74,603	\$8,492,345	\$3,005,652	\$1,102,336	\$1,302,119	\$13,977,055
HI	\$23,094	\$1,639,514	\$126,261	\$254,625	\$82,056	\$2,125,550
ID	\$0	\$628,731	\$362,024	\$141,020	\$100,628	\$1,232,403
IL	\$114,822	\$10,149,686	\$2,978,415	\$1,398,336	\$1,774,869	\$16,416,128
IN	\$42,868	\$5,075,147	\$1,575,991	\$886,210	\$1,115,553	\$8,695,769
IA	\$107,793	\$2,214,073	\$946,544	\$466,816	\$315,151	\$4,050,377
KS	\$91,962	\$2,202,456	\$649,267	\$303,591	\$534,361	\$3,781,637
KY	\$113,825	\$7,034,464	\$2,818,221	\$1,043,126	\$503,256	\$11,512,892
LA	\$188,889	\$6,790,021	\$2,712,168	\$994,143	\$1,024,255	\$11,709,476
ME	\$58,771	\$1,524,563	\$961,058	\$651,240	\$450,978	\$3,646,610
MD	\$170,883	\$3,002,242	\$806,851	\$380,461	\$635,426	\$4,995,863
MA	\$264,907	\$7,045,885	\$3,403,694	\$2,268,336	\$1,892,800	\$14,875,622
MI	\$190,796	\$6,035,354	\$2,265,802	\$1,066,638	\$1,519,281	\$11,077,871
MN	\$281,102	\$2,314,440	\$819,652	\$436,559	\$1,219,035	\$5,070,788
MS	\$229,820	\$5,554,735	\$1,163,041	\$821,755	\$803,121	\$8,572,472
MO	\$346,632	\$7,156,135	\$2,708,105	\$1,424,124	\$1,827,332	\$13,462,328
MT	\$23,540	\$569,060	\$348,828	\$101,915	\$170,610	\$1,213,953
NE	\$0	\$1,410,465	\$830,382	\$314,470	\$227,740	\$2,783,057
NV	\$24,010	\$567,139	\$201,500	\$79,463	\$71,640	\$943,752
NH	\$16,536	\$638,958	\$356,721	\$179,736	\$147,328	\$1,339,279
NJ	\$416,774	\$6,797,685	\$2,376,534	\$1,250,626	\$1,876,684	\$12,718,303
NM	\$1,035	\$961,389	\$264,183	\$105,225	\$359,112	\$1,690,944
NY	\$2,808,147	\$17,256,167	\$10,803,739	\$6,921,789	\$9,802,253	\$47,592,095
NC	\$306,850	\$9,357,618	\$3,164,528	\$1,873,126	\$1,874,582	\$16,576,704
ND	\$0	\$447,041	\$205,413	\$90,711	\$113,155	\$856,320
OH	\$138,546	\$12,232,847	\$4,179,949	\$2,409,143	\$2,008,410	\$20,968,895
OK	\$143,122	\$2,884,636	\$775,977	\$332,858	\$448,475	\$4,585,068
OR	\$10,221	\$1,155,375	\$683,147	\$239,600	\$357,520	\$2,445,863
PA	\$638,065	\$8,487,761	\$2,626,034	\$1,538,311	\$4,327,312	\$17,617,483
RI	\$24,337	\$1,101,391	\$451,384	\$287,725	\$197,271	\$2,062,108
SC	\$551,180	\$4,230,469	\$1,555,163	\$989,131	\$475,392	\$7,801,335
SD	\$24,708	\$529,067	\$185,538	\$70,849	\$162,028	\$972,190
TN	\$0	\$843,647	\$1,760,753	\$0	\$350,013	\$2,954,413
TX	\$1,027,238	\$16,442,131	\$5,522,496	\$2,624,294	\$3,466,356	\$29,082,515
UT	\$108,758	\$770,939	\$459,424	\$128,473	\$126,671	\$1,594,265
VT	\$5,850	\$732,577	\$464,286	\$370,329	\$138,092	\$1,711,134
VA	\$227,593	\$4,916,009	\$1,583,279	\$927,365	\$1,777,487	\$9,431,733
WA	\$234,564	\$3,704,749	\$1,527,343	\$875,195	\$788,695	\$7,130,546
WV	\$13,532	\$3,292,154	\$1,244,430	\$941,231	\$306,863	\$5,798,210
WI	\$152,112	\$4,111,844	\$1,268,390	\$873,842	\$1,433,271	\$7,839,459
WY	\$10,817	\$220,796	\$147,592	\$29,655	\$103,556	\$512,416
<b>SETTLEMENT TOTALS</b>	<b>\$14,001,521</b>	<b>\$242,126,580</b>	<b>\$85,042,568</b>	<b>\$49,262,647</b>	<b>\$56,703,196</b>	<b>\$447,136,512</b>

Source: National Association of Medicaid Fraud Control Units, 2004.

ments have indirect, non-quantifiable benefits in the form of increased compliance and deterrence of fraudulent conduct.<sup>46</sup> In the Medicaid prescription drug context, the 10 settlements to date, along with the seven CIAs in place, will in all likelihood promote compliance by the affected manufacturers with Medicaid rebate and FDA off-label marketing rules. In addition, the 100 or so cases under seal are likely to encourage accurate Medicaid rebate reporting and discourage prohibited off-label marketing of drugs by the named defendant manufacturers. Given the size of Medicaid spending on prescription drugs (nearly \$30 billion in 2002) and the high rate of growth in drug spending (18.8 percent per year between 2000 and 2002), even a small improvement in manufacturer compliance can yield substantial dollar savings for federal and state taxpayers alike.<sup>47</sup>

<sup>46</sup> J. Meyer and S. Anthony, *New Directions for Policy, Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act* (September 2001), p. 32, [www.taf.org](http://www.taf.org).

<sup>47</sup> B. Bruen and A. Ghosh, *Medicaid Prescription Drug Spending and Use* (June 2004), pp. 3-4, [www.kff.org/medicaid](http://www.kff.org/medicaid).

