



Department of Justice

STATEMENT OF
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INTRODUCTION

Chairman Obey, Ranking Member Tiahrt, and Members of the Subcommittee, thank you for inviting me here today to testify about the Administration's Fiscal Year 2011 Budget request to support the joint efforts of the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) to fight and deter health care fraud. Under the leadership of the Attorney General, I supervise the Department of Justice'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 our partners at HHS.

We have a paramount duty to the taxpayers to ensure that health care dollars are not stolen through fraud. 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 billions of dollars that could be spent on patient care.

It is those wrongdoers who we must stop. We have a duty to our citizens who receive treatment paid for by Medicare, Medicaid, and other government programs to see to it that taxpayer funds are well spent and that beneficiaries are receiving proper medical care. 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 redoubled its efforts to protect the public and ensure the integrity of patient care.

Our coordinated law enforcement and litigation efforts have resulted in an impressive return on investment of \$4 per every dollar spent. In fact, we have returned at least \$13.1 billion to the Medicare Trust Fund since funding under Health Care Fraud Abuse and Control Program was established by the HIPAA statute in 1996. Just as important is the significant *deterrent* effect that our enforcement efforts have had. For example, 12 months after we launched a Medicare Fraud Strike Force operation in the Miami area in 2007 – our very first Strike Force operation – there was an estimated reduction of \$1.75 billion in durable medical equipment (DME) claim submissions and a reduction of \$334 million in DME claims paid by Medicare compared to the preceding 12-month period. The Strike Force's success translates into real dollars that can be used to pay for legitimate and desperately needed medical treatment for thousands of Americans.

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

At the recent National Summit on Health Care Fraud, experts in both the public and private sectors concluded that a reliable measurement of fraud did not exist, and there was no evidence that fraud in Medicare and Medicaid was greater than that among private insurers. However, we believe health care fraud in this country constitutes billions of dollars in losses to taxpayers and private industry, that it drives up the cost of health care, and requires an urgent response from every level of government and the private sector. 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, Attorney General Holder and Secretary Sebelius together have pledged to fight waste, fraud and abuse in Medicare and Medicaid. 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, which I oversee along with my HHS counterpart, Deputy Secretary of HHS William Corr – that is 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 the HEAT team, we recommitted to making fighting Medicare and Medicaid fraud a Cabinet-level priority for both DOJ and HHS.

The goals of the HEAT initiative are clear:

- 1) To prevent and detect fraud through increased prepayment reviews and audits; site visits to providers; more effective anti-fraud edits; real-time sharing of claims data; new data mining techniques; and expanded use of suspension and debarment authorities;
- 2) To strengthen enforcement efforts through expansion of the Medicare Fraud Strike Force teams; increased investigative and prosecutorial resources for institutional health care fraud cases; using cutting-edge technology and data analysis to better target and accelerate enforcement actions; expanded capacity for False Claims Act, Food, Drug & Cosmetic Act, and Anti-Kickback cases; and increased enforcement of emerging fraud schemes, such as pharmaceutical, device, home health, and durable medical equipment cases;
- 3) To leverage partnerships through private sector outreach, better coordination with State and local anti-fraud efforts; and provider and beneficiary education on health care fraud; and

- 4) To provide more effective legal authorities by identifying and eliminating statutory and regulatory impediments to our health care fraud prevention and enforcement efforts.

We have had some remarkable successes thus far. The Department of Justice believes that a targeted data-driven criminal enforcement strategy in key geographic locations has a substantial impact on deterring fraud and abuse, protecting patients and the elderly from scams, and ensuring that those who steal taxpayer funds are held accountable. Based on the success of our Medicare Fraud Strike Force model, we expanded Strike Force operations last summer from two to four cities, and in December we added three more cities. Strike Forces are now operating in seven locations: South Florida, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge and Tampa. These expanded efforts have already produced substantial results, including several takedowns of numerous health care fraud perpetrators which I will discuss in more detail later in my testimony. In total, since the announcement of the HEAT Initiative last May, Strike Force prosecutors have filed over 60 cases charging more than 200 defendants, negotiated more than 50 guilty pleas, and litigated six jury trials obtaining convictions of six defendants. Also, during Fiscal Year 2009, federal prosecutors in districts throughout the country filed criminal charges in 481 health care fraud cases involving charges against 803 defendants and obtained 583 convictions for health care fraud offenses. In addition, they opened 1014 new criminal health care fraud investigations involving 1786 subjects.

