

Reducing Medicare and Medicaid Fraud by Drug Manufacturers

The Role of the False Claims Act

prepared for

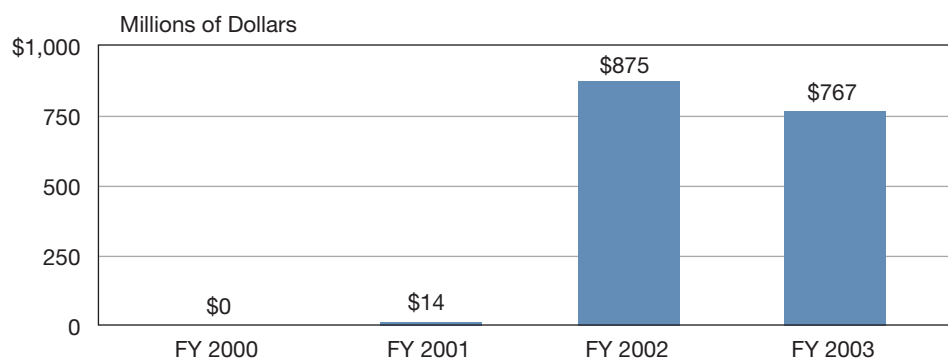
Taxpayers Against Fraud Education Fund

by

Andy Schneider, Principal

Medicaid Policy, LLC

Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid, FY 2000–FY 2003



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About the Author

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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 serves to inform and educate 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.

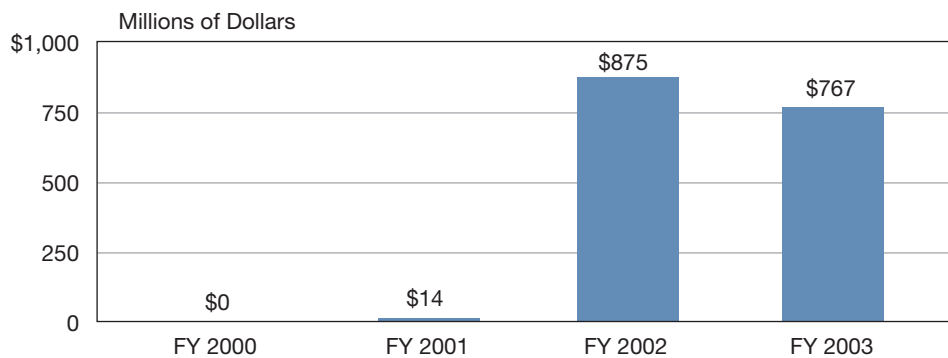
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Executive Summary

Since 2001, the Department of Justice (DOJ) has settled seven cases involving allegations of Medicare and Medicaid drug pricing and marketing fraud against six pharmaceutical manufacturers: AstraZeneca, Bayer, Dey, GlaxoSmithKline, Pfizer, and TAP Pharmaceuticals (a joint venture of Abbott Laboratories and Takeda Chemical Industries).¹ Among these are three of the top five companies (by sales volume) in the industry: Pfizer (#1), GlaxoSmithKline (#2), and AstraZeneca (#5). As shown in Figure 1, the total paid out by these manufacturers to settle these cases over the last three years is nearly \$1.66 billion. Of this amount, roughly \$1.23 billion, including \$360 million in criminal fines, was returned to the federal treasury; \$217 million was returned to state treasuries; and \$188 million was paid out to whistleblowers for bringing the allegations to the attention of DOJ. To put these figures in context, the total amount spent by the federal government in FY 2003 on prevention and control of infectious diseases like HIV/AIDS, TB, West Nile Virus, and SARS was \$1.6 billion.²

Figure 1 Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid, FY 2000–FY 2003



Source: U.S. Department of Justice press releases and settlement agreements

¹ On June 23, 2003, DOJ settled Medicare fraud allegations against another pharmaceutical manufacturer, Abbott Laboratories, for \$622 million. This case arose not from a whistleblower lawsuit but from an undercover operation by the Federal Bureau of Investigation, the U.S. Postal Inspection Service, and the Office of Inspector General for DHHS. It involved fraud allegations relating to the marketing of durable medical equipment (DME), in this instance enteral feeding pumps, tubing, and liquid food. It is not among the cases reviewed in this report, which focuses on whistleblower suits involving allegations of fraud relating to prescription drug pricing and marketing.

² In FY 2003, the Centers for Disease Control and Prevention budgeted \$1.235 billion for HIV/AIDS, STDs and TB prevention and an additional \$335 million for infectious disease control. Department of Health and Human Services, *FY 2004 Budget in Brief* (January 2003), p. 24.

All but one of these cases began as a lawsuit filed under the federal False Claims Act (FCA) by a whistleblower.³ Under this Civil War-era statute, private citizens who learn of fraud by a federal contractor may file what is known as a *qui tam* suit against the contractor. The suit is filed under seal in federal court to give the government an opportunity to investigate. If DOJ believes the suit has merit, it may intervene and, in effect, take over the case. If the case results in a recovery to the government, the whistleblower receives a share, generally 16 to 17 percent. This share is an incentive for the whistleblower to come forward with information about contractor fraud, particularly fraud that is sophisticated and difficult for government contract officers and auditors to detect.

FCA settlement agreements with health care providers also commonly involve Corporate Integrity Agreements (CIAs) entered into between the defendants and the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS). These agreements generally run for five years and are designed to prevent a recurrence of the conduct that triggered the allegations of fraud against federal health care programs. The OIG has entered into CIAs with each of these six manufacturers except Dey.

Table 1 gives a brief overview of the seven settlements reviewed in this report. Despite their size and potential significance, these settlements are not widely known. The purpose of this report is to inform policymakers and the public of these cases and their implications for Medicare, Medicaid, and other federal health programs. It is unlikely that, in the absence of information supplied by the whistleblowers in these cases, federal or state government officials would have uncovered the allegedly fraudulent practices at issue.

All of the settlements involve Medicaid liability, but two—AstraZeneca and TAP—involve Medicare liability as well. The two Medicare cases also include significant criminal fines. Two of the settlements are with the same firm—Bayer—but involve different products and different pricing and marketing conduct. All but one of the settlements—Dey—involve brand-name drugs, which are subject to special reporting requirements under the Medicaid rebate program. In the majority of the cases, the whistleblower was an employee of the manufacturer (or the manufacturer’s competitor). In the remaining cases, the whistleblower was a pharmacy doing business with the manufacturers.

Judging from the cases already out from under seal but not settled, as well as from press accounts,⁴ these seven cases will almost certainly not be the last whistleblower cases settled by drug manufacturers or otherwise resolved by litigation under either the FCA or state false claims acts. This prospect, combined with the size of the recoveries to date and of the firms involved, suggests that we may be in the midst of a sea change in the relationship between Medicaid and Medicare on the one hand and the pharmaceutical industry on the other. Whistleblowers, federal prosecutors, and state attorneys general appear to be on the verge of forcing fundamental changes in the mar-

³ In the case of the settlement with Dey, Inc., the case was brought under the Texas version of the False Claims Act, its Medicaid Fraud Prevention statute, Tex. Hum. Res. Code §§ 36.001–36.117.

⁴ Susan Winkler, lead civil prosecutor in the U.S. Attorney’s Office in Boston, recently commented on her caseload: “They start stacking up like airplanes. Our job is to land them before they run out of gas.” Alice Dembner, “Prosecutors here lead in health fraud cases,” *Boston Globe* (May 13, 2003).

Table 1 Whistleblower Cases Under Federal and State False Claims Acts Settled with Prescription Drug Manufacturers as of September 30, 2003

Company	Settlement	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
Bayer	1/23/01	Kogenate, Koate-HP (hemophilia) Gamimmune (immune deficiency)	\$14 million	Marketing the spread Concealment of "Best Price"	Independent pharmacy
Bayer	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	Independent pharmacy
GlaxoSmithKline	4/16/03	Paxil (antidepressant) Flonase (nasal allergy spray)	\$88 million	Concealment of "Best Price"	(derived from Bayer marketing executive allegations)
Pfizer	10/28/02	Lipitor (cholesterol)	\$49 million	Concealment of "Best Price"	National account manager for Pfizer subsidiary
TAP Pharmaceuticals	10/3/01	Lupron (prostate cancer)	\$875 million	Marketing the spread Concealment of "Best Price"	HMO physician and TAP sales executive

keting and pricing practices of the pharmaceutical industry, much as the 1992 *National Health Laboratories* settlement and its progeny led to fundamental changes in the billing practices of the clinical laboratory industry.⁵ At a minimum, it is highly likely that the marketing and pricing policies that were the basis for the settlements to date will change within the firms involved, to the benefit of Medicare, Medicaid, and the more than 80 million Americans they cover.

This report examines the six federal False Claims Act (FCA) cases and one state false claims act case involving allegations of pricing fraud by prescription drug manufacturers that had been settled as of September 30, 2003. It begins with a brief overview of how Medicaid and Medicare purchase prescription drugs and how the FCA applies to those purchasing regimes. It then reviews each of the settlements, discusses the types of fraudulent conduct alleged, and summarizes the remedies imposed by the govern-

⁵ For a summary of these cases and their impact on the clinical laboratory industry, see Jack Meyer and Stephanie Anthony, *Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act* (September 2001), pp. 52–65, www.taf.org.

ment, including the main elements of the Corporate Integrity Agreements (CIAs). The report also notes some cases against manufacturers that are out from under seal and in active litigation in both federal and state courts. Finally, the report discusses the implications of these settlements for the Medicare program, for state Medicaid programs, and for pharmaceutical manufacturers. It concludes with some recommendations for improvements in federal and state policies and for further research.

The report makes the following findings:

- Since 2001, six pharmaceutical manufacturers have settled seven cases with the Department of Justice (DOJ) involving allegations of pricing fraud against Medicare and Medicaid for a total of \$1.66 billion. Two of these settlements included criminal fines in the amount of \$360 million. Among the six manufacturers are three of the top five companies (by sales volume) in the industry with a market share in excess of 27 percent (Pfizer, GlaxoSmithKline, and AstraZeneca). At least five cases are out from under seal, and according to press reports, additional settlements with other manufacturers are likely.

- Six of these settlements resulted from the filing of a whistleblower lawsuit under the federal False Claims Act. The seventh resulted from a whistleblower lawsuit under a state false claims act. In each case, the whistleblowers had inside information about the marketing and sales practices of the manufacturers involved of which federal and state officials were evidently unaware. Given the sheer size of the Medicare and Medicaid programs and the volume of drug products they purchase, it is highly unlikely that the complex frauds alleged in the lawsuits underlying these settlements would have been uncovered and remedied by program or law enforcement officials in the absence of the information provided by whistleblowers.

- Of the \$1.66 billion, \$360 million in criminal fines was deposited in the Crime Victims Fund. Federal civil recoveries totaled nearly \$1.3 billion, the majority of which was attributable to Medicare. Nearly \$217 million was paid to the states as their share of the federal-state Medicaid recoveries. Nearly \$188 million, or 17.4 percent of the federal civil recoveries, was paid to whistleblowers.

- In addition to the \$1.66 billion in monetary recoveries, six of the seven settlements include corporate integrity agreements (CIAs) between the manufacturers and the Office of Inspector General (OIG) that provide for detailed auditing and reporting of manufacturer policies and practices between now and at least 2007. Three of the manufacturers (AstraZeneca, Bayer, and TAP Pharmaceuticals) are required to report Average Sales Prices (ASPs) on some or all of the products they sell to government programs to enable federal and state officials to assess the reasonableness of the prices these programs are actually paying.

- “Marketing the spread” is a manufacturer business practice common to several of the FCA settlements. Medicare and the majority of state Medicaid programs pay for the drugs they cover on the basis of what is called “average wholesale price” (AWP), as that price is reported by manufacturers to commercial price listing services. By reporting AWP for purposes of Medicare and Medicaid reimbursements at very high (and often unrealistic) levels and then discounting steeply from those prices, a manufactur-

er is able in effect to use government program funds to reward health care providers that purchase and dispense its products.

- Medicare beneficiaries must pay a coinsurance of 20 percent of the price paid by Medicare for the physician-administered drugs that it covers (e.g., 95 percent of the AWP reported by the manufacturer). The more inflated the AWP, the greater the beneficiary's out-of-pocket spending. In some instances, the "spread" to the physician is so great that the coinsurance amount paid by the beneficiary exceeds the actual price of the drug to the physician.

- "Lick and stick" is another technique used by manufacturers in some of the FCA cases. Manufacturers that use this technique give steep discounts on brand-name drugs to large customers, often managed care plans, and then place labels on the packages of drugs shipped to the customer identifying the drugs as those of the customer, not of the manufacturer. The purpose of this labeling is to exclude the discounted price at which the drug was sold to the customer from the prices that the manufacturer is required to report to the Medicaid program for purposes of calculating the rebate owed on the drug.

- Concealment of deep discounts, whether given to physicians through "marketing the spread," to managed care plans or other large customers through "lick and stick," or through other marketing schemes, results in lower Medicaid rebates paid on the discounted brand-name drugs, which in turn means higher net prices to hard-pressed state Medicaid programs. It also means a greater financial burden on the safety net clinics and hospitals that are entitled to at least the same price (net of rebates) that Medicaid receives on the drugs they dispense to their uninsured patients.

- These seven settlements have yielded over \$250 million in recoveries paid to state Medicaid programs. Corresponding federal Medicaid recoveries also exceeded \$200 million. The size of these recoveries, combined with the auditing and reporting requirements contained in the CIAs, will likely improve compliance with the Medicaid rebate law by the manufacturers involved and deter noncompliance by other manufacturers. This in turn should result in additional savings to state Medicaid programs and the federal treasury.

- DOJ's investigation of these practices, and OIG's monitoring of the CIAs entered into with the manufacturers, have already informed the federal policy process and have the potential to do so in the future. For example, the Average Sales Price (ASP) reporting incorporated into some of the CIAs has been advanced as one option for reforming the way in which Medicare pays for physician-administered drugs. This option has been suggested by the Centers for Medicare and Medicaid Services (CMS), as well as the Medicare Payment Advisory Commission (MedPAC), the independent agency established by Congress to advise it on Medicare issues. A provision relying in part on ASP reporting was included in the Medicare prescription drug legislation adopted in June 2003 by the House of Representatives.

- A number of whistleblower cases alleging drug manufacturer pricing fraud against Medicaid have been filed in state courts under state false claims acts, and at least three — one in California, one in Florida, and one in Texas — are out from under seal. In the Texas case, one of the manufacturers has settled allegations of Medicaid fraud with

the state and the federal governments for \$18 million. In addition, the Massachusetts Attorney General has filed suit under the state false claims act against 13 generic drug manufacturers alleging fraud against that state's Medicaid program.

- The settlements reviewed in this report are unlikely to be the last of the settlements between DOJ and pharmaceutical manufacturers. In addition to the state false claims act cases already out from under seal, there is at least one federal FCA price manipulation case out from under seal, and press accounts suggest that other cases involving allegations of drug pricing and marketing fraud against Medicare and Medicaid remain under seal. In short, we are in the midst of an unfolding story.

The report concludes with the following recommendations:

1. Congress should reject any efforts to weaken the FCA and its whistleblower provisions.

2. The federal government should pay for prescription drugs currently covered under Medicare on a basis other than AWP as reported by manufacturers to commercial price listing services.

3. If the federal government expands the Medicare program to cover outpatient prescription drugs, it should learn from the lessons of the FCA drug settlements.

4. The OIG should vigorously enforce the CIAs agreed to by the pharmaceutical manufacturers.

5. CMS should revise its August 2003 regulation relating to the Medicaid drug rebate program to ensure that FCA lawsuits and investigations are not compromised by the premature destruction of drug pricing data by manufacturers.

6. State Medicaid programs should pay for prescription drugs covered under Medicaid on a basis other than AWP as reported by manufacturers to commercial price listing services.

7. States that have not yet enacted their own false claims acts with whistleblower provisions should do so.

8. Pharmaceutical manufacturers should review their pricing and marketing policies and practices to ensure that they fully comply with Medicare and Medicaid program requirements.

9. Further research is needed to fully understand the impact of these FCA settlements and CIAs on the pricing and marketing practices of the drug manufacturers involved and the pharmaceutical industry as a whole.

