The Role of the False Claims Act in Combatting Medicare & Medicaid Fraud by Drug Manufacturers: An Update

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prepared for Taxpayers Against Fraud Education Fund
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This is the third in a series of reports issued by Taxpayers Against Fraud Education Fund (TAFEF) describing the role the False Claims Act (FCA) has played in protecting the Medicare and Medicaid programs against fraud by drug manufacturers. Viewed as "one of the most important tools" available to federal prosecutors and investigators, the FCA imposes treble damages and civil penalties on companies that knowingly present false claims for payment to the federal government programs.[2] Medicare is the federal program of health insurance coverage for 43 million elderly and disabled Americans. Medicaid is the federal-state program of health and long-term care for 55 million low-income Americans. This year, the federal government is expected to spend a total of $621 billion on both of these programs.[3]

The previous two TAFEF reports found that, as of September 2004, seven 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[4] of pricing or marketing fraud against Medicare and Medicaid. These settlements resulted in criminal fines of $652 million, over $2.4 billion in civil fines to the federal government, and payments of $413 million to state governments to compensate them for losses incurred by their Medicaid programs. The two reports speculated that additional settlements would follow, noting that there were under seal in the fall of 2004 in the neighborhood of 100 whistleblower cases involving allegations against over 200 drug manufacturers with respect to 500 different products.[5]

In the two years since that time, six more whistleblower cases against drug manufacturers were settled for a total of $1.4 billion. One of these cases was settled in FY 2005 for a total of $149 million; the others were settled in FY 2006 for a total of $1.3

1. The author gratefully acknowledges the contributions Vikki Wachino, Wachino Health Policy Consulting, for her analysis of all Medicaid FCA settlements between FY 2004 and FY 2006; Amy Wilken, J.D., for her analysis of the recent corporate integrity agreements that appear in Table 3; and Jeb White, Staff Attorney at TAFEF, for his careful editing and assistance with relevant case law. The author also thanks Daniel R. Anderson, Assistant Director, Commercial Litigation Branch, Civil Division, Department of Justice, and Patrick O'Connell, Assistant Attorney General, State of Texas, for their assistance in understanding the terms of certain settlements. However, the data and analysis presented in this report are solely the responsibility of the author.

2. Department of Health and Human Services and the Department of Justice, *Health Care Fraud and Abuse Control Program: Annual Report for FY 2005* (August 2006), p. 33, *available at* http://www.oig.hhs.gov/publications/hcfac.html#1 (last visited February 14, 2007).

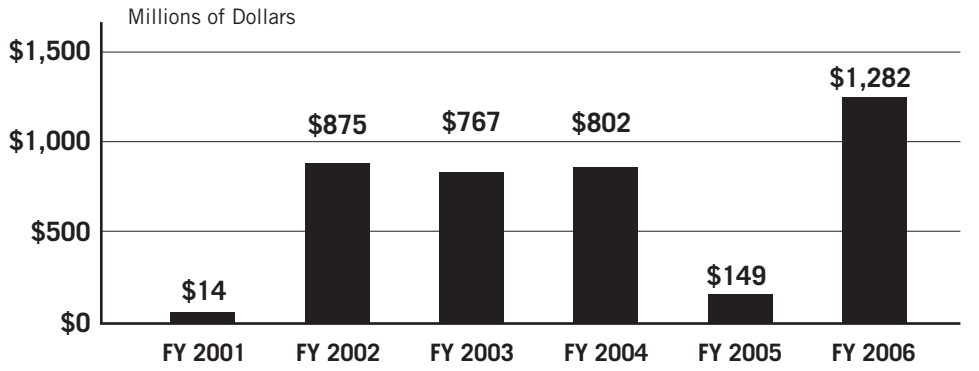
3. Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2008 to 2017* (January 2007), Table 3-3, p. 55, *available at* www.cbo.gov (last visited February 14, 2007).

4. Under the False Claims Act, whistleblowers are referred to as "relators." For a brief summary of the FCA, see http://www.taf.org/whyfca.htm (last visited February 14, 2007).

5. A. Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (November 2003); A. Schneider, *The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update* (November 2004), p.5, *available at* www.taf.org (last visited February 14, 2007).

billion. Over the FY 2001–2006 period, recoveries in such cases total nearly $3.9 billion. (See Figure 1.)

Figure 1. Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid. FY 2001–FY2006



Source: DOJ press releases and settlement agreements

These six settlements during FY 2005 and FY 2006 bring to sixteen the total number of settlements of whistleblower cases against drug manufacturers involving allegations of Medicaid or Medicare fraud. Twelve of these cases were brought under the FCA; the remaining four were brought under the Texas false claims act. In ten of these sixteen cases, the whistleblowers were employees of the manufacturer or the manufacturer's competitor (see Table 1 at the end of this report). In six cases the whistleblower was a specialty pharmacy doing business with the manufacturers and having access to pricing data not available to federal or state governments.[6] It is highly unlikely that, in absence of the information supplied by these employee-whistleblowers and the specialty pharmacy, 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.

As noted, nearly $3.9 billion has been recovered from drug manufacturers over the past six fiscal years as the result of cases brought by whistleblowers. During this period, two other FCA cases involving drug manufacturers were settled: Abbott Laboratories, settled on July 23, 2003 for $622 million;[7] and Eli Lilly and Company, settled on December 21, 2005 for $36 million.[8] Neither of these cases was initiated by whistleblowers. Thus, between FY 2001 and FY 2006, the FCA produced $4.5 billion in recoveries from drug manufacturers; of this amount, $3.9 billion, or 85 percent, is directly attributable to actions brought by whistleblowers.

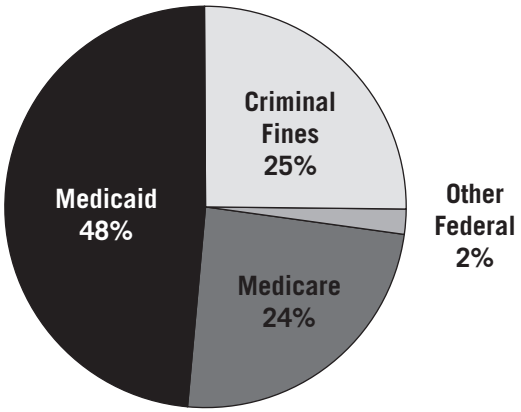
6. Ven-a-Care of the Florida Keys, *available at* http://66.98.181.12/venacare.htm (last visited February 14, 2007).

7. *U.S. v. Abbott Laboratories, Inc.* (S.D. Ill.), July 23, 2003, noted in *False Claims Act & Qui Tam Quarterly Review* (October 2003), p. 59.

8. *U.S. v. Eli Lilly and Co.*, No IP05-CR-0206-01-B/F (S.D.Ind., Dec. 21, 2005), *available at* http://www.usdoj.gov/civil/ocl/cases/Lilly/index.htm (last visited February 14, 2007).

