Department of Justice

STATEMENT

OF

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BEFORE THE

SUBCOMMITTEE ON HEALTH CARE, DISTRICT OF COLUMBIA, CENSUS AND THE NATIONAL ARCHIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM UNITED STATES HOUSE OF REPRESENTATIVES

ENTITLED

"WASTE, ABUSE, AND MISMANAGEMENT IN GOVERNMENT HEALTH CARE"

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Statement of Loretta E. Lynch United States Attorney Eastern District of New York

Before the

Subcommittee on Health Care, District of Columbia, Census and National Archives Committee on Oversight and Government Reform United States House of Representatives

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INTRODUCTION

Chairman Gowdy, Ranking Member Davis, and distinguished Members of the Subcommittee: Thank you for inviting me to speak with you today about the Department of Justice's efforts to combat health care fraud. I am honored to appear before you on behalf of the Department of Justice, along with my colleagues, Deborah Taylor, Peter Budetti, and Gerald Roy. The Department appreciates the opportunity to testify here today.

Health care fraud is a serious problem facing our country. It threatens the long term health of Medicare, as well as all federal, state and private health care programs. Every year the federal government spends hundreds of billions of dollars to provide health care to the most vulnerable of our society - our seniors, children, disabled individuals, and low-income individuals. We have a duty to ensure that these funds are spent on providing proper medical treatment to our citizens, and while most medical providers and health care companies are doing the right thing, there are some health care providers, as well as criminals, that target Medicare and other government and private health care programs for their own financial benefit. With the rising cost of medical care, every dollar stolen from our health care programs is one dollar too

many. Medicare and Medicaid fraud can also corrupt the medical decisions health care providers make with respect to their patients, placing them at risk of harm from unnecessary or unapproved treatments. For these reasons, fighting health care fraud is a priority of the Department of Justice. Through its United States Attorneys' Offices, Civil, Criminal and Civil Rights divisions and the Federal Bureau of Investigation (FBI) – the entities responsible for enforcing laws against all forms of health care fraud – the Department has enhanced its efforts to protect the public fisc from health care fraud and to help ensure the integrity of patient care.

FIGHTING MEDICARE AND MEDICAID FRAUD IS A PRIORITY OF THE DEPARTMENT OF JUSTICE

Because coordination across agencies is an integral part of preventing and prosecuting health care fraud, Attorney General Holder and Secretary Sebelius together have pledged to strengthen our fight against waste, fraud and abuse in Medicare and Medicaid. As you know, to improve that coordination, in May 2009, they announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) a senior level, joint task force, designed to marshal the combined resources of both agencies in new ways to combat all facets of the health care fraud problem. With the creation of HEAT, we re-committed to fighting health care fraud as a Cabinet- level priority for both DOJ and HHS, and our efforts have been extremely successful.

The Justice Department has a multi-faceted litigation approach to fighting health care fraud, with the U.S. Attorneys' Offices, FBI, Criminal, Civil, and Civil Rights Division, all contributing substantial resources to the effort. As you know, the United States Attorneys and their assistants, or AUSAs, are the principal prosecutors of federal crimes, including health care

fraud, representing the Department of Justice and the interests of the American taxpayer in both criminal and civil cases in the federal courts in the 94 judicial districts across the country.

