Testimony of Patrick J. O'Connell
Chief, Civil Medicaid Fraud Section
Office of the Attorney General of Texas

Mr. Chairman and members of the Committee:

Good morning. My name is Patrick O'Connell. I am an Assistant Attorney General and Chief of the Civil Medicaid Fraud Section of the Texas Attorney General's Office. Thank you for inviting me to testify this morning. In fiscal year 2005, the combined federal and state spending by the Texas Health and Human Services Commission on Medicaid was nearly $18 billion. Payments for prescription drugs by Texas Medicaid for that same time period amounted to $2.413 billion. The sheer volume of the dollars involved provides a huge enticement for those who would attempt to defraud the program.

In 1999, in response to concerns about growing claims of fraud and abuse, the Texas Attorney General created a special Civil Medicaid Fraud Section within the AG's office, and I have had the privilege of heading up the section since its inception. We have investigated and pursued claims against doctors, dentists, hospitals and other providers which involved typical claims of false billing, false cost reporting and over-billing; however, the overwhelming majority of our time and efforts have been concentrated on drug manufacturers. Did we target or place special emphasis on drug manufacturers on purpose? The answer is : No. The fact is that whistle blowers brought us cases which showed significant fraud in amounts which dwarfed the cases against

other providers. Because of the limited number of staff and resources we can bring to any one case, we chose to pursue those cases which provided the greatest recovery for the Medicaid program.

Texas was the first state to intervene in a qui tam case involving pharmaceutical manufacturer pricing fraud and aggressively pursue those claims. In the last six years, we have recovered $64.1 million from four manufacturers, and we continue to pursue cases against other wrongdoers. It is important to remember that these were Texas state settlements only. We have developed close and cooperative working relationships with the United States Department of Justice and with other state attorneys general who have instituted similar litigation. While Congress has made great strides in passing legislation to curb this type of fraud in Medicare and Medicaid and litigation continues in pricing fraud cases, some unscrupulous manufacturers continue to devise ways to defraud Medicaid. Besides pricing fraud, there are a number of other ways in which we believe drug manufacturers are defrauding the Medicaid system. These methods include the following:

1. Rebate fraud

In order to allow the free market system to determine prices while allowing the Medicaid programs to obtain the best price available for drugs, you passed legislation which required drug manufacturers to pay rebates to the State Medicaid programs based upon either a percentage of the Average Manufacturer Price("AMP") or the difference

between the AMP and the manufacturer's "Best Price" as reported to CMS. Some manufacturers have failed to accurately report their AMP and/or their Best Price. When they do so, the Medicaid program does not end up paying the lowest price as the legislation intended. Methods used to perpetrate this fraud include fraudulent reporting AWP or the wholesale cost of drugs, fraudulent reporting of AMP by failing to account for discounts, rebates and chargebacks and fraudulent reporting of Best Price through the use of what is known as nominal pricing and/or bundling.

A) Reports of false AWP or Wholesale Cost

The rebate system assumes that the Medicaid program has paid an estimated acquisition cost that is reasonably close to the actual acquisition cost. Then, the rebate brings the program's price down near the Best Price. If the estimated acquisition cost is inflated due to fraud, the rebate does not bring the net price to the program down to the Best Price. Congress attempted to resolve this problem in the last session changing the methodology of creation of the Federal Upper Limit("FUL") on multi-source drugs to 250% of the lowest published AMP. Our experience in Texas shows that multi-source drugs are sold in a very narrow range in the market place, and we are concerned that an FUL of 250% does not limit the potential for fraud enough.

B) Reporting of AMP/Best Price

The reporting of AMP/Best Price is supposed to take into account all rebates, discounts and chargebacks for sales to the retail class of trade. The AMP for a generic product is 11% of the AMP. The lower the AMP, the lower the rebate. So, if discounts are applied in a calculation of AMP that should not have been applied, the AMP is fraudulently reduced. The AMP for a branded product is 15.1% of the AMP or the difference between AMP and Best Price, whichever is greater. If discounts are not applied to the Best Price calculation, the Best Price remains artificially high and the difference between AMP and Best Price is reduced. Consequently, the rebate is reduced. This fraud can be accomplished in a number of different ways. The main method is to provide free goods and services, educational grants or other valuable monetary incentives to influence the purchasing decision. These incentives are not reported as discounts, thereby artificially inflating the Best Price.

