Department of Justice

STATEMENT OF

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ASSISTANT ATTORNEY GENERAL

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"EFFECTIVE STRATEGIES FOR PREVENTING HEALTH CARE FRAUD"

PRESENTED

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ASSISTANT ATTORNEY GENERAL
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INTRODUCTION

Chairman Leahy, Senator Sessions, and Members of the Committee, thank you for inviting me here today to testify on the Department of Justice's efforts in fighting and deterring health care fraud. Under the leadership of the Attorney General, Deputy Attorney General David Ogden is supervising the Department's day-to-day efforts to marshal our resources in combating health care fraud, recovering Medicare funds stolen through fraud and abuse, and coordinating with the Department of Health and Human Services. Deputy Attorney General Ogden very much wanted to be here today but was unable to attend because of a prior commitment. He asked me to relay the important work that the Department of Justice, in close coordination with the Department of Health and Human Services and our other law enforcement partners, is doing to deter, detect and defend against health care fraud and express how important this issue is to him and the Attorney General.

We have a duty to the taxpayers. Every year, hundreds of billions of dollars are spent to provide health security for American seniors, children, and the disabled. While most medical or pharmaceutical providers are doing the right thing, when Medicare or Medicaid fraud occurs, it costs the American taxpayer real dollars. Every year, billions of dollars are lost to Medicare and Medicaid fraud.

It is those wrongdoers who we must stop. Those billions represent health care dollars that could be spent on services for Medicare and Medicaid beneficiaries – on seniors, children and families in need – but instead are wasted on fraud and abuse. This is unacceptable. We have a duty to our citizens who receive treatment paid for by the Medicare, Medicaid, and other government programs to see to it that their care meets acceptable medical standards. We know that when Medicare and Medicaid fraud occurs, it can corrupt the medical decisions health care providers make with respect to their patients and thereby put the public health at risk. For these reasons, the Department of Justice, through its Civil, Criminal, and Civil Rights divisions, along with U.S. Attorneys' Offices and the FBI – the entities responsible for enforcing laws against all forms of health care fraud – has prioritized much of our enforcement efforts on protecting the integrity of health care that is provided to patients.

FIGHTING HEALTH CARE FRAUD IS A PRIORITY OF THE DEPARTMENT OF JUSTICE

Federal and state spending on Medicare and Medicaid exceeds $800 billion per year. While there is no official federal estimate of the level of fraud in Medicare, Medicaid, or the healthcare sector more generally, external estimates project the amount at three to ten percent of total spending. The Department of Justice, in coordination with the Department of Health and Human Services, and other federal and state law enforcement agencies, recognizes both the

urgency in the need to recover those funds and the need to ensure that such fraud does not reoccur.

Because coordination across agencies is an integral part of preventing and prosecuting health care fraud, Secretary Sebelius and Attorney General Holder together have pledged to fight waste, fraud and abuse in Medicare and Medicaid and in May 2009 announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). With the creation of the HEAT team, fighting Medicare and Medicaid fraud became a Cabinet-level priority for both DOJ and HHS.

The HEAT initiative, which is supervised by Deputy Attorney General David Ogden and the Deputy Secretary of the Department of Health and Human Services William Corr, has had some remarkable successes thus far. We have already expanded the Medicare Fraud Strike Force to Houston and Detroit, bringing the total number of cities and or regions where the Strike Force is operating to four: South Florida, Los Angeles, Detroit and Houston. These expanded efforts have already shown results. On June 24, 2009, the Criminal Division and United States Attorney's Office for the Eastern District of Michigan announced seven indictments charging 53 people in schemes involving physical, occupational, and infusion therapy to defraud Medicare of more than $50 million in the Detroit metropolitan area. Since the Detroit announcement, the Criminal Division and United States Attorneys' Offices in Houston and Los Angeles have conducted two additional arrest takedowns indicting another 52 defendants for allegedly submitting $42 million in fraudulent billings to the Medicare program.