As shown in Figure 2 below, of the nearly $3.9 billion recovered in sixteen whistleblower settlements with drug manufacturers over the past six years, about three quarters is civil recoveries and the remaining quarter is criminal fines.[9] The single largest source of the recoveries is Medicaid: nearly half of the total recoveries, and over two thirds of the total civil recoveries, are attributable to allegations of violations of Medicaid requirements. Of the $1.89 billion in Medicaid recoveries, just over $1 billion went to the federal government, and the remaining $830 million was distributed among the states.[10] A breakdown of the recoveries in each of the sixteen settlements is provided in Table 2 at the end of this report.

Figure 2. Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid (FY2001–FY2006), by Type



Note: Due to rounding, percentages do not add to 100

Source: DOJ press releases and settlement agreements

Cases involving drug manufacturers have been the single largest source of FCA recoveries in whistleblower cases involving Medicare, Medicaid, and other programs administered by the Department of Health and Human Services. According to DOJ, between FY 2001 and FY 2006, there were $5.7 billion in total FCA whistleblower recoveries. [11] Over this same period, over $2.9 billion, or about half of this amount, was attributable to civil settlements in cases initiated by whistleblowers against drug

9. Six of the sixteen whistleblower settlements included criminal fines totaling $968 million, or 25 percent of all recoveries. As shown in Table 2 at the end of this report, the largest of the criminal fines was paid in the *TAP Pharmaceutical*s case in 2001 ($290 million), followed by *Pfizer II* ($240 million), *Schering-Plough III* ($180 million), *Serono* ($136.9 million), *AstraZeneca* ($63.9 million), *Schering-Plough II* ($52.5 million), and *Bayer II* ($5.6 million).

10. State-by-state distributions of the $830 million (for states other than Texas) by settlement are in the possession of the National Association of Medicaid Fraud Control Units.

11. Civil Division, U.S. Department of Justice, *Fraud Statistics – Health & Human Services, October 1, 1986 – September 30, 2006, available at* http://www.taf.org/statistics.htm (last visited February 14, 2007).

manufacturers. The whistleblowers' shares account for about 13 percent of the civil recoveries.[12]

This update focuses on the six whistleblower cases against drug manufacturers settled during FY 2005 and FY 2006. It briefly reviews the main types of illegal conduct alleged and the remedies provided, which include Corporate Integrity Agreements (CIAs) summarized in Table 3 at the end of this report. (CIAs, which are part of each of the settlements other than those with the State of Texas, are negotiated by the Office of Inspector General (OIG) of the Department of Health and Human Services).[13] The update concludes with a short discussion of the impact of these drug manufacturer settlements on Medicare and Medicaid spending on prescription drugs.

THE FY 2005 AND FY 2006 SETTLEMENTS

Over the two-year period from October 1, 2004 through September 30, 2006, there were six settlements in cases initiated by a whistleblower against a drug manufacturer: *GlaxoSmithKline II*; *King Pharmaceuticals*; *Schering-Plough III*; *Serono*; *Roxane* and *Baxter*. All six of these settlements involved allegations of fraud against Medicaid; *GlaxoSmithKline II* also involved allegations of fraud against Medicare. The *Roxane* and *Baxter* settlements resulted from whistleblower cases brought under the Medicaid false claims act of the State of Texas and settle only FCA claims relating to the Texas Medicaid program. All six settlements are summarized in Table 1 at the end of this report. The amounts recovered by each settlement are summarized in Table 2. The corporate integrity agreements (CIAs) entered into by GlaxoSmithKline, King Pharmaceuticals, Serono, and Schering-Plough Corporation are summarized in Table 3.

The allegations of fraud against Medicaid and Medicare in these and previous whistleblower cases fall into three broad categories: "marketing the spread;" concealment of "best price;" and off-label marketing. Three of the cases involve marketing the spread (*Baxter*, *GlaxoSmithKline II* and *Roxane*). Two involve concealment of best price (*King Pharmaceuticals*, *Schering-Plough III*), and two involve off-label marketing (*Serono*, *Schering-Plough III*).

Marketing the Spread

This occurs when a manufacturer uses the "spread"—i.e., the difference between (1) the price paid for a drug by Medicaid to a pharmacist and (2) the actual cost of the

12. As show in Table 2 at the end of this report, whistleblowers received a share of the recoveries in all but two of the sixteen settlements. The whistleblower's share in *Schering-Plough III* is not resolved, so this case was excluded from the computation (the remaining fifteen cases were included). The whistleblower in *GlaxoSmithKline I* was also the whistleblower in *Bayer II*, settled on the same day. *See* A. Schneider (November 2003), *op. cit*., pp. 33–34.

13. Under section 1128(b)(7) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(7), the OIG has the authority to exclude from participation in Medicare, Medicaid, and other federal health care programs any provider or entity that submits a false claim in violation of the FCA. In exchange for OIG's agreement not to seek exclusion, the defendant in an FCA settlement enters into a CIA that is enforced by the OIG. All CIAs are posted on the OIG website at http://www.oig.hhs.gov/fraud/cias.html (last visited February 14, 2007).

drug to the pharmacist—as a tool for selling its product to the pharmacist. The illegality results from the manufacturer's decision to inflate the price of the drug that it provides to an independent price reporting service, knowing that the Medicare and Medicaid programs will use that reported price information in determining how much they will pay the pharmacist. For example, many state Medicaid programs have used the "average wholesale price" (AWP) as a basis for paying pharmacists for prescriptions they fill for Medicaid beneficiaries. The AWP, in turn, is based upon what the manufacturer reports. If the reported AWP for a particular drug is much higher than what the pharmacist actually pays to acquire the drug, and if the pharmacist can keep all or most of the difference between AWP and the actual cost, then the pharmacist has a strong incentive to fill prescriptions with a drug with the greatest "spread." (Marketing the spread has also occurred when Medicare or Medicaid pays physicians for drugs that they administer in their offices directly to patients).

In June of 2005, the Assistant Attorney General for the State of Texas testified before the Senate Finance Committee that:

> "…some manufacturers make conscious, deliberate business decisions to create enhanced spreads and market the sale of their products based on the spreads. For example, manufacturers engaged in the following activities:
>
> - purposefully reported false and inflated prices to Texas Medicaid—as well as to third party price reporting services— in order to create enhanced spreads;
>
> - deliberately failed to report prices to certain classes of trade in violation of Texas law;
>
> - instructed their sales personnel to market spreads to consumers;
>
> - created spread sheets showing pharmacies how much more profit they can make off Medicare and Medicaid when purchasing one product over another;
>
> - tied sales personnel compensation to success in marketing the spread.
>
> We also found that some manufacturers actually kept two sets of computer records with prices: one with inflated prices that are reported to the price reporting services like First Data Bank, or in Texas' case, directly to the Medicaid program; and another with real contract prices that are used in every day fussiness transactions with the manufacturer's customers."[14]

Three of the cases settled in FY 2005 and 2006 involved marketing the spread:

14. Testimony of Patrick J. O'Connell, Assistant Attorney General, State of Texas, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

GlaxoSmithKline II.[15] On September 20, 2005, GlaxoSmithKline, the second largest drug manufacturer as measured by U.S. sales,[16] settled FCA whistleblower allegations of marketing the spread for Zofran and Kytril, two anti-emitic drugs used to control nausea resulting from oncology and radiology treatments, from 1994 though 2002. The settlement totaled $150 million, of which $126 million was attributable to Medicare and TRICARE and $24 million was attributable to Medicaid (Table 2). This was the company's second settlement of an FCA whistleblower case; in 2003 the company settled allegations of concealing "best price" for $88 million (See Table 1). In addition to allegations of marketing the spread, the 2005 settlement involved allegations that the company encouraged customers to "double dip" by billing Medicare for an injection of Kytril, then pooling Kytril leftover from several vials to create a full dose, and then bill Medicare again for administering that dose. The whistleblower, Ven-A-Care of the Florida Keys, received $26 million. As part of the settlement, the corporate integrity agreement (CIA) into which the company had previously entered with the Office of Inspector General was amended to require the company to report accurate average sales prices (ASPs) and accurate average manufacturer prices (AMPs) for drugs covered by Medicare, Medicaid, and other federal health care programs (Table 3).

