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
United States House of Representatives

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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 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 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.

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.

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 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 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

· 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)

· TAP Pharmaceuticals U.S. ex rel. Gerstein v. TAP Holdings, Inc., No. 00-10547 (D. Mass. 2001)

Footnotes

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

[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.
[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

[5] See Attachment A.

[6] See Sections 1128C(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

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

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 Senate Finance Committee
June 28, 2005

Mr. Chairman and Members of the Committee, thank you for inviting me to testify at this important and timely hearing. We are in a situation where Congress is wrestling with whether to reduce Medicaid spending. Several states have done so and others are currently debating the issue. This is very painful because Medicaid is essential to the financing of needed health care for over 58 million low-income Americans. It is therefore imperative that savings in Medicaid come at the expense of those who have enriched themselves by defrauding the program. The False Claims Act has already demonstrated its ability to uncover complex corporate fraud

against Medicaid and to return ill-gotten gains to the federal and state treasuries. The purpose of my testimony today is to explain the results that the False Claims Act has already achieved, why it is effective, and how the Federal Government can make it even more effective, generating concrete savings for the federal and state governments without harming low-income beneficiaries or honest providers.

First, let me introduce myself and my organization. My name is James W. Moorman and I am the President of Taxpayers Against Fraud, also known as TAF or as The False Claims Act Legal Center, a position I have held for the past five 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 through the promotion of the use of the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729- 33 ("FCA"). Qui tam is the singular mechanism in the FCA that allows persons with evidence of fraud in federal programs or contracts to bring suit on behalf of the federal government. Under the FCA, those that commit fraud are subject to treble damages and civil penalties. To encourage whistleblowers to come forward, the FCA provides that they share between 15 and 30 percent of the federal government's recoveries. I would like to note for the record that neither TAF nor TAF Education Fund has ever received any support from PhRMA or any drug manufacturer.

Thanks in large part to the tireless efforts of Chairman Grassley, the public over the past few years has become more aware of the effectiveness of the FCA and its whistleblower provisions in curbing Medicare fraud. In press releases and public statements, the Chairman has highlighted important settlements and other achievements that have returned over $4 billion to the Medicare trust fund to date. As health economist Jack Meyer concluded in a report just released by TAF Education Fund, Fighting Medicare Fraud: More Bang for the Federal Buck, April 2005, the federal government has realized $13 in direct recoveries for every $1 it has invested in investigating and prosecuting Medicare fraud through the FCA.

The role of the FCA is curbing Medicaid fraud is less well understood, which is one reason why today's hearing is so important. In 2003, the TAF Education Fund published a report authored by Andy Schneider

explaining the potential of the FCA to reduce Medicaid fraud. Since that report was published, the FCA has clearly established itself as a potent tool against Medicaid fraud, returning about $1.2 billion to the federal and state treasuries over the past 5 years. Whistleblower lawsuits under the FCA have uncovered fraud in a variety of industries in the health care sector of the economy, ranging from hospitals to nursing homes to clinical laboratories to chain drug stores. However, by far the largest share of recoveries—about 80 percent—have resulted from cases involving pharmaceutical manufacturers.

As of the end of FY 2004, there were ten settlements of FCA cases brought by whistleblowers alleging false or fraudulent claims against Medicaid by pharmaceutical manufacturers. (There have been no reported settlements so far in FY 2005). These ten settlements, which involved three different types of fraudulent conduct, returned $535 million to the federal treasury and $413 million to state treasuries in satisfaction of losses to the Medicaid program. A number of these cases also involved allegations of false or fraudulent claims against the Medicare program. Total recoveries in these ten cases to Medicare and Medicaid, plus criminal fines, totaled $2.5 billion. The Appendix contains tables and figures summarizing these settlements.

