TESTIMONY
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BEFORE

U.S. HOUSE JUDICIARY SUBCOMMITTEE ON
CRIME, TERRORISM AND HOMELAND SECURITY

"Enforcement of the Criminal Laws Against Medicare and Medicaid Fraud"

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Mr. Chairman and Members of the Committee, thank you for the opportunity to appear before you today to discuss the role of the states in investigating and prosecuting Medicaid fraud. I am Mark Collins, Director of the Nebraska Medicaid Fraud Control Unit in the Nebraska Attorney General's Office. I am very pleased to speak to you today as the representative of the National Association of Medicaid Fraud Control Units, of which I currently serve as President.

INTRODUCTION

The Medicare-Medicaid Anti-Fraud and Abuse Amendments, enacted by Congress in the 1970s, established the state Medicaid Fraud Control Unit Program and provided the states with incentive funding to investigate and prosecute Medicaid provider fraud, to prosecute the abuse and neglect of patients in all Medicaid-funded residential health care facilities and to investigate fraud in the administration of the Medicaid program. The Ticket to Work and Work Incentives Improvement Act of 1999 authorizes Medicaid Fraud Control Units (MFCUs), with the approval of the Inspector General of the relevant federal agency, to investigate fraud in other federally-funded health care programs if the case is primarily related to Medicaid. This law authorizes MFCUs, on an optional basis, to investigate and prosecute resident abuse or neglect in non-Medicaid board and care facilities and emphasizes the necessity of having an integrated multi-disciplinary team of attorneys, investigators and auditors working full-time on Medicaid fraud cases in order to successfully prosecute these complex financial crimes. MFCUs are required to be separate and distinct from the state Medicaid programs to avoid institutional conflicts of interest.

MFCUs are usually located in the state Attorney General's office, although some Units are located in other state agencies with law enforcement responsibilities, such as the state police or the state Bureau of Investigation. Since the inception of the national MFCU program in 1978, the fifty Medicaid Fraud Control Units have obtained thousands of convictions and recovered hundreds of millions of dollars in restitution. Perhaps even more important than any specific prosecution or recovery, these Units have demonstrably deterred the loss of many more hundreds of millions of dollars in Medicaid overpayments.

Because the federal government provides 75 percent of each Unit's costs, with the remaining 25 percent funded by the state, each MFCU operates under the administrative oversight of the Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) and each Unit must be annually recertified. This funding formula allows the federal government to ensure that each Unit's activities are directed exclusively at provider fraud, fraud in the administration of the program and resident abuse or neglect, rather than at crimes lacking an appropriate Medicaid nexus.

HISTORY OF THE MFCU PROGRAM

Medicaid was enacted by Congress in 1965 to provide a comprehensive range of medical services to people with disabilities and America's poorest citizens. It is sometimes confused with Medicare, the federal health insurance program for people sixty-five years of age and older and their eligible dependents. However, unlike Medicare, which is federally-funded and provides the

same benefit coverage nationwide, Medicaid is financed by both federal and state funds and is administered by each state. In addition to all fifty states, the District of Columbia and the territories participate in the Medicaid program.

Although Medicaid benefits might differ from state to state, a common problem plaguing the program since the mid-1960s has been its skyrocketing costs. The reasons are many; they include pay and chase claims processing, increased enrollment, the rising cost of medical care and prescription drugs, the frequency with which services are used and the lack of explanation of benefit forms sent to Medicaid recipients. Although most taxpayer dollars go directly toward providing essential medical care for the intended beneficiaries of the program, a tremendous amount of money is lost to fraud, waste and abuse.

The lack of comprehensive safeguards in the initial Medicaid legislation gave a small but greedy group of individuals free rein to steal millions of taxpayer dollars during Medicaid's first decade of operation. Additionally, Medicaid's costs began their upward spiral shortly after the program was begun. Congressional hearings confirmed that widespread misappropriation of taxpayer funds by a handful of unscrupulous health care providers was partly to blame for this rapid cost increase.

While numerous Congressional hearings were bringing such abuses to light, it became clear that states such as New York, where a separate statewide investigative entity had been established, were able to substantially increase the rate of prosecutions and convictions and the recovery of taxpayer dollars.

