Testimony of James W. Moorman, President and CEO
Taxpayers Against Fraud
on
The False Claims Act and Fraud Against Medicaid by Drug Manufacturers
before the
Committee on Oversight and Government Reform
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Summary of Testimony

The federal government is spending hundreds of billions of dollars to fund Medicare, Medicaid and other health care programs. It is essential that as much as possible be done to ensure that these funds are not lost to fraud, but are spent on purchasing health care services for the more than 90 million Americans these programs serve.

One particular area, fraud by pharmaceutical companies against Medicaid, is ripe for effective anti-fraud action. Whistleblower cases under the False Claims Act have brought three types of fraud into view that are costing Medicaid many billions of dollars:

- Medicaid Best Price fraud,
- Average Wholesale Price fraud, and
- Off-label marketing fraud.

So far there have been 16 settlements that have recouped nearly $4 billion in civil damages and criminal penalties from drug manufacturers. There are more than 180 additional unresolved cases. The potential liability involved has not been reported, but based on the cases settled to date, it's likely to be in the $60 billion range.

There is a serious danger that the Justice Department will be unable to resolve most of these cases in a timely and satisfactory manner. The reason is a lack of resources and top-level leadership. Cases are being resolved at the rate of less than three a year. Many cases are over a decade old. A seriously inadequate number of lawyers are assigned to the cases. Only a few U.S. Attorneys offices (principally Boston and Philadelphia) are seriously involved. Money allocated from the Health Care Fraud and Abuse Control ("HCFAC") Account for health care fraud cases has been withheld. Support from investigative agencies is skimpy. The active support of the Attorney General and his Deputy are not in evidence. The drug manufacturer defendants are aware of these deficiencies and many of them appear to be trying to run out the clock on the Justice Department's attorneys.

These problems are particularly frustrating because the entire set of cases provides the government with an opportunity to close a multi-billion dollar fraud gap---

the difference between fraudulent conduct that has occurred and fraudulent conduct held to account. In order to grasp this opportunity, however, the Department of Justice must alter the *status quo*. The top officers of the Department must take an active interest in these cases; adequate resources must be deployed quickly; HHS must provide more support; full support by investigative agencies is mandatory; the Civil Division's fraud section must be augmented; more US Attorney offices must participate in these cases in a significant way; and action must be taken to prevent these cases from languishing or allowing the clock to run out on them.

Introduction

My name is James W. Moorman and I am the President of Taxpayers Against Fraud, also known as "TAF" and as "The False Claims Act Legal Center," a position I have held for the past seven years. I am an attorney by training and served as an Assistant Attorney General of the Department of Justice under Attorneys General Griffin Bell and Benjamin Civiletti. Between my service at Justice and TAF, I was a partner in the law firm of Cadwalader, Wickersham & Taft.

Taxpayers Against Fraud and its sister organization, Taxpayers Against Fraud Education Fund, are non-profit charitable organizations dedicated to combating fraud against the Federal Government and state governments through the promotion of the use of the *qui tam* provisions of false claims acts, especially the federal False Claims Act, 31 U.S.C. §§ 3729- 33 ("FCA"). *Qui tam* is the mechanism in the FCA that allows persons with evidence of fraud involving government programs or contracts to bring suit on behalf of the federal government. The cases are filed in federal court under seal, giving the Justice Department an opportunity to review the allegations and decide if it wants to intervene. Under the FCA, those that commit fraud are subject to triple damages and civil penalties.

Thanks to the efforts of whistleblowers that use false claims acts, their lawyers, lawyers on the fraud team in the Civil Division of the Department of Justice, Assistant United States Attorneys in several very active US Attorneys offices, and certain members of Congress, the public, over the past few years, has become aware of fraud against government health care programs and the potential of the FCA and its whistleblower provisions to curb such fraud. Since the enactment of the 1986 amendments to the FCA, settlements and judgments related to health care fraud have totaled more than $12 billion. This money has, further more, been recouped very efficiently. As health economist Jack Meyer concluded in a report, updating earlier reports and released by TAF Education Fund, the federal government has realized $15 in direct recoveries for every $1 it has invested in investigating and prosecuting health care fraud through the FCA. [1]

Types of Fraud Against Medicaid

My testimony focuses on fraud by some drug manufacturers against Medicaid, which, until the enactment of Medicare Part D, was the largest government purchaser of drugs and remains the second largest. TAF Education Fund has been monitoring cases in

[1] Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck*, July 2006. See www.taf.org

this area, the first of which was settled in 2001. We have published two reports on the subject that are posted on our website, and we are about to release a third. [2]This testimony draws upon the information in these reports.