The HEAT initiative also has an important civil fraud enforcement component. In FY 2009, False Claims Act health care recoveries exceeded \$1.6 billion, the eighth year that the Department obtained in excess of \$1 billion in civil health care fraud recoveries. During that same time period, the Department opened 886 new civil health care fraud matters and filed complaints in 283 civil health care fraud cases. Last fall, 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.

In addition to our litigation and prosecution efforts, 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. And on January 28, 2010, in an effort to enhance public-private partnerships, we hosted a National Health Care Fraud Summit that brought together Federal and State policy officials, private sector leaders including insurance companies and providers, law enforcement, beneficiary advocates, and other key stakeholders.

While the HEAT Initiative is new, the collaborative efforts between the DOJ and the HHS are not. In 1997, Congress established the Health Care Fraud and Abuse Control (HCFAC) Program under the joint direction of the Attorney General and 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 HCFAC program, our Departments have returned more than \$15 billion to the Federal government, with \$13.1 billion of that amount being returned to the Medicare Trust Fund and the remaining amounts primarily being returned to federal agencies in the form of restitution and compensatory damages. These efforts have resulted in more than 5600 criminal convictions for health care fraud offenses.

The litigating components of DOJ, as well as the FBI, are actively engaged in investigating and litigating a wide range of civil and criminal health care fraud cases involving public and private plans, and we work closely with HHS, other federal agencies, as well as state agencies and private insurers.

In addition, the President has recently released a health insurance reform proposal that builds on provisions proposed by the House and the Senate health reform bills, as well as Republican bills, to crack down on fraud, waste, and abuse. These efforts include further authorities and initiatives at CMS and other federal agencies to provide proper oversight of Medicare. For example, the President's Proposal speeds access to claims data to identify potentially fraudulent payments more quickly. It also establishes a system for using technology to provide real-time data analysis of claims and payments under public programs to identify and stop fraud, waste, and abuse, among other efforts. It assists in reducing the number of individuals and agencies participating in Federal health programs who have a history of fraudulent activities. It improves coordination and information sharing in anti-fraud efforts. The Proposal would also expand the use of the Recovery Audit Contractors (RACs) to the Part D program to increase scrutiny over MA and Part D prescription drug plans by having them audit anti-fraud plans, audit reinsurance payments, and review member enrollment data submitted to CMS. It would also give CMS needed authority to deny plan bids to provide better plan choices to beneficiaries. If adopted, we anticipate these efforts will improve our enforcement efforts and stand ready to work with Congress to implement health insurance reform legislation.

FISCAL YEAR 2011 BUDGETARY RESOURCES

In Fiscal Year 2011, the President's Budget request includes an increase of \$60 million in discretionary HCFAC resources for DOJ, bringing the total FY 2011 discretionary request for DOJ to \$90 million. In addition to these discretionary resources, the Department also receives mandatory funding for HCFAC purposes, although these mandatory resources will not increase in FY 2011. One goal of DOJ is to increase the number of Strike Forces, and part of the additional \$60 million in discretionary funding that has been requested will be used, among other things, to expand the current number of Strike Forces from 7 to as many as 20 locations throughout the Nation. New Strike Force locations are chosen based on thorough analysis of Medicare claims data, which helps us identify hot spots of unexplained high-billing levels in concentrated areas, and a review of the most effective allocation of investigative and prosecutorial resources. The cost associated with Strike Forces expansion resulting in 20 locations by end-of-year FY 2011 is an estimated \$46 million. In addition to the Strike Forces, these additional discretionary dollars will expand DOJ's capacity to handle and expedite

resolution of civil False Claims Act, including failure of care cases; Food, Drug, and Cosmetic Act; and Anti-Kickback Act cases; as well as enable the Department to improve infrastructure for increased data sharing and analysis as part of the Strike Force teams and other criminal and civil enforcement, enhance Automated Litigation Support to expedite case development; and increase the recovery of assets for restitution and forfeiture. In addition, new HEAT-related initiatives may be considered to address emerging health care fraud schemes.