Introduction

Since 2001, the Department of Justice (DOJ) has settled seven cases involving allegations of Medicare and Medicaid drug pricing and marketing fraud against six pharmaceutical manufacturers: AstraZeneca, Bayer, Dey, GlaxoSmithKline, Pfizer, and TAP Pharmaceuticals (a joint venture of Abbott Laboratories and Takeda Chemical Industries).⁶ Among these are three of the top five companies (by sales volume) in the industry: Pfizer (#1), GlaxoSmithKline (#2), and AstraZeneca (#5).⁷ The total paid out by these manufacturers to settle these cases is nearly \$1.66 billion. Of this amount, roughly \$1.23 billion, including \$360 million in criminal fines, was returned to the federal treasury; \$217 million was returned to state treasuries; and \$188 million was paid out to whistleblowers for bringing the allegations to the attention of DOJ. All but one of these cases began as a lawsuit filed under the federal False Claims Act (FCA) by a whistleblower (in most cases an employee of the manufacturer).⁸ Remarkably, these recoveries resulted from allegations involving just a handful of drug products (Adalat CC, Albuterol Sulfate, Cipro, Flonase, Ipratropium Bromide, Kogenate, Lipitor, Lupron, Paxil, Zoladex).⁹ Press reports suggest that there are numerous cases in the pipeline and that additional settlements can be expected.¹⁰

The size of these recoveries, the market share of the firms involved, and the indications of additional settlements to come, suggests that we may be witnessing a sea change in the relationship between Medicaid and Medicare on the one hand and the pharmaceutical industry on the other. Whistleblowers, federal prosecutors, and state attorneys general appear to be on the verge of forcing fundamental changes in the marketing and pricing practices of the pharmaceutical industry, much as the 1992 *National Health Laboratories* settlement and its progeny led to fundamental changes in the billing practices of the clinical laboratory industry.¹¹ These settlements are

⁶ On June 23, 2003, DOJ settled Medicare fraud allegations against another pharmaceutical manufacturer, Abbott Laboratories, for \$622 million. This case arose not from a whistleblower lawsuit but from an undercover operation by the Federal Bureau of Investigation, the U.S. Postal Inspection Service, and the Office of Inspector General for DHHS. It involved fraud allegations relating to the marketing of durable medical equipment (DME), in this instance enteral feeding pumps, tubing, and liquid food. It is not among the cases reviewed in this report, which focuses on whistleblower suits involving allegations of fraud relating to prescription drug pricing and marketing.

⁷ For the July 2002 through June 2003 period, these three firms had a total market share of 27.7 percent. IMS Health, *Leading 20 Corporations by U.S. Sales, MAT June 2003*, www.ihshealth.com (Press Room, Top-Line Industry Data).

⁸ In the case of the settlement with Dey, Inc., the case was brought under the Texas version of the False Claims Act, its Medicaid Fraud Prevention statute, Tex. Hum. Res. Code §§ 36.001–36.117.

⁹ For the period July 2002 through June 2003, Lipitor was the number 1 selling drug in the U.S.; Paxil ranked 12th. IMS Health, *Leading 20 Products by U.S. Sales, MAT June 2003*, www.ihshealth.com (Press Room, Top-Line Industry Data).

¹⁰ "In their latest high-profile gambit, Boston's prosecutors let Schering-Plough Corp. know last month that the Kenilworth, N.J. company faces the threat of indictment for a host of violations, including allegedly cheating the government out of Medicaid rebates by submitting false pricing information, document destruction and obstruction of justice, and offering inducements to managed-care organizations to purchase Schering products." Phyllis Plitch, "Health-Care-Fraud Prosecutors Target Big Pharmaceutical Firms," *Wall Street Journal* (July 2, 2003). See also Melody Petersen, "Pfizer Nears Drug Settlement," *New York Times* (March 12, 2003).

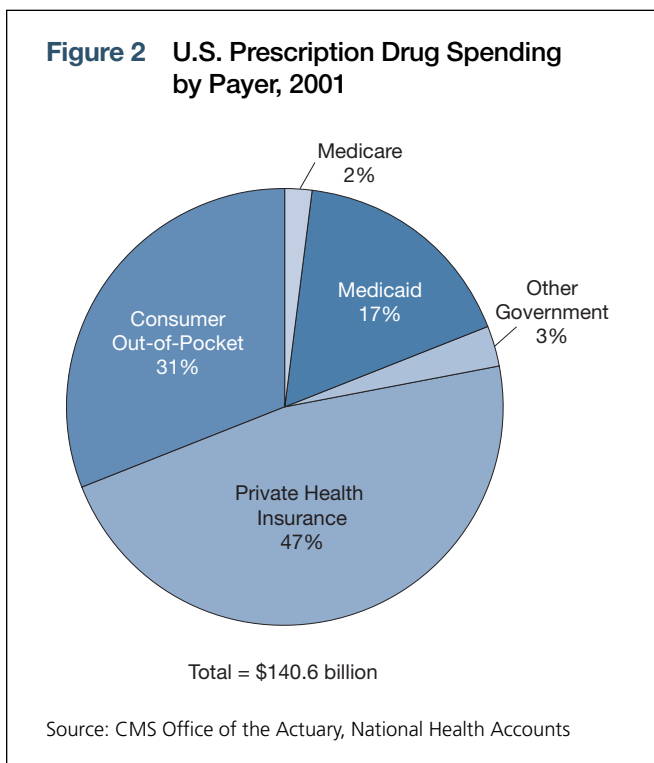
¹¹ For a summary of these cases and their impact on the clinical laboratory industry, see Jack Meyer and Stephanie Anthony, *Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act* (September 2001), pp. 52–65, www.taf.org.

clearly of benefit to the Medicaid program, the nation's single largest purchaser of prescription drugs (Figure 2) as well as to Medicare, which in FY 2002 purchased over \$8 billion in prescription drugs.¹² These settlements also have important implications for other federal health care programs.

Despite their size and potential significance, these settlements are not widely known. The purpose of this report is to inform policymakers and the public of these cases and

their implications for Medicare, Medicaid, and other federal health programs. The report is based upon a review of documents in settled cases, documents in cases that are still in litigation but are out from under seal, and discussions with relators' counsel, government prosecutors, and industry consultants.

The report begins with a brief discussion of the way in which Medicaid and Medicare purchase prescription drugs and provides a short explanation of the False Claims Act. The report then summarizes the types of fraudulent pricing and marketing practices in which manufacturers have been alleged to engage. With this background, the report then describes the seven settlement agreements involving drug manufacturers as of September 30, 2003,



as well as the corporate integrity agreements (CIAs) accompanying these settlements. The report concludes by outlining the potential implications of these settlement agreements and the CIAs for state Medicaid programs and for the current Medicare program, and by making some recommendations.

This report is limited in scope to FCA or state false claims act cases involving allegations of pricing fraud against Medicaid or Medicare by drug manufacturers. The report does not address litigation by the Federal Trade Commission, State Attorneys General, and consumer groups against pharmaceutical manufacturers. The consumer cases involve allegations that manufacturers have illegally kept generic versions of brand-name products off the market by manipulating patent law, filing baseless lawsuits against generic manufacturers, or paying competitors to delay the introduction of generics; that generic manufacturers collude with each other or with brand-name manufacturers to limit competition among generics; that manufacturers of brand-name

¹² Medicare prescription drug spending for purposes of the National Health Accounts for FY 2001, used to construct Figure 2, is reported as \$2.4 billion. Katherine Levit et al., "Trends in U.S. Health Care Spending, 2001," *Health Affairs* (January/February 2003), Exhibit 5, p. 158. Medicare prescription drug spending for FY 2001 reported by MedPAC, used to construct Figure 3, is \$6.4 billion. MedPAC, *Report to Congress: Variation and Innovation in Medicare* (June 2003), Figure 9-2, p. 154, www.medpac.gov.

drugs illegally promote the off-label use of their products; and that manufacturers grossly overstate average wholesale price (AWP) of their products, thereby overcharging Medicare and Medicaid patients.¹³ Similarly, the report does not address FCA whistleblower litigation against Medco Health Solutions, a pharmacy benefits manager (PBM) that is alleged to have defrauded the Federal Employees' Health Benefits Program.¹⁴ Finally, the report focuses on the manner in which Medicaid and Medicare purchase prescription drugs; it does not address the prices or procedures used by the Veterans Administration, the Department of Defense, the Coast Guard, and the Public Health Service to buy drugs for their program beneficiaries.

¹³ "Update on Previously Filed Litigation," *PAL News* (Winter 2003) www.prescriptionaccesslitigation.org.

¹⁴ U.S. Attorney's Office News Release, *U.S. to Intervene in Two 'Whistleblower' Actions Against Medco Health Solutions* (June 23, 2003), www.usao-edpa.com/Pr/2003/jun/medco.html; Milt Freudenheim, "U.S. Attorney Says Ex-Employee Lied to Conceal Fraud at Medco," *New York Times* (September 30, 2003).

I. Medicaid and Prescription Drugs

Medicaid is the federal-state program that purchases health and long-term care services for over 50 million low-income Americans. The program is financed jointly by the federal government and the states, with the federal government paying at least 50 percent and as much as 77 percent of the cost of services, depending on the state's per capita income.¹⁵ The program is administered by states within broad federal guidelines, which allow states to cover outpatient prescription drugs; all have elected to do so. Spending on outpatient prescription drugs varies considerably from state to state; in FY 2001, for example, Mississippi spent 16.6 percent of its Medicaid budget to purchase prescription drugs, while New Mexico spent 3.2 percent.¹⁶

In fiscal year 2003, federal Medicaid spending on outpatient prescription drugs is projected to be \$15.7 billion; state spending could be as high as \$12 billion, bringing total Medicaid spending to nearly \$28 billion. Prescription drug spending is the fastest-growing category of Medicaid spending, rising at about 14 percent per year. As shown in Figure 3, Medicaid spending on prescription drugs is nearly three times as great as Medicare spending.¹⁷ Nearly 11 percent of total Medicaid spending on services is attributable to prescription drugs; in contrast, only 3.0 percent of Medicare spending pays for outpatient prescription drugs.¹⁸

States may offer Medicaid prescription drug coverage to eligible individuals through managed care plans or on a fee-for-service basis. Although the majority of Medicaid beneficiaries is enrolled in some form of managed care, the majority of outpatient prescription drug spending appears to occur on a fee-for-service basis because the elderly and individuals with disabilities, who are the heaviest users of prescription drugs, tend not to be enrolled in managed care. Moreover, it is not uncommon for state Medicaid agencies that contract on a risk basis with managed care organizations to "carve out" prescription drugs from those contracts so that drugs are paid for by the agency on a fee-for-service basis rather than by the managed care organization.¹⁹

In fee-for-service arrangements, state Medicaid programs reimburse pharmacists for each medically necessary prescription they fill. This reimbursement comes in two pieces: payment for the drug product itself, and a dispensing fee. States also receive rebates from manufacturers on a quarterly basis for the drugs that they pur-

¹⁵ For a detailed discussion of the way in which Medicaid is financed and administered, see Kaiser Commission on Medicaid and the Uninsured, *The Medicaid Resource Book* (July 2002), www.kff.org.

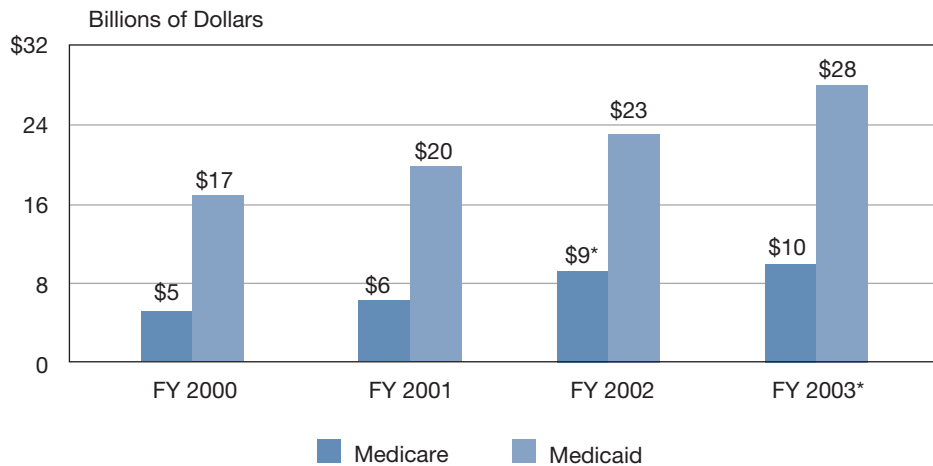
¹⁶ Vic Miller, "Senate to Consider Medicare Prescription Drug Legislation," (June 6, 2003), *FFIS Issue Brief 03-31*, Table 1.

¹⁷ Figure 3 somewhat understates the difference between Medicare and Medicaid prescription drug spending. The reason is that Medicare drug spending data include payments to physicians for drugs they administer, while the Medicaid drug spending data do not include these payments. If the Medicare data also excluded these payments, the difference between the Medicare and Medicaid totals would be larger.

¹⁸ Congressional Budget Office, *Fact Sheet for CBO's March 2003 Medicaid Baseline* (March 2003); MedPAC, *Report to Congress: Variation and Innovation in Medicare* (June 2003), Figure 9-2, p. 154.

¹⁹ Sara Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts* (4th Edition), Table 2.1, www.gwhealthpolicy.org.

Figure 3 Medicare and Medicaid Spending on Outpatient Prescription Drugs, FY 2000–FY 2003



*estimated

Source: FY 2000–2002 Medicaid data based on Urban Institute estimates from HCFA/CMS Form 64 reports. FY 2003 Medicaid data are based on CBO projections. FY 2000–2002 Medicare data are from MedPAC, June 2003 Report to the Congress. FY 2003 Medicare data are preliminary estimates from CMS Office of the Actuary.

chase on a fee-for-service basis. (Manufacturers are not required to pay rebates on drugs covered through managed care organizations). The federal government shares in the savings resulting from manufacturer rebates, as well as in the costs of the drugs that states purchase.²⁰

It is important to note that the way in which Medicaid purchases prescription drugs differs fundamentally from the way in which Medicaid purchases most other services it covers. In the case of hospital or physician or nursing home services purchased on a fee-for-service basis, for example, Medicaid programs generally set the prices they pay through a reimbursement formula or fee schedule. In the case of prescription drugs, however, manufacturers set the prices for their products and report them to a private price reporting service or the state Medicaid program itself, and Medicaid pays on the basis of the price the manufacturer reports. Medicaid generally does not negotiate drug prices directly with manufacturers as many private purchasers do. This makes the program as a buyer vulnerable to unconstrained price inflation. This vulnerability is compounded if the manufacturer fails to report, or falsely reports, the “best prices” it charges to favored customers other than the Medicaid program on its brand-name drugs, thereby reducing the rebates that would otherwise be paid to the states and federal government.

Payments to Pharmacies. When states purchase brand-name drugs on behalf of program beneficiaries on a fee-for-service basis, they generally pay the drug’s estimated acquisition cost (EAC) plus a dispensing fee. States have discretion in setting both. The EAC is the state Medicaid agency’s best estimate of the price generally and currently

²⁰ For a more detailed explanation, see Kaiser Commission on Medicaid and the Uninsured, *Medicaid: Purchasing Prescription Drugs* (January 2002), www.kff.org.

paid by providers for the drug. Most states use the Average Wholesale Price (AWP) of a drug to determine its EAC. The AWP is the price the manufacturers report to drug price compendia such as First Data Bank and the Red Book; it represents the manufacturer's suggestion as to the price the wholesaler should charge a retail pharmacist. Most states pay at a percentage off AWP; in 2000, the range was from AWP — 4% to AWP — 15.1%. Some states also base their EAC on the Wholesale Acquisition Cost (WAC), and add a percentage markup (e.g., WAC + 5%). California pays on the basis of Direct Price (DP), which it defines as the price at which a manufacturer sells its drugs to a pharmacy or end distributor without the involvement of a wholesaler. Texas pays on the basis of "price to wholesaler or distributor."

Whatever manufacturer prices the state uses to calculate what it pays for a drug — AWP, WAC, DP, or some other price — the pharmacy keeps the difference between the amount Medicaid pays and its actual cost of acquiring the drug from the manufacturer or wholesaler. Depending on the purchasing leverage of the pharmacy, its actual acquisition cost may be significantly below the price that Medicaid pays. The pharmacy also receives a dispensing fee, which in 2000 ranged from \$2.50 to \$15.70 per prescription.