Over the past six years, there have been 16 settlements of FCA cases involving allegations of fraud by drug manufacturers against federal health care programs, 14 of which have involved Medicaid. These settlements total nearly $4 billion, including $3 billion in civil damages recouped by the federal government and the states, as well as nearly $1 billion in criminal penalties.[3]

The settlements involve three general categories of fraud: concealment of best price; inflation of average wholesale prices (AWP); and off-label marketing:

- **Concealment of Best Price**. In order for a drug manufacturer to sell its prescription drug products to Medicaid, the manufacturer must enter into an agreement with the Secretary of HHS to provide rebates to the federal and state governments for the drugs that Medicaid buys on behalf of its beneficiaries. In the case of generic drugs, the rebate is 11% of average manufacturer price, or AMP (the average price paid by wholesalers to manufacturers for drugs distributed to retailer pharmacies.) In the case of brand-name drugs, the rebate amount is the greater of (1) 15.1% of AMP or (2) the difference between AMP and the "Best Price" (the lowest price a manufacturer sells its product to most customers.) Manufacturers must report AMP and Best Price information to HHS, which calculates the rebates due based on the data. More than half of the FCA settlements involve manufacturers concealing Best Prices that they gave to customers on brand-name drugs in order to avoid paying higher Medicaid rebates. As a result, the cost of these drugs to federal and state governments was higher than it should have been. Nine of the settlements to date, totaling over $2.5 billion, have involved concealment of Best Price.

* **Average Wholesale Price (AWP).** When State Medicaid programs pay for prescriptions, they pay the pharmacist a dispensing fee plus the estimated cost to the pharmacist of acquiring the drug from the wholesaler or directly from the manufacturer. Many states base their estimated acquisition cost on a drug's "Average Wholesale Price," or "AWP," which is reported by the manufacturer to price reporting services or, in some cases, directly to the state. AWP fraud occurs when a manufacturer reports inflated prices that bear no relation to the actual price that the pharmacist pays for the drug. The pharmacist keeps the difference between what the Medicaid program pays for the drug and the price the pharmacist actually pays the wholesaler or the manufacturer. Manufacturers use this differential in order to incent

[2]Andy Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers*, November 2003; Andy Schneider, *The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update*, November 2004; see www.taf.org

[3] Attachment B contains tables and figures summarizing these settlements. Attachment C is a list of citations of the cases.

pharmacies to purchase their drug instead of that of a competitor. This is often referred to as "marketing-the-spread." The result is that Medicaid pays inflated prices for the ingredient cost of the drug.

* **Off-label Marketing.** Medicaid covers all prescription drugs approved by the Food and Drug Administration when they are prescribed by a physician and are medically necessary. The FCA approves drugs only for specific purposes, which appear on the drug's labeling materials. Doctors are legally permitted to prescribe drugs for unapproved, or "off-label" uses as well, and many physicians do so. Manufacturers, however, may not lawfully promote or market their products for unapproved, off-label uses to physicians or others. However, such marketing does occur, often accompanied by the use of illegal kickbacks. When off-label marketing induces physicians to prescribe drugs for unapproved uses and Medicaid pays for those prescriptions, Medicaid spending goes up.

Best Price Fraud

As noted, FCA settlements involving concealment of Best Price account for the largest share of recoveries to date. While this may change as future settlements are announced, I want to explain this type of fraud in more detail because of the importance of drug coverage to Medicaid beneficiaries and the importance of the Medicaid rebate program to lowering Medicaid spending on prescription drugs. The more the federal government can reduce fraud against the Medicaid rebate program, the farther that federal and state tax dollars will go in purchasing needed medicines for low-income Americans.

Assume that a manufacturer reports to HHS that the average manufacturer price, or AMP, of a specific unit of one of its brand-name drugs is $79. If the manufacturer charges all of its customers $68 or more for that unit of that drug, then the rebate the manufacturer is required to pay on each prescription sold to Medicaid is 15.1% of the AMP, or $11.93. Thus, if Medicaid buys 100 prescriptions, the rebate owed is $1193.

