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 my remarks, I will describe for you the experience of the Texas Attorney General's office in its efforts to identify and obtain reimbursement from drug companies and other persons and companies that have defrauded the Medicaid system in Texas.

As you know, the Medicaid budget for both the Federal government and the states has increased dramatically over the last ten years. In fiscal year 2005, the combined federal and state spending by the Texas Health and Human Services Commission on Medicaid is estimated to be $12.6 billion. The budget for the payment for prescription drugs by Texas Medicaid for that same time period is $2.6 billion or 20% of the total. The sheer volume of the dollars involved provides a huge enticement for those who would attempt to defraud the program.

You are familiar with the Federal False Claims Act which has provided redress for the United States since the Civil War . Texas adopted its own version of the FCA in 1995 which is limited to recovery for fraud against the Medicaid Program. In 1999, in response to concerns about growing claims of fraud and abuse, then Texas Attorney

General, now your colleague Senator John Cornyn, created a special Civil Medicaid Fraud Section within the AG's office. I have had the privilege of heading up the section since its inception.

When the section was formed, our plan was to aggressively pursue all types of fraud against the Medicaid program. We have investigated and pursued claims against doctors, hospitals and other providers which involved typical claims of false billing, false cost reporting and overbilling; 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? 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 return to the Medicaid program.

To date, we have sued six drug manufacturers in cases brought to us by Ven-a-Care of the Florida Keys, Inc. State Medicaid programs are required by Federal law to pay pharmacists for prescriptions filled for Medicaid beneficiaries an amount equal to the programs' best estimate of the pharmacists acquisition cost plus a reasonable dispensing fee.

Ven-A-Care brought information to us showing that certain drug manufacturers violated Texas law by intentionally reporting prices to the Texas Medicaid Program that

did not bear a reasonable relationship to the prices for their products that were generally and currently available in the market place. Unlike most other states which derive pricing information from third party price reporting services like First Data Bank, Texas requires manufacturers who want their products to be eligible for Medicaid reimbursement to fill out a questionnaire for each drug they wish placed on the Texas Medicaid formulary. For each drug, the manufacturer must report its prices to various classes of trade: e.g., its AWP; its price to wholesaler and/or distributor; its direct price; special price to chain warehouse, etc. A drug company representative is required to sign the form and certify that the information included in it is accurate. Texas law also requires drug companies to update the Medicaid Program with any changes in reported pricing within 15 days of the change.

When Texas relies upon an inflated price report in calculating a provider's estimated acquisition cost ("EAC"), the resulting reimbursement to providers is well above the providers' actual acquisition cost, thus providing pharmacies with windfall profits. This difference between what a pharmacy pays for a drug and what it is reimbursed by Medicaid is referred to in the industry as the "Spread." The information brought to us by Ven-a-Care indicated that certain drug companies have knowingly and purposefully misrepresented their reported prices to Texas in order to enhance or drive up the reimbursement spread for their provider customers.

Under the Texas statute, we have broad powers to compel document production and testimony of potential witnesses. In 1999 and 2000, we used these civil investigative demand powers to require several manufacturers to produce documents. We also took examinations under oath of several industry representatives. Based on the information that we received from Ven-a-Care, as well as the information we received pursuant to the CID process, General Cornyn authorized us to intervene against three of the VAC defendants in September 2000: Warrick Pharmaceuticals, Dey Laboratories, and Roxane Laboratories. The Texas lawsuit was the first state intervention in a qui tam case involving pharmaceutical manufacturer pricing fraud. These three manufacturers competed with one another in the market for certain generic inhalant medicines that are typically prescribed for diseases like asthma. The defendant drug companies are all very ably defended by first rate, nationally prominent counsel. The defendants spared no expense or effort to defend themselves against our allegations. In the almost four years from the State's intervention until the settlement with Warrick in May 2004, the litigants took approximately **120 oral and videotaped depositions**, and exchanged literally hundreds of thousands of pages of written documents. Over this same time period, the State and Relator devoted tens of thousands of man-hours to this litigation, incurring millions of dollars in costs and attorneys' fees.

The evidence we have discovered in the lawsuits as well as in our pre-litigation investigations shows that some manufacturers make conscious, deliberate business

decisions to create enhanced spreads and to market the sale of their products based on the spreads. For example, manufacturers engaged in the following activities:

- purposefully reported false and inflated prices to Texas Medicaid - as well as to third party price reporting services - in order to create enhanced spreads;
- deliberately failed to report prices to certain classes of trade in violation of Texas law;
- instructed their sales personnel to market spreads to customers;
- created spread sheets showing pharmacies how much more profit they can make off Medicaid and Medicare when purchasing one product over another;
- tied sales personnel compensation to success in marketing the spread.

We also found that some manufacturers actually kept two sets of computer records with prices: one, with inflated prices that are reported to the price reporting services like First Data Bank, or in Texas' case, directly to the Medicaid Program; and another with real contract prices that are used in every day business transactions with the manufacturer's customers.

In June 2003, we settled our case with Dey for **$18.5 Million.** In this settlement, we recovered more than two times the actual damages to the Medicaid Program, as well as all of our costs and attorneys' fees. In May 2004, the case against Warrick settled for **$27 Million**. Again, Texas recovered more than two times the actual damages to the Medicaid Program, plus our costs and attorneys' fees.

In the two settlements with Dey and Warrick, Texas recovered for the federal and state treasuries a total of **$45.5 Million**. Together with collections in other cases, we have recovered approximately **$63 Million** in the last 5 years.