Rebates from Manufacturers. The price that a state Medicaid program pays a pharmacy for a prescribed drug is effectively reduced by the rebate that the manufacturer pays to the state. Manufacturers are not required to sell their products to Medicaid, but if they want to do so, they must enter into an agreement with the Secretary of HHS to provide rebates to states for the drugs that Medicaid purchases on an outpatient basis. In exchange for agreeing to give rebates, manufacturers are guaranteed that state Medicaid programs will cover almost all of their FDA-approved products. The states and the federal government share in the rebates, which are paid on a quarterly basis, in proportion to their share of the cost of Medicaid prescription drug benefits. About 500 manufacturers have entered into rebate agreements with the Secretary of HHS that cover some 56,000 drugs products.²¹ Between 1991 and 2002, manufacturers paid \$29.4 billion in rebates;²² the Urban Institute estimates that since 1996, the rebate program has reduced Medicaid fee-for-service drug spending by about 17 percent per year.²³

Federal Medicaid law sets forth two rebate formulas, one for brand-name drugs (i.e., drugs under patent) and the other for generic drugs (i.e., drugs that are chemically equivalent to brand-name drugs with expired patents). In the case of brand-name drugs, there are two elements, a basic rebate and an additional rebate; only the basic rebate is relevant here. The basic rebate is the greater of:

- (1) 15.1 percent of the Average Manufacturer Price (AMP) for the drug;
- or
- (2) the difference between the AMP and the "best price" for the drug.

The AMP for a drug is the average price paid to the manufacturer for the drug by wholesalers for distribution to retail pharmacies, after deducting customary prompt pay discounts.²⁴ The "best price" for a drug is the lowest price at which the manufac-

²¹ www.hcfa.gov/medicaid/drugs/drug.mpg.htm

²² Muse & Associates, "Pharmaceutical Manufacturers' Rebates to Medicaid: 1991–2002," in PhRMA, *Private and Public Sector Pharmaceutical Financing in the United States*, Figure 4.6, p. 48, www.phrma.com.

²³ Brian Bruen, *Urban Institute, Medicaid and Prescription Drugs: An Overview* (2001), p. 6, www.kff.org.

²⁴ Section 1927(k)(1) of the Social Security Act, 42 U.S.C. §1396r-8(k)(1).

turer will supply the drug to any wholesaler, retailer, provider, HMO, or nonprofit or governmental entity in the U.S., subject to certain exceptions (e.g., the VA).²⁵

In the case of generic drugs, the rebate is much more straightforward: 11 percent of AMP. There is no adjustment for “best price.”

The policy logic of these rebate formulas, which were enacted in 1990 as part of that year’s deficit reduction legislation, was to reduce the extent to which Medicaid cross-subsidizes other large purchasers of prescription drugs. If a manufacturer of a brand-name drug is willing to give a deep price discount to, say, a managed care plan or a hospital buying group, Medicaid should receive the same discount. (As noted, exceptions are made for certain favored purchasers, such as the VA). With respect to generics, prices at the time were perceived to be so significantly discounted by competition that capturing a standard discount off AMP was felt to be the most efficient approach to extracting savings. While the rebate requirement has reduced the price of both brand-name and generic drugs to Medicaid, other federal purchasers such as the Veterans Administration and the Department of Defense obtain significantly better prices.²⁶

The following example illustrates how state Medicaid programs purchase a brand-name drug from a pharmacy (assuming only the basic rebate applies):

AWP (average wholesale price)	\$100
State Pays Pharmacy AWP minus 10% (\$90), plus	
\$3 Dispensing Fee	\$ 93
AMP (average manufacturer price)	\$ 80
Best Price	\$ 60
Manufacturer’s Rebate (the greater of:	
(1) 15.1% of AMP (\$16.61) or	
(2) AMP minus Best Price (\$20)	\$ 20
State’s Price Net of Rebate (\$93 - \$20)	\$ 73
Cost to Federal Government (at a 57% matching rate)	\$ 42
Cost to State (at a 43% matching rate)	\$ 31

Rebates are calculated by the Department of HHS based upon AMP data and, in the case of brand-name drugs, upon “best price” data submitted to the Department by the manufacturers. By statute, these pricing data are confidential and may not be disclosed by the Secretary of HHS or a State Medicaid agency (or contractor) except for certain specified purposes.²⁷ Obviously, if the pricing data submitted to the Secretary are inaccurate, then the rebate calculations will be inaccurate. If the pricing data do not reflect “best prices” actually paid by private purchasers, the Medicaid program will not realize the intended savings and will continue to cross-subsidize these other purchasers.

²⁵ Section 1927(c)(1)(C) of the Social Security Act, 42 U.S.C. §1396r-8(c)(1)(C).

²⁶ The OIG has calculated that the prices (net of rebates) paid by the 10 state Medicaid agencies with the largest volume of drug purchases for 25 high-volume mental health drugs exceeded the prices paid by the VA, DOD and other federal purchasers by 11 to 29 percent. OIG, *Medicaid’s Mental Health Drug Expenditures* (August 2003), OEI-05-02-00080, p. 6. In the case of 16 HIV/AIDS drugs, OIG calculated that Medicaid paid up to 33 percent more than other federal purchasers. OIG, *Cost Containment of Medicaid HIV/AIDS Drug Expenditures* (July 2001) OEI-05-99-00611, www.oig.hhs.gov.

²⁷ Section 1927(b)(3)(D) of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D).

The rebate provisions in the federal Medicaid statute, first enacted in 1990, have not been implemented by regulation. In 1995, CMS (then the Health Care Financing Administration) published a proposed rule to implement many of these provisions.²⁸ On April 29, 2003, the CMS Administrator approved a final rule addressing just two provisions of the proposed rule. One of these limits the amount of time a manufacturer must retain pricing data from which it derives the average manufacturer prices and “best prices” it reports to the Secretary to 3 years from the date manufacturer initially reports the prices. At the time the Administrator approved the rule, five of the seven settlements reviewed in this report had been announced. This final rule was published four months later, after the remaining two settlements had been announced, during the Congressional summer recess.²⁹ As published on August 29, the final rule was to be effective on October 1. On September 26, CMS published a “correction” announcing that the Office of Management and Budget (OMB) had declared the final rule a “major rule.” The import of this action is to delay the effective date of the final rule to January 1, 2004 in order to give the Congress an opportunity to review and, if it sees fit, disapprove it.³⁰

A Congressional review seems warranted. The final regulation provides only one exception to the 3-year requirement. It requires a manufacturer to retain pricing records beyond the 3-year period if the records are the subject of an audit or of a government investigation “of which the manufacturer is aware,” or if the audit findings or investigation have not been resolved.³¹ This exception does not appear to cover FCA cases filed under seal of which the manufacturer is not aware or in which the government investigation has not begun. By way of comparison, the statute of limitations that applies to FCA cases generally is a minimum of 6 years from the date of the submission of the false claim and may run as long as 10 years.³²

²⁸ 60 Fed. Reg. 48442 (September 19, 1995).

²⁹ 68 Fed. Reg. 51912 (August 29, 2003).

³⁰ 68 Fed. Reg. 55527 (September 26, 2003). Under the Congressional review procedures enacted in the Contract with America Advancement Act of 1996, P.L. 104-121, Congress has 60 days from notification of the issuance of a “major rule” to pass a joint resolution of disapproval with respect to any such rule with which it disagrees. See 8 U.S.C. § 802.

³¹ 42 C.F.R. § 447.534(h)(ii).

³² 31 U.S.C. § 3731(b).

II. Medicare and Prescription Drugs

Unlike Medicaid, Medicare does not cover outpatient prescription drugs. Medicare does, however, cover a limited number (about 450) of prescription drugs, primarily physician-administered drugs. Medicare's spending on prescription drugs, while less than Medicaid's, is not trivial: \$8.4 billion in FY 2002.³³ The Medicare methodology for purchasing the drugs it covers is central to the criminal and civil fraud allegations resolved by the *TAP Pharmaceuticals* and *AstraZeneca* settlements discussed below. And although Medicare, unlike Medicaid, does not obtain rebates from manufacturers on the products it purchases, the prices at which Medicare providers obtain covered brand-name drugs affect the rebate amounts owed by the manufacturers to Medicaid.

There is one important similarity between Medicare and Medicaid as purchasers of prescription drugs. The way in which Medicare buys drugs differs fundamentally from the way in which Medicare purchases most other services it covers on a fee-for-service basis. In the case of hospital or physician services, for example, Medicare generally sets the prices it pays through a reimbursement formula or fee schedule. In the case of prescription drugs, however, manufacturers set the prices for their products and report them to a private price reporting service, and Medicare pays on the basis of the price the manufacturer reports. Like Medicaid, Medicare generally does not negotiate drug prices directly with manufacturers as many private purchasers do.

Part B of Medicare covers three categories of drugs: (1) injectable or intravenous drugs administered by a physician, for which the physician incurs the cost and bills (e.g., prostate cancer drugs); (2) drugs administered through a covered item of durable medical equipment (DME) such as inhalants delivered through a nebulizer; and (3) certain drugs specified in the Medicare statute, such as immunosuppressive drugs, hemophilia blood clotting factors, and oral anti-cancer drugs. Nearly half — \$3.8 billion, or 45 percent — of Medicare spending on drugs in FY 2002 for drugs went to oncologists.³⁴ In 2001, two of the top five Medicare Part B drugs were prostate cancer drugs: Lupron (#2 at 10.4 percent of all Part B drug spending) and Zolodex (#4 at 6.8 percent).³⁵ Virtually all of the drugs covered by Medicare are also covered by Medicaid.³⁶

By statute, Medicare is required to pay for these drugs on the basis of 95 percent of

³³ 68 Fed. Reg. at 50429 (August 20, 2003). This represents about 3 percent of total Medicare spending that year. In comparison, federal Medicaid spending on outpatient prescription drugs in FY 2002 (net of rebates) is estimated by the Congressional Budget Office at \$13.5 billion, implying that total federal and state Medicaid spending was \$23.7 billion. *Fact Sheet for CBO's March 2003 Medicaid Baseline* (March 2003).

³⁴ 68 Fed. Reg. at 50429 (August 20, 2003).

³⁵ MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), Table 9-1, p. 151, www.medpac.gov.

³⁶ This includes the drugs at issue in the state Medicaid false claims act cases discussed below. For example, one of the generic inhalation drugs at issue in the *Dey* settlement accounted for more than half of all Medicare spending on such drugs in 2000. OIG, *Excessive Medicare Reimbursement for Ipratropium Bromide* (March 2002), OEI-03-01-00411, p. 1, www.oig.hhs.gov. Appendix A lists similar OIG reports relating to Albuterol and Albuterol Sulfate, two other generic drugs at issue in the *Dey* case.

AWP.³⁷ Neither the Medicare statute nor its regulations define AWP; the administering agency defines it as “the AWP published in commercial compendia such as Red Book, Price Alert, and Medispan”(“list AWP”).³⁸ As discussed above, AWP’s are supplied to these price reporting services by the manufacturers and may or may not correspond to actual transaction prices. Medicare beneficiaries are responsible for a coinsurance payment of 20 percent of these amounts.³⁹ The physician keeps the difference between the amount that Medicare pays (plus the beneficiary’s coinsurance payment) and his or her cost of acquiring the drug. The physician also receives a fee from Medicare for administering the drug.

The following example illustrates how Medicare pays a physician for a brand-name drug administered to a beneficiary. This example does not include the fee paid the physician for administering the drug.⁴⁰

AWP (average wholesale price)	\$100
Medicare Program pays 95% of AWP	\$ 95
Medicare pays Physician 80% of 95% of AWP	\$ 76
Beneficiary pays Physician 20% of 95% of AWP	\$ 19
Physician purchases drug at 77% of AWP	\$ 77
Physician profit on drug	\$.18

In contrast to the Medicaid example in the previous section, there is no manufacturer rebate to Medicare and no state contribution to the cost of the product.

The Medicare payment rate of 95 percent of AWP is significantly higher than the amounts that manufacturers actually charge to physicians purchasing and administering covered drugs to their patients. A 2001 GAO study found that the “spread” between the amount Medicare pays and the actual price to the physicians ranged on average from 13 to 34 percent, although in two instances the “spread” was 65 and 85 percent.⁴¹ In some cases, the “spread” is so great that the beneficiary’s coinsurance payment exceeds the physician’s actual cost. CMS offers the example of leucovorin calcium: the list AWP is \$18.44, but the widely available market price is \$2.77. Medicare pays 95 percent of AWP, or \$17.52, and the beneficiary co-insurance is 20 percent of this amount, or \$3.69 — more than the cost of the drug to the physician (\$2.77).⁴²

Not surprisingly, the current Medicare payment methodology has been sharply criticized by GAO⁴³ and the OIG.⁴⁴ MedPAC, the independent federal agency established

³⁷ Section 1842(o)(1) of the Social Security Act, 42 U.S.C. 1395u(o)(1).

³⁸ 68 Fed. Reg. 50429 (August 20, 2003).

³⁹ Section 1842(o)(3) of the Social Security Act, 42 U.S.C. 1395u(o)(3).

⁴⁰ Example based on MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), Figure 9-4, p. 157, www.medpac.gov

⁴¹ General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers’ Costs* (September 2001) (GAO-01-1118).

⁴² 68 Fed. Reg. at 50430 (August 20, 2003).

⁴³ General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers’ Costs* (September 2001) (GAO-01-1118), www.gao.gov.

⁴⁴ Office of Inspector General, *Medicare Reimbursement of Prescription Drugs* (January 2001) (OEI-03-00-00310), www.oig.hhs.gov.

by Congress to advise it on Medicare issues, characterizes the Medicare payment methodology as “flawed” because, among other things, Medicare payments for drugs “far exceed provider acquisition costs” and “the system creates incentives for manufacturers to raise their list prices, resulting in increased Medicare payments.”⁴⁵ At least one Congressional committee has held a hearing on the matter featuring testimony from a whistleblower.⁴⁶ The Congressional Budget Office has presented Congress with an option for changing the payment methodology that would reduce Medicare spending by \$3.6 billion over five years.⁴⁷ Both the House and Senate versions of the Medicare drug legislation currently in conference committee contain provisions that would revise the current statute.⁴⁸ In addition, CMS has proposed to change the payment methodology administratively.⁴⁹ These changes are being vigorously opposed by oncologists, among others.⁵⁰

⁴⁵ MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), p. 149, www.medpac.gov.

⁴⁶ Subcommittee on Oversight and Investigations and the Subcommittee on Health, House Committee on Energy and Commerce, *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers* (September 21, 2001), <http://energycommerce.house.gov/107/Hearings09212001hearing371/>.

⁴⁷ CBO, *Budget Options* (March 2003), Option 570-10, p. 151, www.cbo.gov.

⁴⁸ Section 303 of H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003, as passed by the House on June 27, 2003; section 432 of S. 1 as passed by the Senate on June 27, 2003. The Congressional Budget Office estimates that the House provisions would reduce Medicare spending by \$13 billion over 10 years and that the Senate provisions would save Medicare \$14 billion over the same period. CBO, *Cost Estimate H.R. 1 and S. 1* (July 22, 2003), pp. 46–47, www.cbo.gov.

⁴⁹ 68 Fed. Reg. 50428 (August 20, 2003).

⁵⁰ Leila Abboud, “Deep in Medicare Bill, a Drug Fight,” *Wall Street Journal* (June 19, 2003).