The Department of Justice's largest expenditure of health care fraud enforcement funding is on our people. The expertise and commitment of our litigators, prosecutors, Strike Force team members, law enforcement agents, and investigators are the reasons DOJ's health care fraud strategies are so successful. The majority of discretionary HCFAC funding is spent on personnel costs. Because most of DOJ's FY 2011 enforcement activities rely on the hiring of additional personnel, ensuring that those resources continue to be provided in the outyears is DOJ's top priority as it relates to funding for health care fraud. Our ability to effectively investigate and prosecute health care fraud is directly related to our ability to retain personnel from year-to-year.

CRIMINAL DIVISION'S EFFORTS TO FIGHT HEALTH CARE FRAUD 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 by the Criminal Division in collaboration with the United States Attorneys Offices (USAOs) and HHS in 2007 – is an example of the Department's recent strategic thinking about how to bolster our efforts to combat health care fraud.

The Strike Force's mission is to supplement the criminal health care fraud enforcement activities that are ongoing in each of the USAOs by targeting 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 then gather and develop additional investigative intelligence to identify potential targets who are operating as health care providers or suppliers and may be billing for totally fictitious or medically unnecessary services.

Technology is enabling Strike Force investigators to expedite cases and identify patterns of fraud. That said, there is more that needs to be done and a key focus of the HEAT initiative is to make sure that investigators and prosecutors are getting real-time access to claims data in a useable format so that we can develop these cases quickly and effectively.

Typically in each Strike Force city, three to five teams of federal, state, and local investigators, work under the guidance of Criminal Division prosecutors and Assistant United States Attorneys to investigate fraudulent activity and, where appropriate, bring criminal and civil cases against the most serious perpetrators, although Miami has had as many as eight teams. 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 Strike Force was first launched in Miami to target durable medical equipment (DME) and HIV infusion fraud in March 2007. In March 2008, we 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. In May 2009, we expanded the Strike Force to Houston and Detroit, and in December of last year we added three more cities – Brooklyn, Tampa, and Baton Rouge – bringing the total number of Strike Force locations to seven.

The Strike Force has proven to be extremely cost-effective and efficient. We have obtained a significant number of indictments with a modest annual investment in the Criminal Division and the U.S. Attorneys for these efforts, and the Strike Force cases proceed expeditiously. After developing evidence to support arrests of individual targets and suspects, court processing of Strike Force cases from indictment to disposition and sentencing can occur within a matter of months. While variations in case processing time occur from district to district, the median time from indictment to sentencing for more than 200 defendants sentenced in Miami Strike Force cases to date has been about six months. Strike Force defendants are also more likely to receive prison sentences and longer terms of imprisonment than more traditional criminal health care fraud defendants. During the three fiscal years since the Strike Force's inception, over 94 percent of all Strike Force defendants were convicted and sentenced to terms of imprisonment compared to 64 percent of all criminal health care fraud defendants. The average prison term for Strike Force defendants was 45 months, which was about 10 percent longer than the overall national average for federal health care fraud defendants over this same period.

The HEAT Initiative has produced significant enforcement results since last May following our expansion of Strike Force locations and the scope of targeted schemes to include fraudulent physical and occupational therapy clinics, home health agencies, and enteral nutrition and feeding supplies, in addition to DME and HIV infusion:

- 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.
- On June 26, 2009, the Criminal Division and United States Attorney's Office for the Southern District of Florida indicted eight Miami-area residents in connection with a \$22 million scheme to submit false claims to Medicare from two fraudulent providers for purported home health services.
- On July 29, 2009, the Criminal Division and United States Attorney's Office for the Southern District of Texas announced the unsealing of seven indictments charging 32 people in schemes involving false billing for "arthritis kits," which consist of sets of orthotic braces that are purportedly used for the treatment of arthritis-related conditions, power wheelchairs and enteral feeding supplies to defraud Medicare of more than \$16 million in the Houston metropolitan areas.
- On October 21, 2009, Strike Force prosecutors in the Central District of California announced arrests of 20 defendants, most of them residing in the Los Angeles area, for participating in Medicare fraud schemes that resulted in more than \$26 million in

fraudulent billings to the Medicare program. The same day, Houston Strike Force prosecutors announced charges against six additional defendants in a new case and a superseding indictment involving fraudulent billings for “arthritis kits.”

