Lanny A. Breuer
Assistant Attorney General
Criminal Division
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Thank you, Maggie, for that gracious introduction. I would also like to thank you, Colleen and Lori for your terrific work in putting together this year's Congress. And I commend all of you for being so engaged and proactive on compliance issues.

As lawyers and compliance officers for one of the largest and most important industry sectors in America, you have an obligation to ensure that your corporate clients act responsibly. That mission is even more important now, as the country grapples with the future of our health care system. I agree with Tony that the pharmaceutical industry has much to be proud of – every day you develop new medicines that allow people to live longer and healthier lives. But, of course, your industry's invaluable work must also be carried out lawfully. Pharmaceutical companies must ensure that they are dealing honestly and fairly with patients, health care providers, private insurers and government programs. And if they don't, the Department of Justice will be vigilant in holding companies and individuals who break the law accountable, not only through civil actions, as Tony just described, but also by bringing criminal indictments if the facts and the law warrant.

I would like to share with you this morning one area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead – and that's the application of the Foreign Corrupt Practices Act (or "FCPA") to the pharmaceutical industry. According to PhRMA's 2009 Membership survey, close to $100 billion dollars, or roughly one-third, of total sales for PhRMA members were generated outside of the United States, where health systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States. As a result, a typical U.S. pharmaceutical company that sells its products overseas will likely interact with foreign government officials on a fairly frequent and consistent basis. In the course of those interactions, the industry must resist short-cuts. It must resist the temptation and the invitation to pay off foreign officials for the sake of profit. It must act, in a word, lawfully.

But who exactly qualifies as a "foreign official" in the context of a public health system, and what constitutes a corrupt offer or payment that violates the FCPA? Of course, the answers to those questions depend on the facts and circumstances of every case, and I can't give you binding guidance from the podium today. But, I can tell you that the types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States – cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements, to name a few.

As important for your clients, consider the possible range of "foreign officials" who are covered by the FCPA: Some are obvious, like health ministry and customs officials of other countries. But some others may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities. Indeed, it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a "foreign official" within the meaning of the FCPA.

The depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process. The Criminal Division stands ready to ferret out this illegal conduct and we are uniquely situated to do so. As some of you may know, the Criminal Division has primary enforcement responsibility for the FCPA, and in recent years, FCPA enforcement has been one of our top priorities. Since 2005, we have brought 57 cases—more than the number of prosecutions brought in the almost 30 years between the enactment of the FCPA in 1977 and 2005. As a result, the Fraud Section of the Criminal Division has developed a group of experienced, hard-working and talented prosecutors who specialize in FCPA investigations and prosecutions. In addition, in 2007, the FBI created a squad of dedicated FCPA agents in its Washington Field Office. That group of dedicated FCPA agents has grown exponentially, both in size and in expertise, over the last two years—and we hope and expect that growth will continue. Working together with the FBI, and often with our civil counterparts at the SEC, the Department currently is pursuing more than 120 FCPA investigations.

In the pharmaceutical context, we have additional expertise that significantly enhances our ability to proactively investigate and prosecute these often complex cases. That additional expertise is located in our health care fraud group, where we have prosecutors and analysts with the industry knowledge necessary to quickly identify corrupt practices. These two groups – our FCPA unit and our health care fraud unit – are already beginning to work together to investigate FCPA violations in the pharmaceutical and device industries in an effort to maximize our ability to effectively enforce the law in this area. Moreover, we will continue to work closely with our partners at the SEC to ensure that the full range of the federal government's enforcement tools and remedies are utilized. And we are seeing increasing international cooperation, coordination and information sharing. Last year's record-breaking resolution with Siemens in the United States and Germany, in which Siemens agreed to pay a combined total of more than $1.6 billion in fines, penalties and disgorgement of profits in connection with violations of and charges related to the FCPA, is but one example of this increase in coordination and cooperation with foreign law enforcement.

Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in your industry. That will mean investigation and, if warranted, prosecution of corporations to be sure, but also investigation and prosecution of senior executives. Effective deterrence requires no less. Indeed, we firmly believe that

for our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant. To take just one example outside the pharmaceutical industry, and frankly, a case from which I am personally recused, earlier this year, the Department reported that Kellogg, Brown & Root pleaded guilty to FCPA violations and agreed to pay a $402 million fine. The Department did not, however, just stop at the prosecution of the corporation, but instead prosecuted a number of individuals for the same criminal conduct. Jack Stanley, KBR's former Chairman and CEO, pleaded guilty and agreed to a seven year prison sentence. In the past few months, we have the completed the trials of the Greens in California, of Mr. Bourke in New York and of former Congressman William Jefferson in Virginia. In each of these cases, individuals were found guilty of FCPA violations and face jail time.