III. The False Claims Act and Medicare and Medicaid Fraud

The False Claims Act (FCA) establishes civil liability for individuals or entities who knowingly submit false or fraudulent claims for federal funds.⁵¹ The FCA applies to all federal spending, not just health care programs like Medicare and Medicaid. And, as discussed below, the FCA is not the only federal statute establishing liability for fraud against Medicare and Medicaid. But the FCA is unique in rewarding private citizens for bringing fraud to the attention of federal authorities. These *qui tam* provisions of the FCA, combined with its treble damages provisions, have made it the most powerful tool available to the federal government for identifying and deterring complex, large-scale corporate fraud against federal health care programs. In the view of the Department of Justice, the FCA is “the United States’ primary tool against fraud upon the government.”⁵²

Under the FCA, a private party acting on the government’s behalf may sue any government contractor that has knowingly submitted false or fraudulent claims for federal funds. The private party is the *qui tam* plaintiff, also known technically as the relator and colloquially as the whistleblower.⁵³ The federal government may also bring suit under the FCA on its own behalf, but the large majority of FCA cases involving Medicare and Medicaid are initiated by whistleblowers. Cases brought by whistleblowers are filed under seal in federal court, which means that the defendant is not initially served with the complaint or otherwise made aware of the case. While the case is under seal, the DOJ investigates the case (often with the assistance of the FBI or OIG) to decide whether to intervene. If DOJ decides to intervene, it typically attempts to negotiate a settlement with the defendant while the matter is still under seal. If DOJ decides not to intervene, the court will lift the seal and the relator may proceed on his own.⁵⁴

A defendant found liable under the FCA faces treble damages plus penalties ranging from \$5,500 to \$11,000 for each false claim.⁵⁵ The *qui tam* plaintiff is entitled to share in favorable settlements or judgments depending upon his or her level of contribution to the case. If the government decides to intervene in the case, the relator may receive between 15% and 25% of the recovery; if the government elects not to intervene, the relator receives between 25% and 30% of the recovery.⁵⁶ On average in FCA health care cases in which the government intervenes, whistleblowers receive about 16 per-

⁵¹ 31 U.S.C. § 3729(a)-(b). The text of the FCA appears at www.taf.org/theact.html.

⁵² United States’ Statement of Interest in Opposition to Defendant Parke-Davis’ Motion for Summary Judgment, May 23, 2003, in *U.S. ex rel. Franklin v. Pfizer, Inc.*, CA No. 96-11651-PBS (D. Mass.) at p. 1.

⁵³ *Qui tam* (pronounced “kwee tahm”) is shorthand for the Latin *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, “he who sues on behalf of the king as well as himself.” *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 768 n.1 (2000).

⁵⁴ For a discussion of *qui tam* suits, see “Frequently Asked Questions,” www.taf.org.

⁵⁵ 31 U.S.C. § 3729(a)(7) provides for civil penalties ranging from \$5,000 to \$10,000 per claim. These penalties were adjusted for inflation in 1999 pursuant to 28 U.S.C. § 2641(4)(1), as implemented by 28 C.F.R. § 85.3(9).

⁵⁶ 31 U.S.C. § 3730(d).

cent of recoveries. In cases in which the government does not intervene, whistleblowers receive an average of 28 percent of the recovery.⁵⁷ In either event, the federal government retains the lion's share of the recovery.

The FCA is not the only law used by the federal government to protect Medicare and Medicaid from fraud. DOJ has available to it a number of criminal authorities for prosecuting false claims, including the prohibitions against "false, fictitious, or fraudulent claims" (18 U.S.C. § 287), against "false, fictitious, or fraudulent statements or representations" (18 U.S.C. § 1001), and against mail fraud (18 U.S.C. § 1341).⁵⁸ OIG has the authority to exclude providers from federal health care programs for certain types of fraud,⁵⁹ or to impose civil money penalties,⁶⁰ or both.

The FCA, in combination with other anti-fraud laws, has had a significant impact on fraud against the Medicare program. A recent report by health economist Jack Meyer

These *qui tam* provisions of the FCA ... have made it the most powerful tool available to the federal government for identifying and deterring complex, large-scale corporate fraud against federal health care programs.

found that, over the five-year period FY 1997 through FY 2001, the government recovered \$2.75 billion from fraudulent health care providers (after deducting payments to whistleblowers) while spending \$315 million to investigate and prosecute these cases — a benefit

to cost ratio of nearly 9 to 1.⁶¹ To date, the FCA has not generated equally large recoveries from providers defrauding Medicaid: over the same five-year period, recoveries from Medicare fraud were more than 12 times as great as those from Medicaid fraud, even after adjusting for the relative size of federal spending in the two programs.⁶² These data do not, however, reflect the settlements discussed in this report, which have resulted in significant recoveries for the federal government and state Medicaid programs.

Figure 1 above shows the recoveries resulting from these settlements by fiscal year. The first of the settlements, resulting in \$14 million in recoveries, occurred during FY 2001 and represented only one percent of the total health-related civil fraud recoveries of \$1.2 billion reported by DOJ for that fiscal year.⁶³ By FY 2002, however, the role of these settlements had expanded dramatically. Of the \$1.6 billion in health-related civil fraud recoveries for FY 2002, \$875 million, or 55 percent, were attributable to settlements of allegations of drug pricing and marketing fraud.⁶⁴ Final DOJ data for FY 2003 are not available. However, based on DOJ press releases through September 30,

⁵⁷ J. Meyer and S. Anthony, *Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act* (September 2001), Executive Summary p. 17.

⁵⁸ Timothy Jost and Sharon Davies, *Medicare and Medicaid Fraud and Abuse 2002–03 Edition* (2002), pp. 52–66.

⁵⁹ Section 1128 of the Social Security Act, 42 U.S.C. § 1320a-7.

⁶⁰ Section 1128A of the Social Security Act, 42 U.S.C. § 1320a-7a.

⁶¹ Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck* (June 2003), p. 2, www.taf.org.

⁶² Andy Schneider, *Reducing Medicaid Fraud: The Potential of the False Claims Act* (June 2003), p. 8, www.taf.org.

⁶³ Total health-related recoveries data from Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck* (June 2003), Figure 4, p. 7, www.taf.org. \$14 million is the total recovery in *U.S. ex rel. Florida Keys v. Bayer Corp.*

⁶⁴ DOJ and OIG report \$1.6 billion in collections in FY 2002 from "cases resulting from health care fraud and abuse." Department of Health and Human Services and the Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2002* (September 2003), p. 5, www.usdoj.gov/dag/pubdoc/hcfacreport2002.htm. The \$875 million figure represents the recovery in *U.S. ex rel. Gerstein v. TAP Holdings, Inc.*, No 98-10547 (D. Mass).

2003, health-related recoveries are likely to total over \$2 billion. Of this amount, \$767 million, or about 37 percent, derived from settlements of allegations of drug pricing and marketing fraud.⁶⁵ These data reflect an increase in the number of cases filed against manufacturers by whistleblowers as well as a heightened interest in these allegations among DOJ lawyers and Assistant U.S. Attorneys.⁶⁶

⁶⁵ The estimate of \$2.056 billion in total health-related recoveries includes \$622 million in the Abbott Laboratories case, which involved durable medical equipment (DME) not prescription drugs. This recovery is not included in the \$767 million estimate, which comprises the recoveries in the Pfizer (\$49 million), Bayer II (\$257 million), GlaxoSmithKline (\$88 million), Dey (\$18 million), and AstraZeneca (\$355 million) settlements. See Table 2.

⁶⁶ Phyllis Plitch, "Health-Care-Fraud Prosecutors Target Big Pharmaceutical Firms," *Wall Street Journal* (July 2, 2003).

IV. Types of Alleged Fraud by Prescription Drug Manufacturers

Unfortunately, fraud occurs in Medicare and Medicaid, and it occurs across the range of services those programs cover, from prenatal care to hospice services. Providers throughout the health care sector, including physicians, laboratories, hospitals, and nursing homes, have settled allegations of health care fraud with DOJ. In the case of prescription drugs, pharmacies, including national chains like Walgreens Drugs⁶⁷ and Eckerd,⁶⁸ have allegedly defrauded the program, as have prescribing physicians.⁶⁹ The recent spate of FCA settlement agreements and related criminal pleas indicates that DOJ, for one, believes that Medicare and Medicaid have been defrauded by some drug manufacturers as well. As evidenced by these settlement agreements, at least two types of fraudulent behavior are alleged with respect to drug pricing and marketing. In the case of brand-name drugs, some manufacturers have engaged in “marketing the spread” to physicians and concealing “best prices;” in the case of generic drugs, some manufacturers allegedly “market the spread” to pharmacies. Although the focus of this report is on the manufacturers, it should be noted that those benefiting from these practices include physicians and pharmacists as well.

“Marketing the Spread” to Physicians. Manufacturers of brand-name drugs market to physicians in a number of ways. In the case of drugs that are administered to patients by physicians, one technique is to offer the physician a deep discount on the price of the drug. The physician then keeps the “spread” or difference between the amount the government program (or private insurer) pays for the drug and the discounted price charged by the manufacturer. For example, if Medicare (or a state Medicaid program) reimburses a physician at 95 percent of the AWP for such a drug, and the manufacturer, in order to induce the physician to prescribe the drug, charges him only 25 percent of AWP, the physician keeps the spread (70 percent of AWP). This revenue is in addition to whatever reimbursement the physician receives from Medicare or Medicaid for actual physician services provided during the encounter at which the drug was prescribed.

Obviously, a manufacturer can increase either the size of the “spread” or the amount of revenue it generates under such an arrangement (or both) by raising the AWP for the drug. If the AWP is \$100 in the above example, the physician receives \$95 from the government for administering a drug for which he pays \$25, a spread of \$70. To increase the amount the manufacturer makes on a prescription while enabling the

⁶⁷ Walgreen paid \$7.6 million to settle allegations that it had received reimbursement for full prescriptions when in fact it had only partially filled the prescriptions. *U.S. ex rel. Louis H. Mueller v. Walgreen Corp.*, No. 96-84-CIV-T23E (M.D. Fla), September 15, 1999, www.justice.gov/civil/press/press99.htm.

⁶⁸ Eckerd paid \$5.8 million to settle allegations that it dispensed partial or “short” prescriptions but billed Medicaid and other federal programs for the full prescription. *U.S. ex rel. Louis H. Mueller v. Eckerd Corporation*, No. 8:95-CV-2030-T-17EAJ (M.D. Fla., June 3, 2002), www.justice.gov/opa/pr/2002/May/02_civ_327.htm

⁶⁹ For example, in connection with the AstraZeneca settlement, two urologists pleaded guilty to conspiring to bill Medicare for free Zoladex samples. DOJ Press Release, “AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime: Company Agrees to Pay \$355 Million to Settle Charges” (June 20, 2003), www.usdoj.gov.

physician to continue to receive the same spread, the manufacturer simply raises the AWP to, say \$110. The government now pays the physician 95 percent of \$110, or \$104.50. The physician keeps the \$70 spread and pays the difference of \$34.50 to the manufacturer, an increase of \$9.50. In the alternative, if the manufacturer wished to increase the prescribing physician's compensation, the manufacturer could increase the physician's spread to \$79.50 by continuing to charge him \$25 for the drug. In both cases, the increases are at government expense.

The implications of this arrangement for the fiscal integrity of the Medicare and Medicaid programs have not gone unnoticed. As the recent *Compliance Program Guidance* issued by the HHS Office of Inspector General (OIG) makes clear:

"Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product. ...The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product."⁷⁰

The impact of marketing the spread to increase sales to Medicare is not limited to the federal treasury. It also affects Medicare beneficiaries to whom such drugs are prescribed. Under Medicare, beneficiaries are responsible for a coinsurance payment set at 20 percent of the price that Medicare pays — in the case of prescription drugs, 20 percent of 95 percent of AWP. Thus, in the example above, if AWP is \$100, the beneficiary's coinsurance requirement is 20 percent of \$95, or \$19. (The coinsurance amount is paid to the administering physician). If the manufacturer increases AWP to \$110, the beneficiary's coinsurance requirement rises to \$20.90, or 20 percent of \$104.50. This issue was raised by the whistleblower in the January 2001 *Bayer* settlement described below as well as by OIG and GAO witnesses testifying at a Congressional hearing in September 2001.⁷¹ In December 2001, the Prescription Access Litigation Project (PAL) filed a class action on behalf of Medicare beneficiaries against over 20 pharmaceutical manufacturers alleging fraudulent overstatement of AWP.⁷² In May 2002, this lawsuit was consolidated with other cases and transferred to the U.S. District Court in Massachusetts, which in May 2003 denied the manufacturers' motion to dismiss.⁷³

⁷⁰ OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers* (April 2003), p. 27, www.oig.hhs.gov.

⁷¹ Subcommittee on Oversight and Investigations and Subcommittee on Health, House Committee on Energy and Commerce, *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers* (September 21, 2001), <http://energycommerce.house.gov/107/Hearings09212001hearing371/>.

⁷² PAL News (Summer 2003), p. 3, www.prescriptionaccesslitigation.org.

⁷³ *In re Pharmaceutical Industry Average Wholesale Price Litigation*, M.D.L. No. 1456, C.A. 01-12257-PBS (D. Mass. May 13, 2003).

The decision by the District Court in this case provides a sampling of AWP markups by one of the defendant manufacturers, Abbott Laboratories. The following examples are drawn from data presented by the Court based on the Master Consolidated Complaint:⁷⁴

Drug	Abbott's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir	\$1,047.38	\$349.05	\$698.33	200%
Diazepam	\$28.50	\$2.03	\$26.47	1,304%
Furosemide	\$74.52	\$14.38	\$60.14	418%
Vancomycin Hydrochloride	\$382.14	\$4.98	\$377.16	7,574%

Concealing “Best Prices.” As discussed above, the Medicaid program requires manufacturers to pay rebates as a condition of covering their products. In the case of brand-name drugs, the rebates are designed to give Medicaid the benefit of the “best price” that the manufacturer gives to any other domestic purchaser (with a few exceptions like the VA and safety net hospitals and clinics). For example, if a manufacturer gives a deep discount to a large managed care plan, it must give the same price (net of rebate) to Medicaid. This creates an incentive for the manufacturer to conceal actual “best price” information from the federal government. By not reporting steep discounts given to a private purchaser to win market share for brand-name drugs, a manufacturer will not have to give that same low price to all state Medicaid programs in the form of a large rebate.

Concealment of — that is, knowing failure to report — actual “best prices” gives rise to FCA liability. In its recent *Compliance Program Guidance*, OIG stated:

“A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to reimbursement by Medicare and Medicaid) for the manufacturer’s product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately....Given the importance of the Medicaid rebate program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.”⁷⁵

There are numerous techniques for concealing actual “best price.” One is to give a steep discount to a customer but not report that discounted price to the Secretary. This is what allegedly occurred in the first of the *Bayer* cases, as well as in the *TAP*

⁷⁴ *Ibid.* at p. 7.

⁷⁵ OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers* (April 2003), pp. 11–12, www.oig.hhs.gov.

Pharmaceuticals and *AstraZeneca* cases with respect to physicians. It is also what allegedly occurred in the *Pfizer* case, where the customer was a large managed care plan.

Another concealment technique is called “private labeling.” In this scheme, the manufacturer sells a drug to a large managed care plan or other high-volume customer at a deeply discounted price. In order to conceal the steep discount, the manufacturer disguises the product to make it appear to be that of the plan rather than one of the manufacturer’s drugs. The relabeled drug is identical to the drug sold to Medicaid patients — i.e., same ingredients, same dosage form and strength, same packaging — in all respects but one: the National Drug Code (NDC) number, which is that of the plan, not of the manufacturer. Because manufacturers report “best prices” by NDC number, the “best prices” for the drug sold to Medicaid programs will not capture the deeply discounted price for the same drug sold to the managed care plan. This concealment technique was at the core of the most recent *Bayer* settlement, also discussed below. The *Glaxo* settlement included allegations of both “private labeling” and “repackaging,” in which Glaxo made bulk sales of a drug to the plan, which then repackaged and relabeled the drug itself, using its own NDC number.

“Marketing the Spread” to Pharmacists. In the case of brand-name drugs, a manufacturer will generally market to the prescribing physician. In the case of generic drugs, however, the manufacturer tends to market not to the physician but to the pharmacist. That is because when patents expire on brand-name drugs, there will often be several manufacturers offering generic products in competition with one another and the brand-name drug. If the pharmacist has discretion to dispense a generic product rather than the brand name, it is the pharmacist, not the physician, who generally decides which generic drug will be dispensed. The generic manufacturers tend to compete for the pharmacist’s business on the basis of price. Among the price-based sales techniques used by some generic manufacturers is “marketing the spread.” In the case of Medicaid, which pays pharmacists both the ingredient cost and a dispensing fee, this price competition takes the form of increasing the potential profit realized by the pharmacist through the ingredient cost. The pharmacist’s profit can be increased either by raising the reported price that is relied on by Medicaid for paying the ingredient cost, or by lowering the price net of discounts at which the product is actually sold to the pharmacy, or both. These pricing and marketing practices gave rise to allegations that were the basis of the \$18.5 million settlement in the *Dey* case discussed below.