Medicaid Fraud Control Units are the law enforcement agencies primarily responsible for monitoring each state's Medicaid program. The MFCUs have uncovered some of the largest and most sophisticated frauds ever committed against the program. The Units have seen wave after wave of fraud sweeping through nursing homes and hospitals, clinics and pharmacies, podiatrists, labs, home health care providers and durable medical equipment vendors and, more recently, pharmaceutical companies. Each surge has brought its own special brand of profiteer in search of the next great loophole in the Medicaid program.

In addition to fulfilling their primary investigative and prosecutorial functions, the MFCUs work to identify and implement systemic reform initiatives in the administration of the Medicaid program. In an effort to maximize their effectiveness, the MFCUs have:

- Identified pharmaceutical products not subject to federal upper limit pricing, leading to the imposition of state upper limits on the pricing of many high-volume and high-cost prescription drugs;

- Developed and implemented changes in the approval process for Medicaid payments for durable medical equipment (including wheelchairs, specialty beds and therapeutic footwear) to ensure that expenditures for these goods are made only when they are medically necessary and accurately coded;

- Identified, investigated and remedied abusive or fraudulent patterns and practices in the submission of expenses in the nursing home cost reporting system;

- Implemented computer edits and controls in the automated Medicaid payment process to safeguard against improper disbursements;

- Redefined program integrity protocols;

- Identified computer software problems in Medicaid pharmacy billing programs;

- Provided training and technical assistance to improve fraud detection methods utilized by medical peer review organizations employed by the Medicaid program;

- Recommended and implemented changes in Medicaid provider enrollment screening processes to provide for effective background checks;

- Identified improper billing for clinical laboratory testing that was not medically necessary;

- Developed a computerized tracking system to identify and prevent perpetrators of resident abuse from being rehired;

- Worked with the HHS-OIG to develop protocols and procedures for a voluntary disclosure program that provides ongoing guidance to the health care industry and encourages providers to evaluate themselves, promptly report overpayments and voluntarily disclose improper conduct;

- Drafted and successfully advocated for passage of legislation requiring background checks of home health aides and nursing home employees; and

- Assisted the Offices of the State Auditor and the United States Attorney in the investigation of mental health counseling corporations.

NATIONAL ASSOCIATION OF MEDICAID FRAUD CONTROL UNITS (NAMFCU)

The National Association of Medicaid Fraud Control Units (NAMFCU) was established in 1978 to provide a forum for the nationwide sharing of information concerning the challenges of Medicaid fraud control. NAMFCU fosters interstate cooperation on law enforcement and federal issues affecting the MFCUs, conducts training programs to improve the quality of Medicaid fraud investigations and prosecutions, gives technical assistance to Association members and provides the public with information about the MFCU program. The Association also gathers, coordinates and disseminates information to the various MFCUs, maintains a library of resource materials and provides informal advice and assistance to its member Units.

Of the 50 MFCUs that comprise the Association, 43 are located in state the Offices of the Attorney General and seven are located in other state agencies.

NAMFCU is called upon regularly to supply speakers for numerous health care fraud seminars. The Association's newsletter, the *Medicaid Fraud Report*, is published six times a year and contains information concerning prosecutions by various states and reports of legal decisions affecting fraud control. Beginning with the first global settlement case in 1992, NAMFCU has effectively coordinated multistate/federal investigations and settlements, primarily involving pharmaceutical companies.

PROVIDER FRAUD SCHEMES

In the past decade, state MFCUs have seen a rapid increase in both the number of fraudulent schemes targeting Medicaid dollars and the degree of sophistication with which they are perpetrated. Although the typical fraud schemes – billing for services never rendered, double-billing, misrepresenting the nature of services provided, providing unnecessary services, submitting false cost reports and paying illegal kickbacks – still regularly occur, new and often innovative methods of thievery continue to appear.

Perpetrators of Medicaid fraud run the gamut from the solo practitioner who submits claims for services never rendered to large institutions that exaggerate the level of care provided to their patients and then alter patient records in order to conceal the resulting lack of care. MFCUs have prosecuted psychiatrists who demanded sexual favors from their patients in exchange for prescription drugs, nursing home owners who stole money from residents and even funeral directors who billed the estates of Medicaid patients for funerals they did not perform.