- On December 15, 2009, the Departments of Justice and HHS announced indictments of another 30 individuals charged by Strike Force prosecutors in Miami, Detroit, and Brooklyn with submitting more than \$61 million in fraudulent billings to Medicare for various schemes involving unnecessary medical tests, durable medical equipment, home health services, and injection and infusion treatments. DOJ and HHS also announced plans to expand Strike Force operations to the Eastern District of New York, Middle District of Louisiana, and Middle District of Florida.
- On January 14, 2010, 13 defendants were indicted in Detroit for a home health care scheme to defraud the Medicare program of more than \$14.5 million.

Typically, defendants in Strike Force indictments include physicians, nurses and other medical professionals, along with DME company or medical clinic owners, executives and/or employees, who are charged with participating in schemes to submit claims for services or products that were medically unnecessary and oftentimes, never provided. In many if not most cases, defendants paid kickbacks to medical professionals and beneficiaries for use of their Medicare information to support fictitious claims for items or services that were never provided. In other cases, defendants have been charged with aggravated identity theft for stealing physician or beneficiary information to support fraudulent claims. In some cases, indictments allege that beneficiaries were deceased at the time they allegedly received the items or services. Finally, a few cases have involved actions which put patients at risk of harm or injury by subjecting them to infusion or injection treatments that they did not need.

In addition to providing a leadership role in launching new Strike Force teams and training investigative agents and prosecutors, Criminal Division attorneys have litigated 17 of 20 trials in Strike Force cases located in four districts, obtaining guilty verdicts against 23 defendants over the past three years.¹

Since its inception nearly three years ago, Strike Force prosecutors from the Criminal Division and USAOs together have:

- filed more than 250 cases charging over 500 defendants who collectively billed the Medicare program more than one billion dollars;
- taken more than 260 guilty pleas;
- litigated 20 jury trials resulting in convictions of 25 defendants and only five acquittals;
- obtained sentences to imprisonment for 94% of defendants convicted; and
- imprisoned defendants received an average sentence of 45 months.

¹ Assistant United States Attorneys and HHS Office of Inspector General attorneys detailed to the Strike Force have assisted in several of these trials. AUSAs in the Central District of California and Southern District of Florida have litigated the other three jury trials in Strike Force cases, to date.

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.

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. 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 \$24 billion on behalf of the various victim federal agencies. Of that amount, \$15.9 billion was the result of fraud against federal health care programs – primarily the Medicare program.

The Department's settlement with Pfizer, Inc., which was agreed to in 2009, was historic. In that matter, Pfizer paid \$2.3 billion 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. The company paid a criminal fine of \$1.195 billion, the largest criminal fine ever imposed in the United States. Pharmacia & Upjohn also forfeited \$105 million, for a total criminal resolution of \$1.3 billion. Further, Pfizer paid \$1 billion to resolve allegations under the federal and state civil False Claims Acts 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 was \$668.5 million and the state Medicaid share of the civil settlement was \$331.5 million.

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. For example, in January of this year, DOJ secured a \$10 million consent judgment against two former hospital executives of City of Angels Hospital in Los Angeles who scammed our Medicare system by preying upon homeless people. In that case, the two hospital executives paid kickbacks to recruiters employed

at homeless shelters in order to deliver homeless clients to the hospital for medical services, many of which were medically unnecessary.

The insidious effect of kickbacks permeates almost every corner of the health care system, including nursing homes. In January, DOJ filed a civil False Claims Act complaint against drug manufacturer Johnson & Johnson (J&J), and two of its subsidiaries, for paying millions of dollars in kickbacks to Omnicare, Inc. ("Omnicare"), the nation's largest provider of institutional pharmacy services. In that lawsuit, the United States alleges that J&J paid kickbacks to Omnicare to induce Omnicare to purchase and to recommend J&J drugs, including the antipsychotic drug Risperdal, for use in nursing homes.

The civil enforcement efforts by the Department of Justice also focus on cases addressing substandard care delivered to federally insured beneficiaries. The most notable example is the recent \$24 million recovery from FORBA, Inc., a dental management company that operates a nationwide chain of pediatric dental clinics known as Small Smiles. The government alleged that the clinics often performed unnecessary and painful dental procedures on their low-income pediatric patients in order to maximize Medicaid reimbursement. Investigations of the individual dentists are now ongoing.