V. FCA Settlements with Prescription Drug Manufacturers

As of September 30, 2003, DOJ had announced seven settlements of FCA cases against six prescription drug manufacturers involving allegations of drug pricing fraud against Medicare or Medicaid.⁷⁶ These settlement agreements account for \$1.66 billion in recoveries over the past two years, or more than half of the \$2.9 billion in health-related fraud recoveries by DOJ during that period.⁷⁷ Of this amount, \$1.23 billion was returned to the federal treasury; \$217 million was returned to state treasuries for Medicaid losses; nearly \$188 million was paid out to whistleblowers for bringing the allegations to the attention of DOJ; and \$12 million was paid by manufacturers to certain safety net clinics and hospitals.⁷⁸ Six of the cases were initiated by a whistleblower under the FCA, and the seventh by a whistleblower under a state false claims act. It is unlikely that, in the absence of information supplied by the whistleblowers in these cases, federal or state government officials would have uncovered the allegedly fraudulent practices at issue.⁷⁹

As shown in Table 2, three of the cases (*AstraZeneca*, *Bayer II*, and *TAP*) involve the payment of criminal fines as well as civil recoveries. These fines, totaling \$360 million, were deposited in the federal Crime Victims Fund. Both *AstraZeneca* and *TAP* Pharmaceuticals pleaded guilty to a conspiracy to violate the Prescription Drug

⁷⁶ On June 23, 2003, DOJ settled Medicare fraud allegations against another pharmaceutical manufacturer, Abbott Laboratories, for \$622 million. This case involved allegations of fraud relating to the marketing of durable medical equipment (DME), not the marketing or pricing of prescription drugs, and it did not arise from a whistleblower lawsuit, as in the case of the settlements discussed in this report.

⁷⁷ DOJ reports \$1.3 billion in health care fraud recoveries in FY 2001 and \$1.6 billion in FY 2002; the amounts returned to the Medicare Trust Fund were \$1 billion and \$1.4 billion respectively. See DHHS and DOJ, *Health Care Fraud and Abuse Control Program Annual Report for FY 2001* (April 2002) p. 2; *Health Care Fraud and Abuse Control Program Annual Report for FY 2002* (September 2003), p. 5; www.usdoj.gov/dag/pubdoc/.

⁷⁸ In two of the cases, *Bayer II* and *Glaxo*, the total recoveries include payments made by the manufacturers to "public health service (PHS) entities." These are "safety net" clinics and hospitals specified in section 340B of the Public Health Service Act, 42 U.S.C. § 256b. Under the so-called "340B Program," manufacturers that seek 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 to their non-Medicaid patients. Section 1927(a)(5) of the Social Security Act, 42 U.S.C. § 1396f-8(a)(5). The greater the Medicaid rebate on a particular drug, the larger the discount to which the 340B clinic or hospital is entitled. See <http://bphc.hrsa.gov/opa>.

⁷⁹ The *Bayer II* case offers a classic example of information the government is likely to receive only from a whistleblower: "Bayer's Cipro scheme began in 1995 when Kaiser threatened to stop buying the antibiotic after Johnson & Johnson offered its medicine, Floxin, at a much lower price, according to documents, including internal memos that Mr. Couto gave to prosecutors. Bayer was desperate to keep the business of Kaiser, a nonprofit health insurer with eight million members, according to documents. Kaiser was buying about \$7 million of Cipro each year. In addition, other health groups often follow Kaiser's lead in drug-buying decisions. But if Bayer offered to beat the price offered by Johnson & Johnson, Cipro's new price would fall below what Bayer was charging Medicaid, forcing it to pay tens of millions of dollars in additional rebates. Alan Mello, a market manager for Bayer, looked for a way to avoid paying the rebates... In April 1995, according to Mr. Couto's testimony, Kaiser suggested a solution. Bayer would ship Cipro to Kaiser in the usual way, but the words "Distributed by Kaiser Foundation Hospitals" would be typed on each bottle's label along with Kaiser's national drug code number rather than Bayer's. National drug codes, which are kept on a list maintained by the Food and Drug Administration, serve to identify medicines. According to Mr. Couto, the executives' reasoning at the time was that the responsibility for reporting the new Cipro price fell to Kaiser. Because Kaiser did not have a Medicaid agreement with the government, the reasoning continued, it did not have to report the new price or pay additional rebates to the government." Melody Petersen, "Bayer Agrees to Pay U.S. \$257 Million in Drug Fraud," *New York Times* (April 17, 2003).

Table 2 Recoveries in Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2003)

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Relator's Share
AstraZeneca (6/20/03)	\$355 million	\$63.9 million	\$266.1 million ^a	\$24.9 million	\$13.7 million	\$11.2 million	\$47.6 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 ^b	\$5.6 million	None	\$242.1 million	\$133.2 million	\$108.9 million	\$34.2 million
Dey (6/11/03)	\$18 million ^c	None	None	\$14.8 million	\$9.2 million	\$5.6 million	\$3.2 million
GlaxoSmithKline (4/16/03)	\$88 million ^d	None	None	\$85.1 million	\$46.8 million ^c	\$38.3 million	None
Pfizer (10/28/02)	\$49 million	None	None	\$49 million	\$27.9 million	\$21.1 million	\$5.9 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	\$1.656 billion	\$359.9 million	\$794.4 million	\$486.6 million	\$269.8 million	\$216.8 million	\$187.6 million

Source: Settlement agreements on file at TAF Education Fund library

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

^b This amount includes Bayer payments to PHS entities of \$9.5 million.

^c This amount includes \$2.3 million in attorneys' fees and costs to relator and to state of Texas.

^d This amount includes GSK payments to PHS entities of \$2.6 million.

Marketing Act by providing free samples of their prostate cancer drugs to physicians and encouraging them to bill the Medicare program (and program beneficiaries) for the free samples. These two settlements also involve allegations that the manufacturers, by marketing the spread to physicians, caused false and fraudulent claims for the deeply discounted prostate cancer drugs to be submitted to Medicare. In its second settlement, Bayer pleaded guilty to as violation of the Drug Listing Act, 21 U.S.C. § 360(j) for failing to list with the Food and Drug Administration (FDA) a drug product that it privately labeled for a managed care customer.

Six of the settlements — all but *Dey* — involved brand-name drugs (see Table 1). Common to each of these settlements are allegations of failing to accurately report “best price” for Medicaid rebate purposes. As shown in Table 2, the amount recovered by the federal and state governments in connection with these Medicaid “best price” allegations is \$487 million.⁸⁰ The techniques alleged for concealing “best price” varied among the cases. In *AstraZeneca*, *Bayer I*, and *TAP Pharmaceuticals*, the allegations involved failure to report steep discounts to physicians used in “marketing the spread.” In *Bayer II* and *GlaxoSmithKline*, the allegations involved failure to report deeply dis-

⁸⁰ The state Medicaid recoveries are specified in each of the settlements; they total \$217 million. The federal recoveries attributable to Medicaid are available from documents for all but the *TAP* case; they total \$239 million.

counted prices to large managed care purchasers on privately labeled drugs disguised through “lick and stick.” *Pfizer* also involved allegations of the failure to report deeply discounted prices given to a large managed care plan, but the technique allegedly used was cash discounts, not “lick and stick.”

The *Dey* case involves generic products, for which “best price” is not a relevant factor in determining the rebate. It also differs from the other settlements in that it was brought not under the federal FCA but under a state false claims act, and the manufacturer did not enter into a corporate integrity agreement with the OIG at the same time as it settled the allegations against it with the state and federal governments and the relator. Finally, *Dey* is just one of the defendant manufacturers in the case that gave rise to the settlement; that case is pending in state court against most of the remaining defendants.

A brief synopsis of each settlement, presented in chronological order, follows:

Bayer I (1/23/01).⁸¹ In the first FCA settlement involving a drug manufacturer, Bayer Corporation agreed to pay a total of \$14 million to the U.S. and 45 state Medicaid programs to settle allegations of fraud in connection with the marketing of certain biologic products used in treating hemophilia and immune deficiency diseases. Of this amount, \$6.2 million was distributed among the states and \$7.8 million was retained by the federal government. The principal allegation was that Bayer falsely inflated the AWP it reported for these products in order to market the spread to physicians and home health agencies that administered the drugs to induce them to use Bayer’s drugs rather than those of competitors. The company was further alleged to have failed to report, for purposes of “best price” calculations, the discounted prices at which it actually sold these products to physicians and home health agencies. The whistleblower initiating the case was Ven-A-Care of the Florida Keys, a specialty pharmacy; Ven-A-Care received a relator’s share of \$1.6 million.

TAP (10/3/01).⁸² This landmark settlement stemmed from allegations of fraudulent drug pricing and marketing by TAP Pharmaceutical Products, a joint venture between Abbott Laboratories and Takeda Chemical Industries. It was the first FCA settlement with a drug manufacturer involving both civil and criminal fines. The criminal fine of \$290 million is the largest ever in a health care fraud prosecution. It was imposed in connection with TAP’s plea of guilty to a conspiracy to violate the Prescription Drug Marketing Act by giving physicians free samples of its prostate cancer drug, Lupron, so that they could bill Medicare (and, for the 20 percent coinsurance, Medicare beneficiaries).⁸³ In 2001, Lupron accounted for over 10 percent of all Medicare Part B spending on

⁸¹ *U.S. ex rel. Ven-A-Care of the Florida Keys v. Bayer Corporation et al.*, (S.D. Fla. No. 95-1354-Civ.).

⁸² *U.S. ex rel. Gerstein v. TAP Holdings, Inc.*, Civ. No. 98-10547 (D. Mass.)

⁸³ DOJ, in announcing the settlement, also announced the unsealing of a federal grand jury indictment against a physician and six TAP managers: “The investigation commenced in the District of Massachusetts in 1997 after a physician employed by Tufts Associated Health Maintenance Organization in Waltham, Dr. Joseph Gerstein, reported to law enforcement authorities that he had been offered an educational grant if he would reverse a decision that had been made on behalf of Tufts that it would only cover the less expensive drug Zoladex. As charged in the indictment, [two of the TAP managers] met with Dr. Gerstein after he began working with the FBI and the Office of Inspector General, and during those meetings, offered him \$65,000 in educational grants that he could use for any purpose ‘whatever,’ together with discounts on other products, if he would reverse Tufts’ decision not to include Lupron on its formulary for treating patients that it insured who were suffering from prostate cancer.” DOJ Press Release, “TAP Pharmaceutical Products, Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges” (October 3, 2001), www.usdoj.gov/opa/pr/2001/October/513civ.htm.

drugs.⁸⁴ TAP also paid the federal government \$559.5 million to settle its civil liabilities under the FCA, the largest amount paid by a drug manufacturer to date. Finally, TAP paid \$25.5 million to the 50 states and the District of Columbia to settle the non-federal portion of its Medicaid FCA liabilities. The types of civil fraud alleged involved marketing the spread to physicians who administer Lupron to their patients and failure to report the steeply discounted prices given to physicians for purposes of the Medicaid rebate program. There were two sets of whistleblowers: Dr. Joseph Gerstein, an internist, and Tufts Associated Health Maintenance Organization, at which he practiced; and Douglas Durand, at the time a Vice President for Sales at TAP. They were awarded \$17.2 and \$77.9 million respectively, for a total of \$95 million.

*Pfizer (10/28/02).*⁸⁵ Pfizer Inc., the world's largest pharmaceutical manufacturer, agreed to pay \$49 million to the U.S. and 40 states to settle allegations of Medicaid fraud in connection with the marketing of Lipitor, an anti-cholesterol drug and the top-selling drug in the U.S. for the year ending June 30, 2003.⁸⁶ Of this amount, \$21.2 million was distributed among the states, and the remaining \$27.9 million was retained by the federal government. The specific allegations were that a Pfizer subsidiary, Parke-Davis, concealed \$250,000 of cash discounts (characterized as "unrestricted educational grants") that it gave to Ochsner Health Plan, a managed care organization in Louisiana, in exchange for favorable placement on the Plan's formulary to encourage Plan doctors to write Lipitor prescriptions for Plan enrollees. By failing to report the discounts, the government alleged, Pfizer underpaid Medicaid rebates by over \$20 million. The whistleblower was John David Foster, a national account manager for Parke-Davis, who received a relator's share of \$5.9 million.

*Bayer II (4/16/03).*⁸⁷ In its second settlement agreement with DOJ, Bayer Corporation agreed to pay \$5.6 million in criminal fines and \$251 million in civil recoveries to the U.S. and 49 states and the District of Columbia to settle allegations of fraud against the Medicaid program in connection with the marketing of Cipro (antibiotic) and Adalat CC (blood pressure). Of the civil recoveries, \$109 million was distributed among the states, \$9.5 million was distributed among certain safety net hospitals and clinics, and the remaining \$133 million was paid to the federal government.

The criminal fine was imposed in connection with Bayer's guilty plea to violating the Federal Food, Drug & Cosmetic Act by failing to list a private label product with the Food and Drug Administration. The civil liability resulted from allegations that Bayer underpaid Medicaid rebates by concealing the deeply discounted prices that it gave on Cipro and Adalat CC to two large managed care plans (Kaiser and PacifiCare) in order to have the drugs included in the plans' formularies. The concealment technique used was "lick and stick" — i.e., the manufacturer places the plan's NDC number rather than the manufacturer's NDC number on the label and does not report the plan's discounted price to the federal government for purposes of calculating the

⁸⁴ MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), Table 9-1, www.medpac.gov.

⁸⁵ *U.S. ex rel. Foster v. Pfizer (E.D. Tex.)*.

⁸⁶ IMS Health, "Leading 20 Products by U.S. Sales, MAT June 2003," www.imshealth.com.

⁸⁷ *U.S. ex rel. Estate of Couto v. Bayer Corp.*, No. 00-10339 (D. Mass.)

Medicaid rebate. The whistleblower was the late George Couto, then a Bayer marketing executive; his estate received a relator's share of \$34.2 million.

GlaxoSmithKline (4/16/03).⁸⁸ This settlement arose out of the same whistleblower complaint that triggered the *Bayer II* settlement. Glaxo, the world's second-largest pharmaceutical manufacturer, agreed to pay \$87.6 million in civil fines to the U.S. and 49 states and the District of Columbia to settle allegations of fraud against the Medicaid program in connection with the marketing of Paxil (antidepressant) and Flonase (nasal allergy spray). Of this amount, \$38.3 million was paid to the states, \$2.6 million was distributed to safety net hospitals and clinics, and the remaining \$46.8 million was returned to the federal government. The allegations centered around Glaxo's efforts to market Flonase and Paxil to Kaiser Health Plans through steeply discounted prices that were not reported to the federal government for purposes of calculating the rebate owed to Medicaid. In the case of Flonase, Glaxo was alleged to have engaged in "lick and stick," placing a different label and Kaiser's NDC number on the drugs delivered to Kaiser. In the case of Paxil, Glaxo was alleged to have sold the drug in bulk quantities to Kaiser, which in turn repackaged and relabeled the drug with its own NDC number. The whistleblower whose complaint triggered the investigation was the late George Couto, then a Bayer marketing executive. There was no relator's share in connection with this settlement.

Dey, Inc. (6/11/03).⁸⁹ This settlement is the first involving allegations of fraudulent pricing and marketing of a generic drug. It arose from a whistleblower complaint filed under the Texas false claims act against Dey, Roxane Laboratories, Warrick Pharmaceuticals, and Schering-Plough Corporation, among others. One of the defendants, Dey, paid a total of \$18.5 million to the U.S. and the Texas Medicaid program to settle allegations of civil fraud in connection with the pricing and marketing of Albuterol Sulfate and Ipratropium Bromide, inhalants used in treating asthma and other lung conditions, as well as other generic products.⁹⁰ Of the \$18.5 million recovery, the federal government received \$9.2 million and the state \$5.6 million (plus \$1.1 million in attorneys fees). The principal allegation was that Dey falsely reported "price to wholesaler or distributor" for these drugs to the state of Texas Vendor Drug Program in order to market the spread to pharmacists. The whistleblower was Ven-a-Care of the Florida Keys, a specialty pharmacy; its share was \$3.2 million.

AstraZeneca (6/20/03).⁹¹ The manufacturer in this settlement is the competitor to TAP Pharmaceutical Products in the market for prostate cancer drugs. Like the TAP settlement, this settlement involves both criminal and civil fines, although in smaller amounts. AstraZeneca, the world's fourth-largest pharmaceutical manufacturer,

⁸⁸ *Id.*

⁸⁹ *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc.*, No. GV002327 (Travis County District Court, 53rd Judicial District).