By definition, FCA whistleblower cases address false or fraudulent claims presented to federal government programs like Medicare and Medicaid. There are, however, other parties to these transactions—notably, program beneficiaries. In the case of Medicare Part B, which covers physician-administered drugs like Zofran and Kytril, the program at the time of the litigation paid 80 percent of the cost of the drug, with the beneficiary responsible for the remaining 20 percent coinsurance. Because the coinsurance amount is tied to the drug's AWP, beneficiaries paid more out of pocket than they would have paid if manufacturer had not inflated the AWP. On August 10, 2006, GlaxoSmithKline paid $70 million to settle a class action brought on behalf of Medicare beneficiaries who paid some or all of the cost of these two drugs. The plaintiffs also included private insurers and union benefit funds that pay for these drugs on behalf of their members, and state Medicaid programs who paid Part B cost-sharing amounts for low-income Medicare beneficiaries.[17]

Roxane.[18] On November 25, 2005, Roxane Laboratories settled allegations that it marketed the spread on albuterol drugs (asthma inhalants) by knowingly inflating the

15. *U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. GlaxoSmithKline PLC*, docket number sealed, settlement announced (D. Mass. Sept. 20, 2005).

16. GlaxoSmithKline had prescription pharmaceutical sales of $19.1 billion in the U.S. in 2005, giving it a market share of 7.9 percent, second only to that of Pfizer (10.8 percent). IMS Health, *Leading 20 corporations by U.S. Sales, 2005, available at* www.imshealth.com (last visited July 16, 2006).

17. *In re* Pharmaceutical Industry Average Wholesale Price Litigation, No. 01-CV-12257-PBS settlement announced (D.Mass. Aug. 10, 2006). The settlement also involved allegations of marketing the spread for Amoxil, an antibiotic. Under the terms of the settlement, GSK will establish a national restitution fund of about $40 million from which Medicaid beneficiaries may make claims for reimbursement for excess coinsurance payments for these drugs. *See* www.oag.state.ny.us/press/2006/aug/aug10a_06.html (last visited February 14, 2007).

18. Settlement Agreement and Release, November 25, 2005, *State of Texas ex rel. Ven-A-Care of the Florida Keys,Inc. v. Roxane Laboratories Inc.*, No. GV3-03079 (District Court Travis County, 201st Judicial District) and No. GV002327 (District Court Travis County, 53rd Judicial District).

prices it reported to the Texas Vendor Drug program. Roxane was one of three manufacturers competing in the Texas Medicaid market for generic inhalant medicines for asthma; the other two had previously settled allegations of marketing the spread with the Texas Attorney General in June 2003 (Dey Laboratories, $18.5 million) and May 2004 (*Schering-Plough I*/Warrick Pharmaceuticals, $27 million).[19] The whistleblower in the Roxane case was the same as in the other two settlements: Ven-A-Care of the Florida Keys. The United States was not a party to the settlement, and Roxane did not enter into a CIA.

Baxter.[20] On June 9, 2006, Baxter Healthcare Corporation settled allegations that it marketed the spread on various intravenous fluids and injectables by knowingly reporting inflated prices for these products to the Texas Medicaid program. Like *Roxane*, this case was brought under the Texas Medicaid Fraud Prevention Act by Ven-A-Care. The settlement amount was $10 million, of which about $3.8 million went to the federal government for its share of the alleged damages to Medicaid. As in *Roxane*, the United States was not a party to the settlement and Baxter did not enter into a CIA.

Concealment of Best Price

This fraud is specific to Medicaid. In order for a manufacturer to sell drugs to Medicaid, it must enter into an agreement to provide rebates for drugs purchased by the program. The federal and state governments share in the rebates in the same proportion as they share in the cost of the Medicaid program (on average, 57 percent of the cost is born by the federal government). In the case of brand-name drugs, the rebate amount is the greater of two amounts: (1) 15.1 percent of the Average Manufacturer Price (AMP) of the drug (i.e., the average price paid to the manufacturer by wholesalers for drugs distributed through retail pharmacies), and (2) the difference between the AMP and the best price—i.e., the lowest price at which the manufacturer sells the drug to wholesalers, pharmacists, HMOs, hospital buying groups, or most other private sector customers. When the best price is below 84.9 percent of the AMP, the manufacturer must make higher rebate payments to Medicaid than 15.1 percent of the AMP. Under the terms of its rebate agreement, the manufacturer must provide both the AMP and the best price during each reporting period. If the manufacturer does not report the actual best price at which it sells a drug, and if the best price is lower than 84.9 percent of AMP, then Medicaid overpays for the drug, because the rebate amount paid by the manufacturer is lower than it should be. A Congressional Budget Office analysis of a sample of top-selling brand-name drugs in 2003 found that, on average, if the AWP for a drug was 100, the AMP was 79, and the best price was 63.[21] (The amount of the Medicaid rebate on a drug also determines the discount

19. Testimony of Patrick J. O'Connell, Assistant Attorney General, State of Texas, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

20. Settlement Agreement and Release, June 9, 2006, *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc. et. al.*, No. GV401286 (District Court Travis County, 201st Judicial District), *available at* www.oag.state.tx.us/oagnews/index (last visited February 14, 2007).

21. Congressional Budget Office, *Prices for Brand-name Drugs Under Selected Federal Programs* (June 2005), Table 1, p. 4, *available at* http://www.cbo.gov/showdoc.cfm?index=6481&sequence=0 (last visited February 14, 2007).

that manufacturers are required to give to community health centers, AIDS drug purchasing assistance programs, and other "PHS entities" specified in section 340B of the Public Health Service Act that purchase the drug for their non-Medicaid patients).[22]

Two of the settlements in FY 2005 and FY 2006 involved concealment of "best price."