SELECTED STATE MEDICAID FRAUD INVESTIGATIONS, PROSECUTIONS AND SETTLEMENTS

MFCUs have identified serious incidents of fraud in numerous sectors of the health care industry, including hospitals, home health care agencies, medical transportation and durable medical equipment companies, pharmacies and medical clinics. They have prosecuted individual providers such as physicians, dentists and mental health professionals.

Examples of recent Medicaid Fraud cases follow:

PHYSICIANS

- In Arizona, a physician was charged with 14 felony crimes related to his health care practice, including conspiracy, assisting a criminal syndicate, money laundering and illegally administering narcotic drugs.

In addition, the investigation determined that the physician filed more than 31,900 claims for insurance reimbursement between 2004 and 2009, far in excess of what could be possible to comply with appropriate medical standards during the hours he saw patients. Claims submitted to the Arizona Medicaid program totaled nearly $8 million. Medicaid paid the physician $2.5 million. In addition, more than $1 million was paid to the physician for claims submitted to Medicare and other insurance companies. The Arizona Attorney General's Office has seized over $2 million of the physician's assets as part of this joint state/federal case.

- Following a two week trial, a physician in the District of Columbia was found guilty of one count of Health Care Fraud and sixteen counts of false statements in a health care matter for billing Medicaid over $700,000 for procedures and office visits that never occurred.

- A Nevada pediatric group was accused of submitting claims for multiple dates of service and for tests and services that were either not performed or were improperly billed. The corporation pled guilty to one count of felony Medicaid Fraud and entered into a civil settlement agreement, without admission of liability, in which it agreed to pay $475,000 ($350,000 in restitution and $125,000 in costs).

- In Pennsylvania, a physician who was board certified in neonatal medicine submitted hundreds of false claims for an expensive procedure that he did not perform. He defrauded the South Carolina and Pennsylvania Medicaid programs, the TriCare program and several private insurance programs for a total of more than $8 million. He is expected to plead guilty, be sentenced to 96 months in a federal prison and pay the remaining restitution of $7,116,423.

- Two Washington state providers, one a physician, maintained a medical practice where they treated patients for pain management. They were indicted for unlawfully billing several governmental health care benefit programs and prescribing Methadone, Oxycontin and Oxycodone for improper purposes, resulting in at least one death. The physician was sentenced to nine months in prison and ordered to pay restitution and fees.

- A South Dakota physician reached a civil settlement to resolve allegations that he employed unlicensed personnel as nurses. The $57,000 settlement includes reimbursement to the Medicaid and Medicare programs.

MEDICAL TRANSPORTATION

- An investigation in North Carolina revealed that a Medicaid provider of medical transportation services had routinely transported approximately fifteen Medicare and Medicaid recipients to their dialysis treatments by wheelchair vans, but billed the government programs as if ambulance transport was necessary and provided.

Hours of surveillance and consensual monitoring provided evidence that the company was falsifying medical records to disguise wheelchair transports as ambulance transports. The owner of the company was sentenced to 24 months in prison and ordered to pay full restitution of $948,542.36 to the Medicare and Medicaid programs.

- In Rhode Island, surveillance of a medical transportation company showed that elderly individuals were transported in vehicles that were not equipped with wheel chair lifts, as required by state Medicaid policy. An audit of the company's billing revealed that the company billed $303,984 for services in unauthorized vehicles. The company entered into a settlement agreement with the state for the full amount along with $10,000 in investigative costs.

MENTAL HEALTH PROVIDERS

- A MFCU investigation established that a Florida psychiatrist submitted claims to both Medicaid and Medicare for treating up to 78 patients a day and billing up to 58.8 hours a day over a period of 18 months. He was paid $317,286.63 by Medicare and $313,170.71 by private insurance during this period. A civil action filed by the MFCU resulted in a settlement in the amount of $720,000 to resolve allegations of Medicaid fraud.

NURSING HOMES

- Following an audit of a Tennessee nursing home, questions were raised about possible misappropriation of funds relating to bonuses paid to the administrators and other staff. An agreement directed that the two former administrators and the nursing home collectively pay a total of $200,000 in fines and restitution.