It is important to remember that these were Texas State settlements only. In addition, our office, working in conjunction with the National Association of Medicaid Fraud Control Units, the Department of Justice and various U.S. Attorneys around the country, has recovered an additional **$58 Million** over the last few years. Again, this figure represents recoveries for damages in Texas only. My office continues to provide assistance to those authorities in other jurisdictions who are pursuing these and other companies. 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. So far, California, Kentucky, Florida, Illinois, Massachusetts, Minnesota, Missouri, Connecticut, New York, Ohio, Arkansas, Wisconsin, Nevada, West Virginia and Alabama have followed Texas' lead and sued drug companies for false price reporting. Representatives of these States and the DOJ have visited Texas on many occasions, and we are pleased to share with them the lessons learned in our litigation against Dey and Warrick.

The case against Roxane Laboratories is still pending in Travis County, and we have also intervened against three additional defendants, Abbott Labs, Baxter Healthcare, and B. Braun Medical. The cases against all four of these drug companies are

proceeding and we are in the discovery phase, where we are taking depositions and exchanging documents. The Roxane case is scheduled to go to trial next Spring; and the case against Abbott, Baxter and B. Braun will be scheduled for trial later in 2006.

Despite our efforts, some unscrupulous drug manufacturers continue to devise ways to defraud Texas Medicaid, and we are doing everything in our power to bring those companies to justice. Besides pricing fraud, there are a number of other ways in which we believe drug manufacturers are defrauding the Medicaid system. These methods include:

1. Rebate fraud;
2. Nominal pricing fraud; and
3. Off label marketing fraud;

In order to prevent the imposition of price controls by the federal government and 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. In addition, when calculating Best Price, manufacturers do not have

to include sales to entities at "nominal pricing." This provision was designed to allow manufacturers to provide product to charitable entities at basically no cost or little cost without requiring them to use that price to calculate their rebates. However, some manufacturers have illegally used this provision to discount the prices of their drugs to their normal customers without lowering the Best Price.

Another type of fraud which can affect the rebate is illegal bundling. Bundling is a discount offered to a customer for purchases of package of multiple products. When a manufacturer does not properly apply the discount across the array of drugs in the bundle, it can improperly lower its rebate obligations to the states.

Recently the states and DoJ settled a case against Pfizer for off-label marketing of Neurontin. Off-label marketing is the inappropriate representation by a manufacturer of a drug's efficacy for indications that have not been approved by the FDA. Some manufacturers engage in off-label marketing schemes to increase sales and utilization of their products. When that happens, Medicaid pays for inappropriate and ineffective drugs.

New cases are filed with our office virtually every day. We are currently investigating allegations of the kinds of fraud I have just described, or similar fraudulent acts or behaviors in over 100 open cases.

I would also like to bring to your attention a recent case we have filed against Caremark, one of the largest pharmacy benefit managers ("PBMs") in the country.

Federal law makes clear that, when a Medicaid beneficiary is also covered by other insurance, Medicaid should be the payer of last resort. When Medicaid pays for a prescription for a "dual eligible", it can either require the pharmacist to "cost avoid" (meaning that the pharmacist must determine whether other insurance is available) or it can pay the pharmacist and go after the primary insurer for reimbursement. Texas is a "pay and chase" state. Caremark has developed plans for its customers which do not pay for paper claims, do not pay for claims not made at the point of sale, and do not pay for claims not filed within short periods of time. These restrictions are then applied to demands by Medicaid programs for reimbursement which has the effect of negating any ability of the Texas Medicaid program to be paid. We believe that this behavior was not what you intended when you passed the Medicaid legislation. During the course of our discussions with Caremark, we required the production of records which showed all of the individuals who had been covered by Caremark plans. We discovered that, not only had Caremark failed to reimburse Medicaid for those claims which Medicaid knew there was primary Caremark coverage, but there were than ½ million prescriptions paid by Medicaid for individuals covered by these plans for which Medicaid had no prior knowledge and had made no prior claim. The reason for this is that there is NO requirement for Caremark, Medco, Express Scrips (which handle 90% of drug reimbursement in the nation) or any other PBM to report their covered lives to CMS or Medicaid. We believe it is imperative that all PBMs be required to report on a quarterly

basis to CMS their covered lives. If this is required and the state Medicaid programs are allowed access to this centralized information, each State will be assured the ability to collect from the primary insurer those funds being missed today.

In closing, I would like to make clear that, while Texas is pleased to have recovered significant sums of money in these *qui tam* cases, litigation is not the most efficient way to run this system. The Texas VDP has been required to spend thousands of man hours responding to discovery requests and preparing for and attending depositions in our litigation. The program could have used our hard earned tax dollars to provide more and better services if VDP personnel were not tied up in litigation caused by manufacturers who game the system.

One way that federal law could be strengthened, to protect against manufacturer pricing fraud, is to expand ASP + 6% payment you created in the Medicare Modernization Act. Such a payment system, while still relying on the truthfulness of drug manufacturers, would allow states like Texas to save significant funds expended to estimate provider acquisition cost.

Our current Texas Attorney General, Greg Abbott, has committed the resources of the agency to our efforts to fight Medicaid fraud in Texas. Through his leadership and vision, we have obtained the funding to increase our staffing to 8 lawyers plus support staff. Even with this additional staffing, we cannot pursue <u>every</u> participant in the system that we find has engaged in this type of activity. We simply do not have the man-power.

For this reason, we are hopeful that Congress will continue to support the efforts of our partners in the Department of Justice. In our opinion, it is also vitally important that Congress maintains the strength and integrity the federal False Claims Act. We would not be able to obtain the successes that we have enjoyed without the participation of relators who have had the courage to come forward.

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