C) Bundling fraud

Bundling is the practice of selling a number of drugs by a manufacturer with the provision of a discount so long as the purchase is of all of the drugs in the transaction. For example, a manufacturer tells a provider that they can obtain a 25% discount on four of the manufacturer's drugs so long as the provider buys a particular drug at a higher undiscounted price. Under the current rules, the discount is to be apportioned across all of the drugs in the transaction. If the discount is all applied to the generic drugs in the

transaction, the rebate for the generics stays unchanged; however, the rebate for the branded products could have been affected because the Best Price for the branded product could have been lower than the reported Best Price.

D) Nominal pricing fraud

In addition, when calculating Best Price, manufacturers do not have to include sales to entities at " merely nominal pricing". This provision was designed to allow manufacturers to provide product to charitable entities at little or no cost without requiring them to use that price to calculate their rebates. CMS issued a ruling that said that any sale at less than 10% of AMP was "nominal". Some manufacturers have illegally used this provision to discount the prices of their drugs to their normal customers without reporting a lowered Best Price. For example, some manufacturers have provided their drug to hospitals at 8% of the regular rate under an agreement with the hospital that the drug is used more than 80% of the time or if the drug has been declared to be the preferred drug on the hospital's formulary. In other words, the low price is tied to a performance measure. We believe this is not "merely nominal", and it has the effect of improperly influencing prescription decisions at the hospital or in the future for that patient.

2. Off-label marketing fraud

As you know, a drug manufacturer may not market a drug for use against a particular condition or disease unless the FDA has approved the drug for such use. We have seen numerous instances of such behavior, and there have been a number of settlements completed in this area already. The Texas Attorney General just recently unsealed a case against Jannsen, a subsidiary of Johnson & Johnson, for the off label marketing of its drug Risperdal for use in children when the FDA has not approved it for such use. Jannsen's aggressive marketing caused the Texas Medicaid program to pay for $117 million of Risperdal over the last 5 years. Not only has Texas paid this sum, but we do not know yet the increased costs of medical care for those children who used Risperdal and developed other symptoms such as diabetes.

3. Misrepresentation of safety and effectiveness

The Texas Medicaid program has for years had an open formulary. That is, if a drug was approved by the FDA and a drug manufacturer signed a rebate agreement and the manufacturer asked to be placed on the Texas Medicaid formulary, the drug was placed on the formulary and was reimbursable under the Texas Medicaid rules. When the drug manufacturer asks for its drug to be included on the formulary, the manufacturer must swear to its safety and efficacy. If, in fact, the drug is not safe, the Medicaid program is

reimbursing for a drug that it would not otherwise have paid for. The Texas Medicaid program paid for $57 million for Vioxx prior to the time Merck voluntarily removed it from the market. Texas and a number of other states have sued under our state false claims act for the return of these funds.

When Texas and other states pursue these types of Medicaid fraud, we are often met with a scorched earth defense where we are forced into extensive pre-trial discovery battles. These maneuvers not only increase the cost to the State to try the lawsuit but place an inordinate burden on the Medicaid program. The monetary and time burdens on the Medicaid agency take away from the funds and time which would otherwise be available to the program to provide the very benefits it is designed to provide.

The Medicaid program places a great amount of trust in our pharmaceutical manufacturers to provide accurate figures to the program. Some of these manufacturers have not earned that trust, and, without strong false claims acts and without strong administrative rules to punish such behavior, many manufacturers will continue to violate that trust. Furthermore, without the funding and staffing to pursue false claims act cases, neither the Department of Justice nor the Texas Attorney General will be able to utilize these laws to effectively deter continued diversion of the taxpayers dollars.

My time is about up. Thank you for your attention. I am happy to answer any questions.