We are actively analyzing Medicare data in unprecedented coordination between our two agencies, and in as real-time as possible, to identify fraud "hot spots" and expand strike force operations to those areas where there is the most need. We have enhanced training programs on enforcement measures for prosecutors and investigators, and we have increased compliance training for providers to prevent honest mistakes and help stop potential fraud before it happens. Because health care fraud drives up the cost of health care for all of us, we also are actively engaged in efforts to educate the public about ways they can assist us to detect, prevent and prosecute fraud. HEAT's website – www.stopmedicarefraud.gov – is an easy way for beneficiaries to report suspected fraud to the HEAT task force.

The HEAT initiative also has focused on misconduct by pharmaceutical companies and device manufacturers. Last month, Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. agreed to pay $2.3 billion to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. This is the largest health care fraud settlement in the history of the Department of Justice, the largest criminal fine of any kind imposed in the U.S., and the largest ever civil fraud settlement against a pharmaceutical company.

While the HEAT Initiative is new, the collaborative efforts between the Department of Justice and the Department of Health and Human Services are not. In 1997, Congress established the Health Care Fraud and Abuse Control (HCFAC) Program under the joint direction of the Attorney General and the Department of Health and Human Services, acting through HHS's Inspector General, to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse.

Since the inception of the program, our Departments have returned more than $15 billion to the federal government, of which $13.1 billion went back to the Medicare Trust Funds. These efforts have resulted in more than 5600 criminal convictions for health care fraud offenses. With $13.1 billion returned to the Medicare Trust Funds, the average return on investment to the Trust Fund for funding provided by the 1996 law that created the program, HIPAA, to law enforcement agencies is $4.02 per dollar spent.

During fiscal year 2008, the Department of Justice's vigorous efforts to combat health care fraud accounted for $1.12 billion in civil settlements and judgments. During that same time period, the Department opened 849 new civil health care fraud matters and filed complaints or intervened in 226 civil health care fraud matters. Also, during that time period, federal prosecutors filed criminal charges in 502 health care fraud cases involving charges against 797 defendants and obtained 588 convictions for health care fraud offenses. In addition, they opened 957 new criminal health care fraud investigations involving 1641 defendants. Our monetary recoveries in fiscal year 2009 have already exceeded those of the previous year, and we appear on track to soon report over $1.6 billion in settlements and judgments in health care fraud matters.

The litigating components of the Department of Justice, as well as the FBI, are actively engaged in investigating and litigating a wide range of civil and criminal health care fraud cases, and we work closely with the Department of Health and Human Services and other federal and state agencies.

CIVIL DIVISION'S HEALTH CARE FRAUD EFFORTS

The primary enforcement tool possessed by the Department of Justice to pursue civil remedies in health care fraud matters is the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733. The Department of Justice worked closely with Congress on the recently enacted Fraud Enforcement and Recovery Act (FERA) to amend the FCA to strengthen the government's ability to combat fraud. In addition to the Department of Justice being able to go after false claims directly, lawsuits are often brought by private plaintiffs, known as "relators," under the *qui tam* provisions of the FCA. The *qui tam* provisions allow private citizens to sue, on the government's behalf, companies and others that defraud the government. The government then can intervene in appropriate cases to pursue the litigation and recovery against the defendant. Since the False Claims Act was substantially amended in 1986 and through FY 2008, the Civil Division, working with United States Attorneys, has recovered $21.6 billion on behalf of the various victim federal agencies. Of that amount, $14.3 billion was the result of fraud against federal health care programs – primarily the Medicare program. These totals do not include the significant recoveries in the fiscal year just ended.