Now assume that the manufacturer charges a customer $64 for that unit of the drug in question. In that case, $64 becomes the Best Price and the rebate that the manufacturer has to pay on each prescription sold to Medicaid is AMP ($79) minus Best Price ($64), or $15 dollars. If Medicaid pays for 100 prescriptions of the drug, the rebate owed becomes $1500.

Best Price fraud involves concealing the $64 Best Price from HHS, so that HHS calculates the rebate amount to be 15.1%, or $11.93. The gain to the manufacturer is the difference between $11.93 and $15, or $3.07, multiplied by the number of prescriptions Medicaid buys. Thus if Medicaid buys 100 prescriptions, that amount is $307 ($1,500 minus $1,193 equals $307). In other words, $307 is the loss to Medicaid and federal and state taxpayers, who are paying $307 more for the 100 prescriptions than federal law allows.

There are several ways Best Price has been concealed from HHS. The most straightforward is to simply not report the cash discounts given to a customer. That is what happened in the $49 million settlement with Pfizer in 2002. Pfizer marketed Lipitor

to the Ochsner Health Plan by giving it cash discounts to list the drug in its formulary. The cash discount reduced the price of Lipitor to Ochsner. However, when Pfizer reported its Lipitor prices to HHS, it did not report the discount to HHS. Because the discounts were not reported, the rebate amount on the drug was less than it should have been, and Medicaid ended up paying over $20 million more for Lipitor than it should have during the time period covered by the case.

A variation on this theme is the $345 million settlement with Schering-Plough in 2004. In order to place its most profitable product, the anti-histamine Claritin, on the formularies of certain national HMOs, Schering-Plough paid the HMOs kickbacks disguised as "data fees" or "risk share" payments. These kickbacks had the effect of lowering the price of Claritin to the HMO, but when Schering-Plough reported to HHS the price charged to the HMO, it did not report the price net of the "data fees" or "risk share" payments. As a result, Schering-Plough paid a significantly smaller rebate to Medicaid than it was required to pay.

An even more creative approach to concealing Best Price is known as "lick and stick." This is what happened in the $257 million settlement with Bayer Corporation in 2003, which involved, among other drugs, the antibiotic Cipro. An HMO insisted on a deep discount, but Bayer did not want to give Medicaid a rebate based on that discounted price. In order to evade reporting that price as its Best Price, Bayer placed the HMO's National Drug Code number instead of its own on the label of the drugs it sold to the HMO at the deeply discounted price. Bayer did not include the price of the mislabeled drugs in its reports to HHS.

It is worth stressing that in each of these settlements (and others), the reason the federal government found out about the fraud was not because of a government audit or HHS oversight. Rather, it was because a private whistleblower, using the FCA, brought the information to the federal government's attention.

The Extent of the Fraud

The scale of the fraud problem with the pharmaceutical manufacturers is only hinted at by the sixteen settlements (nine of which included Best Price fraud) and the $4 billion in civil damages and criminal penalties they have produced. In addition to those sixteen cases, there are a very large number of cases on file involving extensive fraud liability that have not been resolved. Because of a peculiarity of the False Claims Act, cases brought by whistleblowers under the Act are filed under seal and remain under seal while government investigations are undertaken. For that reason, it is difficult to obtain precise information about this litigation. However, Mr. Peter Keisler, the Assistant Attorney General for the Civil Division of the Justice Department informed the House Judiciary Committee on August 11, 2006 that the Department had "over 180" such cases on its docket.[4] Added to these cases would be cases filed in state courts under state false claims acts and cases filed by state attorneys general under other statutes.

[4] *Written Responses of Peter D. Keisler, Assistant Attorney General, Civil Division, before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, United States House of Representatives, Concerning Budget and Resource Needs of the Justice Department Civil Division for Fiscal Year 2007*, submitted August 11, 2006

In addition to the cases under seal, there are some cases out from under seal that have not been resolved, most prominently a series of cases against Abbott Laboratories in California, Florida, Massachusetts, and Texas. In addition to Abbott, cases now out from under seal in Massachusetts involve at least 48 drug companies.[5] Also, a preliminary settlement for half a billion dollars with Bristol Myers Squibb has been announced, though details have not been released. As recently as January 29, 2007, the Justice Department announced that it had unsealed and joined a case against Boehringer Ingelheim Roxane, Inc alleging damages of $500 million.