So what can you do to protect your clients? First and foremost, every company should have a rigorous FCPA compliance policy that is faithfully enforced. Second, any pharmaceutical company that discovers an FCPA violation should seriously consider voluntarily disclosing the violation and cooperating with the Department's investigation. If you voluntarily disclose an FCPA violation, you will receive meaningful credit for that disclosure. And if you cooperate with the Department's investigation, you will receive a meaningful benefit for that cooperation—without any request or requirement that you disclose privileged material. Finally, if you remediate the problem and take steps to ensure that it does not recur, you will benefit from that as well.

We are fully aware that internal investigations and remedial measures may be costly. But the costs of not doing the responsible thing can be much higher – including significant criminal fines for the corporation, unwanted negative publicity, a potentially devastating impact on stock prices, and possible exclusion from Medicare and Medicaid. Conversely, a voluntary disclosure may result in no action being taken against a company, or the company may secure other preferred dispositions, such as a deferred or non-prosecution agreement, or a reduced fine under the Sentencing Guidelines. In this, as in so many areas, doing the right thing, in my view, also makes good business sense.

Before I conclude, I would like to take a moment to discuss the great work of HEAT and our Medicare Fraud Task Force.

For the last several years, we have pursued an inter-agency effort with the Department of Health and Human Services – called the Medicare Fraud Strike Force – to target and prosecute entities and individuals who steal from Medicare by billing for unnecessary or non-existent services. The Medicare Fraud Strike Force represents an innovative, data- and intelligence- driven approach to health care fraud prosecutions. Under the leadership of the Criminal Division, coordinated teams of investigators and prosecutors, including personnel from HHS-OIG, the FBI and U.S. Attorney's Offices, analyze Medicare claims data to target specific geographic areas showing unusually high levels of Medicare billing far above the national average – all in an effort to combat ongoing fraud by the worst offenders in the highest intensity regions.

These criminals are not legitimate health care providers. They create dummy companies with nominee owners; they bribe doctors to write prescriptions for medically unnecessary or non-existent services; they pay kickbacks to beneficiaries for Medicare numbers; and they submit utterly false bills to Medicare. But with the Strike Force model, we have greatly enhanced our ability to target, investigate, prosecute and deter corrupt businesses and business owners, as well as complicit health care professionals and beneficiaries whose sole purpose is to steal from Medicare. The key is to operate in real time – to learn from the data and from the community what fraud is currently taking place and then bring the cases as quickly and responsibly as possible to assure that viral fraud schemes do not spread unchecked.

In connection with the HEAT initiative that Tony described, we recently expanded the Medicare Fraud Strike Force to Houston and Detroit, bringing the total number of metropolitan areas where the Strike Force is operating to four: South Florida, Los Angeles, Detroit and Houston. These expanded efforts have already shown results. This past summer, we charged 85 people in the Detroit and Houston areas in connection with more than $66 million in false Medicare billings involving physical, occupational and infusion therapy, as well as durable medical equipment or DME. This Fall, another 20 defendants were charged in the Los Angeles area for allegedly participating in Medicare fraud schemes involving power wheelchairs, orthotics and hospital beds that resulted in more than $26 million in fraudulent bills to the Medicare program.

Overall, since its inception more than two years ago, the Strike Force has brought cases relating to more than $700 million dollars in false Medicare billing. Moreover, the Strike Force has had a stunning, deterrent effect. Strike Force operations in the Miami area contributed to estimated reductions of $1.75 billion in DME claim submissions and $334 million in DME claims paid by Medicare in just one county in South Florida in the 12 months following the Strike Force's inception when compared to the preceding 12-month period. And prison sentences in Strike Force cases tend to be longer than the average federal health care fraud case.

We know that the Strike Force model works, but there is more that we can, and will, do to fight Medicare fraud. Particularly in these difficult economic times, as the government faces so many challenges, we feel a tremendous responsibility to protect the public fisc. That's why the Criminal Division, in partnership with CMS, HHS-OIG, the FBI and U.S. Attorney's Offices around the county, is committed to devoting significant resources and energy to continuing the work of the Strike Force, including expansion in the near future to new cities. We are also thinking creatively about new applications for the Strike Force model in order to further enhance our effectiveness in fighting health care fraud. Stay tuned.

In closing, I would like to repeat what I said at the beginning of my remarks: given the current state of our health care system and our economy, it is imperative that pharmaceutical companies act responsibly and lawfully. The work you all do as lawyers and compliance officers is key to that effort, so I thank you for letting us share our thoughts with you today. And remember – doing the right thing is good business.

Tony and I would be happy to take your questions