This calendar year, the Department settled a matter with Pfizer Inc. in which Pfizer agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from illegal promotion of certain pharmaceutical products. Pfizer's subsidiary, Pharmacia & Upjohn Company Inc., pled guilty to a felony violation of the Food, Drug, and Cosmetic Act for its off-label promotion of

Bextra, an anti-inflammatory drug, with the intent to defraud or mislead. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. Bextra was withdrawn from the market in 2005 after studies confirmed an increased cardiovascular risk in certain types of uses for which Pfizer had marketed the drug. The company was ordered to pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States. Pharmacia & Upjohn was also ordered to forfeit $105 million, for a total criminal resolution of $1.3 billion. Further, Pfizer paid $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolved allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668.5 million and the state Medicaid share of the civil settlement is $331.5 million.

The Department completed another substantial settlement in January 2009 when Eli Lilly pled guilty to violating the Food, Drug, and Cosmetic Act for its illegal marketing of the anti-psychotic drug Zyprexa for uses that were not approved by the FDA. The global settlement totaled $1.415 billion and included a $515 million criminal fine, $100 million in forfeiture, and $800 million in civil recoveries to federal and state governments under the False Claims Act. And just last week, Mylan Pharmaceuticals, Inc. paid $118 million to resolve allegations that it had sold innovator drugs that were manufactured by other companies and had classified those drugs as non-innovator drugs for Medicaid rebate purposes.

In addition to these matters, the Civil Division, as a part of our health care fraud enforcement efforts, investigates and pursues False Claims Act matters that are predicated on claims that doctors and others were paid kickbacks or other illegal remuneration to induce referrals of Medicare or Medicaid patients in violation of the Physician Self-Referral laws, commonly referred to as the "Stark" laws, the Anti-kickback Statute, and the civil monetary penalties statute. These statutes have been extremely important in protecting the integrity of our health care system and have proven useful in going after fraudsters.

Another way the Civil Division fights health care fraud is through the criminal prosecutions by the Office of Consumer Litigation (OCL). OCL, under the statutory authority of the Federal Food, Drug and Cosmetic Act, investigates and prosecutes drug and device manufacturers and responsible individuals believed to be illegally promoting and distributing misbranded and adulterated drugs or devices. Unlawful conduct by pharmaceutical and device manufacturers subverts our healthcare system which relies on the sound medical judgment of practitioners, and puts patients at risk. OCL works with the United States Attorneys on these complex criminal matters in conjunction with law enforcement agencies like the Federal Bureau of Investigation, the Department of Health and Human Services Office of Inspector General and the Food and Drug Administration's Office of Criminal Investigations.

Finally, the Civil Division houses the Elder Justice and Nursing Home Initiative to coordinate and support law enforcement efforts to combat elder abuse, neglect and financial exploitation of this population. Too often, our most vulnerable citizens are the ones that are

taken advantage of, so special attention is needed to prevent and prosecute these crimes. Each year Medicare and Medicaid spend over $120 billion on long-term care services, including nursing homes. At the same time, research shows that 11 percent of our seniors report experiencing at least one form of abuse, neglect, or exploitation. The Department created the Elder Justice and Nursing Home Initiative to focus on preventing this abuse and protecting our seniors. The Initiative has invested significant dollars to study elder abuse risk factors so that we can develop systems to prevent abuse before it occurs.

But when abuse and/or neglect does occur, the Elder Initiative coordinates the Department's litigation against long-term care providers, including nursing homes that fail to provide the quality of care to which our Medicare and Medicaid beneficiaries are entitled. Over the years, the Department, through the Elder Initiative, has worked with the HHS Inspector General and his office to recover fraudulently received money from long-term care facilities and to force these nursing homes to improve the care they provide to their residents.

The Department recognizes that the face of health care fraud is ever-changing and that it is therefore critical for law enforcement to be properly trained to identify, investigate, and prosecute the fraud. To accomplish this, the Department provides substantial training to its attorneys and agents and it includes all our law enforcement partners in those efforts. The Civil Division provides specific training and guidance in connection with pharmaceutical and device fraud matters. Given the nationwide scope of the defendants' conduct, as well as the complex legal and factual issues raised in these cases, the Civil Division plays a critical role in coordinating extensive trainings for representatives of various federal and state enforcement and regulatory agencies.