PHARMACIES

- Eleven individuals and corporations, including three pharmacies, were indicted in connection with New Jersey's Operation PharmScam. The PharmScam investigation revealed a group of health care providers and pharmacists defrauding the state in connection with expensive HIV and AIDS drugs. The pharmacies would pay cash, usually $40 to $50, for prescriptions for HIV/AIDS drugs, then bill Medicaid as though the medication was dispensed to the patient. However, no medication was ever dispensed.

- A South Carolina pharmacist who operated a family-owned independent pharmacy allegedly billed for medications that were not dispensed. The South Carolina MFCU obtained records to verify that the pharmacist billed for more units of two antibiotics than he actually dispensed. The pharmacist was arrested and charged with two counts of filing false claims. The overall exposure to the Medicaid program over the 15-month period of the scheme was approximately

$145,000. The pharmacist pled guilty and the state Medicaid program was fully reimbursed.

DENTISTS

- A dentist in Kentucky engaged in a pattern of pulling patients' teeth, generally one at a time, and prescribing 16 doses of hydrocodone each time. Most patients had all of their teeth extracted by the dentist. He billed Medicaid for the extractions, many of which were medically unnecessary. Additionally, he made more money from Medicaid by extracting the teeth one at a time. The dentist entered an "Alford" plea and received concurrent sentences of five years on one count of Medicaid fraud and three counts of drug trafficking. Additionally, he was ordered to pay restitution of $4,900 and investigative costs of $3,000.

- In Missouri, a dentist was charged with 13 felony counts of Medicaid fraud. The dentist engaged in upcoding, unbundling services and billing for x-rays, root canals and fillings that were not performed. During the investigation, the dentist withheld records, created false dental records and even cut off portions of the records to conceal his fraud.

HOME HEALTH

- In Alaska's largest Medicaid fraud case, the owner of a home health care agency pled guilty to a felony count for defrauding the Alaska Medicaid program of over $1.3 million. There were several different schemes involved, including billing for services never rendered and billing for Medicaid recipients who did not qualify for the personal care attendant program. The owner was sentenced to three years in jail with 28 months suspended, ten years of suspended probation and was ordered to pay $800,000 in restitution.

- A Minnesota personal care provider agency that provided private duty nursing services and personal care assistant services was owned and operated by a licensed practical nurse. The nurse was providing LPN services without a current registration with the state Board of Nursing. A MFCU investigation revealed that the owner submitted claims for RN services when the services were provided by an LPN. The provider pleaded guilty to theft and was ordered to serve 364 days in jail, to pay Medicaid restitution of $57,185.56 and to be on supervised probation for five years.

- The New York MFCU and the federal government reached a $24 million settlement with three home health agencies, alleging that the agencies defrauded the Medicaid program. This is the largest settlement that the New York MFCU has reached with the home health industry.

During the course of its industry-wide investigation, the MFCU discovered that one of the agencies employed hundreds of home health aides who had fraudulent certifications obtained from corrupt training schools. These improperly-trained aides were subsequently assigned to work for the other two home health agencies, which sent them daily into the homes of New York's elderly, frail and indigent to provide care. As a result, these aides caused Medicaid to be billed millions of dollars for services they were not qualified to provide.

The settlement resolved allegations that the home health agencies knowingly presented, or caused to be presented, false claims to Medicaid. In addition to the payment of the settlement amount, all three agencies will be subject to the terms of a corporate integrity agreement.

- A family of four was convicted of masterminding an eight-year fraud in Oregon. The four received more than $230,000 in Social Security disability and Medicaid in-home care payments. Although the state conducted annual in-home assessments, the husband and wife were able to fool investigators into believing that the husband needed around-the-clock care. Surveillance by the MFCU revealed that the husband was not disabled.

DURABLE MEDICAL EQUIPMENT

- The California MFCU and HHS-OIG conducted an expansive joint-investigation of a durable medical equipment (DME) provider. Investigators identified over 1,400 persons of interest, pursued approximately 100 leads across the United States and executed searches of established DME locations, banks and co-conspirators.

  One family linked to the operation of this criminal enterprise lived in a million-dollar home and drove luxury vehicles, yet they also took advantage of Medi-Cal and county assistance, including school lunch programs and rent programs to cover their residential loan payments. To date, over $6.3 million has been seized from bank accounts related to the DME provider

OTHER PROVIDERS

- Two Idaho denturists billed Medicaid for dentures that were never made. When a Medicaid patient came to the clinic, the denturists obtained the patient's Medicaid card and immediately billed Medicaid. This forced the patient to return to those denturists, thus cutting out competitors. In some instances, the denturists even billed for people who still had teeth in their mouths.