In addition to the direct recoveries, these settlements have had an important indirect effect. Pharmaceutical manufacturers now have a much better appreciation of the importance of full compliance with the reporting requirements of the Medicaid drug rebate program. Given the volume of drugs that Medicaid buys—it is the nation's single largest drug purchaser, accounting for 18 percent of all drug spending—the difference between partial and full compliance can literally mean hundreds of millions of dollars in savings to the federal and state governments each year. Even after Medicare Part D is launched next January, Medicaid will still account for 9 percent of the nation's drug spending—no small matter in a market expected to grow to $249 billion next year.[1]

The deterrent effect of the FCA has not been quantified, but to appreciate its potential, consider the following: We know from CMS data that during this fiscal year (2005) manufacturers will pay almost $10 billion in rebates to Medicaid. It would be reasonable for one to assume that the deterrent effect of FCA cases is at least 10 to 15 percent of expenditures. That is, one could reasonably assume manufacturers would pay 10 to 15 percent less in rebates if they operated in a world without the whistleblower provisions of the FCA. On this conservative assumption, the FCA is worth between $1 to $1.5

billion in additional annual rebates to the federal and state governments. Of course, the FCA's deterrent effect may be significantly higher than 10 to 15 percent. If so, these savings would increase accordingly. Under any scenario—other than no deterrent effect, which is simply not plausible—the savings to federal and state taxpayers are significant.

Why has the FCA been so successful in uncovering complex corporate fraud on the part of some drug manufacturers against Medicaid? The answer lies in the amendments authored by Chairman Grassley in 1986, which incentivized whistleblowers to come forward with inside information about fraud against government programs despite the threat of retaliation. When the management of a firm develops a business plan to take advantage of a large government program like Medicaid, the company usually takes steps to cleverly mask what they are doing from the federal and state officials that administer the program. FBI "sting" operations have been successful at uncovering some of these fraudulent business plans. As a practical matter, however, by far the most effective source of information about such plans is whistleblowers.

The $257 million settlement with Bayer Corporation in 2003 is a classic example. In 2003, Bayer agreed to pay $251 million in civil recoveries and $5.6 million in criminal fines to settle allegations of fraud against the Medicaid program in connection with marketing of the antibiotic Cipro and the blood pressure medicine Adalat CC. The allegations were that Bayer underpaid Medicaid rebates owed to the federal and state governments by concealing deeply discounted prices that it gave on these products to managed care plans in order to have the drugs included in the plans' formularies. The concealment technique, known as "lick and stick," was very clever. Bayer placed the managed care plan's NDC number on the label of the drugs it sold the plan rather than its own. Though manufacturers are required to report prices to the Medicaid rebate program by their own NDC numbers, Bayer did not report the prices it was giving to the managed care plans to the federal government for purposes of calculating the "best price" rebate amount. Neither Bayer nor the managed care plans disclosed the actual deep discounts. The federal government would almost certainly never have found out about it but for the whistleblower, the late George Couto, then a Bayer marketing executive, who was troubled by his employer's conduct. Couto's disclosures also led to an $88 million settlement by GlaxoSmithKline foe similar conduct.

FCA cases filed by whistleblowers have become our main hope for curbing drug manufactures' Medicaid cheating. In addition to the 10 settlements that have occurred so far, there are a large number of additional cases against drug manufacturers that have been brought by whistleblowers. Mr. Peter Keisler, the Assistant Attorney General for the Civil Division of the U.S Department of Justice told the Wall Street Journal (See P.1, June 7, 2005) that the Department was aware of 150 more such cases, which he said involved nearly 500 different drugs. Because of specific requirements of the False Claims Act, these cases are under seal and public information about most of them is unavailable. Nevertheless, there is no doubt that these cases exist.

With regard to these cases, we at TAF believe the following to be true: Many of the cases are being handled by the U.S. Attorney offices in Boston and Philadelphia, though others are scattered around the country, venued in other U.S. Attorney offices.

Many of these cases involve damages in the nine-figure range. The total value of these cases could be in the neighborhood of $25 billion dollars.