It is also difficult to get a precise handle on the amount of the potential liability involved in the unresolved cases, but it appears to be very large. The announced half-billion dollar settlement with Bristol alone equals 12% of the $4 billion recovered in the sixteen previous settlements. The alleged half-billion dollars of damages owed by Boehringer is another 12%. The potential liability in the cases against Abbott and others out from under seal are in the same magnitude or larger. There are indications that many of the other cases under seal also involve quite large liabilities. Thus it would not be unreasonable to assume that the total potential liability of the 180 outstanding cases could be somewhere in the $60 billion range, or above.

The Dangers and Opportunities Presented

This astounding situation presents us with a danger and with an opportunity. The danger is that these cases will not be satisfactorily resolved; that one way or another the drug manufacturers will find a way to dodge their liability; and that they would be able to continue to develop and implement business plans and practices designed to plunder Medicaid and other government health programs, damaging those programs, taxpayers, and the beneficiaries of these programs.

The opportunity to be found in these cases is that the leaders of the departments responsible for pursuing the drug company fraud cases, the Attorney General and the Secretary of Health and Human Services, could, if they chose, use these cases to force the drug manufacturers to disgorge their fraudulently obtained funds. At the same time they could impose corporate integrity agreements with the settling companies that would put an end to the fraudulent practices and establish honest dealing with Medicaid and other health care programs. Such agreements could become the keystone of the companies' future good citizenship.

As things stand now, failure is far more likely than that the opportunity will be grasped. A drift toward failure is the current *status quo*, while grasping the opportunity would require a change of course.

Major Program Insufficiencies

The Committee will no doubt be interested in why the current course of conduct will lead to failure, especially in the light of the successes so far. The answer is complex, involving insufficiencies in manpower and the leadership necessary to bring the cases to a satisfactory resolution.

[5] See Attachment A.

To begin with, the Department of Justice attorneys handling the cases against the drug manufacturers are simply overwhelmed and unable to prosecute a large portion of the cases in a timely manner. This is not because they are not good lawyers or because they are not trying. To the contrary, the Justice Department's attorneys involved in cases against drug manufacturers are very capable, hard working and dedicated. They are simply stretched to the breaking point.

The Justice Department in recent years has been able, on an annual basis, to resolve only between 90 and 100 FCA cases of all kinds. Of those cases, in the last six years, they have averaged less than three drug fraud cases resolved per year. At that rate, it will take many decades to resolve the 180 cases against drug manufacturers currently on the Departments docket. Actually, the backlog is not declining and cannot decline under the *status quo*, because more cases against drug manufacturers are filed each year than are resolved.

A further indication of the Justice Department's resource problem is the length of time the cases in question remain under seal. Many have remained under seal for ten years or more. When the Justice Department recently unsealed and joined a case against Abbott Laboratories that it could not settle, the case had been under seal for eleven years. The reason for this situation relates directly to the shortage of resources. The FCA provides that cases brought by whistleblowers be filed under seal in order to give the government a chance to investigate the cases in order to determine whether they wish to join the cases or leave them to the whistleblowers to pursue. A complicated fraud case, such as those against the drug manufacturers, could easily require two or three years of intensive investigation. However, the extensive time periods that drug fraud cases remain under seal indicates that the Department does not want to decline the cases, but does not have the resources to make timely investigations or to litigate the cases it cannot settle. Furthermore, the manufacturers are aware of this and are attempting to use Justice's lack of resources as leverage to reduce the amount they are required to repay or to delay settlement indefinitely with the hope of running out the clock on Justice.

A review of the Department's resources dedicated to FCA cases indicates that funds available for such a major set of cases are woefully inadequate. The monetary resources available for FCA cases at the Civil Division, which houses the central FCA fraud section, has been in the $20 million to $23 million range in the years FY2004 through FY2006. This pays for a fraud section that includes about 70 or so attorneys and is responsible for all civil matters involving fraud against the United States. How many of these have been deployed on drug manufacturer fraud cases in recent tears is not clear to me, but I estimate, very uncertainly, that it adds up to a dozen or so full time attorneys.