CRIMINAL DIVISION'S ENFORCEMENT EFFORTS IN FIGHTING FRAUD, WASTE AND ABUSE

The Department of Justice's efforts to fight health care fraud have succeeded in part because of strategic thinking about how to respond to this growing problem. The Medicare Fraud Strike Force (Strike Force) – launched in 2007 – is a recent example of the Department's latest strategic thinking about how to further combat health care fraud.

The Strike Force's mission is to supplement the criminal health care fraud enforcement activities of the United States Attorneys' Offices by targeting emerging or migrating schemes along with chronic fraud by criminals operating as health care providers or suppliers. The Strike Force is now operating in South Florida, Los Angeles, Detroit, and Houston, and is the perfect example of how federal, state, and local law enforcement working together can strike back against crime in our communities. The Strike Force analyzes Medicare data to identify hot spots of unexplained high-billing levels in concentrated areas. Teams of federal, state, and local investigators then work together to investigate fraudulent activity, and where appropriate, to bring criminal and civil cases against the most serious perpetrators. Our goal is to bring these cases as quickly and responsibly as possible once the fraud is identified to assure that viral fraud schemes do not spread between regions within our country.

The Criminal Division and the United States Attorney's Office for the Southern District of Florida launched the Strike Force in Miami to target durable medical equipment (DME) and HIV infusion fraud in March 2007. In March 2008, the Criminal Division expanded the Strike Force to a second phase, partnering with the United States Attorney's Office for the Central District of California and HHS to combat DME fraud in the Los Angeles metropolitan area. The Strike Force model for criminal health care fraud prosecutions has now become a permanent component of the United States Attorneys' Office in both the Southern District of Florida and the Central District of California.

We have already seen significant success since the Strike Force was expanded in May in connection with the HEAT initiative. In addition to the Detroit indictments described above that were announced in June, on July 29, the Department and United States Attorney's Office for the Southern District of Texas announced 32 people were indicted in Houston for schemes to submit more than $16 million in false Medicare claims for durable medical equipment involving "arthritis kits," power wheelchairs and enteral feeding supplies. According to the indictments, the defendants, which include physicians, company owners and executives, are charged with participating in a scheme to submit claims for products that were medically unnecessary and oftentimes, never provided. In some cases, indictments allege that beneficiaries were deceased at the time they allegedly received the items.

On October 21, the Department and United States Attorney's Office for the Central District of California announced indictments of another twenty defendants, most of them residing in the Los Angeles area, who are charged in seven cases for allegedly participating in Medicare fraud schemes that resulted in more than $26 million in fraudulent bills to the Medicare program. The charging documents outline criminal schemes involving the fraudulent ordering of power wheelchairs, orthotics (devices designed to assist with orthopedic problems) and hospital beds.

Since its inception over two years ago through the end of fiscal year 2009, the Strike Forcehas:

- filed 130 cases charging 313 defendants who collectively billed the Medicare program more than $690 million dollars;
- taken 149 guilty pleas;
- handled 15 jury trials resulting in convictions of 21 defendants. [1]

The Strike Force also has the potential to have a powerful deterrent effect. Strike Force operations in the Miami area contributed to estimated reductions of $1.75 billion in durable medical equipment (DME) claim submissions and $334 million in DME claims paid by Medicare over the 12 months following the Strike Force's inception, compared to the preceding 12-month period.

[1] These figures exclude recent health care fraud prosecutions initiated by the Southern District of Florida and Central District of California since the Strike Force model for criminal health care fraud prosecutions became a permanent component of each office. The Department is working to develop a comprehensive Strike Force prosecution tracking system that will capture and track all DOJ Criminal Division initiated cases and USAO follow-on litigation under the auspices of the Strike Force and Health Care Prevention and Enforcement Action Team (HEAT) Initiative.

As the Attorney General stated, "The Department believes that a targeted civil and criminal enforcement strategy in key geographic locations will have a substantial impact on deterring fraud and abuse, protecting patients and the elderly from scams, and ensuring that taxpayer funds are simply not stolen."