The number 150 is a low number because it does not include cases filed in state courts, under state False Claims Acts. Because Medicaid cases involve Fraud against states as well as the federal government, federal FCA cases are frequently mirrored by one or more state FCA cases. In addition there are a number of cases filed by state attorneys general involving Medicaid fraud by drug manufactures that rely on other fraud statures. Overall the number of federal and state cases against drug manufactures for cheating Medicaid could be as high as 200 to 250.

The Department of Justice appears to be having difficulty resolving these cases in a timely fashion. Though these cases are numerous, only three were resolved in FY 2004 and none have been resolved in the first half of FY 2005. Based on conversations I have had with lawyers on a confidential basis (conversations which did not breach the requirements of the seal provisions of the False Claims Act), the members of the private bar representing whistleblowers in these cases are deeply concerned that the Department of Justice's lawyers assigned to drug manufactures cases are seriously overburdened. The number of lawyers assigned to handle these cases and the collateral support for the cases appears to be insufficient.
This brings me to what this committee can do to further the FCA program to curb Medicaid fraud by drug companies.

First, this committee can take action to enhance the resources devoted to the FCA litigation. This can be done by increasing and/or re-adjusting the allocation of the money provided to the Health Care Fraud and Abuse program (HCFAC) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for FCA litigation support. More HCFAC money needs to be devoted to the Justice Department's health care False Claims Act cases in general and to the cases against drug manufacturers in particular. As I understand it, $240 million is now provided each year to DoJ and HHS under the HCFAC program. This money originates mostly from FCA health care fraud settlements and judgments (the FBI apparently gets a separate $114 million to investigate health care fraud.[2]) The $240 million is allocated each year by the Attorney General and the Secretary of HHS. Based on the Annual HCFAC Report for FY 2003 and TAF's recently released report on Medicare Fraud by Jack Meyer, the following amounts were provided to the following components of the government in FY 2003[3]:

DoJ's Civil Division is at the center of the FCA litigation program. In FY 2003, Civil spent $17.5 million on heath care fraud cases, of which $14.5 million came from HCFAC. It is our view that this in not nearly enough for the Civil Division and that at least an additional $10 million should be provided to the Civil Division to support the drug company cases and other health care FCA cases.

The U.S. Attorney Offices spent $76.3 million on heath care related civil fraud cases in FY 2003, of which $30.4 came from HCFAC. It is our view that two things need to be done with regard to the U.S Attorneys Offices:
First, a review should be made to determine whether the HCFAC money is allocated to the offices carrying the big health care FCA cases. I understand an allocation was made of the positions supported by HCFAC in 1997 before the big caseload arose and that that allocation has not been revised since.

Second, we believe another $25,000,000 should be allocated to the U.S Attorneys Offices with significant civil health care fraud dockets. HHS should spend more of its HCFAC money to support FCA litigation. HHS gets by far the largest share of the HCFAC fund at $191 million (in FY 2003), of which $160 million went to the Office of Inspector General and $23.3 million went to CMS. However, not enough of that money is being used to support the crucial civil fraud litigation. Thus, in FY 2003, OIG may have spent only $9.5 million and CMS may have

spent nothing to support the FCA litigation. The FCA provides the government with the largest recoupment of health care money diverted by fraud. Also, False Claims Act cases are returning $13 for every $1 dollar invested in FCA litigation. Under these circumstances, it seems sensible for OIG to spend a more significant amount of its money to support the FCA cases.

Second, as Chairman Grassley has suggested in his August 2004 letter to PhRMA, firms receiving large amounts of federal Medicaid or Medicare funds should be required to provide basic information about the FCA to their employees. TAF believes this idea has merit. If the management of companies that receive significant amounts of money from Medicaid (and Medicare) were to educate their employees in the workings of the FCA, they would be far less tempted to devise business plans that involve fraud. This deterrent effect could save large amounts of money. When employees understand that the submission of false or fraudulent claims to the federal government is against the law, and that violation of the law gives rise to civil liability for their employer, they will be less likely to engage in such conduct or to tolerate such conduct by other employees. We recommend that the Committee build upon Senator Grassley's idea by requiring all large entities receiving more than $1 million per year in federal funds under Medicare or Medicaid to provide basic information about the FCA and its qui tam provisions to their employees on an annual basis.