The money available for all FCA cases in the U.S. Attorneys offices has dropped from $58.5 million to $57.3 million in the years from FY2004 to FY2006. It is unclear, however, how much of the money and how many attorneys in the U.S. Attorneys offices are actually working on FCA cases, much less working on drug fraud cases. It appears that the money referred to is widely distributed to the various U.S. Attorneys offices, but that only a small percentage of those offices evidence concerted efforts to pursue FCA cases. Thus, an unusually large percentage of cases seem to be lodged in only a few U.S. Attorneys offices – for example, in Boston and Philadelphia, which appear to be completely swamped by the cases. A few other offices may also have begun to pursue a

significant number of cases, but most U.S. Attorneys offices are simply missing in action. Though a guess, probably about 25 Assistant U.S. Attorneys are pursuing the 180 cases against the drug manufacturers on a full time basis. Whatever the precise number, though, there are simply far too few attorneys deployed to seriously pursue all of these huge cases.

The lack of resources available to pursue drug FCA cases cannot be a matter of economy. To the contrary, the resources deployed by the Justice Department in health care fraud cases have been repaid many fold. As noted above, health economist Jack Meyer calculates that the government, principally the Justice Department, gets back $15 for every dollar it spends on health care FCA cases. Despite this outstanding return-on-investment, it appears that the Department is actually withholding funds intended for health care fraud cases from the offices pursuing such cases. The Attorney General and the Secretary of Health and Human Services have routinely reported that they are providing $14.5 million to the Civil Division and $30 million to the U.S. Attorneys offices for health care fraud. Money appropriated to the Health Care Fraud and Abuse Control (HCFAC) Account is allocated annually by the Attorney General and the Secretary of HHS.[6] In FY 2005, for example, the HCFAC Report[7] reveals that $30,400,000 was allocated to U.S. Attorneys and $14,459,000 to the Civil Division for "anti-fraud activities." These numbers are typical of such allocations in recent years. However, as reported by Assistant Attorney General Peter Keisler to the House Judiciary Committee on August 11, 2006, it seems that only $10 million was actually provided to the U.S. attorneys in each of the years 2004-2006 and a varying amount as low as $6.5 million to the Civil Division in those years.

It also appears that the key investigative agencies have not stepped up to the plate to support these cases. Jack Meyer, in making the report mentioned above, determined that the Office of Inspector General at HHS is only supporting the Justice Department's health care FCA cases to the amount of $10 million or less.[8] The FBI, which has been provided $114 million from the HCFAC Account on an annual basis to combat health care fraud, simply spends nowhere near that amount to support health care FCA cases. While this cannot be quantified without the FBI's cooperation, the FBI appears to be spending far, far less, but has not been candid about what it has spent.

It is not just resources that are lacking, it is also leadership that is lacking. The Department of Justices fraud section is lodged within the Commercial Litigation Branch of the Civil Division. Its attorneys do not have the standing within the government to command additional resources from within or without their own Department or to cause other elements of the government to give priority to any particular set of their cases. Only the Attorney General and the Deputy Attorney General have such standing. Thus, the actual attorneys struggling with the fraud cases are not going to receive the additional assistance they need without leadership initiative from above.

The consequences of allowing the FCA drug cases to drift along on their current course, with only two or three cases resolved each year, no matter how much effort the

[6] See Sections 112C(a) and 1817(k)(5) of the social security Act.
[7] oig.hhs.gov/publications
[8] Jack A. Meyer, *Fighting Medicaid Fraud, More Bang for the Federal Buck*, July 2006 (Table 4, p.10); see www.taf.org

current set of attorneys put into them, is predictably negative. A few more cases will be settled with apparent good results, but eventually this set of cases will falter. One cannot predict with certainty how they will falter, but falter they will. One way they could falter would be as the result of an unexpected judicial development. Recently the Court of Appeals for the Second Circuit ruled that the government, when it unsealed an FCA case and filed its own complaint, could not, for purposes of the statute of limitations, take advantage of the date when the whistleblower filed the original complaint.[9] Because the government has been forced to keep the drug cases under seal for so long, were that ruling to be followed and applied to the drug cases, many could falter on that ground alone. That is but an example of how an unexpected development could undermine the drug cases. Certainly, as time drags on, legal, political and other developments can and, over time, are likely to occur that will erode the government's ability to prevail. If not timely pressed to resolve these matters, eventually the companies could find a way to beat the rap.