- An investigation in Illinois alleged that an optometrist and his corporation operated a scheme to fraudulently bill Medicare and Medicaid for optometry services as rural health services and to use unqualified personnel to conduct the

eye exams over a five-year period. Undercover visits confirmed the fraud. The defendant entered a negotiated plea of guilty to misdemeanor Health Care Fraud and a negotiated plea of guilty to felony Health Care Fraud for his corporation in federal district court. As part of the plea, the optometrist immediately paid approximately $325,000 in restitution for fraud committed against the Illinois Medicaid program and the federal Medicare program.

- The owner of an Oklahoma respiratory services company was renting oxygen concentrators to Medicaid recipients. The concentrators were supposed to come with all the tubing, cannulas and other supplies. However, the owner devised a scheme to unbundle the accessories and bill for them separately. A jury trial was held and the owner was found guilty and ordered to pay a fine of $95,222.

- A West Virginia physician assistant wrote medically unnecessary prescriptions to patients in exchange for money or cocaine. He falsified patient records in an attempt to show medical necessity for the fraudulent prescriptions. He pled guilty to Intent to Distribute Hydrocodone and was sentenced to one year in prison.

- A community-based drug and alcohol abuse treatment provider in Kansas billed and was paid by the state Medicaid program for substance abuse treatment services reportedly provided to 81 Medicaid beneficiaries, all of whom were younger than 12 years old. As a result of these fraudulent claims, the provider was paid in excess of $3.76 million.

  A federal grand jury indicted the provider on 81 counts of Health Care Fraud for billing services that were not medically necessary and were never provided. On the eve of trial, the defendant pled guilty to one count of Health Care Fraud. She was ordered to serve two years in a federal penitentiary, followed by three years supervised probation. She was also ordered to pay full restitution to the Medicaid agency. A forfeiture judgment in the amount of $3.76 million was also entered against the provider.

- A Maryland podiatrist fraudulently billed both the Medicaid and Medicare programs for podiatry services allegedly provided to residents in nursing homes and at senior centers. However, those services either were not necessary, not documented or not provided. The podiatrist billed for invasive surgical procedures such as an incision and drainage, when in fact all he did was cut the patients' toe nails.

  Following an extensive joint investigation by the MFCU and HHS-OIG, the podiatrist pled guilty to Medicaid fraud and theft from the Medicare program. He was sentenced to five years incarceration, with all but 14 months suspended, with the 14 months to be served on home detention. He was also ordered to pay restitution and penalties of $400,000, placed on five years unsupervised probation

and ordered to perform 200 hours community service. The podiatrist paid $50,000 in restitution to the Medicaid program on the day of sentencing.

- In Vermont, a provider who owned and operated a traumatic brain injury program agreed to pay $201,043 in Medicaid restitution pursuant to a civil agreement with the Vermont Medicaid Fraud and Resident Abuse Unit. The agreement resolved allegations that the provider billed Medicaid for more than the maximum allowable number of days in the month and for more overnight charges than were possible. In other instances, the same provider billed for services when a client was hospitalized or had died.

- A husband and wife operated a therapy center in Arkansas and contracted with therapists to perform services for Medicaid recipients. The owners submitted false claims to Medicaid, including claims for services that recipients could not have received because they were in the hospital, out of town or involved in an activity that would have prevented them from receiving therapy. In addition, the therapy center made fraudulent claims by overstating the number of hours the therapists worked. The owners pled guilty to felony Medicaid fraud and were excluded from participating in the Medicaid program.

- A settlement was reached in a Medicaid quality of care case involving a profoundly disabled resident of a group home in Nebraska. The group home was not equipped to properly care for her and as a result she was severely neglected. Medicaid paid the group home owners more than $75,000 to care for the resident. The owners agreed to settle the matter with the Medicaid Fraud Control Unit for $175,000, including restitution, additional damages and costs.