No doubt the drug manufactures and other health care providers will resist this idea. They have already advanced a number of reasons in opposition the FCA, which, in essence boil down to two things. First, they argue that whistleblowers are unworthy people – that they are bounty hunters, that they participate in the frauds, or that they are vindictive about unrelated problems they are having with their employer. But whether or not such charges are true in any individual case, these things are beside the point where significant fraud is uncovered. The second argument is that use of the FCA disrupts companies' internal compliance programs and to encourage FCA cases will make it harder for the companies to suppress fraud. However, this argument only suggests that many companies are in denial. Very large frauds are being uncovered which could not have occurred without management approval or acquiescence. Current compliance programs may be well intended, but they cannot suppress large-scale business plans frauds, because the frauds have the support of those who have the authority to remedy the frauds.

Third, the Medicaid statute should be amended to require all states, as a condition of receiving federal Medicaid matching funds, to put in place their own false claims acts with whistleblower provisions. This is necessary because the FCA only applies to fraud against the federal government, not the states, and therefore does not cover the states' share of Medicaid spending. Passage of state FCAs will plug this loophole.

Some states have enacted their own false claims acts with qui tam provisions that reward whistleblowers with a share of the state portion of recoveries in cases of Medicaid fraud. Currently, thirteen states and the District of Columbia have enacted such laws: California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Tennessee, Texas, and Virginia. These states account for about 35 percent of all federal Medicaid spending.

The enactment of FCAs by the remaining states would generate Medicaid savings for the federal government for three reasons.

One, the existence of a state FCA, and the financial incentives at work in its qui tam provisions, supplements the incentives in the Federal FCA for whistleblowers to file actions involving fraud against the Medicaid.

Two, the availability of a state FCA increases the procedural options for the filing and prosecution of Medicaid fraud cases. For example, if DoJ is unable, due to staffing constraints or competing priorities, to investigate a case, the availability of a state FCA in this situation means that, in the absence of DoJ activity, a state Attorney General can bring his or her own investigative resources to bear.[4] Also, the filing of state FCA cases can stimulate the federal government to pursue fraud feasors that might otherwise be neglected.

Third and finally, there is the deterrent effect of state FCAs—difficult to quantify but impossible to discount. In states like Texas, where the Attorney General has publicized state FCA settlements and made clear that additional cases would be brought as necessary, Medicaid providers have yet another reason to file only accurate claims.[5] Certainly, after two large settlements totaling $45 million and a public commitment by the Attorney General to bring similar cases as needed, only the most foolish drug manufacturer would continue to inflate prices reported to the Texas Drug Vendor Program.

Some may be concerned that such a requirement would constitute a mandate on the states. There is no question that, under our proposal, the 37 states representing 65 percent of all Medicaid spending that do not currently have a state FCA in place would have to enact such legislation. However, Federal Medicaid law already requires states to enact certain laws that achieve savings, such as laws relating to medical child support [6] and giving a state the right to payment from legally liable third parties (principally insurers) for payments made to health care providers by Medicaid.[7] Just as these requirements were designed to achieve Medicaid savings for both the state and federal governments, so would be a requirement that each state have an FCA with qui tam provisions.

In sum, requiring all states to enact FCAs with whistleblower provisions will reduce federal Medicaid funds lost to fraud. It will also reduce state Medicaid funds lost to fraud. Most importantly, such a requirement would enable both levels of government to save money on Medicaid without cutting eligibility or benefits or provider reimbursement.