U. S. ATTORNEYS' OFFICES' WORK WITH THE CIVIL DIVISION

The Department's civil attorneys – both in the United States Attorneys' Offices and the Department's Civil Division – aggressively pursue civil enforcement actions to root out fraud and recover funds stolen in health care fraud schemes, often through the use of the False Claims Act, 31 U.S.C. §§ 3729-3733, one of the Department's most powerful civil tools. Through its Office of Consumer Protection Litigation ("OCPL"), the Civil Division also invokes the Federal Food, Drug, and Cosmetic Act ("FDCA"), which authorizes both civil and criminal actions. OCPL pursues the unlawful marketing of drugs and medical devices, fraud on the Food andDrug Administration, and the distribution of adulterated products, among other violations. In FY 2010, OCPL's efforts yielded more than \$1.8 billion in criminal fines, forfeitures, restitution, and disgorgement, the largest health care-related one-year recovery under the FDCA in Department history. Since 2000, the U.S. Attorneys' Offices, working with our colleagues in the Civil Division, as well as with the FBI, HHS-OIG, and other federal, state and local law enforcement agencies, have recovered over \$1 billion every year on behalf of defrauded federal health care programs; in FY 2010 the Department secured approximately \$2.5 billion in civil health care fraud recoveries, more than in any other previous year.

The attorneys in my own district, the Eastern District of New York (EDNY), with our colleagues in the Civil Division, have handled a wide variety of health care matters, including false billings by doctors, and other providers of medical services, overcharges by hospitals, Medicaid fraud, kickbacks to induce referrals of Medicare and Medicaid patients, fraud by pharmaceutical and medical device companies, and failure of care allegations against nursing

home owners. The following are two significant EDNY civil/criminal global settlements that were national in scope:

• Quest Diagnostics Inc ("Quest")/Nichols Institute Diagnostics ("Nichols")

In April 2009, Quest and its subsidiary, Nichols, entered into a global settlement with the United States to resolve criminal and civil claims concerning various diagnostic test kits that Nichols manufactured, marketed and sold to laboratories throughout the country until 2006. The total payment of \$302 million to the United States represented one of the largest amounts ever recovered in a case involving a medical device.

As part of the criminal resolution, Nichols pled guilty to a felony misbranding charge in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. The charge related to the Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay (the "Intact PTH Assay"), which was used by laboratories throughout the country to measure parathyroid hormone levels ("PTH") in patients. In particular, this test was widely used by medical practitioners to determine if patients suffering from conditions such as End State Renal Disease were also suffering from hyperparathyroidism, a condition which involves the overactivity of the parathyroid glands and the release of excessive amounts of PTH. Common treatments for hyperparathyroidism include calcium and Vitamin D supplementation, and, under certain circumstances, the surgical removal of the parathyroid glands. As alleged in the Information that was filed in the criminal cases, there were periods of time in which the Intact PTH Assay provided elevated results of which the company was aware, but did not disclose or correct. As part of the criminal plea, Nichols paid a criminal fine of \$40 million.

Quest and Nichols also entered into a civil settlement agreement with the United States pursuant to which Quest paid \$262 million to resolve federal False Claims Act allegations relating to the Intact PTH assay and four other assays manufactured by Nichols. All of the assays allegedly provided inaccurate and unreliable results, thereby causing some clinical laboratories that purchased and used the Intact PTH and Bio-Intact PTH test kits to submit false claims for reimbursement to federal health programs, and some medical providers to submit false claims for reimbursement to federal health programs for unnecessary treatments.

• <u>Jazz Pharmaceutical, Inc. ("Jazz")/Orphan Medical, Inc. ("Orphan")</u>

In July 2007, Jazz and its subsidiary, Orphan, entered into a \$20 million global settlement with the United States to resolve criminal and civil claims concerning Orphan's allegedly illegal "off-label" marketing of the drug Xyrem for uses not approved by the FDA. The scheme allegedly induced physicians throughout the country to write prescriptions for Xyrem that were not reimbursable by private health insurers or public insurance programs like Medicare and Medicaid, and caused millions of dollars of losses to those insurers.

As part of the criminal resolution, Orphan pled guilty to felony misbranding in violation of the Federal Food, Drug and Cosmetic Act, 21, U.S.C. §§ 331(a) and 333(a)(2), and paid restitution as well as a criminal fine. Jazz and Orphan also entered into a civil settlement agreement resolving the United States' civil False Claims Act allegations stemming from the allegedly illegal marketing scheme.