Another way the Civil Division fights health care fraud is through the criminal prosecutions by the Office of Consumer Litigation (OCL). OCL prosecutes drug and device manufacturers and responsible individuals believed to be illegally promoting and distributing misbranded and adulterated drugs or devices in violation of the Federal Food, Drug and Cosmetic Act. Unlawful conduct by pharmaceutical and device manufacturers subverts our health care system which relies on the sound medical judgment of practitioners, and it puts patients at risk. OCL works with the United States Attorneys on these complex criminal matters in conjunction with law enforcement agencies, including the Federal Bureau of Investigation (FBI), HHS 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 victimized by fraud, neglect, and exploitation schemes, so special attention is needed to prevent and prosecute this misconduct. When abuse and/or neglect is detected, 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 and for which the government pays. 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.

For example, in January of this year, five Missouri nursing homes pled guilty to felony health care fraud related to their failure to provide adequate care to Medicare and Medicaid residents living in those homes. As part of the plea deal, the nursing homes admitted that at various times their staffing levels were insufficient to provide adequate nursing care, that they

failed to provide wound care, that their residents failed to received prescribed medications, that they falsified records to hide these failures, and that they submitted fraudulent claims to Medicare and Medicaid for services that were not provided or were worthless. As part of the global resolution, the defendants paid over \$1.6 million in criminal and civil fines and penalties

The Department recognizes that the face of health care fraud is ever-changing. As such, it is absolutely critical that the Department have the resources to keep apace with innovative or developing fraud trends, while at the same time, continuing to aggressively investigate and litigate our traditional health care fraud cases. As part of the HEAT initiative, we intend to devote additional resources to ensure that we adequately and expeditiously investigate these *qui tam* whistleblower cases and make the government's intervention decision as expeditiously as possible. These cases often allege extremely sophisticated fraud schemes that can only be ferreted out by teams of attorneys, auditors, investigators, and expert consultants. These cases require that we develop electronic databases in order to effectively contain and retrieve substantial documentary proof, that we retain top notch experts, and that we sufficiently staff these complex cases to counter the teams of attorneys we often face on the other side. The HCFAC funding requested in FY 2011, will permit the Department to expand its capacity--through additional attorneys, investigators, and litigation support—to more expeditiously move these cases already under investigation and to address those that continue to be filed each and every day. At the same time, we are mindful of the need to proactively attack new fraud schemes before they take root.

Likewise, the request will help insure that our personnel are properly trained to identify, investigate, and prosecute health care fraud. As new health care fraud schemes continually evolve, law enforcement cannot afford to fall behind. It is for that reason that the Department provides substantial training to its attorneys, agents, and our law enforcement partners in those efforts. For example, the Civil Division provides specific training and guidance in connection with the investigation and litigation of pharmaceutical and device fraud matters and it also has provided training through the auspices of the Executive Office of United States Attorneys (EOUSA) in multiple areas of expertise.

UNITED STATES ATTORNEYS' ENFORCEMENT EFFORTS

The 93 United States Attorneys and their AUSAs are the nation's principal prosecutors of federal crimes, including health care fraud. Each district has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator charged with overseeing the USAOs' commitment to fighting health care fraud wherever it occurs. The USAOs play a major role in this Department priority by investigating and litigating affirmative civil cases 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 investigate and litigate a wide variety of HCF 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 and medical device companies, and failure of care allegations against nursing home and mental health facility owners. The USAOs partner with the Civil Division in investigating and resolving significant cases, including the landmark Pfizer settlement, the FORBA recovery, the City of Angels resolution, and the

Omnicare litigation, as detailed above. In addition, the USAOs are partnering with the Criminal Division in the Medicare Fraud Strike Force Initiative.

Other notable health care fraud successes of U.S. Attorneys' Offices which illustrate the kinds of cases the USAOs handle across the nation include:

- In the Northern District of California, the former CEO of InterMune, Inc. was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of InterMune's Actimmune (Interferon gamma-1b) as a treatment for idiopathic pulmonary fibrosis ("IPF"). The CEO has not been sentenced yet, but faces a maximum sentence of 20 years.
- In the Southern District of Texas, a hospital group based in McAllen, Texas, has agreed to pay the United States \$27.5 million to settle claims that it violated the False Claims Act, the Anti-Kickback Statute and the Stark Statute between 1999 and 2006, by paying illegal compensation to doctors in order to induce them to refer patients to hospitals within the group.
- In the District of New Hampshire, four pharmaceutical companies, Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., AstraZeneca Pharmaceuticals LP, and OrthoMcNeil Pharmaceutical, Inc., entered into settlement agreements for a total of \$124 million to resolve claims that they violated the False Claims Act by failing to pay appropriate rebates to state Medicaid programs for drugs paid for by those programs.