Thank you again for the opportunity to testify today. I would be pleased to answer any questions.

Appendix:

Figure 1: Disposition of Recoveries in Cases for Drug Pricing in Medicare and Medicaid, (FY 2001 - FY 2004)

Figure 2: Whistleblower Cases Under Federal and States FCA's Settled with Prescription Drug Manufacturers as of September 30, 2004

Figure 3: Recoveries in Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2004)

Sources

Background Information on Medicare and Medicaid Fraud available from Taxpayers Against Fraud Education Fund (TAFEF) at www.taf.org

J. Meyer, Fighting Medicaid Fraud: More Bang for the Federal Buck. (April 2005)

A. Schneider, The Role of size="2" face="Verdana"> sp; More Bang for the Federal Buck (June 2003)

A. Schneider, Reducing Medicaid Fraud: The Potential of the False Claims Act (June 2003)

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

TAFEF also publishes the False Claims Act and Qui Tam Quarterly Review, which provides an overview of major FCA and qui tam developments involving health care and other fraud against the federal government, including case decisions, DOJ interventions, and settlements.

[1] S. Heffler et al., "U.S. Health Spending Projections for 2004-2014," Health Affairs Web Exclusive (February 23, 2005), Exhibit 5.

[2] Government Accountability Office, Federal Bureau of Investigation: Accountability over the HIPAA Funding of Health Care Fraud Investigations is Inadequate, GAO-05-388 (April 2005).

[3] The amounts reported by Meyer are consistent with those subsequently determined by the Government Accountability Office, Heath Care Fraud and Abuse Control Program: Results of Review of Annual Reports for Fiscal years 2002 and 2003, GAO-05-134 (April 2005), Figure 2, p. 11.

[4]The Medicaid Fraud Control Units focus most of their resources on criminal fraud against the program. By making the State Attorney General responsible for investigating whistleblower cases, a state FCA has the practical effect of increasing the staff allocated to civil Medicaid fraud matters. These investigative costs are often financed with proceeds from the state FCA settlements.

[5] Attorney General Abbott Sues Three More Drug Makers in Multimillion Dollar Whistleblower Fraud Case (May 26, 2004) http://www.oag.state.tx.us/oagnews.

[6] Sections 1902(a)(60) and 1908A of the Social Security Act.

[7] Section 1902(a)(25)(H) of the Social Security Act.

Statement of James Moorman

President and Chief Executive Officer
Taxpayers Against Fraud
(former Assistant Attorney General, U.S. Department of Justice)

Committee on House Ways and Means

July 17, 2003

I wish to thank the Committee on Ways and Means for inviting me to present a statement at this important hearing on waste, fraud and abuse in programs under the Committee's jurisdiction.

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 three and a half 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 ("TAFEF"), are non-profit charitable organizations dedicated to combating fraud against the Federal Government through the promotion of the use of the qui tam provisions of the False Claims Act, 31 U.S.C. SS 3729- 33("FCA").

Qui tam is the unique mechanism in the FCA that allows persons with evidence of fraud in federal programs or contracts to bring suit on behalf of the government.

TAF and TAFEF serve to inform and educate the general public, the legal community and other interested groups and entities about the FCA and its qui tam provisions. Based in Washington, D.C., TAF and TAFEF serve to increase understanding of the FCA's importance in suppressing fraud. They provide information to whistleblowers and their attorneys, publish the False Claims Act and Qui Tam Quarterly

Review and other educational materials, file amicus curiae briefs in important cases, and provide testimony on issues where the workings of the FCA are relevant. TAF and TAFEF maintain a comprehensive FCA library for public use, and a professional staff available to assist anyone interested in the FCA and qui tam. For more information, see www.taf.org .