Program Opportunities

One can hope that the faltering of the cases against drug manufacturers through delay and want of prosecution does not occur, for surely they present us with golden opportunities, including

- An opportunity to bring many billions of dollars defrauded from the government back to the taxpayers;
- An opportunity, going forward, to greatly reduce fraud against Medicaid and other government health care programs;
- An opportunity to redirect important companies that have become addicted to bilking Medicaid and Medicare;
- An opportunity for the pharmaceutical companies to put a shameful era of questionable billing practices behind them; and
- An opportunity to set rules of conduct in corporate integrity agreements that would prevent any one company from gaining an economic advantage over its competitors by cheating Medicaid and Medicare.

Recommendations

In order to grasp these opportunities, the following things must occur:

1. First and foremost, the highest officials of the Department of Justice, the Attorney General and the Deputy Attorney General, should act now to provide leadership, in word and deed, to force a resolution of the FCA cases against the pharmaceutical manufacturers on a basis favorable to the government.
2. The resource shortage dragging down the Justice Department's fraud fighters must be addressed quickly and affirmatively. The fraud team requires significant augmentation. Its status should be raised to the branch level. The missing HCFAC Account money should be immediately provided to both the Civil Division's fraud team and to the U.S. Attorneys Offices that are actually engaged. More U.S. Attorneys offices should be recruited into the action. The

[9] *U.S. ex rel. Cosens v. The Baylor University Medical Center*, 468 F.3d 263 (2d Cir. Nov.16 2006).

missing FBI's HCFAC Account funds should be located and put to their appointed use.

3. The full support of the Department of Health and Human Services is necessary from the Secretary on down. The full support, with significantly augmented resources, by the HHS--OIG and by CMS should be insisted on to provide support of the FCA cases against drug manufacturers.
4. The Departments of Justice and of Health and Human Services should use their full authority and leverage to bring the pharmaceutical companies to the table and impose agreements that will end the fraudulent practices that characterize the FCA cases. Only the direct efforts of these officials can end the manipulations on a basis that prevents any one company from victimizing its competitors and the taxpayers by cheating.
5. The Attorney General should take all possible action to keep the clock from running out on these cases and to prevent these cases from languishing.

Conclusion

If the recommended actions are taken, we could see an end to the business plan frauds by the pharmaceutical manufacturers against Medicaid and other government programs. If the *status quo* continues, we can expect the FCA cases against drug manufacturers to limp along with some more settlements, but at some point the effort will fail and there will be no reform of the massive fraud drug practices weighing down Medicaid and other health care programs.

- Attachment A -

Pharmaceutical Companies in Unsealed Medicaid Fraud False Claims Act Cases

- Abbott Laboratories
- Amgen
- Armour Pharmaceutical
- Aventis Pharmaceuticals
- Baxter Healthcare
- Bedford Laboratories
- Ben Venue Laboratories
- Boehringer Ingelheim Pharmaceuticals
- Braun of America
- C.H. Boehringer Sohn
- Centocorps Inc.
- Dey Pharmaceuticals
- Forest Pharmaceuticals
- Grundstucksverwaltung GMBH & Co.
- EMD
- Geneva Pharmaceuticals
- GlaxoSmithKline
- Glaxo Wellcome
- Burroughs Wellcome
- Hoechst Marion Roussell
- Hoffman-LaRoche
- Hospria Inc.
- Immunex
- Ivax–Pharmaceuticals
- Janssen Pharmaceutical Products
- Johnson & Johnson
- Lipha
- McGaw
- Merck
- Mylan Laboratories
- Mylan Pharmaceuticals
- Novartis
- Ortho Biotech Products
- Pfizer
- Pharmacia
- Pharma Investment
- PurePac Pharmaceutical
- Roche Laboratories
- Roxane Laboratories
- Sandoz
- Sicor
- Gensia Pharmaceuticals
- Schering-Plough Corp.
- SmithKline Beecham Corp.
- GlaxoSmithKline
- Teva Pharmaceuticals
- Warrick Pharmaceuticals
- Z.L.B. Behring