MFCU GLOBAL INVESTIGATIONS AND SETTLEMENTS

One important feature of the MFCU program is to cultivate close and effective working relationships between state and federal agencies to combat fraud and abuse in the Medicaid programs of the various states. These cooperative efforts have grown out of the relationship between MFCUs and HHS-OIG, which has oversight over the MFCU program. Medicaid fraud is a crime under both state and federal statutes and may be prosecuted in both state and federal courts. Consequently, all MFCUs work closely with the Offices of the United States Attorneys in their respective states and with federal law enforcement agencies such as the U.S. Department of Justice, the FBI, HHS-OIG, the Internal Revenue Service and the U.S. Postal Service. MFCUs actively participate in state-federal health care fraud task forces and working groups that operate in virtually every state in the nation.

Cooperative efforts between state and federal authorities are very effective in protecting the Medicaid and Medicare programs from health care providers or vendors who defraud both programs and whose misconduct occurs in multiple states. Multi-state cases in which the MFCUs played a role have resulted in the recovery of over $5 billion to the Medicaid program. Defense

attorneys recognize that settling an investigation brought by one state Medicaid program does not resolve Medicaid claims in other states and that most states, like the federal government, have the authority to exclude a convicted provider from their health care programs. Accordingly, resolution of these cases would be difficult or impossible if the targets were required to negotiate separate terms and obtain separate settlement agreements from each state.

The National Association of Medicaid Fraud Control Units encourages states to look beyond their individual state perspective and to participate in global cases. These cases succeed only with the cooperation of all state MFCUs, whose goal is to protect the integrity of the entire state Medicaid program.

The federal False Claims Act (FCA) includes *qui tam* provisions that provide the authority and financial incentive for private individuals or "relators" to enforce the Act on behalf of the government. *Qui tam* relators, often called "whistleblowers," generally are current or former employees of target entities. The FCA protects relators from retaliatory actions by their employers. A *qui tam* complaint is filed under seal in federal district court and remains under seal for at least 60 days (and often much longer) to allow the government to conduct a thorough investigation. In addition, twenty-five states currently have state false claims statutes with *qui tam* provisions, and an increasing number of relators are filing their cases with the states as well as the federal government. This development has fostered a significant increase in state/federal investigative partnerships.

The state MFCUs are generally notified about an ongoing investigation when the United States Department of Justice or a United States Attorney's Office, relator's counsel, defense attorney, or other source, contacts the National Association of Medicaid Fraud Control Units and requests the assistance of the MFCUs. NAMFCU obtains relevant information and then prepares a list of states affected by the suspected wrongdoing. The NAMFCU President then determines if it is appropriate for the states to participate and whether a NAMFCU investigative team should be appointed.

If the investigation reaches the settlement stage, the NAMFCU team contacts the defendant to set out basic ground rules, including the framework for negotiations (exclusion/ non-exclusion, criminal pleas and/or civil settlement, the payment of the team's expenses attributable to the negotiations, etc.). In joint state-federal cases, this process takes place in cooperation with federal attorneys assigned to the matter.

There are other crucial factors to consider in a settlement. These include the provider's ongoing economic viability, the effect on shareholders, potential employment impact on specific communities and the effect that exclusion from Medicaid, Medicare and other state and federal health care payment programs will have upon a Medicaid beneficiaries' access to adequate and convenient medical care. Settlements may include additional terms such as incarceration of employees or officers, corporate reorganization and compliance or corporate integrity agreements. The negotiations are highly confidential and often are governed by grand jury secrecy requirements, *qui tam* provisions, privilege issues and Securities and Exchange Commission statutes and regulations.

Per NAMFCU protocols, all state recoveries are allocated based upon a state's actual damages. The participating states usually supply state-specific data regarding the defendant's billings, although it is sometimes possible to calculate state losses from information supplied by the federal government or through discovery from the defendant. Each NAMFCU settlement team, in conjunction with its partners in the federal government, is committed to negotiating for the best settlement possible for its member states and will, in appropriate circumstances, seek penalties as well as damages.

Examples of recent state-federal global settlements follow:

PFIZER

Pfizer, Inc. agreed to settle civil and criminal allegations that the company and its subsidiaries paid kickbacks and engaged in off-labeling marketing campaigns that improperly promoted numerous drugs that Pfizer manufactures. This is the largest settlement in history in a health care fraud matter. Pfizer paid the states and the federal government a total of $1 billion in civil damages and penalties to compensate Medicaid, Medicare and various federal healthcare programs for harm suffered as a result of its conduct.