Though I understand this hearing concerns waste, fraud and abuse with regard to all the programs within the Committee's jurisdiction, I will restrict my remarks to fraud in the Medicare program. In September of 2001, TAF published a detailed report addressing Medicare fraud, titled Reducing Health Care Fraud, prepared by economist Jack A. Meyer, President of New Directions for Policy. Last month we published an update of that report, titled Fighting Medicare Fraud: More Bang for the Buck, also by Dr. Meyer. Both reports can be found at www.taf.org.

"The federal government has, through the use of the False Claim Act, a highly successful tool for fighting Medicare fraud."

Based on the analyses set forth in these reports, for the five- year period FY1997 - FY2001, the Federal Government's civil healthcare fraud recoveries totaled $3.1 billion. Most of this $3.1 billion involved fraud against Medicare, though a small part involved other health care programs. The government's cost to recover the lost Medicare funds was an estimated $315 million, so the government got back about nine dollars for every dollar spent to investigate, prosecute and recover funds lost to fraudulent Medicare billings.

I should note that the Justice Department has publicly stated it recovered $980 million in healthcare fraud cases in FY 2002, most of which involved Medicare. I also note that False Claims Act settlements announced so far this year involving Medicare appear to be in the billion dollar range, bringing the amount of Medicare funds recovered through the use of the FCA during the seven years from FY 1997 through FY 2003 to over $5 billion.

I would like to make three points about these developments:

FIRST, the federal government has, through the use of the FCA, a highly successful tool for fighting Medicare fraud. In addition to the

actual money recovered, which is significant in itself, FCA suits have created a powerful deterrent to fraud among healthcare contractors doing business with the federal government. Anecdotal evidence points to changes of behavior and the reduction of fraud in many sectors of the healthcare industry. Factors that have led to changed behavior include increased provider awareness of the False Claims Act, increased awareness on the part of internal watchdogs and whistleblowers in health care organizations, regulatory targeting of reimbursement problem areas revealed by FCA cases, and the inclusion of stringent corporate integrity agreements, or CIAs, in FCA settlements. All of the activity to fight fraud on the part of the Justice Department, the Office of the Inspector General at HHS and whistleblowers has contributed to a dramatic reduction in the Medicare error rate as calculated by the Office of Inspector General, which fell from 14 percent of fee for service payments in 1996 to 6.3 percent in 2001, a reduction of 55 percent over six years.

SECOND, the qui tam provisions of the False Claims Act are the key to the success the government has had in fighting Medicare fraud. Whistleblowers provide the Federal Government with the inside information it needs to uncover complex business frauds - frauds that are otherwise invisible to federal regulators. For example, the FCA settlements with the Hospital Corporation of America (HCA) involved allegations stemming from the hospitals' use of two sets of books, one for the benefit of federal regulators, and one for internal purposes. According to the Department of Justice, of the $1.2 billion in False Claims Act recoveries in FY 2002 in all fields, "Recoveries associated with suits brought by whistleblowers . . . accounted for $1.1 billion in settlements and judgments during the fiscal year."

"The qui tam provisions of the False Claims Act are the key to the success the government has had in fighting Medicare fraud. Whistleblowers provide the Federal Government with the inside information it needs to uncover complex business frauds."

A number of aspects of the False Claims Act are responsible for the mobilization of whistleblowers to spark successful actions on behalf of the Medicare program, but none more so than the combination of the provisions for treble damages and the provisions allowing whistleblowers to receive anywhere from 15 to 30 percent of the awards against fraudfeasors, depending on the circumstances. Historically, the whistleblower awards have run about

16 percent, but I have been informed that they may have averaged 19 percent in FY2002.

THIRD, FCA cases frequently reveal flaws in the Medicare reimbursement systems that foster fraud. A recent example are cases involving drug company fraud against Medicare that reveal an urgent need to devise an alternative to the current use of the "Average Wholesale Price," or "AWP" mechanism as the basis for reimbursement for prescription drugs.