The Strike Force is just one tool designed to fight the most aggressive criminal schemes. We maintain 93 United States Attorney's Offices throughout the nation with criminal and civil prosecutors who work on health care fraud cases along with attorneys in the Department's Criminal, Civil and Civil Rights Divisions, and are aided significantly by FBI field offices around the country.

UNITED STATES ATTORNEYS' ENFORCEMENT EFFORTS

The 93 United States Attorney's Offices are an integral part of our commitment to go after health care fraud wherever it occurs. Each district has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator. The U.S. Attorneys' Offices play a major role in health care fraud enforcement by bringing affirmative civil cases with our colleagues in the Civil Division, and criminal cases to recover funds wrongfully taken from the Medicare Trust Fund and other taxpayer-funded health care systems as a result of fraud. Civil and criminal AUSAs litigate a wide variety of health care fraud matters including false billings by doctors and other providers of medical services, overcharges by hospitals, Medicaid fraud, kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical companies, and failure of care allegations against nursing home owners. The USAOs have partnered with the Civil Division in the landmark Eli Lilly and Pfizer, Inc. global settlements resulting in multi-billion dollar recoveries detailed above. Other notable health care fraud successes of U.S. Attorneys' Offices include:

- In the Northern District of Illinois, ten people were charged and convicted with a health care fraud scheme that affected thousands of patients and victimized numerous health care plans. The defendants were paid approximately $2.6 million by insurers based on fraudulent claims. Nine of the defendants pled guilty. The one defendant, a doctor, who went to trial, was convicted. The leader of the scheme, John Froelich, who was a nurse, was sentenced to 9 years incarceration.

- In the Eastern District of New York, Quest Diagnostics Incorporated ("Quest") and its subsidiary, Nichols Institute Diagnostics ("NID"), entered into a global settlement with the United States to resolve criminal and civil claims concerning various types of diagnostic test kits that the company manufactured, marketed and sold to laboratories throughout the country that allegedly provided inaccurate and unreliable results. The global resolution of $302 million was one of the largest recoveries ever in a case involving a medical device.

- In the Central District of California, a former anesthesiologist and pain management specialist pled guilty to criminal conspiracy and health care fraud for allowing his

Medicare provider numbers to be used to bill the Medicare program for fraudulent respiratory treatments. The defendant entered into a $2.1 million civil settlement in resolution of these allegations, and he is barred from participating in the Medicare program for 15 years.

The U.S. Attorneys' Offices are assisted in their efforts through Health Care Fraud and Abuse Control allocations (HCFAC). The funding supports attorneys, paralegals, auditors and investigators, as well as litigation of resource-intensive health care fraud cases. HCFAC funding is supplemented by Executive Office of U.S. Attorneys discretionary appropriations. IN FY 2009, EOUSA allocated $36.2 million in discretionary funds to target health care fraud. In FY 2008, it allocated $24.5 discretionary dollars to that effort.

The Executive Office for United States Attorneys' Office of Legal Education (OLE) also recognizes the importance of the continuing education of AUSAs and other DOJ attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In 2009, OLE offered a Health Care Fraud Seminar for AUSAs and DOJ attorneys, which was attended by over 100 attorneys, and offered an Affirmative Civil Enforcement Conference, which include health care fraud issues, for paralegals, auditors, and investigators.

FBI'S HEALTH CARE FRAUD INVESTIGATIONS

Health care fraud investigations are among the highest priority investigations within the FBI's White Collar Crime Program, along with Public Corruption and Corporate Fraud. Through national initiatives focusing on Internet pharmacy, durable medical equipment, and infusion therapy fraud, the FBI is utilizing sophisticated investigative techniques—from undercover operations to wiretaps—not only to collect evidence for prosecution, but also to find and stop criminals before they take action.

