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
6/28/2005

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

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

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]:

---

[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.

1. 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.
2. 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.

3. 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

[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.

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.

---

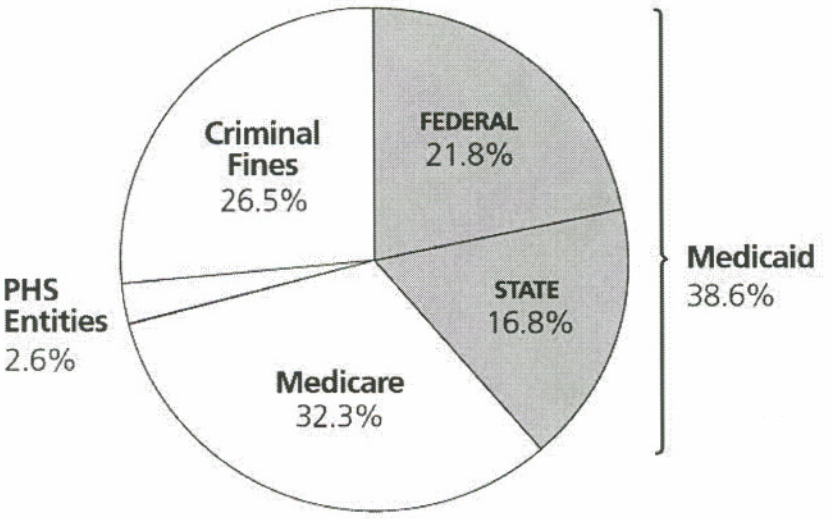
[5] *Attorney General Abbott Sues Three More Drug Makers in Multimillion Dollar Whistleblower Fraud Case* (May 26, 2004) http://www.oag.state.tx.us/oagnews.

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

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

Appendix

Figure 1 Disposition of Recoveries in Cases for Drug Pricing Fraud in Medicare and Medicaid (FY 2001 – FY 2004)



TOTAL = $2.458 Billion

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

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

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

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

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

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

Source: Settlement agreements on file at TAF Education Fund library

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

[31] This amount includes payments to settle claims by TRICARE and Department of Defense.
[32] This amount includes Bayer payments to PHS entities of $9.5 million.
[33] This amount includes $2.3 million in attorneys' fees and costs to relator and to state of Texas.
[34] This amount includes GSK payments to PHS entities of $2.6 million.
[35] This amount includes Pfizer payments of $38 million to states for harm to consumers and to fund remediation program.
[36] This amount includes $5.4 million payment for relator's share and attorneys' fees and costs presented in "Relator's Share" column.
[37] This amount includes Schering-Plough payments to PHS entities of $10.6 million.

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 the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update* (November 2004)

A. Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (November 2003)

J. Meyer, *Fighting Medicare Fraud: 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.