King Pharmaceuticals.[23] On October 31, 2005, King Pharmaceuticals settled allegations that, over the period 1994 through 2002, it knowingly submitted inaccurate best price and AMP data to the federal government, resulting in Medicaid rebate amounts on its drug products that were lower than they should have been. The products at issue involved King's entire products line, including Altace, an ACE inhibitor that reduces the likelihood of heart attack and stroke. The total settlement amount was $124.1 million, of which $73.4 million was paid to the federal government and $50.6 million to the states. (The government asserted a claim of $186.1 million).[24] Of the federal government's share, a portion (not specified in the settlement agreement) was allocated to community health centers, AIDS drug purchasing assistance programs, and other entities entitled under the Public Health Service (PHS) Act to discounts based on the Medicaid rebates, as well as the Department of Veterans Affairs (VA) drug pricing program. As part of the settlement, King entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) that, among other things, requires the company to engage an Independent Review Organization (IRO) to test periodically the accuracy of (1) the best price and AMP data for any of its products that it submits to the federal government in connection with the Medicaid rebate program as well as (2) the Average Sales Price (ASP) data it submits to CMS in connection with Medicare Part B. The IRO is required to report the results of its reviews to the OIG.[25]

Schering-Plough III.[26] On August 29, 2006 the Schering-Plough Corporation entered into a global settlement totaling $435 million in criminal and civil liability in connection with the marketing of several different drug products.[27] This was the second settlement between DOJ and Schering-Plough disposing of allegations of concealment of best price.[28] A portion of the August 2006 settlement addresses allegations

22. The 340B program, 42 U.S.C. § 256b, is described at http://www.hrsa.gov/opa/introduction.htm (last visited February 14, 2007).

23. *U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, CA No 03-1538 (E.D. Pa Dec. 14, 2005).

24. Stipulation and Order of Agreement, *U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, CA No 03-1538 (E.D. Pa Oct. 31, 2005), p. 18, *available at* www.usdoj.gov/usao/pae/News/Pr/2005/oct/oct05.html (last visited February 14, 2007).

25. *Appendix B to the CIA for King Pharmaceuticals, Inc. Government Pricing and Medicaid Drug Rebate Engagement*, (October 28, 2005), *available at* http://www.oig.hhs.gov/fraud/cia/index.html (last visited February 14, 2007).

26. The settlement agreement and criminal information in this case are posted at http://www.justice.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

27. Michael J. Sullivan, U.S. Attorney, District of Massachusetts, "Schering to Pay $435 Million for the Improper Marketing of Drugs and Medicaid Fraud," August 29, 2006, *available at* http://www.justice.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

28. The prior settlement with DOJ, *Schering-Plough II*, is discussed in the November 2004 Update, *op. cit.*, at pp. 11–12. The whistleblower in that case testified about the conduct at issue before the Senate Finance Committee on August 29, 2005, *available at* http://www.finance.senate.gov/sitepages/hearing062905.htm (last visited February 14, 2007).

that Schering-Plough knowingly and willfully misreported its best price for Claritin Redi-Tabs (an antihistamine) and K-Dur 20 (a potassium chloride supplement) to the federal government in 1998 and 1999.[29] Allegedly, Schering-Plough failed to report deeply discounted prices for these drugs that it gave to a health maintenance organization (Kaiser Permanente Medical Care Program) in order to enable it to retain the HMO as a customer without giving the Medicaid program the same deep discounts. For example, in the case of Claritin Redi-Tabs, the HMO was willing to include the drug on its formulary only if the price was reduced to $1.10 per RediTab, which would represent a new best price. According to the criminal information in the case, the Schering-Plough Sales Corporation, a subsidiary of the Schering-Plough Corporation, shipped sufficient free "samples" of Claritin Redi-Tabs to the HMO so that cost of the drug purchased by the HMO and the zero cost of the "samples" resulted in a blended price of $1.10 per RediTab. Schering-Plough did not report the $1.10 price as best price, resulting in a loss to the Medicaid program of $4.4 million in rebate payments.

Off-Label Marketing

This conduct is prohibited not by the Medicare or Medicaid statutes but by the Food, Drug and Cosmetic Act (FDCA).[30] Under the FDCA, manufacturers may not sell a drug to U.S. consumers unless it is approved as safe and effective by the Food and Drug Administration (FDA). When a manufacturer applies for FDA approval of a new drug, it must specify the use(s) for which the drug is safe and effective. Generally, once the FDA has approved a drug as safe and effective for a specified use, physicians may prescribe it for the approved use as well as for unapproved—"off-label"—uses. Manufacturers may market or promote their products among physicians for approved uses. However, the FDCA prohibits a manufacturer from marketing or promoting its drug products among physicians for any off-label uses. Medicaid purchases drugs on behalf of its low-income beneficiaries if they are prescribed by licensed physicians as medically necessary, regardless of whether the use is specifically approved by the FDA or off-label. When a manufacturer promotes an off-label use of a drug and physicians respond by prescribing the product for such unapproved uses, the Medicaid program spends more for the drug than it would if its purchases were limited to approved uses. In FCA terms, the manufacturer's violation of the FDCA has "caused" the presentation of false or fraudulent claims to the Medicaid program because the manufacturer's illegal promotion of off-label uses lead physicians to write prescriptions for these uses that they otherwise would not have written.[31]

29. The marketing of K Dur 20 is also the subject of an FTC complaint and a consumer class action summarized at http://www.prescriptionaccess.org/index.php?doc_id=586 (last visited February 14, 2007).

30. 21 U.S.C. § 331(d), 355.

31. Because physicians are permitted to prescribe drugs for off-label purposes, some have argued that off-label marketing does not cause a "false" claim to be submitted to the government. However, the two courts that have addressed this argument rejected it and held that FCA liability attaches for off-label marketing. *See U.S. ex rel. Fraklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D.Mass. 2001) and *U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127 (E.D. Mo. April 21, 2006).

Two of the settlements in FY 2005 and 2006 involved off-label marketing. The civil recoveries in these two settlements totaled $818 million, making them the largest and third largest Medicaid FCA recoveries to date.

Serono.[32] On October 17, 2005, DOJ announced that Serono S.A., a Swiss firm, had agreed to pay $567 million in civil liabilities and $136.9 million in criminal fines as a consequence of off-label marketing of the drug Serostim from 1996 through 2004. Serostim is an injectable recombinant human growth hormone used to treat AIDS wasting, or large involuntary weight loss, especially of lean body mass, in patients with AIDS. At the time the FDA approved Serostim for this use, in August 1996, AIDS wasting was the leading cause of death among AIDS patients. A twelve-week course of therapy cost over $21,000. The majority of AIDS patients with health care coverage were insured through Medicaid. Approximately 80 percent of all Serostim prescriptions written during the 1997–2004 period were covered by Medicaid, which spent over $600 million in federal and state funds on these claims.

Around the same time as Serostim came to market a new class of drugs, protease inhibitors (Highly Active Anti-Retroviral Therapy, or HAART), also became available. These drugs proved highly effective in reducing the viral loads in HIV-positive patients, so the incidence of AIDS wasting syndrome declined markedly. As a result, the demand for Serostim began to drop. The whistleblowers, former Serono employees, alleged that Serono undertook a marketing campaign to redefine AIDS wasting in order to induce physicians to prescribe, and Medicaid to pay for, the administration of Serostim to patients for whom the drug was not medically necessary. The company allegedly sought to persuade physicians and patients that loss of "body cell mass" was an indicator of AIDS wasting. Integral to this marketing effort was a medical device that used bioelectrical impedance analysis (BIA) and certain software packages to estimate body cell mass by measuring the rate at which low levels of electrical current pass through the body. In some instances, Serono Labs employees directly administered BIA tests to patients in order to induce physicians to prescribe Serostim. The BIA device and software packages had not been approved for this use by the FDA, which regulates medical devices as well as drugs.