The FBI is actively pursuing health care fraud in every region. It has task forces and working groups to address health care fraud in every one of its 56 field offices, and it is shifting resources to regions where increased fraud trends are detected. FBI's field office-level task forces and working groups are comprised of HHS-OIG, U.S. Attorneys' Offices, state and local law enforcement agencies and, in many districts, private insurance company special investigative units and Medicare contractors that refer suspected fraud activity that is investigated jointly by the law enforcement agencies that are involved in the task force or working group. These task forces and working groups, which meet regularly, provide a structure to address the unique health care fraud in each region.

The FBI's Headquarters-based Health Care Fraud Program supports these field offices and serves as a veritable fusion center, sharing information on inter-region trends and providing training to include lessons learned and best practices.

In the past few years, the number of pending FBI health care fraud investigations have steadily increased. In FY 2008, alone, FBI-led investigations resulted in over 800 indictments and informations, and nearly 700 convictions, for health care fraud in federal and state courts

collectively. In FY 2009, the FBI recorded over 840 indictments and informations, and 555 convictions for health care fraud.

In late July, working in concert with our partners, the FBI arrested more than 30 suspects in a major Medicare anti-fraud operation that spanned the country. In New York, Louisiana, Boston, and Houston, more than 200 agents worked on a $16 million fraud that ensnared several physicians. In short, the FBI and its partners are uniquely positioned to combat this particular crime problem every step of the way.

CIVIL RIGHTS DIVISION'S WORK TO FIGHT FRAUD, WASTE AND ABUSE

The Civil Rights Division plays a critical role in the Department's protection of the nation's health care system. The Special Litigation Section of the Civil Rights Division is the Department component responsible for the Civil Rights of Institutionalized Persons Act (CRIPA) and its role is to ensure that the civil rights of residents in public, state or locally-run, institutions (including facilities for persons with developmental disabilities or mental illness, and nursing homes) are fully protected. CRIPA authorizes the Department to seek injunctive relief to remedy a pattern or practice of violations of the Constitutional or federal statutory rights possessed by residents in such facilities. The review of conditions in facilities for persons who have mental illness, facilities for persons with developmental disabilities, and nursing homes comprises a significant portion of the program.

The Americans with Disabilities Act requires that services be provided to residents of such facilities in the most integrated setting appropriate to their needs. It is through that prism that the Department's Civil Rights Division evaluates residential placements in each of its investigations under CRIPA and seeks to eliminate the unjustified institutional isolation of persons with disabilities. The Department recognizes that unnecessary institutionalization is discrimination that diminishes individuals' ability to lead full and independent lives and, as a result, our CRIPA enforcement activities have enabled thousands of unnecessarily institutionalized individuals to live safely in the community with adequate supports and services.

As part of the Department's Institutional Health Care Abuse and Neglect Initiative, the Civil Rights Division conducts reviews of conditions in health care facilities. In FY2009, it pursued 19 CRIPA investigations regarding conditions in 23 healthcare public facilities. Also in FY 2009, the Division addressed conditions and practices at 13 state facilities for persons with intellectual and developmental disabilities, eight state facilities for persons with mental illness, and three state operated nursing homes. The Division entered five settlement agreements regarding these 24 facilities. The Division was unable to settle one case involving a facility for persons with developmental disabilities, and that case is currently in contested litigation.

CRIPA investigations require cooperation of jurisdictions to allow investigators access to facilities under investigation or to produce requested documents. Absent this cooperation, it is difficult for the Department to gain sufficient information to make the requisite findings to initiate litigation.

CONCLUSION: LOOKING FORWARD

We hope you will look at the Department's successes thus far in combating waste, fraud and abuse and recognize the role we can continue to play, with the help of our federal and state government partners, in protecting both taxpayers' funds and patient safety. As we have seen time and time again, the only way we can be truly effective in protecting the integrity of our public health programs is by combining the full panoply of our federal resources, our expertise, and our information across agency and jurisdictional lines. The Department of Justice looks forward to working with Congress as we continue to prevent, deter, and prosecute health care fraud.