⁹⁰ Although this is a Medicaid case, it is worth noting that the two generic products, Ipratropium Bromide and Albuterol ranked 3rd and 5th in Medicare Part B drug spending in 2001, immediately behind Lupron (#2) and Zoladex (#4), respectively. They accounted for nearly 13 percent of all Medicare Part B drug spending that year. MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), Table 9-1, p. 151, www.medpac.gov.

⁹¹ *U.S. ex rel. Durand v. AstraZeneca Pharmaceuticals LP*, No. 03-122-JJF (D. Del.).

pleaded guilty to conspiring to violate the Prescription Drug Marketing Act by supplying free samples of its product, Zoladex, to physicians, knowing that they would in turn bill Medicare (and, for the 20 percent coinsurance, Medicare beneficiaries) for the drug. In 2001, Zoladex accounted for nearly 7 percent of all Medicare Part B spending on drugs.⁹² As part of the plea agreement, AstraZeneca agreed to pay a criminal fine of \$63.9 million. To settle its civil FCA liabilities resulting from the pricing and marketing of Zoladex, AstraZeneca paid \$279.8 million to the U.S. and \$11.2 million to the states. The principal allegations were that AstraZeneca marketed the spread to physicians by setting the AWP for Zoladex at levels far higher than the prices actually paid by physicians after off-invoice price concessions, and that it failed to report these steep discounts as “best prices” for purposes of calculating Medicaid rebates. The whistleblower initiating the case was Douglas Durand, formerly the Vice President of Sales for AstraZeneca’s competitor, TAP Pharmaceuticals. He received a relator’s share of \$47.6 million.

Table 3 Timeline of Whistleblower Cases Against Pharmaceutical Manufacturers Settled as of September 30, 2003

Case	Complaint Filed under Seal	Period During Which Fraud Allegedly Occurred	Settlement Announced	Corporate Integrity Agreement (CIA) expires
Bayer I	June 1995	January 1993–August 1999	January 2001	2009 (originally 2006, extended by Bayer II)
TAP Pharmaceuticals	May 1996	January 1991–September 2001	October 2001	2008
Bayer II	February 2000	July 1995–September 2000	April 2003	2009
GlaxoSmithKline	February 2000	January 1997–March 2001	April 2003	2008
Pfizer	May 2000	January 1999–December 1999	October 2002	2007
AstraZeneca	May 1996	January 1991–December 2002	June 2003	2008
Dey	March 2000	September 1995 – March 2003	June 2003	No CIA

A litigation and policy history of these settlements is beyond the scope of this report. However, a few observations can be made based on the timelines of these settlements summarized in Table 3. Of course, this Table does not reflect any similar federal or state court cases, sealed or unsealed, that have not gone to settlement or otherwise been disposed of.

As shown in Table 3, the earliest of these cases (*Bayer I*) was filed under seal in June

⁹² MedPAC, *Report to the Congress: Variation and Innovation in Medicare* (June 2003), Table 9-1, www.medpac.gov

1995. The whistleblower in the case was Ven-A-Care of the Florida Keys, Inc., a specialty pharmacy in Key West, Florida. Ven-A-Care is also the relator in the *Dey* case, filed in March 2000. In September, 2001, one month before the announcement of the settlement in the *TAP* case, the head of Ven-A-Care testified before a Congressional Subcommittee that in addition to prosecuting FCA cases, he had shared information about the pricing and marketing practices of certain manufacturers with the Administrator of CMS (then the Health Care Financing Administration, or HCFA), DOJ, and OIG.⁹³ In September 2000, HCFA made available price data supplied by DOJ for use by Part B carriers that process claims for Medicare-covered drugs in determining the AWP. This DOJ-supplied data was intended to function as an alternative to the prices reported by manufacturers to commercial price listing services.⁹⁴

Second, in six of the seven settlements, the fraudulent conduct was alleged to have taken place during most of the 1990's or the second half of that decade. Only in the *Pfizer* case were the allegations limited to one 6-month period. For the most part, the periods of alleged fraud preceded the settlement of the landmark \$875 million settlement in the *TAP* case in October 2001.

Finally, six of these cases have now entered the post-settlement phase in which each of the manufacturers is operating under a corporate integrity agreement. As discussed in the next section, these CIAs involve a heightened degree of government scrutiny and will not expire until 2007 at the earliest. For these manufacturers, the history of these cases is still being written. For other manufacturers in the industry, the effect of these settlements (or pending cases, whether under seal or not) remains to be seen.

⁹³ Statement of Zachary T. Bentley before the Subcommittee on Oversight and Investigations and Subcommittee on Health, House Committee on Energy and Commerce, *Hearing on Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers* (September 21, 2001), www.energycommerce.house.gov.

⁹⁴ "Partly in response to recent enforcement efforts, in September, HCFA alerted its contractors through a Program Memorandum that new, more accurate estimates of AWP for 32 drugs were available and could result in potential savings of \$400 million per year. Contactors may take advantage of the new pricing data beginning in 2001. Section 429(c) of P.L. 106-554, establishes a moratorium on decreases in payment rates for drugs and biologicals furnished on or after January 1, 2001, until review of a Comptroller General study on appropriate payment methodologies." DHHS and DOJ, *Annual Report on the Health Care Fraud and Abuse Control Program FY 2000* (January 2001), p. 12, www.usdoj.gov. The more detailed CMS exposition of this history appears at 68 Fed. Reg. at 50430 (August 20, 2003).

VI. Corporate Integrity Agreements

In six of the seven cases, the manufacturers have entered into Corporate Integrity Agreements (CIAs) with the Office of Inspector General (OIG) of the Department of Health and Human Services. (As of September 30, 2003, there is no CIA in the *Dey* case). These CIAs are separate from the settlement agreements that the manufacturers have entered into with the Department of Justice. The CIAs establish an extensive regulatory regime at each of the manufacturers that extends beyond the individual products at issue. The CIAs obligate the manufacturers to follow a variety of auditing and reporting procedures designed to ensure compliance with Medicare and Medicaid requirements across all product lines. In four of the cases — *AstraZeneca*, *Bayer I*, *Bayer II*, and *TAP* — the manufacturers must also report their average sales prices for some or all products paid for by Medicare, Medicaid, and other federal programs.

These CIAs range in duration from five to seven years from the date of the agreement. As of October 2003, most of the CIAs are in their early stages; the first to expire (Pfizer) is not scheduled to do so until October 2007. It is therefore premature to evaluate the effectiveness of the CIAs and their monitoring and enforcement by OIG. A review of their major elements, however, suggests that they have the potential to provide important information to federal health programs concerning changes in manufacturer pricing and marketing practices. This information, in turn, may help federal program administrators improve their methods for purchasing drug products and identify potential vulnerabilities to fraud. Indeed, the extensive reporting requirements of these CIAs may in and of themselves have a deterrent effect on other manufacturers interested in avoiding such entanglement with federal regulators, perhaps promoting more accurate reporting of “best price” data for purposes of calculating Medicaid rebates.

CIAs are not unique to these pharmaceutical cases. It is common practice for the OIG, in settling allegations of civil fraud under the False Claims Act or other federal statutes, to negotiate a CIA in exchange for an agreement not to exclude the provider or entity from Medicare, Medicaid, and other federal health care programs.⁹⁵ CIAs typically run for five years and include requirements designed to ensure compliance with federal program requirements. These include: (1) hiring a compliance officer, (2) developing written standards and policies, (3) conducting employee training, (4) reviewing claims submitted to federal health care programs for accuracy, (5) establishing a program for confidential disclosure of fraud, (6) not employing or contracting with individuals excluded from federal health care programs, and (7) submitting annual compliance reports to OIG. The CIAs, which vary somewhat from case to case, are posted in their entirety on the OIG website.⁹⁶

⁹⁵ OIG, “General Information on Corporate Integrity Agreements,” www.oig.hhs.gov/fraud/cias.html.

⁹⁶ www.oig.hhs.gov. The ready accessibility of CIAs contrasts sharply with the accessibility of settlement agreements, which are generally available only through the filing of a Freedom of Information Act (FOIA) request with DOJ.

Six CIAs were reviewed for this report.⁹⁷ A summary of the compliance obligations imposed under each CIA appears in Table 4 at page 55.⁹⁸ As shown in the Table, while many of the compliance obligations apply to each of the manufacturers, some do not. Most notably, three of the six manufacturers are required to report average sales prices on some or all of their products. In addition, although each of the manufacturers is required to retain Independent Review Organizations (IROs) to review and report on the extent of compliance with the Medicaid rebate law, the scope of the required IRO review is broader in some cases than others.

The CIAs have much in common. Each contains all of the elements that the OIG has identified as necessary to an effective compliance program in its May 2003 *Compliance Program Guidance for Pharmaceutical Manufacturers*.⁹⁹ These elements, intended “to foster the development of a corporate culture of compliance,”¹⁰⁰ are:

- (1) development and distribution of written standards of conduct covering identified risk areas (e.g., accurate reporting of Medicaid “best price” data);
- (2) designation of a compliance officer and corporate compliance committee responsible for implementing the compliance program;
- (3) development and implementation of education and training programs;
- (4) establishment of a line of communication to the compliance officer to allow confidential reporting by employees of potentially fraudulent conduct;
- (5) auditing and monitoring of compliance by internal or external evaluators;
- (6) enforcement of standards of conduct through disciplinary guidelines; and
- (7) responding to detected problems through investigation and, if necessary, corrective action.

Of course, while the May 2003 *Guidance* is voluntary, when imposed through CIAs, these elements become mandatory compliance obligations of the manufacturers involved.

The six CIAs include compliance obligations that go well beyond the elements in the May 2003 *Guidance*. Each of the CIAs includes a requirement that the manufacturer submit a report annually documenting the extent of the manufacturer’s compliance with the terms of the CIA and the provisions of laws and regulations relating to federal health care programs.¹⁰¹ Each of the CIAs prohibits manufacturers from hiring

⁹⁷ One other pharmaceutical manufacturer, Abbott Laboratories, has entered into a CIA with OIG on July 22, 2003 in connection with the \$622 million settlement of allegations of fraudulent sales tactics with respect to the marketing of enteral nutrition liquids and pumps to hospitals and nursing homes. This settlement is omitted from this analysis because, unlike the other settlements, it was not initiated by a whistleblower under the *qui tam* provisions of the False Claims Act and it does not involve prescription drugs. The CIA is posted at www.oig.gov.

⁹⁸ The CIAs contain provisions in addition to the compliance obligations summarized in Table 4. These include: the right of OIG to inspect, audit, and review the manufacturer’s compliance with the CIA; the obligation of the manufacturer to retain all documents and records relating to compliance; stipulated penalties in the event of a failure by the manufacturer to comply with the requirements of the CIA; and discretion for OIG to exclude the manufacturer from participation in federal health care programs in the event of a material breach.

⁹⁹ 68 Fed. Reg. 23731 (May 5, 2003). The *Guidance* is also posted at www.oig.gov.

¹⁰⁰ 68 Fed. Reg. at 23732 (May 5, 2003).

¹⁰¹ The *AstraZeneca* and *GlaxoSmithKline* CIAs also require the manufacturer to notify the OIG, in writing, of a “reportable event,” defined as “anything that involves a matter, brought to the attention of senior management at [manufacturer’s] corporate headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.”

**Table 4 Obligations under Corporate Integrity Agreements (CIAs)
Whistleblower Cases Against Pharmaceutical Manufacturers
(Settlements as of September 30, 2003)**

Manufacturer (CIA effective date)	Term (Expiration)	Compliance Program ^a	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 (4/15/03)	5 Years (2008)	Yes	No	Yes	Yes (contract pricing)	Yes
Pfizer (10/24/02)	5 Years (2007)	Yes	No	Yes	Yes (managed care transactions)	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

^a 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); bar against employment or engagement of individuals excluded from Federal health care programs.

or employing in sensitive positions individuals who have been excluded from federal health care programs. As noted above, four of the six CIAs require the manufacturer to submit to OIG, on a quarterly basis, the average sales price of some or all of the drug products sold by the manufacturer to Medicare, Medicaid, or other federal health care programs. Finally, each of the CIAs requires the manufacturer to retain an Independent Review Organization (IRO) to audit the manufacturer's compliance with certain requirements, including the provisions of the Medicaid rebate law.

In general, the IRO provisions require the manufacturer to retain an accounting, auditing, or consulting firm to assess and evaluate the manufacturer's systems, policies and practices relating to the determination and reporting of "best price" for purposes of the Medicaid drug rebate program. The IRO review must be performed at least in the first and fourth years of the CIA, and must follow a methodology set forth in the CIA. The results of these reviews must be reported to the OIG. Some of the CIAs require the IROs to review the manufacturer's systems, policies, and practices with respect to matters other than compliance with the Medicaid rebate program. For example, the *AstraZeneca* CIA also requires an IRO review of (1) the manufacturer's sales and marketing activities in three of its Business Centers and (2) the manufacturer's calculation and reporting of

Average Sales Prices under the CIA. As in the case of the Medicaid rebate review, the CIA prescribes a detailed methodology for these additional IRO reviews.

As shown in Table 3, four of the six CIAs require the manufacturers to report, on a quarterly basis, the Average Sales Prices (ASPs) of specific drugs to the OIG, to CMS, and to state Medicaid programs. Three manufacturers are currently subject to this reporting requirement: AstraZeneca, Bayer (which was the first to have it imposed),¹⁰² and TAP. In the case of AstraZeneca, this reporting obligation is limited to 8 products, including the drug at issue in the settlement.¹⁰³ In the case of the other two manufacturers, it applies to all of the drug products they sell to federal health care programs,

Corporate Integrity Agreements have the potential to provide important information to federal health programs concerning changes in manufacturer pricing and marketing practices.

not just those at issue in the settlement. The requirement that ASPs be reported not just to the federal government but also to state Medicaid agencies gives those agencies access to pricing data certified as accurate to enable them to assess the reasonableness of

the prices they are paying for the drugs of these particular manufacturers. Such pricing data are not otherwise available to state Medicaid programs.

The CIAs generally define the ASP as “the average of all final sales prices charged by the manufacturer for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of “Best Price” for Medicaid Drug Rebate purposes ... and excluding identifiable direct sales to hospitals.” The prices used to calculate ASP must be net of all price concessions provided by the manufacturer to non-excluded purchasers that result in a reduction of the ultimate cost to the purchaser, including volume discounts, prompt pay discounts, cash discounts, chargebacks, short-dated product discounts, free goods, and rebates. The ASP for each product must be weighted to reflect the volume of sales at each sale price (net of all price reductions). OIG expressly acknowledges that these pricing data are “confidential commercial information and proprietary trade secrets.”

ASPs differ from Average Manufacturer Prices (AMPs), which all manufacturers participating in Medicaid must report to the Secretary of HHS for purposes of calculating Medicaid rebates. AMPs are “the average price paid to the manufacturer for the drug in the United States by *wholesalers* for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.”¹⁰⁴ (emphasis added). ASPs, in contrast, are the final sales prices charged to *all purchasers* (with certain exceptions), not just wholesalers. Similar concepts of Average Sales Prices are included in one of the options proposed by CMS for revising the Medicare drug payment methodology¹⁰⁵ and in the House-passed version of the Medicare prescription drug bill.¹⁰⁶

¹⁰² *Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer Corporation* (January 23, 2001) pp. 11–12, www.oig.hhs.gov/fraud/cia/agreements/BayerCorporation120301.PDF.

¹⁰³ Cefotan; Elavil Injection; Faslodex; Foscovir; Merrem; Tenormin Injection; Xylocaine Injection; and Zoladex. Injectable products sold to medical practitioners for in-office administration and developed after the effective date of the CIA are also subject to this reporting requirement. Appendix A to CIA between AstraZeneca and Office of Inspector General, www.oig.hhs.gov.

¹⁰⁴ Section 1927(k)(1) of the Social Security Act, 42 U.S.C. § 1396r-8(k)(1).

¹⁰⁵ 68 Fed. Reg. at 50436 (August 20, 2003).

¹⁰⁶ Section 303 of H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003, as passed by the House of Representatives on June 27, 2003.