The state and federal governments alleged that Pfizer, the largest pharmaceutical manufacturer in the world, engaged in a pattern of unlawful marketing activity to promote multiple drugs for uses that were not approved by the Food and Drug Administration (FDA). While it is not illegal for a physician to prescribe a drug for an unapproved use, federal law prohibits a manufacturer from promoting a drug for uses not approved by the FDA. This promotional activity included:

- Marketing Bextra for conditions and dosages other than those for which it was approved;
- Promoting the use of the antipsychotic drug Geodon for a variety of off-label conditions such as attention deficit disorder, autism, dementia and depression for patients that included children and adolescents;
- Selling the pain medication Lyrica for unapproved conditions;
- Making false representations about the safety and efficacy of Zyvox, an antibiotic only approved to treat certain drug resistant infections.

Pfizer was also alleged to have illegally paid health care professionals to induce them to promote and prescribe thirteen different drugs. These payments allegedly took many forms, including entertainment, cash, travel and meals. Federal law prohibits payment of anything of value in exchange for prescribing a product paid for by a federal health care program.

As a condition of the settlement, Pfizer entered into a corporate integrity agreement with HHS-OIG, which will closely monitor the company's future marketing and sales practices.

In addition, a Pfizer subsidiary, Pharmacia & Upjohn Company, Inc., pled guilty to a felony violation of the Food, Drug, and Cosmetic Act for engaging in the illegal marketing and promotion of Bextra, an anti-inflammatory drug that Pfizer pulled from the market in 2005. The subsidiary paid a criminal fine and forfeiture of $1.3 billion.

This settlement was based on nine federal and state *qui tam* cases that were filed in the United States District Court for the Districts of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky.

FORBA HOLDINGS, LLC

Twenty-two states and the federal government settled allegations against FORBA Holdings, LLC, a dental management company that provided management services to a national chain of pediatric dental clinics operating under the name of "Small Smiles." It was alleged that these services were either medically unnecessary or performed in a manner that failed to meet professionally-recognized standards of care. These services included performing pulpotomies (baby root canals), placing crowns, administering anesthesia (including nitrous oxide), performing extractions, providing unneeded fillings and/or sealants and using inappropriate behavior management techniques to restrain pediatric patients.

To resolve these allegations, FORBA agreed to pay $24 million plus interest. In addition, FORBA agreed to enter into a five-year corporate integrity agreement with HHS-OIG. The agreement establishes procedures and reviews to avoid and promptly detect any further inappropriate conduct. Specifically, FORBA must engage external reviewers to monitor its quality of care and reimbursement. In addition, the Chief Dental Officer must develop and implement policies and procedures to ensure that the Small Smiles clinics provide services consistent with professionally-recognized standards of care.

This investigation was initiated by three whistleblower lawsuits filed under the *qui tam* provisions of the federal False Claims Act pending in the United States District Court for the District of Maryland, the Western District of Virginia and the District of South Carolina.

OMNICARE AND IVAX

Omnicare, Inc. is a Delaware corporation headquartered in Covington, Kentucky that specializes in providing pharmacy services to long term care facilities. IVAX Pharmaceuticals, Inc. is a Florida corporation headquartered in Weston, Florida that manufactures generic drugs.

State and federal governments alleged that Omnicare and other entities engaged in several unlawful kickback schemes including the following:

- Omnicare solicited and received $8 million in exchange for agreeing to purchase $50 million in generic drugs from IVAX Pharmaceuticals and to drive utilization of the generic drugs for their nursing home patients;

- Omnicare paid $50 million to certain nursing home chains in exchange for 15-year contracts with each company to refer residents to Omnicare for their drug purchases;

- Omnicare provided pharmacy consultants to long term care facilities throughout the country at below market rates in exchange for the facilities' agreement to exclusively use the company's pharmacy services for their patients; and

- Omnicare solicited and received kickback payments in exchange for the company's agreement to convince physicians to prescribe the antipsychotic drug Risperdal as an initial drug or in place of competitors' antipsychotic drugs.