I also want to highlight a significant EDNY civil settlement involving one of our local hospitals:

• Staten Island University Hospital ("SIUH")

In September 2008, the United States entered into a civil settlement with SIUH in which it paid the United States approximately \$74 million to settle allegations that it defrauded federally funded insurance programs such as Medicare. SIUH also agreed to pay the State of New York approximately \$14 million, representing damages sustained by the state's Medicaid program. The total recovery of over \$88 million is one of the largest civil fraud recoveries ever against a single U.S. hospital. The civil settlement resolved allegations of fraudulent billing for inpatient alcohol and substance abuse detoxification treatment, as well as the hospital's use of incorrect billing codes to obtain reimbursement for cancer treatment that was not covered by Medicare.

U.S. ATTORNEYS' OFFICES' WORK WITH THE CRIMINAL DIVISION

Working with our colleagues in the Criminal Division, our criminal health care fraud efforts have also been a tremendous success. In FY 2010, this Department wide coordination led to the largest number of criminal health care fraud convictions since the inception of the Health Care Fraud and Abuse Control Program (HCFAC) program. Today our criminal enforcement efforts are at an all time high. In FY 2010, the Department brought criminal charges against 931 defendants, 16 percent more than in FY 2009. Moreover, we secured 726 criminal health care fraud convictions, approximately 24 percent more than in FY 2009. In total, last fiscal year the Justice Department opened 1,116 new criminal health care fraud investigations involving 2,095 potential defendants.

The Medicare Fraud Strike Force, a supplement to the Department's criminal health care fraud enforcement efforts, is currently operating in nine districts - Miami, Los Angeles,

Houston, Detroit, Tampa, Baton Rouge, Chicago, Dallas, and my own district, Brooklyn. Each district has allocated several AUSAs and support personnel to this important initiative and partner with the Criminal Division attorneys, as well as agents from FBI, HHS, and state law enforcement. The Strike Force teams use data analysis techniques to identify aberrational billing patterns in Strike Force cities, permitting law enforcement to target emerging or migrating schemes, along with chronic fraud by criminals operating as health care providers or suppliers. Federal agents and analysts review Medicare data and other intelligence information to identify potential targets that may be billing for fictitious or medically unnecessary services.

The Strike Force initiative has been an unqualified success. In FY 2010, the Strike Forces secured 240 convictions (217 guilty pleas and 23 trial convictions), more than in any other year of Strike Force operations. One goal of the Strike Forces is to identify targets using the "data-driven" approach described above, and then bring those cases as expeditiously as possible. This model is working. Cases are initiated and brought to conclusion quickly, and defendants are going to prison. In FY 2010, the average amount of time from indictment to sentencing in Strike Force cases was approximately 9 months; more than 94 percent of Strike Force defendants were convicted; and over 86 percent were sentenced to prison terms. Since HEAT's inception, the average prison term for Strike Force defendants is over 40 months.

Just last month, Attorney General Holder and Secretary Sebelius announced that charges had recently been brought in all nine Strike Force cities against more than 110 defendants - including doctors, nurses, health care company owners and executives. Just this one group of cases reflected over \$225 million in fraudulent billings to the Medicare program. Typical Strike Force cases include schemes to submit claims to Medicare for treatments that were medically unnecessary or never provided; or allegations that patient recruiters, Medicare beneficiaries, and

other co-conspirators were paid cash kickbacks in return for supplying beneficiary information to providers so that those providers could submit false Medicare claims using the names of beneficiaries.