CIA, like any other element of an FCA settlement agreement, are only effective if enforced. Responsibility for enforcement of the CIAs rests with OIG, not DOJ. The OIG has built into the CIAs monitoring mechanisms such as IRO reviews that are designed to promote compliance by the manufacturers and to alert OIG in the event of noncompliance. These mechanisms rely heavily on retrospective, annual audits of manufacturer performance; alternative models, such as the Independent Private Sector Inspector Generals (IPSIGs), have successfully employed contemporaneous monitoring techniques.¹⁰⁷ The independence of IROs, which are selected and paid by the manufacturer that is subject to the CIA, in assessing the compliance of the manufacturer with the requirements of the CIA, is a crucial issue. Whether the IRO mechanisms in these CIAs achieve their goals is an empirical question that will be answered over the next four to six years of CIA implementation.

¹⁰⁷ An IPSIG is “an independent, private sector firm with legal, auditing, investigative, management and loss prevention skills, employed by an organization (voluntarily or by compulsory process) to ensure compliance with relevant laws and regulations, and to deter, prevent, uncover and report unethical and illegal conduct by, within and against the organization.” IPSIGs and Integrity Monitors have been used by New York City agencies since the mid-1990s to improve public contracting for construction, public housing, and waste management, including the clean-up of the World Trade Center disaster site. IPSIGs perform ongoing monitoring of designated contractors and report periodically to the City. They are governed by their own code of ethics and professional association, the International Association of Independent Private Sector Inspectors General (IAIPSIG). The definition of IPSIG above is taken from the *IAIPSIG Code of Ethics* (January 1996), p.1. See www.getnicklaw.com.

¹⁰⁸ Chris Adams, “Some Drug Firms Seem to Evade Medicaid Price-Reporting Rules,” *Wall Street Journal* (March 13, 2003).

¹⁰⁹ Consolidated Complaint, *U.S. ex rel. William St. John LaCorte, M.D. v. Merck*, paragraph 10.

VII. Unsealed Federal and State False Claims Act Cases

There are at least two FCA and three state FCA cases involving allegations of fraud against drug manufacturers that, as of September 30, 2003, had been filed and unsealed but not settled or adjudicated. These cases are briefly described below.

Unsealed FCA Cases

U.S. ex rel. William St. John LaCorte, M.D. v. Merck, C.A. 99-3807 (E. D. La, unsealed January 30, 2003). This complaint alleges that Merck defrauded Medicaid in the marketing of Pepcid, an H2 blocker (heartburn and ulcer medication), by selling the drug to some hospitals in New Orleans at steeply discounted prices that it did not report to HHS for purposes of calculating the Medicaid rebate. The relator is a physician who practiced at several of the hospitals that received these discounted prices. Merck contends that it was exempt from reporting the prices because they were “merely nominal,” and therefore excluded from the calculation of “best price” under the master rebate contract it signed with the Secretary of HHS, which defines “merely nominal” as less than 10 percent of the average manufacturer price (AMP). According to Carolyn McElroy, who represents a number of manufacturers, use of nominal prices is a “very common practice.”¹⁰⁸

This complaint expressly links manufacturer marketing efforts to quality of patient care. Among Dr. LaCorte’s allegations is that Merck uses deeply discounted prices to induce hospitals to use Pepcid as the preferred H2 blocker on an inpatient basis so that patients, upon discharge, would continue to use Pepcid rather than a competitor such as generic Zantac. The spread, he alleges, was approximately \$1.55 per tablet (Medicaid paid the hospital \$1.65 for each tablet; the hospital bought each tablet from Merck for \$0.10). Dr. LaCorte alleges that hospitals that received these deep discounts have switched his orders of an H2 blocker such as Zantac to Pepcid without his knowledge or permission.¹⁰⁹

U.S. ex rel. Franklin v. Parke-Davis, No.96-CV-11651 (D. Mass., unsealed March 2002). This complaint alleges that Parke-Davis, a Pfizer subsidiary, caused claims for “off-label” uses of Neurontin, an epilepsy drug, to be submitted to Medicaid and other federal health care programs. Specifically, the allegation is that the manufacturer illegally marketed the use of Neurontin by physicians for the treatment of conditions for which Neurontin did not have FDA approval, such as bipolar disorder, anxiety, and attention deficit disorder. The complaint alleges that the manufacturer’s aggressive promotion of off-label uses for Neurontin was not only illegal under FDA law, but also placed Medicaid patients at risk and fraudulently caused Medicaid to pay for the off-label use of Neurontin. (State Medicaid programs may pay for off-label uses of prescription drugs; however, manufacturers cannot market the off-label use of an approved

¹⁰⁸ Melody Peterson, “Pfizer Nears Drug Settlement,” *New York Times* (March 12, 2003).

¹⁰⁹ United States’ Statement of Interest in Opposition to Defendant Parke-Davis’ Motion for Summary Judgment, May 23,

drug). The whistleblower is Dr. David Franklin, employed by the manufacturer in 1996 as a medical liaison with responsibility for educating physicians about Neurontin.¹¹⁰ The U.S. Attorney's Office in Boston and the Assistant Attorney General recently filed a "statement of interest" with the District Court in opposition to Pfizer's motion for summary judgment, arguing that violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b, gives rise to FCA liability.¹¹¹ The district court denied Pfizer's motion.¹¹²

Unsealed State False Claims Act Cases

State of California ex rel. Ven-A-Care of the Florida Keys v. Abbott Laboratories, No. BC 287198 A (Superior Court, County of Los Angeles, January 7, 2003). This complaint alleges that Abbott Laboratories and Wyeth defrauded California's Medicaid program by inflating the Direct Prices (DPs) in order to market the spread. California's Medicaid program pays for drugs on the basis of DP, the price at which a manufacturer sells its drugs to a pharmacy or end distributor without the involvement of a wholesaler. Manufacturers report the DPs for their drugs to First Data Bank, a commercial drug pricing service from which the state Medicaid program received the DP pricing data on which it based its reimbursement. The whistleblower in this case is the same independent Florida pharmacy that was the whistleblower in *Bayer I*, discussed above.

The complaint contains a stunning example of both the size and volatility of the "spread." The example is Vancomycin, an antibiotic sold by Abbott. The following table is excerpted from the complaint. Note that between January 5, 2001 and June 1, 2001, the Direct Price reported by Abbott (and paid by the California Medicaid program) drops by three fourths, from \$65.35 to \$14.89, while the cost to the customer — the actual price in the marketplace — remains unchanged at \$7.40. Prior to this rapid drop, the small pharmacy price is discounted by 89% off the reported Direct Price of \$64.35. Immediately after the drop, the small pharmacy price is discounted just under 50%. By July 1, 2002, the DP, the small pharmacy price, and the spread have all declined further. The question arises whether this complaint (originally filed under seal on July 28, 1998) as well the FCA Medicaid settlements to date could in part explain these dramatic pricing changes.

State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, No. GV002327 (District Court Travis County, Sixth Amended Petition filed on or about April 11, 2003). Like the California case, this complaint alleges fraud against the state's Medicaid program resulting from false price reporting to create and market the spread. Unlike the California case, however, this case focuses on the marketing of the spread for a generic drug, Albuterol Sulfate (inhalant for asthma) by Dey, Warrick Pharmaceuticals, and Schering-Plough Corporation (other generic inhalants produced by other manufacturers are also implicated). In Texas, the Medicaid program's payment for a drug is based upon the price information reported by manufacturers to the Texas Vendor Drug Program (TVDP). Manufacturers are required to certify to TVDP the "Price to Wholesaler and/or Distributor." The complaint alleges that, among other things, defendants reported false prices to TVDP in order to create and market an illegal spread. As discussed above, one

2003, in *U.S. ex rel. Franklin v. Parke-Davis, Inc.*, CA No. 96-11651-PBS (D. Mass.)

¹¹² *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 (Aug. 22, 2003).

¹¹³ News Release (September 25, 2003), www.ago.state.ma.us/.

Vancomycin 1 gm. (NDC#00074-6533-01)

Reporting Date	Direct Price reported by Abbott	Cost to Ven-A-Care (small pharmacy) (Medi-Cal purchase)	Spread (percent of DP available to customer)
1-05-1999	\$61.29	\$7.40	\$53.89 (87.9%)
1-05-2000	\$64.35	\$7.40	\$56.95 (88.5%)
1-05-2001	\$64.35	\$7.40	\$56.95 (88.5%)
6-01-2001	\$14.89	\$7.40	\$ 7.49 (50.3%)
7-01-2002	\$ 5.76	\$4.36	\$ 1.40 (24.3%)

of the defendant manufacturers, Dey, settled the allegations against it with the U.S. and with the Texas Attorney General in June 2003.

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). The allegations in this case parallel those in the California and Texas cases, above. The defendants are Dey, Roxane Laboratories (a subsidiary of Boehringer Ingelheim Corporation), Warrick Pharmaceuticals, and Schering-Plough. The products at issue are inhalants, including Albuterol Sulfate, Acetylcysteine Solution, and Cromolyn Sodium. The principal allegations are that the manufacturers marketed the spread on these drugs to retail pharmacies and other purchasers, charging these customers far less than the AWP reported for these products to First Data Bank, a commercial compendium. The state alleges that it based its Medicaid payments for the drugs on the reported AWP and that the pharmacies keep the difference between the state's payment and the steeply discounted price at which they acquired the drug from the manufacturer. The state alleges actual damages in excess of \$75 million.

Commonwealth of Massachusetts v. Mylan Laboratories, (D. Mass., September 25, 2003). This case is brought in federal court under the Massachusetts Medicaid False Claims Act and the state's False Claims Act not by a whistleblower but by the state's Attorney General based on an investigation by the state's Medicaid Fraud Control Unit. The 13 defendants are manufacturers of generic products, including two manufacturers named as defendants in the cases described above (Warrick Pharmaceuticals and Roxane Laboratories). The complaint alleges that, in order to increase their market shares, the manufacturers created a spread between reported prices and actual prices charged to pharmacists by inflating the pricing data supplied directly to the state Medicaid agency and to drug pricing publishing services, causing state's Medicaid agency to pay over \$50 million in excessive amounts for their generic products of these manufacturers.¹¹³

¹¹⁴ A June 2003 survey found that every state and the District of Columbia is planning to undertake cost containment actions

VIII. Implications

The story of the FCA whistleblower cases against drug manufacturers is still unfolding. More cases will emerge from under seal in the next year or two. The unsealed cases will either be settled or go to trial in federal and state courts. The manufacturers in almost all of the cases settled to date have four to six years of compliance with CIA obligations remaining. Under these circumstances, a definitive analysis of these cases and their impact is clearly premature. At the same time, these cases have some potential implications for Medicaid, Medicare, and the pharmaceutical industry.

Medicaid. Each of the settlements involves recoveries to Medicaid. Taken together with the accompanying CIAs, they present four potential implications:

First, as shown in Table 2, these seven FCA settlements have generated \$487 million in recoveries from manufacturers for the federal government and various states. Of this amount, \$217 million was paid to participating states and the District of Columbia. These settlement payments to states have the potential to help hard-pressed state Medicaid programs avoid some of the program reductions that they might otherwise have to make in response to their budget shortfalls.¹¹⁴

Second, at least with respect to those manufacturers involved in the settlement agreements, it is reasonable to expect more accurate reporting of “best price” and other Medicaid rebate data on *all* of the products that Medicaid buys from the manufacturer, not just those at issue in the case. This, in turn, could increase the amount of the rebates paid by the manufacturer to the federal government and the states on products for which accurate “best price” data may not otherwise have been reported.

Third, those manufacturers entering into the settlement agreements and CIAs are likely to rethink their AWP pricing strategies on all of their products to ensure their own compliance. If this reconsideration leads to reductions in AWP from current levels, or to a lower rate of increase in AWP, state Medicaid programs that base their payments on AWP will benefit. For example, in 2001, Abbott Laboratories, then under government investigation, reportedly reduced its AWP on about 50 Medicaid drugs; Illinois Medicaid officials estimated that their program alone would save \$2.5 million as a result.¹¹⁵ Presumably, other AWP-based state Medicaid programs benefited as well. In addition, three of the manufacturers in the settlements discussed in this report are required under their CIAs to furnish Average Sales Price (ASP) data directly to state Medicaid agencies; this data should enable these agencies to purchase the drugs of these manufacturers more prudently.

Finally, if enforced by OIG, these settlement agreements and CIAs, in combination

in their Medicaid programs in FY 2004, including restricting eligibility, reducing benefits, and reducing or freezing provider payments. Vernon Smith et al., *States Respond to Fiscal Pressure: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2003 and 2004: Results from a 50-State Survey* (September 2003), p. 2, www.kff.org.

¹¹⁵ Andrew Zajac and Bruce Japsen, “Bayer to cut Medicaid drug prices: Giant must pay states \$14 million,” *Chicago Tribune* (August 19, 2001). Bayer lowered prices on five drugs, including Kogenate.

with the April 2003 OIG *Compliance Guidance*, should deter other manufacturers from engaging in the type of pricing and marketing conduct that triggered these cases. The accuracy of “best price” reporting for Medicaid rebate purposes should improve. The number of “lick and stick” schemes should decline. AWP’s should no longer be aggressively inflated for purposes of marketing the spread. This deterrent effect, while unmeasurable, could significantly reduce the net prices that Medicaid pays for covered drugs vis-à-vis what Medicaid would have paid in a pre-settlement environment.

Medicare. Only two of the FCA settlements (*AstraZeneca* and *TAP*) involve recoveries attributable to Medicare. Nonetheless, the size of the civil recoveries, combined with the large criminal fines, means that manufacturers that ignore the lessons of these cases do so at their peril. There is some evidence that changes in behavior are already occurring. Citing the *TAP* case, MedPAC, the independent federal agency charged with advising Congress on Medicare issues recently observed: “Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy. They leave the AWP’s at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors. In this case, the manufacturers’ profit per unit dose will be less, but overall profits increase if the discounts result in increased market share.”¹¹⁶ Whatever direction the manufacturers take, the settlements have three broad implications for Medicare.

First, they serve as a vivid reminder to policymakers of the fundamental vulnerability in the current Medicare drug payment methodology. By tying payments for physician-administered drugs to an AWP reported by manufacturers to commercial compendia, current Medicare payment policy is vulnerable to inflation in program costs and fraudulent pricing and marketing practices that can corrupt sales personnel and physicians alike. There is a possibility that the current payment methodology will be improved; as noted above, CMS has proposed four options for revising the current methodology, and the Congress is considering two of these alternatives in the context of the Medicare prescription drug legislation.¹¹⁷ Of course, the fact that Medicare’s drug payment methodology is vulnerable in no way justifies or excuses fraud against the program by manufacturers or physicians.

Second, the settlements underscore that it is not just federal taxpayers that bear the fiscal burden of the vulnerable Medicare drug payment methodology. This burden is also borne by program beneficiaries who need physician-administered drugs for treatment of prostate cancer, hemophilia, and other conditions. Under current law a Medicare beneficiary’s cost-sharing obligation rises in direct proportion to the increase in the manufacturer’s AWP, even when that increase is integral to a fraudulent market-

¹¹⁶ MedPAC, *Report to Congress: Variation and Innovation in Medicare* (June 2003), p. 157, www.medpac.gov.

¹¹⁷ The four options offered by CMS for comment are: (1) limit reimbursement to the amounts that Medicare carriers pay when the same drug is provided to their private policyholders and subscribers under comparable circumstances; (2) apply a discount (between 80 and 90 percent) to the AWP’s published in commercial compendia as of April 1, 2003, and update annually by the rate of increase in the consumer price index for medical care; (3) pay the lower of actual charge or the “widely available market price,” the price that a prudent physician or supplier would pay for a drug; and (4) establish a “competitive acquisition program” for covered drugs coupled with the determination of an Average Sales Price (ASP) so that physicians would have the choice of purchasing drugs from entities in each competitive acquisition region or from Medicare at the ASP. 68 Fed. Reg. at 50432-50436 (August 20, 2003). MedPAC has also suggested a number of alternatives for establishing and updating benchmark prices for covered drugs. MedPAC, *Report to Congress: Variation and Innovation in Medicare* (June 2003), pp. 160-164, www.medpac.gov.

ing arrangement. In fact, if the spread is large enough, the patient's co-insurance payment can actually exceed the cost of the drug to the provider. Again, in an ideal world this payment methodology would be revamped. But even in the absence of statutory or regulatory reform, there is reason to hope that these settlements, and enforcement of the CIAs, will discourage not just AstraZeneca and TAP but manufacturers generally from raising AWP in order to increase the spread.¹¹⁸

Finally, the settlements have implications for any expansion of Medicare outpatient prescription drug coverage, such as Congress is currently considering. Taxpayers and Medicare beneficiaries alike have a clear interest in ensuring that payments for drugs covered under any Medicare expansion are not inflated by fraudulent marketing or pricing conduct. The settlements demonstrate that an expanded Medicare program, if not properly designed, is vulnerable to fraud by pharmaceutical manufacturers and by the physicians and pharmacists to whom they market covered products. At a minimum, an expanded Medicare drug benefit should avoid replicating the vulnerabilities of the current payment methodology that reward the conduct that gave rise to criminal and civil liability in the settlements. In addition, if a new Medicare benefit is enacted, the CIAs now in place as a result of the settlements may enable the OIG and DOJ to monitor the pricing and marketing behavior of this set of manufacturers as the benefit is implemented. This could serve as an informal "early warning system" for emerging program integrity issues in connection with the new benefit.