Omnicare and IVAX agreed to settle allegations that they engaged in unlawful kickback schemes that defrauded federal and state healthcare programs. The states and the federal government received a total of $112 million in civil damages to compensate the Medicaid and Medicare programs for harm suffered as a result of the kickbacks. Omnicare and IVAX also entered into corporate integrity agreements with HHS-OIG, which will closely monitor the companies' practices.

These settlements were based on five separate *qui tam* lawsuits filed by private individuals and consolidated in the United States District Court for the District of Massachusetts under state and federal false claims statutes.

MYLAN, UDL LABORATORIES, ASTRAZENECA AND ORTHO McNEIL

Four pharmaceutical companies agreed to pay a total of $124 million to resolve claims that they violated the federal False Claims Act by failing to pay appropriate rebates for drugs paid for by Medicaid.

Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., AstraZeneca Pharmaceuticals LP and Ortho McNeil Pharmaceutical, Inc. are participants in the Medicaid Rebate Program and executed Rebate Agreements with the United States. By agreeing to participate in the Medicaid Rebate Program and signing these Rebate Agreements, the companies agreed to pay quarterly rebates to Medicaid based upon the amount of money that Medicaid paid for each company's drugs. The precise amount of a rebate is determined in part by whether a drug is considered an "innovator" drug or a "non-innovator" drug. The rebate that must be paid for innovator drugs is higher than the rebate for non-innovator drugs.

Each of the companies agreed to pay a settlement to resolve allegations that it had sold innovator drugs that were manufactured by other companies and classified those drugs as non-

innovator drugs for Medicaid rebate purposes. As a result of the improper classification of these drugs, the companies underpaid their rebate obligations to the Medicaid program.

Mylan and UDL paid $118 million to resolve allegations that they underpaid their rebate obligations with respect to twelve Mylan drugs and ten UDL drugs AstraZeneca paid $2.6 million to resolve allegations that it underpaid its rebate obligations with respect to Albuterol. Ortho McNeil paid $3.4 million to resolve allegations that it underpaid its rebate obligations with respect to Dermatop. From the total, $7,279,135 was paid to entities that participated in the Public Health Service's Drug Pricing Program.

QUEST DIAGNOSTICS

A $12.4 million national Medicaid civil settlement was reached with Quest Diagnostics, Inc. and its former subsidiary Nichols Institute Diagnostics.

This settlement followed the April 2009 resolution of federal allegations involving the same conduct. The federal and state cases stemmed from a *qui tam* lawsuit which alleged that certain test kits manufactured by Nichols and used by laboratories to measure parathyroid levels in blood samples produced an unacceptable level of elevated results. The test kits at issue were generally used by medical practitioners to determine if patients suffering from End Stage Renal Disease also had overactive parathyroid glands. The government also alleged that there were problems with the accuracy of certain additional Nichols tests during specified limited time periods. Quest Diagnostics denied the government's civil allegations but agreed to the settlement. The test kits at issue were disproportionately billed to Medicare, meaning the payments by state Medicaid programs for these tests were limited.

In April 2009, Nichols pled guilty in federal court to misbranding charges under the Food, Drug and Cosmetic Act. Quest voluntarily closed Nichols in April 2006, before the federal criminal case was brought.

The $12.4 million civil recovery for the state Medicaid programs correlates with the amount the state Medicaid programs paid for all of the allegedly inaccurate Nichols tests. As part of the federal and state settlements, Quest entered into a corporate integrity agreement that, among other things, requires it to retain an expert to review how compliance concerns are communicated to senior management and the Quest Board of Directors.

CONCLUSION

As they have done for the past thirty years, state Medicaid Fraud Control Units continue to play a national leadership role in investigating and prosecuting health care fraud and resident abuse, and will continue to do so in the future. MFCUs aggressively identify and prosecute, both civilly and criminally, those who seek financial gain at the expense of the Medicaid program. By doing so, MFCUs deter health care fraud, identify program savings, and remove incompetent practitioners from the health care system. Equally important, the MFCUs protect our nation's

most vulnerable citizens – the poor and the frail elderly – by prosecuting those who abuse and neglect them in our nation's nursing homes, thereby ensuring that our nursing homes are safe places to live.

Thank you again for giving me the opportunity to testify today.