- Attachment B –

Settled False Claims Act Cases
Against Pharmaceutical Companies

Company	Settlement Date	Product	Total Recovery	Fraud Type	Whistleblower
AstraZeneca	6/20/03	Zoladex	$355 million	Marketing the spread and concealment of best price	Sales exec from competitor at TAP Pharmaceuticals
Baxter International	6/13/06	Generic drugs made by Baxter	8.5 million	Marketing the spread	Independent pharmacy
Bayer I	1/23/01	Kogenate, Koate-HP, Gamimmune	$14 million	Marketing the spread and concealment of best price	Independent pharmacy
Bayer II	1/23/01	Adelat CC, Cipro	$257 million	Concealment of best price	Bayer marketing executive
Dey I	6/11/03	Albuterol	$18.5 million	Marketing the spread	Independent pharmacy
Dey 2 (Connecticut FCA)	8/7/04	Albuterol	$2.5 million	Marketing the spread	Independent pharmacy
GlaxoSmithKline I	4/16/03	Paxil, Flonase	$88 million	Concealment of best price	Derived from Bayer marketing executive allegations.
GlaxoSmithKline II	9/17/05	Zofran, Kytril	$150 million	Marketing the spread	Independent pharmacy
King Pharmaceutical	10/30/05	Altace, Aplisol, Lorabid, and Fluogen	$124 million	Concealment of best price	Executive of King Pharmaceuticals
Pfizer I	10/28/02	Lipitor	$49 million	Concealment of best price	National account manager for Pfizer subsidiary
Pfizer II	5/13/04	Neurontin	$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
Roxane Labs, Boehringer Ingelheim Pharmaceuticals, and Ben Venue Laboratories (Texas FCA)	11/25/05	Albuterol	$10 million	Marketing the spread	Independent pharmacy
Schering-Plough I	5/3/04	Albuterol	$27 million	Marketing the spread	Independent pharmacy
Schering-Plough II	7/29/04	Claritin	$345 million	Concealment of best price	Three employees of Schering-Plough subsidiary
Schering-Plough III	8/26/06	Temodar, Intron-A, K-Dur, Claritin RediTabs	$435 million	Concealment of best price, Marketing the spread	Three employees of Schering-Plough
Serono	10/17/05	Serostim	$704 million	Off-label marketing and kickbacks	Five Serono employees in two states.
TAP Pharmaceuticals	10/3/01	Lupron	$875 million	Marketing the spread and concealment of best price	HMO Physician and TAP sales executive
TOTAL			**$3.894 Billion**		

- Attachment C –

Citations for Settled False Claims Act Cases Against Pharmaceutical Companies

DEFENDANT	**CASE CITATION**
AstraZeneca	*U.S. ex rel. Durand v. AstraZeneca Pharmaceuticals LP*, No. 03-122-JJF (D. Del. 2003)
Baxter International	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc. et. al*., No. GV401286 (District Court Travis County, 201st Judicial District 2006)
Bayer I	*U.S. ex rel. Ven-A-Care v. Bayer Corporation*, No. 95-1354-Civ. (S.D. Fla. 2001)
Bayer II	*U.S. ex rel. Estate of Couto v. Bayer Corporation*, No. 00-10339 (D. Mass. 2001)
Dey I	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. Dey Pharmaceuticals*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
GlaxoSmithKline I	*U.S. ex rel. Estate of Couto v. Bayer Corporation*. *et al*, No. 00-10339 (D. Mass. 2003)
GlaxoSmithKline II	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. GlaxoSmithKline PLC*, docket number sealed, settlement announced (D. Mass. 2005)
King Pharmaceuticals	*U.S. ex rel. Bogart v. King Pharmaceuticals, Inc*., No 03-1538 (E.D. Pa 2005)
Pfizer I	*U.S. ex rel. Foster v. Pfizer*, No.1:00-cv-00246 (E.D. Tex. 2002)
Pfizer II	*U.S. ex rel. Franklin v. Warner-Lambert*, No. 96-11651-PBS (D. Mass. 2004)
Roxane Labs et al.	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Roxane Laboratories Inc*., No. GV3-03079 (District Court Travis County, 201st Judicial District) and No. GV002327 (District Court Travis County, 53rd Judicial District 2005)
Schering-Plough I	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering-Plough*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
Schering-Plough II	*U.S. ex rel. Alcorn v. Schering-Plough Corporation*, No. 98-5868 (E.D. Pa. 2004)

Schering-Plough III	*In re Pharmaceutical Industry Average Wholesale Price Litigation*, No. 01-CV-12257-PBS settlement announced (D.Mass. Aug. 10, 2006).
Serono	*U.S. ex rel. Driscoll v. Serono Laboratories, Inc*., C.A. No. 00-11680 (D. Mass. 2000)
TAF Pharmaceuticals	*U.S. ex rel. Gerstein v. TAP Holdings, Inc*., No. 00-10547 (D. Mass. 2001)