Pharmaceutical Industry. Pharmaceutical manufacturers have long maintained that government price controls will thwart the development of vital new drugs with the potential to cure diseases and relieve human suffering. The desired alternative, they argue, is a vigorous free market, with prices set through negotiations between buyers and sellers. For this market to work effectively, manufacturers contend, they must retain the right to keep their prices confidential from competitors.

For the most part, government has agreed. This is evident in the federal government's reliance upon pharmaceutical manufacturers to report the prices that the Medicare and Medicaid programs use in determining the amounts they will pay for the prescription drugs they cover. Medicare, which sets its payments at 95 percent of AWP, relies on the prices that manufacturers report to various private data banks. Medicaid, which reduces the net price it pays by demanding a rebate, relies not just on the prices manufacturers report to commercial drug price services, but also on the pricing data manufacturers supply to the Secretary of HHS on a confidential basis from which the Secretary determines a factor that enables each state to calculate the amount of rebate it is owed for each drug. In neither case does the federal government question the reasonableness of a manufacturer's prices or the relationship of those prices to actual costs incurred in developing and producing the drug.

The freedom of manufacturers to price privately — without government price controls or oversight — is premised on an expectation that in reporting pricing data, manufacturers will not mislead or conceal. However, the settlements reviewed in this report indicate that some manufacturers have done just that. These settlements, and

¹¹⁸ The litigation filed by the Prescription Access Litigation Project against 28 manufacturers seeking treble damages for alleged manipulation of AWP for Medicare-covered drugs may also have an impact on manufacturer behavior in this regard. See *Citizens for Consumer Justice v. Abbott Laboratories*, No. 01-12257PBS, (D. Mass., filed December 20, 2001), posted at www.prescriptionaccess.org/pdf/complaint-abbott.pdf.

the others likely to follow, have some important implications for manufacturers. In particular, the size of the civil recoveries, the criminal fines imposed, and the regulatory constraints of the CIAs strongly suggest that the marketing and pricing conduct that gave rise to the settlements is no longer a prudent business plan for a firm intending to continue to participate in federal programs (viz., Medicare, Medicaid, VA, TRICARE). As the former OIG General Counsel recently explained, “the enforcement spotlight has shifted to pharmaceutical manufacturers.”¹¹⁹

What is less clear is the direction in which manufacturers will go. Will they continue to participate in government programs? It seems hard to imagine that manufacturers could afford not to sell their products to the federal government. If so, how will they modify their pricing and marketing strategies to avoid FCA liability? What are the implications of these changes for the prices paid by Medicare and Medicaid for the prescription drugs that they cover? Will AWP of drugs covered by Medicaid or Medicare fall significantly? Will Medicaid rebates on brand-name drugs increase as more accurate “best price” data is submitted by manufacturers? What are the implications for private purchasers, ranging from hospital buying groups to large managed care organizations to pharmacy benefits managers to individual consumers?

Some industry sources believe that the manufacturers have been rapidly changing their practices in such areas as Medicaid rebates in the past year or two, and that this fact has not been recognized in the media treatment of this subject. According to this view, litigation just now coming to light has been years in the making, and reflects practices prevalent in the 1990s. Once the industry figured out that the federal government was, in the industry’s view, “changing the rules of conduct,” manufacturers altered their pricing practices in an effort to comply. It should be noted that, if true, this underscores the importance of the FCA and its whistleblower provisions as a strong deterrent to fraud against federal health care programs.

¹¹⁹ Patricia Callahan, “Health Industry Sees Surge in Fraud Fines,” *Wall Street Journal* (August 18, 2003).

Recommendations

1) Congress should reject efforts to weaken the FCA and its whistleblower provisions.

In the view of the Department of Justice, the FCA is “the United States’ primary tool against fraud upon the government.”¹²⁰ In the health care area alone, the FCA is generating a return for the federal government of almost \$9 for every \$1 invested in fraud investigations and prosecutions.¹²¹ The settlements reviewed in this report further confirm the value of the FCA and its *qui tam* provisions. Whistleblowers brought inside information about abusive pricing and marketing conduct to the attention of DOJ about which federal program staff were apparently unaware. This information, combined with subsequent DOJ and OIG investigations, led to settlements with the manufacturers involved that include large criminal and civil fines and extensive corporate integrity agreements that will remain in place for the next four to six years. Not only have these settlements enabled the federal government to recover over \$1.1 billion for the Medicare program and the Crime Victims Fund, they are likely to deter similar conduct by other manufacturers, potentially reducing the rate of growth in federal and state spending on prescription drugs. As discussed in recommendation 3, the FCA and its *qui tam* provisions will be essential to the federal government’s effort to protect the integrity of any expanded Medicare drug benefit.

2) The federal government should pay for prescription drugs currently covered under Medicare on a basis other than AWP reported by manufacturers to commercial drug price listing services.

The inflationary bias in the current Medicare methodology for purchasing prescription drugs has been thoroughly documented by both GAO and OIG. What the FCA settlements make clear is that basing payment on AWP reported by manufacturers also exposes the program to pricing and marketing conduct by manufacturers and physicians that can give rise to both civil and criminal liability. This serves neither Medicare beneficiaries nor federal taxpayers well. CMS has published four different approaches for improving the current methodology, two of which are under serious consideration by the Congress in the context of the Medicare prescription drug legislation. MedPAC, the independent federal agency that advises Congress on Medicare issues, has also set forth alternatives to the current payment system. Whether administratively or legislatively, current purchasing policy must be improved.

3) If the federal government expands the Medicare program to cover outpatient prescription drugs, it should learn from the lessons of the FCA drug settlements.

There is broad agreement that the absence of an outpatient prescription drug benefit is a major flaw in the Medicare program. As the current Congressional debate indicates, however, there is much controversy about how such a benefit should be structured and administered. The lesson of the FCA settlements for this debate is twofold. First, the payment

¹²⁰ United States’ Statement of Interest in Opposition to Defendant Parke-Davis’ Motion for Summary Judgment, May 23, 2003, in *U.S. ex rel. Franklin v. Parke-Davis, Inc.*, No. 96-11651-PBS (D. Mass.) at p. 1.

¹²¹ Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck* (June 2003), p. 2, www.taf.org

methodology for covered drugs should be designed to avoid rewarding manufacturers for marketing the spread to physicians or pharmacists. At a minimum, this means that covered drugs should be purchased on a basis other than AWP as reported by manufacturers to commercial price listing services. Secondly, to ensure the fiscal integrity of any new Medicare drug benefit — whatever the design of its payment methodology — the federal government will continue to need the FCA and its whistleblower provisions as a potential source of information about any fraudulent conduct by participating providers and contractors, including not just manufacturers but also physicians, managed care plans, and pharmacy benefits managers.

4) The OIG should vigorously enforce the CIAs agreed to by the pharmaceutical manufacturers. The OIG has negotiated extensive corporate integrity agreements with all but one of the manufacturers that have entered into a settlement agreement reviewed in this report. These CIAs contain provisions designed to promote accurate reporting of “best prices” offered by manufacturers on their brand-name products for purposes of calculating the rebate amounts they owe on the products they sell to Medicaid. On paper, these provisions, which include annual audits by Independent Review Organizations (IROs), have the potential to ensure compliance. What is needed over the remaining four to six years of these CIAs is vigorous monitoring and enforcement by the OIG. Prescription drug spending is one of the fastest-growing items in most state Medicaid programs, and many states are currently under severe budgetary pressure due to revenue shortfalls. Accurate reporting of “best price” data is essential to reducing the net prices paid by state Medicaid programs for covered drugs — to the benefit of state and federal taxpayers alike.

5) CMS should revise its August 2003 regulation relating to the Medicaid drug rebate program to ensure that FCA lawsuits and investigations are not compromised by the destruction of drug pricing data by manufacturers. Eight years after it first proposed regulations to implement the Medicaid rebate program, but just two months after the last of the settlements reviewed in this report was announced, CMS issued a final regulation that limits the amount of time a manufacturer must retain relevant pricing data.¹²² Specifically, the regulation requires a manufacturer to retain data from which it derives the average manufacturer prices (AMP) and “best prices” it reports to the Secretary for no more than 3 years from the date the manufacturer initially reports the prices. A manufacturer is required to retain records beyond this 3-year period if the records are the subject of an audit or of a government investigation “of which the manufacturer is aware,” or if the audit findings or investigation have not been resolved.¹²³ This exception does not appear to cover FCA cases filed under seal of which the manufacturer is not aware or in which the government investigation has not begun. In its explanation, CMS states, “we believe this rule is necessary to address the burden to States and manufacturers with respect to recordkeeping in the Medicaid drug rebate program.”¹²⁴ Unfortunately, the agency does not appear to have given appropriate weight to the implications of the

¹²² 68 Fed. Reg. 51912 (August 29, 2003). As published, the final rule was to be effective on October 1. On September 26, CMS published a “correction” announcing that the Office of Management and Budget (OMB) had declared the final rule a “major rule” and delaying the effective date until January 1, 2004. 68 Fed. Reg. 55527 (September 26, 2003).

¹²³ 42 C.F.R. § 447.534(h)(ii).

regulation for FCA cases and the burden that compromising these cases will place on state and federal treasuries alike. CMS, in consultation with DOJ and OIG, should revise this regulation to ensure that FCA lawsuits and investigations are not hindered before the regulation takes effect and the manufacturer pricing data are lost. The most straightforward way of accomplishing this objective is to align the manufacturer recordkeeping requirement with the FCA's 6- to 10-year statute of limitations.¹²⁵

6) State Medicaid programs should pay for prescription drugs covered under Medicaid on a basis other than AWP reported by manufacturers to commercial price listing services. State Medicaid programs have substantial flexibility in paying for prescription drugs. The majority have opted to base their payments on AWP as reported by manufacturers, generally reducing this price by some fixed percentage.¹²⁶ A number of OIG audits document that AWP-based payments can substantially exceed the actual acquisition costs of the pharmacy (which is also being paid a separate dispensing fee for each prescription), resulting in unnecessarily high Medicaid spending. This is true in the case of brand-name drugs (OIG estimated that on average actual acquisition cost to pharmacies was 22 percent below AWP in 1999)¹²⁷ as well as generics (66 percent below AWP in 1999).¹²⁸ Of course, the key is whether the AWP (or some other reference price) is reported by the manufacturer or is objectively determined by an independent party. As the settlement in the *Dey* case illustrates, even state Medicaid programs that do not pay for drugs on the basis of AWP are potentially vulnerable to fraud by generic manufacturers seeking to market the spread to pharmacists if the state relies exclusively on manufacturers for the price data it uses in determining reimbursement for a drug.

7) States that have not yet enacted their own false claims acts with whistleblower provisions should do so. Eleven states and the District of Columbia currently have false claims acts with whistleblower provisions: California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, Virginia.¹²⁹ Whistleblower cases alleging fraudulent pricing conduct against drug manufacturers have been unsealed in California, Florida, and Texas, and one of the defendant manufacturers has settled the Texas case for \$18 million (*Dey*). It is likely that the conduct that gave rise to the allegations in the *Dey* settlement occurred in states without their own false claims acts. Many of these states (as well as those with their own false claims acts) have been able to participate in the recoveries in the FCA settlements reviewed in this report.

¹²⁴ 68 Fed. Reg. at 51916 (August 29, 2003).

¹²⁵ The statute of limitations that applies to FCA cases is a minimum of 6 years and as much as 10 years from the date of the submission of the false claim. More specifically, a *qui tam* action may not be brought after the later of (1) more than six years after the date on which the false claim is made; (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances; or (3) 10 years after the date on which the false claim is made. 31 U.S.C. § 3731(b).

¹²⁶ Kaiser Commission on Medicaid and the Uninsured, *Medicaid: Purchasing Prescription Drugs* (January 2002), Table 7, www.kff.org.

¹²⁷ OIG, *Medicaid Pharmacy — Actual Acquisition Cost of Brand Name Prescription Drug Products* (August 10, 2001) (A-06-00-00023), www.oig.hhs.gov/.

¹²⁸ OIG, *Medicaid Pharmacy — Actual Acquisition Cost of Generic Prescription Drug Products* (March 14, 2002) (A-06-01-00053), www.oig.hhs.gov/.

¹²⁹ Phillips & Cohen website, "The False Claims Act: State Laws," www.phillipsandcohen.com. Two states, Arkansas and Utah, have enacted false claims acts that do not include *qui tam* provisions authorizing whistleblowers to file suit on behalf of the state.

These states do not, however, offer whistleblowers the financial incentives and procedural opportunities to identify and prosecute Medicaid fraud, not only by drug manufacturers, but also by other providers, health plans, and contractors participating in the program.¹³⁰ Given the difficult budget situations faced by most states, enactment of legislation that can help recover state funds lost to fraud against Medicaid and other state programs is simple fiscal prudence.

8) Pharmaceutical manufacturers should review their pricing and marketing policies and practices to ensure that they fully comply with Medicare and Medicaid program requirements. Some 550 pharmaceutical manufacturers participate in the Medicaid rebate program.¹³¹ Only six of these have entered into settlement agreements with DOJ relating to allegations of pricing or marketing fraud with respect to the purchase of prescription drugs by Medicaid or Medicare. While press reports indicate a strong likelihood of additional settlements in the future, there is no evidence that noncompliance with Medicaid and Medicare program requirements is widespread among pharmaceutical manufacturers. That being said, it is clear that the scale of the criminal and civil liability in these settlement agreements — particularly the *TAP* case — was unexpected.¹³² It is now two years after the settlement of the *TAP* and *Bayer I* cases. More cases have been settled, and additional settlements are likely. The interest of federal and state governments in the integrity and cost of the drug benefits offered by the Medicare and Medicaid drug benefits is high. The OIG has issued a *Compliance Program Guidance* for the industry.¹³³ Taxpayers, program beneficiaries, employees and shareholders all have an interest in manufacturer compliance with program requirements.

9) Further research is needed to fully understand the impact of these FCA settlements and CIAs on the pricing and marketing practices of the drug manufacturers involved and the pharmaceutical industry as a whole. The FCA settlements discussed in this report may signal the beginning of an historic shift in the pricing and marketing practices of drug manufacturers in their dealings with Medicare and Medicaid as well as with private purchasers. Much is not known. These settlements are relatively recent, and their CIAs will not expire until 2007 at the earliest. More settlements are likely, both at the federal and state level. But even at this early stage, important research questions present themselves. What effect, if any, do the settlements and their CIAs have upon the prices of (1) the products at issue in the settlements, (2) other drugs sold to Medicare by the manufacturers involved, and (3) other drugs sold to Medicaid by the manufacturers involved? What effect, if any, do the settlements and their CIAs have on compliance with the reporting requirements of the Medicaid rebate program by the manufacturers involved and by other manufacturers? Do the settlements and their CIAs have a deterrent effect on fraudulent pricing and marketing practices by manufacturers not involved in the settlements? What effect, if any, do the settlements have on the cost of prescription drugs to Medicare and Medicaid over time?

¹³⁰ See Schneider, *Reducing Medicaid Fraud: The Potential of the False Claims Act* (June 2003), pp. 36–37, www.taf.org.

¹³¹ 68 Fed. Reg. at 51916 (August 29, 2003).

¹³² See Kathleen McDermott, William H. Maruca, and John T. Brennan, "The Aftermath of United States v. TAP Pharmaceuticals: Mercy, Mercy, Me — Things Ain't What They Used To Be...", *Health Lawyers News* (April 2002), pp. 4–8.

¹³³ 68 Fed. Reg. 23731 (May 5, 2003).

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