Under the civil settlement, Serono Inc. agreed to pay a total of $567.1 million to the federal and state governments to settle allegations that it promoted Serostim for an unapproved use (the treatment of "body cell mass" wasting) and that it knowingly caused false or fraudulent claims to be submitted to the Medicaid program for medically unnecessary prescriptions.[33] Of this amount, the federal share was $305.1 million, while the States received $262 million. Four whistleblowers received a total of $51.9 million, paid by the federal government from its share.

The civil settlement, in turn, was contingent on guilty pleas by Serono Laboratories, an affiliate of Serono's U.S. subsidiary. Serono Laboratories pleaded guilty to

32. *U.S. ex rel. Driscoll v. Serono Laboratories,, Inc.*, C.A. No. 00-11680 (D. Mass. August 17, 2000). Department of Justice, "Serono to Pay $704 Million for the Illegal Marketing of AIDS Drug," October 17, 2005, *available at* www.usdoj.gov/opa/pr/2005/October/05_civ_545.html (last visited February 14, 2007).

33. The federal government also alleged that Serono caused false or fraudulent claims for Serostim to be submitted to FEHBP, TRICARE, and the Department of Veterans Affairs as well as Medicaid.

conspiring with the manufacturer of the unapproved BIA device to increase the market for the device in order to increase the market for Serostim. Serono Laboratories also pleaded guilty to conspiring to offer "thought leader" physicians an all-expense paid trip to an international conference on nutrition and HIV infection in Cannes, France, in return for the physicians writing up to 30 additional prescriptions of Serostim (which, at $21,000 per course of treatment, would generate $630,000 in sales). As a result of its two criminal conspiracy pleas, Serono Laboratories is excluded from participation in Medicaid, Medicare, or any other federal health care program for at least five years. Serono, through its U.S. subsidiary Serono, Inc., will be able to continue to participate, subject to the five-year CIA into which it entered with the HHS Office of Inspector General (Table 3).

In February, 2006, a class action was filed against Serono by consumers and third party payors alleging that Serono's illegal promotion of Serostim caused them to purchase prescriptions that were not medically necessary. The case is currently pending in the U.S. District Court for the District of Massachusetts.[34]

Schering-Plough III. As discussed above, on August 29, 2006, the Schering-Plough Corporation entered into a global settlement of criminal and civil allegations, including allegations relating to concealment of best price. The settlement also resolved allegations relating to off-label marketing of certain oncology drugs, including Temodar and Intron A. The FDA had approved Intron A for various conditions including chronic hepatitis B, chronic hepatitis C, and malignant melanoma. The allegations were the Schering-Plough Sales Corporation, a subsidiary of Schering-Plough, promoted Intron A for treatment of superficial bladder cancer. Similarly, the FDA had approved Temodar for the treatment of three specific types of brain cancers. The Sales Corporation was alleged to have promoted the use of Temodar for other types of brain tumors and metastases. In addition, the government alleged that the Sales Corporation induced physicians to prescribe Temodar and Intron A for these unapproved uses through illegal remuneration in the form of improper preceptorships, advisory boards, entertainment, and placement of clinical studies. These actions, the government alleged, caused the submission of false or fraudulent claims to Medicaid and other federal health care programs.

Schering-Plough settled its civil liabilities for a total of $255 million. Of this amount, $159.5 million was allocated to the federal government for losses to Medicare, Medicaid, and other federal programs; $91.6 million was distributed among the states and the District of Columbia for their share of the losses to Medicaid; and the remaining $3.9 million was paid to community health centers and other PHS entities. (The whistleblowers' share of the settlement has not yet been resolved.) Schering Plough Sales Corporation pleaded guilty to conspiracy for making false statements to HCFA (the federal Medicaid agency) by concealing the best price of Claritin RediTabs and for making false statements to the FDA to avoid scrutiny of its off-label promotion of

34. *Government Employees Hospital Association v. Serono International, S.A.*, MDL No. 1456, C.A. No. 05-cv-11935 (PBS) (D.Mass. Feb. 13, 2006), *available at* http://www.prescriptionaccess.org/index.php?doc_id=997 (last visited February 14, 2007).

Temodar. According to the criminal information, pre-tax profits to Schering-Plough as a result of the off-label marketing of Temodar and Intron A amounted to $124.2 million. The Sales Corporation agreed to pay a criminal fine of $180 million and is permanently excluded from participation in Medicaid, Medicare, and other federal health care programs.

As part of the global settlement, Schering-Plough also agreed to an addendum to the CIA it entered into in July 2004 in *Schering-Plough II*. Under the expanded CIA, Schering-Plough is required to implement three different measures designed to identify potential off-label marketing of any of its products over the five year period covered by the addendum. These measures include monitoring of marketing activities by the company's field sales force; monitoring of responses to requests from physicians for information about off-label uses; and periodic studies of physician recall of marketing messages delivered by the company's sales forces with respect to particular drugs. The CIA also requires Schering-Plough to retain an Independent Review Organization (IRO) to monitor its policies and procedures to determine whether these measures are being implemented and whether off-label marketing is occurring. The findings must be reported annually to the OIG.[35]

TRENDS IN DRUG MANUFACTURER FCA SETTLEMENTS

Two important trends emerge from a review of the drug manufacturer FCA settlements to date. The first has to do with the increasing attention to off-label marketing. The second concerns an increased focus on fraud against Medicaid.

Off-Label Marketing

The 2001 *TAP Pharmaceuticals* case is still the largest of the FCA settlements by a drug manufacturer as measured by total civil and criminal recoveries ($875 million). And, as discussed above, the conduct at issue in that case—marketing the spread and concealment of best price—continues to be the basis of whistleblower settlements with drug manufacturers. But it seems clear that the off-label marketing of drugs has also become increasingly significant as a basis for FCA liability. The 2004 settlement with Pfizer and its Warner-Lambert subsidiary concerning allegations of off-label marketing of Neurontin *(Pfizer II)*, the 2005 *Serono* settlement, and the *2006 Schering-Plough III* settlement, are, after *TAP Pharmaceuticals*, the three largest settlements in whistleblower FCA cases, as measured by total civil and criminal recoveries ($430 million, $704 million, and $435 million, respectively). To underscore DOJ's interest in this area, the Deputy Attorney General Paul J. McNulty, in announcing the *Schering-Plough III* settlement last August, stressed the importance of curbing off-label marketing beyond reducing unnecessary spending by Medicaid and other federal health programs: "It is vital to public health and safety that pharmaceutical companies are

35. *Addendum to Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation*, August 25, 2006, pp. 5–7, *available at* http://www.oig.hhs.gov/fraud/cia/index.html (last visited February 14, 2007).

deterred from improperly marketing their drugs to doctors and patients to treat illnesses that these drugs are not approved to treat."[36]

Medicaid Fraud

A previous report for TAFEF concluded that, between 1997 and 2001, most FCA activity involving health care focused on fraud against Medicare rather than Medicaid.[37] Medicare FCA recoveries continue to outpace federal Medicaid FCA recoveries; between FY 2001 and FY 2005, $6.2 billion was returned to the Medicare Trust Fund, while $416 million in federal Medicaid recoveries were transferred to the Centers for Medicare & Medicaid Services.[38] Nonetheless, since 2001 Medicaid FCA recoveries to both the federal and state governments have grown substantially, largely as the result of the drug manufacturer settlements. The top ten largest FCA settlements of allegations of fraud against Medicaid to date are listed below. Every one involves a drug manufacturer. All but one of these cases *(Abbott Laboratories)*, accounting for over 97 percent of the recoveries, were brought by whistleblowers. In each case in which the whistleblower is known, the whistleblower was an employee of the settling company or a subsidiary, or an employee of a competitor.