EDNY Strike Force criminal prosecutions cover a variety of health care fraud schemes, including kickbacks to patients. The principal focus of the Medicare Fraud Strike Force in Brooklyn has been to shut down medical clinics that pay cash kickbacks to dual Medicare-Medicaid beneficiaries to lure the beneficiaries to the clinics through the illegal use of transportation services reimbursed by Medicaid, and then illegally bill Medicare for services that were either medically unnecessary services or never provided. Three of the major prosecutions are:

Bay Medical

Nine individuals, including two physicians, were indicted for participating in a \$72 million conspiracy to defraud the Medicare program by submitting fraudulent claims for physical therapy and other medical services that were medically unnecessary or were not provided to beneficiaries at all. The government's investigation included the use of a court-ordered camera and microphone hidden in a room at the clinic, identified as the "Kickback Room," in which the conspirators paid cash kickbacks to corrupt Medicare beneficiaries. The camera recorded the conspirators' payment of approximately one thousand bribes totaling more than \$500,000 during a period of approximately six weeks from April to June 2010. The Kickback Room was marked "PRIVATE" and featured a poster depicting a woman with a finger to her lips and the words "Don't Gossip" in Russian. The purpose of the kickbacks was to induce the beneficiaries to receive unnecessary medical services or to remain silent when services not provided to the

patients were billed to Medicare. The conspirators obtained the money for the kickbacks by cashing checks drawn on clinic accounts that had been made payable to shell corporations.

• Prime Care

Seven individuals, including a physician, several medical clinic owners, and three ambulette drivers, were charged with conspiracy to commit health care fraud, health care fraud, and conspiracy to pay health care kickbacks in connection with a \$56.9 million scheme to defraud Medicare and Medicaid by submitting false and fraudulent claims for purported physical therapy services and diagnostic testing. Similar to the Bay Medical case, patients were paid kickbacks, but this time the payments were made in the ambulettes, as opposed to a dedicated room within the clinic.

• Solstice

Four individuals were charged with a health care fraud conspiracy that operated out of the Solstice Wellness Center, a Queens clinic that purported to specialize in providing physical therapy and various diagnostic tests. Executives of the clinic recruited Medicare beneficiaries by paying cash kickbacks to induce those beneficiaries to be transported to and from Solstice, and to purportedly receive physicians' services, physical therapy and diagnostic tests. Fraudulent claims were then submitted to Medicare for services that were not actually rendered and that were not medically necessary.

A second criminal scheme that has been a focus of EDNY Strike Force prosecutions involves the submission of fraudulent claims to Medicare or private insurance companies for durable medical equipment. Major cases include:

• Best Equipment

In July 2010, four individuals were arrested for their roles in a health care fraud conspiracy involving Best Equipment Medical Supply, Inc. in Brooklyn. Between 2006 and 2010, Best Equipment submitted to Medicare thousands of claims for orthopedic shoe inserts which patients were not eligible to receive. The investigation also revealed that the patients often did not receive the inserts at all and instead received ordinary shoes such as sneakers and sandals.

• O2 Home Services

Three individuals were charged for their involvement in a \$3.5 million scheme to defraud the Medicare and Medicaid programs by submitting fraudulent claims for durable medical equipment. One was the owner of an oxygen equipment services company, and the other two served as patient recruiters, who targeted local churches to find Medicare and Medicaid beneficiaries whose personal information the defendants would use for their fraudulent billings.

Finally, EDNY Strike Force investigations have focused on single doctor clinic fraud cases, including:

• Dr. Boris Sachakov

Sachakov, a proctologist, practiced at Colon and Rectal Care of New York, P.C. in Brooklyn. Sachakov was charged with health care fraud in connection with a two-year scheme from January 2008 through January 2010 to defraud Medicare and numerous private health care benefit programs of approximately \$22.5 million. Sachakov accomplished his fraudulent scheme in two ways. First, he billed for surgeries and other procedures that he never performed. Second, he improperly billed for various surgical

procedures separately that should have been billed together as part of the same surgical package. For the two-year period charged in the indictment, his total billings amounted to approximately \$22.5 million: approximately \$6,578,346 in claims to Medicare (approximately \$4,465,003 of which were paid); and \$16,008,850 in claims to private benefit programs (approximately \$5,883,171 of which were paid.)