In FY 2009, the USAOs received dedicated approximately \$75.4 million, including approximately \$42.8 million from the HCFAC allocation, to combat health care fraud. This funding supported attorneys, paralegals, auditors and investigators, as well as the litigation needs of resource-intensive health care fraud cases. In September 2009, utilizing discretionary HCFAC funding, EOUSA provided an additional 37 contract paralegals and data analysts to the USAOs, to support the existing MFSFs, as well as, the complex document intensive health care fraud investigations.

The increased HCFAC discretionary funding requested for FY 2011 is critical to the ability of the USAOs to continue providing attorney, paralegal, and data analyst resources to the existing and potential new Strike Force operations, as well as continue their efforts in investigating and litigating the more traditional, complex HCF cases including those involving pharmaceutical companies, medical device manufacturers, mental health facilities, nursing homes, hospitals and individual health care providers. The USAOs, working with their colleagues within the Department, have recovered more than \$4 billion in these complex health care fraud investigations since January 2009. At the end of FY 2009, the USAOs reported that there were several dozen pharmaceutical, as well as, other complex health care fraud investigations pending - with potential significant recoveries - and following the landmark settlements of the last year, a large number of additional *qui tams* have been filed in the first few months of FY 2010. These cases not only represent potential recoveries in the billions of dollars, but the opportunity to change the current corporate culture that is so harmful to the financial health of the federal, state and private health care programs. This funding for attorney and

support personnel, as well as, for litigation expenses including, the creation of databases to house billions of documents, expert analysis of Medicare and Medicaid data, and medical consultants to unravel the sophisticated fraud schemes is essential to the successful resolution of these important cases.

In addition to supporting the investigation and litigation of pending cases, this funding would provide the AUSAs with the opportunity to pro-actively pursue the large dollar frauds, i.e., pharmaceutical and medical device fraud. Combining the knowledge and experience gained from numerous investigations with sophisticated data analysis, the AUSAs, with their colleagues in the Civil Division, could identify high dollar, over utilized, and inappropriately promoted drugs, procedures, and other services.

Finally, the Executive Office for United States Attorneys' Office of Legal Education (OLE) 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 HCF. In 2009, OLE offered a Health Care Fraud Seminar for AUSAs and DOJ attorneys, which was attended by over 100 attorneys, as well as, a Medicare Fraud Strike Force Seminar for investigators and attorneys who work in the current Strike Force locations, and an Affirmative Civil Enforcement Conference, which included health care fraud issues, for paralegals, auditors, and investigators. As the USAOs receive additional attorney, paralegal, investigator, and auditor resources, additional training opportunities will be essential.

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 has steadily increased to over 2400. It should be noted that in FY 2009 alone, FBI-led investigations in federal and state cases resulted in indictments and informations charging 840 defendants with health care fraud violations, and 555 convictions for health care fraud.

In July of 2009, 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 January 2010, a FBI case in Miami resulted in a defendant being sentenced to 22 years in prison for his ownership of medical clinics involved in infusion therapy fraud in Miami. 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 health care investigations. Thus, in the context of public health institutions, the Department's CRIPA work goes hand-in-hand with its work under Title II of the ADA to uphold individuals' federal rights to receive adequate supports and services in the most integrated setting appropriate to their needs. The Department recognizes that unnecessary institutionalization is discrimination that diminishes individuals' ability to lead full and independent lives. As a result of our CRIPA and ADA enforcement activities, thousands of unnecessarily institutionalized individuals have been able 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 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.

Looking forward, the Civil Rights Division is expanding its health care enforcement efforts through additional outreach, increased litigation and participation as amicus in existing court cases. The Division is hiring additional personnel and taking other steps to expand the number of attorneys and paralegals assigned to these enforcement priorities. In the months

ahead, these efforts should lead to a further expansion of the Division's work in this important area.

CONCLUSION: LOOKING FORWARD

As I hope is clear from this discussion, the Department of Justice, together with our partners at the Department of Health and Human Services and other federal and state agencies, has made combating health care fraud a significant priority and has devoted resources and attention at the highest levels of the Department to the HEAT initiative in order to be smarter and more effective about how we detect, deter and prosecute health care fraud. 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 this important mission to prevent, deter, and prosecute health care fraud.