Consider the case of drugs that are administered to patients by physicians, the principal category of drugs Medicare now pays for. One fraudulent marketing technique that has been uncovered by whistleblowers through FCA cases is called "marketing the spread." Under this technique, a manufacturer offers the physician a deep discount on the price of the drug that the manufacturer does not disclose to the Medicare program. The concealment yields a windfall gain to physicians at the expense of taxpayers because the physician keeps the "spread" or difference between the amount the government program pays for the drug and the discounted price charged by the manufacturer. For example, if Medicare reimburses a physician at 95 percent of the Average Wholesale Price for 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 for actual physician services provided during the encounter at which the drug was prescribed.

"False Claims Act cases frequently reveal flaws in the Medicare reimbursement systems that foster fraud. "

A manufacturer can increase either the size of the "spread" or the amount of revenue it receives under such an arrangement (or both) by raising the Average Wholesale Price for the drug. If the AWP is $100 in the above example, the physician receives $95 from the government for administering a drug he buys for only $25, making $70 on the spread. To increase the amount the manufacturer makes on a prescription while enabling the physician to continue to receive the same spread, the manufacturer simply raises the Average Wholesale Price to, say $110. The government now pays the physician 95 percent of $110, or $104.50. The physician still keeps the $70 spread but now the manufacturer

receives $34.50, an increase of $9.50. Alternatively, if the manufacturer wished to increase the prescribing physician's revenue, it could increase the physician's spread to $79.50 by continuing to charge him only $25 for the drug. In either case, the increase is at the taxpayers' expense.

The impact of marketing the spread 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 co-payment of 20 percent of the price that Medicare pays - in the case of prescription drugs, 20 percent of 95 percent of the Average Wholesale Price. Thus, if the AWP is $100, the beneficiary's co- payment requirement is 20 percent of $95, or $19. If the doctor only pays $25 to the manufacturer, the patient's co-payment is equal to three-fourths of the amount the doctor pays. In some cases, patients have paid doctors more in co-payments than the drug company charged the physicians.

Two very significant settlements of cases involving these issues illustrate the scale of the problem created when drug companies choose to market the spread. Both cases were first brought to the government's attention by whistleblowers bring suit under the False Claims Act. The first settlement, involving TAP Pharmaceuticals, was announced by the U.S. Attorney in Boston on October 3, 2001. TAP agreed at that time to pay the United States $559 million for marketing the spread on an inflated AWP for Lupron, a prostate cancer chemotherapy drug. TAP also agreed to pay back additional money to states for Medicaid fraud and also to pay the United States a hefty criminal fine.

Then, on June 20 of this year, the second settlement was announced by the U.S. Attorney in Wilmington, Delaware against Astra-Zeneca for doing the same thing for its drug, Zolodex, also a prostate cancer chemotherapy drug. Astra-Zeneca paid $355 million for a number of fraudulent pricing schemes, the largest and most troubling of which was for marketing the spread on Zolodex in the same way as TAP marketed the spread for Lupron.

While I do not have the documents, it has been reported that TAP Pharmaceutical and Astra Zeneca exchanged letters, each accusing the other of what they were doing and demanding the other stop. That is an amusing sidelight to a very serious problem. What is really of interest here is a very malignant incentive to commit fraud. Because Medicare reimbursed on the basis of Average Wholesale Price numbers

as reported by the companies, and because the companies sold their drugs to physicians and the physicians were reimbursed by Medicare, the companies saw they could increase their market share by increasing the spread between what they charged the doctors and what Medicare reimbursed the doctors. They did this by inflating the AWP number, effectively using the taxpayers' money to bribe doctors to use their drugs. Thus TAP and Astra- Zeneca apparently entered into a perverse competition to see which could out-fraud the other, with the idea that the company with the most fraudulently inflated AWP would gain the largest market share.

I wish to say in closing that I am not competent to advise this Committee as to how Medicare should pay for drugs. But, I am competent to say that the current system fosters fraud and Congress should take corrective action as quickly as possible.

Thank you again for providing me with this opportunity to present my statement.

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