CIVIL RIGHTS DIVISION

The Civil Rights Division also plays an important role in the Department's efforts to protect the nation's health care system. The Special Litigation Section of the Civil Rights

Division is responsible for enforcing the Civil Rights of Institutionalized Persons Act

("CRIPA"), 42 U.S.C. § 1997, et seq. CRIPA authorizes the investigation of conditions of

confinement at state and local residential institutions and the initiation of civil actions for

injunctive relief to remedy a pattern or practice of Constitutional or federal statutory violations at

such institutions. The Affordable Care Act confers new subpoena power on the Attorney

General to demand records and access to institutions when investigating claims under CRIPA,

greatly assisting the Department in these important investigations of conditions that jeopardize

the safety and welfare of some of our most vulnerable citizens.

FEDERAL BUREAU OF INVESTIGATION

The Justice Department's primary investigative and enforcement arm is the Federal Bureau of Investigation (FBI). Working closely with U.S. Attorneys' Offices and DOJ litigating components throughout the United States, the FBI serves to identify, investigate, and aid in the prosecution of health care fraud. With its large presence and extensive investigative authority, the FBI is uniquely positioned to investigate a broad spectrum of health care fraud activity.

First, by leveraging its 750 FBI personnel dedicated solely to health care fraud investigations, the FBI is able to aggressively address fraud not only in Strike Force locations, but also in any of the more than 450 locations where the FBI has investigative personnel stationed. Second, the FBI is the primary investigative agency involved in the fight against health care fraud that has jurisdiction over both the federal and private health care programs. The FBI not only collaborates with HHS-OIG investigative personnel and other government agencies, but has built established partnerships with Special Investigative Units from all of the country's major private insurance companies. Third, the FBI leverages its intelligence across its multiple investigative programs to identify and attack criminal enterprises that are turning to health care fraud as a mechanism to fund additional criminal activity.

Some of the FBI's recent successes include:

- In October 2010, in response to the growing threat posed to the health care system by organized crime groups, the FBI and HHS-OIG indicted 73 subjects, who operated over 160 clinics throughout the U.S. Fraudulent billings attributed to these groups exceeded \$168 million.
- In January 2011, the FBI and the United States Attorney's Office for the District of Puerto Rico indicted 533 individuals in a scheme which defrauded a major private insurance company out millions of dollars.
- In February 2011, the Medicare Fraud Strike Force in Miami charged more than 20 employees of American Therapeutic Corporation (ATC) in a scheme involving more than \$200 million in fraudulent billings to Medicare. This indictment was a precursor to the more than 110 health care fraud subjects that were indicted as part of Nationwide Strike Force Takedown two days after the ATC announcement.

The FBI is a key component of the Justice Department's efforts against health care fraud and is a vital piece in the increasing return on investment to the Medicare Trust Fund.

CONCLUSION

Coordination of our health care fraud enforcement resources works. AUSAs in the U.S. Attorneys' Offices, trial attorneys in the Civil and Criminal Divisions, FBI and HHS agents, as well as other federal, state and local law enforcement partners are working together across the country with great success. With the passage of the Health Insurance Portability and Accountability Act of 1996, Congress created the HCFAC Program under the joint direction of the Justice Department and HHS to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. Since the HCFAC Program was established, working together, the two Departments have returned more than \$21.3 billion to the federal government, of which over \$18 billion has been returned to the Medicare Trust Funds. Over the life of the HCFAC Program, this amounts to an average return on investment ("ROI") of \$4.90 for every \$1.00 expended. Through our enhanced efforts over the past three years, the average ROI has been even higher. As reported in the HCFAC Program's annual report for FY 2010, the average ROI for the period 2008-2010 was \$6.80 for every \$1.00 expended, nearly \$2.00 higher than the historical average. We are poised to continue these successes in the months and years ahead, and look forward to working with our federal, state and local partners to that end.

Thank you for the opportunity to provide this overview of the Department's health care fraud enforcement efforts.