Largest Medicaid Settlements Under the False Claims Act

Rank	Case (Settlement Date)*	Settlement Amount**
1	Serono (10/17/05)	$567.1 million
2	Schering-Plough II (7/29/04)	$282.4 million
3	Schering-Plough III (8/29/06)	$251.1 million
4	Bayer II (4/16/03)	$242.1 million
5	Pfizer II (Warner-Lambert) (5/13/04)	$152 million
6	King Pharmaceuticals (10/30/05)	$124.1 million
7	GlaxoSmithKline I (4/16/03)	$85.1 million
8	TAP Pharmaceuticals (10/3/01)	$56.7 million
9	Abbott Laboratories (7/23/03)	$50.2 million
10	Pfizer I (10/28/02)	$49.0 million
	Total Medicaid Recoveries	**$1.86 billion**
	*Includes cases brought by government (9) and cases brought by whistleblowers (1–8, 10)	** Federal and state recoveries to Medicaid. Amounts do not include Medicare recoveries or criminal fines

36. Press Release of Michael J. Sullivan, U.S. Attorney, District of Massachusetts, " Schering to Pay $435 Million for the Improper Marketing of Drugs and Medicaid Fraud," August 29, 2006, *available at* http://www.usdoj.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

37. Schneider, *Reducing Medicaid Fraud: The Potential of the False Claims Act* (June 2003), *available at* www.taf.org (last visited February 14, 2007).

38. Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Account Annual Reports*, FY 2001 through FY 2005, *available at* http://www.oig.hhs.gov/reading/hcfac.html (last visited February 14, 2007).

IMPACT ON MEDICARE AND MEDICAID PRESCRIPTION DRUG POLICIES

The FCA whistleblower cases against drug manufacturers have had a demonstrable impact on Medicare and Medicaid prescription drug policy. The contribution is sometimes visible to the public, as when the whistleblower in *Schering-Plough II* testified before the Senate Finance Committee as it considered ways to reduce waste, fraud and abuse in Medicare and Medicaid.[39] The contribution of these cases is often less obvious, however, in part because they often remain out of public view while agency staff identify program vulnerabilities exposed by the whistleblowers and develop policy solutions.

Medicare

As seen in Table 2, four of the sixteen settlements *(TAP Pharmaceuticals, AstraZeneca, GlaxoSmithKline II,* and *Schering-Plough III)* include recoveries for allegations of fraud against Medicare. The Medicare recoveries in these settlements total $950 million, or about one third of the total civil recoveries to date. Congressional concern about the marketing the spread conduct underlying these settlements helped to bring about policy changes in Medicare Part B reimbursement for physician-administered drugs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) eliminated the use of Average Wholesale Price (AWP) as a basis for establishing reimbursement for physician-administered drugs under Medicare Part B and substituted the Average Sales Price (ASP) plus six percent, effective January 1, 2005. [40] ASP was first used in the corporate integrity agreements in connection with the 2001 *TAP Pharmaceuticals* and 2003 *AstraZeneca* settlements.

Medicaid

The drug manufacturer settlements have also prompted a Congressional reexamination of Medicaid policies vis-à-vis drug rebates and drug price disclosure. Under the Deficit Reduction Act of 2005 (DRA), the Secretary of HHS is required to promulgate a regulation by July 1, 2007, clarifying how average manufacturer prices (AMP) are determined for purposes of calculating the Medicaid rebate.[41] In developing this

39. Testimony of Beatrice Manning before the Committee on Finance, U. S. Senate, August 29, 2005, *available at* http://www.finance.senate.gov/sitepages/hearing062905.htm (last visited February 14, 2007).

40. Section 303 of P.L. 108-173, adding a new section 1847A, Use of Average Sales Price Methodology, to the Social Security Act. A June 2005 Office of Inspector General study of over 2000 drug codes found that, on average, ASPs were 26 percent below AWP for sole source brand-name drugs and 68 percent below AWP for generic drugs. OIG, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*, OEI-003-05-00200, June 2005, p. 8, *available at* www.oig.hhs.gov/oei/reports (last visited February 14, 2007).

41. Section 6001(c)(3) of P.L. 109-171. The Centers for Medicare & Medicaid Services (CMS) published a proposed rule on December 22, 2006 (71 *Fed. Reg.* 77174). Unlike average wholesale price (AWP) or wholesale acquisition cost (WAC), both of which are "catalogue" or "sticker" prices published by manufacturers, AMP, to a large extent, reflects actual transactions: it is the average price paid by wholesalers and retail pharmacies to manufacturers for drugs dispensed through retail pharmacies. AMP does not reflect rebates paid by manufacturers to Medicaid or pharmacy benefit managers (PBMs).

regulation, the Secretary is required to consider recommendations from the OIG.[42] And in order to increase transparency, the Secretary of HHS is required to provide on a monthly basis to States the AMPs reported by manufacturers for brand-name and generic drugs and to post this price data on a website accessible to the public.[43]

Under prior law, disclosure of AMP data was prohibited; the DRA extinguished this constraint effective January 1, 2007.[44] State Medicaid programs are now able to use this data to more closely align the prices they pay to pharmacists for drugs with the pharmacists' actual acquisition costs. As the Congressional Budget Office recently noted, and as the *Baxter*, *Dey*, *Roxane*, and *Schering-Plough I* cases confirm, list prices of drugs such as AWP "are not good predictors of actual transaction prices for generic drugs as they are for single-source brand-name drugs."[45] Thus, the availability of AMP data should be especially helpful to States in determining what to pay pharmacists for generic drugs.

The DRA also tightens the "nominal price" exclusion from the Medicaid best price calculation in order to address abuse of this exclusion for marketing purposes, as highlighted by whistleblower allegations in FCA cases.[46] In contrast to its termination of AWP as a reference price for drugs covered by Part B, Congress has not prohibited state Medicaid programs from continuing at their option to use AWP as a reference point for payments to pharmacists for covered drugs. However, class action litigation in federal court in Massachusetts raises questions about the long-term viability of AWP.[47]

The DRA also establishes financial incentives for states to enact their own false claims acts with whistleblower provisions addressing false or fraudulent claims against Medicaid.[48] While this DRA provision is not specific to drug manufacturers, it was advocated before the originating Congressional committee in testimony that discussed the use of the Texas false claims act to recover losses to the state's Medicaid program from marketing of the spread by certain generic drug manufacturers.[49]

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42. OIG, *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005* (A-06-06-00063), May 2006, discussed at 71 *Fed. Reg*. 77177–77189 (December 22, 2006).

43. Section 6001(b) of P.L. 109-171. The requirement, originally effective July 1, 2006, has been postponed.

44. 71 *Fed. Reg*. at 77175 (December 22, 2006).

45. Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (January 2007), p. 52, *available at* www.cbo.gov (last visited February 14, 2007).

46. Section 6001(d) of P.L. 109-171. In *State of Nevada ex rel. Steinke v. Merck & Company, Inc.*, 2006 WL 1506901 (D. Nev. May 31, 2006), the whistleblower alleges the Merck violated the FCA by failing to report as "best prices" for Medicaid rebate purposes discounts of 92 percent off of catalogue price of Vioxx and Zocor given to hospitals in exchange for the hospital's commitment to maintain a specified market share for each drug. The case is discussed at 42 *False Claims Act & Qui Tam Quarterly Review* 33 (July 2006).

47. One of the leading drug price reporting firms, First DataBank, recently settled a class action complaint alleging manipulation of AWP prices based on the ratio of AWP to Wholesale Acquisition Cost (WAC), the price reported by drug manufacturers as the average amounts paid by pharmacies to wholesalers. Settlement Agreement and Press Release (October 6, 2006), *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, C.A. No. 1:05-CV-11148-PBS (D. Mass.), *available at* www.prescriptionaccess.org (last visited February 14, 2007). As part of the settlement, First DataBank agreed to stop publishing AWP data within two years.

48. Section 1909 of the Social Security Act, 42 U.S.C. § 1396h, as added by section 6031 of P.L. 109-171. Office of Inspector General guidance was published at 71 *Fed. Reg*. 48552 (August 21, 2006). OIG reviews of individual state FCAs are posted at http://oig.hhs.gov/fraud/falseclaimsact.html (last visited February 14, 2007).

49. *See* Testimony of Patrick J. O'Connell, *op. cit.*; Testimony of James Moorman, President and Chief Executive Of-

CONCLUDING OBSERVATIONS

This report has focused on recoveries to the federal and state governments resulting from FCA whistleblower cases against drug manufacturers. Although these amounts are large, they almost certainly understate the savings that the FCA and its whistleblower provisions are producing for the federal and state governments with respect to Medicaid spending on prescription drugs. Health economist Jack Meyer has noted that FCA settlements of allegations of fraud against the Medicare program have indirect, non-quantifiable benefits in the form of increased compliance and deterrence of fraudulent conduct.[50] This observation has equal force in the Medicaid context. In all likelihood, the sixteen settlements to date, along with the ten corporate integrity agreements (CIAs) in place, will promote compliance with Medicaid program requirements (and with FDA off-label marketing prohibitions) by all drug manufacturers, not just those directly affected.

It is clear that there will be more settlements, and that some of them will be large. In August 2006, the Assistant Attorney General told the Congress that there are "over 180 matters involving fraud allegations against pharmaceutical manufacturers and other entities" on the DOJ docket.[51] In December 2006, Bristol-Myers Squibb Company announced that it had agreed to pay $499 million to settle allegations relating to fraudulent pricing and marketing of drugs for the treatment of schizophrenia and bipolar disorder.[52] In addition, DOJ intervened in two FCA whistleblower cases in 2006. In May of that year, DOJ announced its intervention in a whistleblower case alleging that Abbott Laboratories' Hospital Products Division violated the FCA by marketing the spread on certain drugs purchased by Medicare and Medicaid since 1991.[53] In September 2006, DOJ intervened in another marketing the spread case involving Dey, Inc.[54] Presumably, DOJ would not join these actions unless it believed

ficer, Taxpayers Against Fraud, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

50. Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck* (July 2006), p. 4, *available at* www.taf.org (last visited February 14, 2007).

51. Written Responses of Peter D. Keisler , Assistant Attorney Geenral, Civil Division, Department of Justice, before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, Hosue of Representatives, August 11, 2006, p. 6.

52. Kaiser Daily Health Policy Report, "Bristol-Myers Squibb Agrees To Settle Federal Investigation of Pricing, Sales, Marketing Practices for $499M," December 22, 2006, *available at* www.kaiserhealthnetwork.org (last visited February 14, 2007).

53. DOJ Press Release, "United States Intervenes in Suit Against Abbott Laboratories, Inc.," May 23, 2006, *available at* http://www.usdoj.gov/opa/pr/2006/May/06_civ_309.html (last visited February 14, 2007). According to the Press Release, "The government's complaint alleges that from at least on or before January 1, 1991 Abbott's Hospital Products Division (HPD) reported prices that were more than 10 times (1000 percent) the actual sales prices on many of the drugs it manufactures. The United States alleges that federal healthcare programs, both Medicare and Medicaid, have reimbursed Abbott's customers in excess of $175 million for the drugs which are the subject of the complaint."

54. DOJ Press Release, "United States Joins Suit Against Dey," September 11, 2006, *available at* http://www.usdoj.gov/opa/pr/2006/September/06_civ_605.html (last visited February 14, 2007). According to the Press Release, "The government's complaint alleges that the pharmaceutical manufacturer from at least on or before January 1, 1993 reported prices that were more than five times (500 percent) the actual sales prices on many of the drugs it manufactures. The United States alleges that Medicare and Medicaid have reimbursed Dey's customers in excess of $500 million for the drugs which are the subject of the complaint. Dey sells generic drugs that are reimbursed by the two federal health care programs."

the claims to be meritorious. Of course, the final outcomes remain to be determined. It is highly likely, however, that the named manufacturers, as well as their competitors, will be focused on the disposition of these cases and the alleged conduct from which they arose.

TABLE 1. Whistleblower Cases Under Federal and State False Claims Acts Settled with Prescription Drug Manufacturers as of September 30, 2006

Company	Settlement Date	Product	Total Recovery	Type of Fraud Alleged	Whistleblower
AstraZeneca	6/20/03	Zoladex (prostate cancer)	$355 million	Marketing the spread Concealment of Best Price	Sales executive of competitor TAP Pharmaceuticals
Baxter*	6/13/06	Intravenous fluids, injectables	$8.5 million	Marketing the spread	Specialty pharmacy
Bayer I	1/23/01	Kogenate, Koate-HP (hemophilia) Gamimmune (immune deficiency)	$14 million	Marketing the spread Concealment of Best Price	Specialty pharmacy
Bayer II	4/16/03	Adalat CC (blood pressure) Cipro (antibiotic)	$257 million	Concealment of Best Price	Bayer marketing executive
Dey*	6/11/03	Albuterol Sulfate and Ipratropium Bromide (asthma inhalants)	$18.5 million	Marketing the spread	Specialty pharmacy
GlaxoSmith-Kline I	4/16/03	Paxil (antidepressant) Flonase (nasal allegy spray)	$88 million	Concealment of Best Price	(derived from Bayer marketing executive allegations)
GlaxoSmith-Kline II	9/20/05	Zofran, Kytril (antiemetics)	$149 million	Marketing the spread	Specialty pharmacy
King Pharmaceuticals	10/30/05	Entire produce line, including Altace (heart attack and stroke risk reduction)	$124 million	Concealment of Best Price	Director of National Accounts at a King subsidiary
Pfizer I	10/28/02	Lipitor (cholesterol)	$49 million	Concealment of Best Price	National account manager for Pfizer subsidiary
Pfizer II (Warner-Lambert)	5/13/04	Neurontin (anti-seizure for epilepsy)	$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
Roxane Laboratories*	11/25/05	Albuterol drugs (asthma inhalants)	$10 million	Marketing the spread	Specialty pharmacy
Schering-Plough I* (Warrick)	5/3/04	Albuterol drugs (asthma inhalants)	$27 million	Marketing the spread	Specialty pharmacy

Company	Settlement Date	Product	Total Recovery	Type of Fraud Alleged	Whistleblower
Schering-Plough II	7/29/04	Claritin family of products (non-sedating antihistamines)	$345 million	Concealment of Best Price	Three employees at Schering-Plough subsidiary
Schering-Plough III	8/29/06	Claritin RediTabs; K-Dur 20 (potassium supplement); Temodar, Intron A (oncology drugs)	$435 million	Concealment of Best Price	Three Schering-Plough sales representatives
Serono	10/17/05	Serostim (AIDS wasting)	$704 million	Off-label marketing, kickbacks	Five Serono employees in two states
TAP Pharmaceuticals	10/3/01	Lupron (prostate cancer)	$875 million	Marketing the spread Concealment of Best Price	HMO physician and TAP sales executive

* Settled under Texas Medicaid Fraud Prevention Act

TABLE 2. Recoveries in Whistleblower Cases Against Pharmaceutical Man ufacturers(Settlements as of September 30, 2006)

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Whistleblower's Share
AstraZeneca (6/20/03)	$355 million	$63.9 million	$266.1 million[55]	$24.9 million	$13.7 million	$11.2 million	$47.6 million
Baxter (6/12/06)	$8.5 million[56]	None	None	$8 million	$4.8 million	$3.2 million	$1.7 million
Bayer I (1/23/01)	$14 million	None	None	$14 million	$7.8 million	$6.2 million	$1.6 million
Bayer II (4/16/03)	$257 million[57]	$5.6 million	None	$242.1 million	$133.2 million	$108.9 million	$34.2 million
Dey (6/11/03)	$18.5 million[58]	None	None	$16.2 million	$9.2 million	$7.0 million	$3.2 million
GlaxoSmith-Kline I (4/16/03)	$88 million[59]	None	None	$85.1 million	$46.8 million	$38.3 million	None
GlaxoSmith-Kline II (9/20/05)	$149 million	None	$125.9 million	$24 million	$13.72 million	$10.35 million	$26 million
King Pharm. (10/30/05)	$124.1 million[60]	None	None	$124.1 million	$73.4 million	$50.6 million	$7.5 million
Pfizer I (10/28/02)	$49 million	None	None	$49 million	$27.9 million	$21.1 million	$5.9 million
Pfizer II (5/13/04)	$430 million[61]	$240 million	None	$152 million	$83.6 million	$68.4 million	$24.6 million
Roxane (11/25/05)	$10.1 million[62]	None	None	$7.1 million	$4.2 million	$2.9 million	$1.6 million
Schering-Plough I (Warrick) (5/3/04)	$27 million[63]	None	None	$20 million	$12 million	$8 million	$4.6 million

55. This amount includes payments to settle claims by TRICARE and Department of Defense.

56. This amount includes payment of $500,000 in costs and fees to relator and state of Texas.

57. This amount includes Bayer payments of $9.5 million to PHS entities.

58. This amount includes payment of $2.3 million in costs and fees to relator and to state of Texas.

59. This amount includes GSK payments of $2.6 million to PHS entities.

60. This amount includes an unspecified amount of King Pharmaceuticals payments to PHS entities.

61. This amount includes Pfizer payments of $38 million to states for harm to consumers and to fund remediation program.

62. The amount includes $3.0 million payment for costs and fees to relator and state of Texas.

63. This amount includes $7.0 million payment for costs and fees to relator and state of Texas.

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Whistleblower's Share
Schering-Plough II (7/29/04)	$345.5 million[64]	$52.5 million	None	$282.4 million	$165.3 million	$117.1 million	$31.7 million
Schering-Plough III (8/29/06)	$435 million[65]	$180 million	$30.2 million[66]	$203.6 million	$112 million	$91.6 million	Not resolved
Serono (10/17/05)	$704 million	$136.9 million	None	$567.1 million	$305.1 million	$262.0 million	$51.9 million
TAP Pharmaceuticals (10/3/01)	$875 million	$290 million	$528.3 million	$56.7 million	$31.2 million	$25.5 million	$95.1 million
Totals	$3.89 billion	$968 million	$950 million	$1.88 billion	$1.04 billion	$833 million	$337 million

Source: Settlement agreements on file at TAF Education Fund library; Joyce Branda, Deputy Director, Commercial Litigation Branch, Civil Division, DOJ (9/6/06); Patrick O'Connell, Assistant Attorney General, State of Texas (9/4/06).

Note: Columns do not add across. Medicare Recovery, and Federal and State Medicaid Recovery columns present gross recoveries, not amounts net of whistleblower's share.

64. This amount includes Schering-Plough payments of $10.6 million to PHS entities.

65. This amount includes Schering-Plough payments of $3.9 million to PHS entities and $17.3 million in disgorgement payments to the federal government.

66. This amount includes payments to settle claims by TRICARE and FEHBP.

TABLE 3. Obligations Under Corporate Integrity Agreements (CIAs) Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2006)

Manufacturer (CIA effective date)	Term (Expiration Date)	Compliance Program[67]	Average Sales Price (ASP) Reporting	Independent Review Organization Review: Rebates	Independent Review Organization Review: Other	Annual Compliance Report
AstraZeneca (6/4/03)	5 years (2008)	Yes	Yes (8 products only)	Yes	Yes (sales and marketing; ASP reporting)	Yes
Bayer I (1/23/01)	5 years (incorporated into Bayer II)	Yes	Yes	Yes	Yes (compliance with CIA)	Yes
Bayer II (1/23/03)	6 years (2009)	Yes	Yes	Yes	Yes (managed care transactions)	Yes
GlaxoSmithKline I (4/15/03)	5 years (2008)	Yes	No	Yes	Yes (contract pricing)	Yes
GlaxoSmithKline II (9/20/05)	5 years (2010)	Yes	Yes	Yes	No	Yes
King (10/30/05)	5 years (2010)	Yes	No	Yes	No	Yes
Pfizer I (10/24/02)	5 years (2007)	Yes	No	Yes	Yes (managed care transactions)	Yes
Pfizer II (Warner-Lambert) (5/11/04)	5 years (2009)	Yes	No	Yes	Yes (managed care contracting; promotional services)	Yes
Schering-Plough II, III (7/29/04)	5 years (2009); Addendum III 5 years (2011)	Yes	Yes (9 products)	Yes	Yes (managed care expenditures; off-label marketing)	Yes

67. 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.

Manufacturer (CIA effective date)	Term (Expiration Date)	Compliance Program[67]	Average Sales Price (ASP) Reporting	Independent Review Organization Review: Rebates	Independent Review Organization Review: Other	Annual Compliance Report
Serono (10/17/05)	5 years (2010)	Yes	No	No	Yes (off-label uses; educational grants)	Yes
TAP (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 (last visited February 14, 2007).