

REMARKS OF ASSISTANT ATTORNEY GENERAL TONY WEST
TENTH ANNUAL PHARMACUETICAL REGULATORY
AND COMPLIANCE CONGRESS AND BEST PRACTICES FORUM
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[THANK Co-Chairs, Colleen Craven, Maggie Feltz, Lori Queisser]

It's a pleasure to be here this morning, at your tenth annual gathering, to talk about the Department of Justice's efforts to fight health care fraud. As those of you in this room know, combating health care fraud is a top priority for the Obama Administration, for Attorney General Eric Holder, and for the Justice Department's Civil Division, which I lead. I am also pleased to be here this morning with Lanny Breuer, the Assistant Attorney General for the Criminal Division, and Mary Riordan from the Health and Human Services Office of Inspector General.

And I'm delighted to speak to you because through your industry—a complex, competitive, global industry comprised of innovators, manufacturers and distributors—you play a central role in promoting the good health and well-being of the American people. It's a role I know you take seriously, this group in particular. For the last decade, you have met to discuss not just the legal and regulatory developments that will affect your businesses, but also how to address compliance issues, to share best practices and assess lessons learned.

What you do here matters because you are such an important part of the investment this country makes in health care. Every year, hundreds of billions of dollars are spent to provide health security for America's seniors, children and the disabled. Federal and state spending on Medicare and Medicaid alone exceeds \$800 billion each year. And while most of that money is being spent on ways that heal sickness, improve our quality of life or bolster our defenses against disease, much too much of that money is wasted by fraud and abuse.

Now, 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 to be anywhere between three and ten percent of total spending, and this fraud affects both public and private insurers alike. This is a multi-billion dollar problem. And it's simply unacceptable.

Because every dollar lost to health care fraud is a dollar that flows from the pockets of American taxpayers to those who are breaking the law. Now, I want to be clear about this: We know that most health care providers are doing the right thing. We know that most drug and device manufacturers are doing the right thing. They're working hard everyday to develop drugs that will save and improve lives; they're working to strengthen compliance efforts throughout a product's lifecycle; they're instituting best practices to meet an evolving regulatory landscape while at the same time maximizing innovation. We know that most players in this industry are honest participants in a complicated system. Yet we also know that there are those who seek to take advantage of that system at the expense of the nation's taxpayers. And it is those actors who will draw our attention.

Because when health care fraud occurs, it drives the cost of health care up for all of us. Consumers pay higher premiums. Companies pay more to cover their employees. And when Medicare and Medicaid dollars are siphoned off by fraud, it's not just the taxpayers who are harmed. Health care fraud means less money for our public health care programs, and that means

fewer children are able see doctors for preventable childhood diseases; seniors are forced to choose between food or medicine at month's end; and fewer people get the health care to which they're entitled. And it doesn't end there. When kickbacks are paid to physicians or hospitals, or drugs are marketed for off-label, unapproved uses, such illegal activity can distort the medical decisions made by health care providers and even put the public health at risk.

That is why this is such a high priority for us at the Justice Department. We have a duty to our citizens who receive treatment paid for by Medicare, Medicaid and other government programs to see to it that the integrity and quality of their care is not undermined by fraud. It is why Attorney General Holder and Secretary Kathleen Sebelius announced last May the creation of the Health Care Fraud Prevention and Enforcement Action Team, or "HEAT," which elevated the fight against Medicare and Medicaid fraud to a cabinet-level priority and placed a renewed emphasis on closely coordinating DOJ and HHS information and resources.

Assistant Attorney General Breuer will discuss HEAT in more detail, so I'll simply add that HEAT is solidifying a partnership between DOJ and HHS that began more than ten years ago with the creation of the Health Care Fraud and Abuse Control Program. Since the program's inception, our two Departments have returned more than \$15 billion to the federal government, of which over \$13 billion went back to the Medicare Trust Fund. And it's cost effective: for every dollar spent to enforce the law through the program, we recover four dollars for the public.

In fact, in the last fiscal year, health care fraud recoveries reached 1.6 billion dollars—that's two-thirds of the United States' total fraud recoveries for all federal agencies and programs for the year. Much of this work is done through the Civil Division's Commercial Branch, where we use the False Claims Act to pursue a variety of deceptive acts relating to Medicare and Medicaid claims. These cases can result in treble damages and penalties for violations, and we often make them with the assistance of whistleblowers in qui tam cases. Since the False Claims Act was substantially amended in 1986 and through the last fiscal year, the Civil Division, working with the United States Attorneys around the country, has recovered more than \$24 billion on behalf of all victim federal agencies, and of that over \$15 billion in matters where there was a related qui tam case.

And through our Office of Consumer Litigation, the Civil Division has both civil and criminal authority to enforce the Food, Drug, and Cosmetic Act, which we have used to investigate and prosecute the unlawful promotion and distribution of misbranded and adulterated drugs or devices.

These Civil Division enforcement activities reflect our belief that health care fraud is a crime that steals from taxpayers, harms our public health care programs, undermines honest providers seeking to play by the rules, and imperils public health. They also outline what you can expect as the Civil Division continues to emphasize health care fraud as a top priority.

For example, we will pursue allegations of off-label marketing—the illegal promotion of drugs or devices that are billed to federal health care programs for uses that were not found to be safe and effective by the FDA. In fact, two months ago, we announced the largest health care fraud settlement in history – a 2.3 billion dollar settlement with Pfizer to resolve criminal and civil liability arising from the illegal promotion of drugs. Pfizer's subsidiary, Pharmacia & Upjohn Company, pled guilty to a felony violation of the Food, Drug, and Cosmetic Act for its off-label promotion of Bextra, an anti-inflammatory drug, 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 uses for which the drug had been marketed.

Likewise, the Civil Division will investigate kickbacks paid to physicians, wholesalers or pharmacies to induce drug or device purchases. Just last week, we announced a \$112 million settlement with Omnicare, the nation's largest, nursing-home pharmacy provider, and Ivax, a drug manufacturer, to resolve allegations over kickback arrangements.

Now, it's also the case that we're not interested in criminalizing clerical errors or good-faith math mistakes. But we will pursue companies that establish inflated drug prices then turn around and market the spread between their lower sales price for the drug and the higher, inflated price that they know the government will reimburse. And the same goes for companies that knowingly fail to report their true best price for a drug in order to reduce rebates owed to Medicaid.

And finally, as I testified recently before the Senate Judiciary Committee, our enforcement efforts will not be limited to corporate actors. In those cases where the facts and law allow us to pursue criminal cases against individuals responsible for illegal conduct, we will do so. But as I also noted in my testimony, stepped up enforcement is only part of the story. In addition to strengthening existing enforcement efforts, we must also work to prevent health care fraud—to stop it before it happens—through expanded public education so that the American public can be a part of the solution by reporting suspected fraud to DOJ and HHS, as well as through increased compliance training for providers, such as at conferences like this.

Because, in the final analysis, our efforts to help protect the integrity of Medicare and Medicaid, to protect the taxpayers, to protect the integrity of the advice patients receive regarding their medical treatment—our efforts to do all of these things, standing alone, will not be enough.

We at the Department of Justice believe that cooperation between the pharmaceutical industry and law enforcement is an essential part of any successful battle against health care fraud.

Because the fact is, your industry is truly unique. Many of your products are household names; the work you do inspires respect and controversy; and your reports of large profits are both admired and criticized. But you also lay claim to a history of scientific research and drug development that brought us breakthroughs like penicillin and insulin; you have a long tradition of funding innovation--innovation that leads to advances which everyday ease our suffering, improve our lives and give us hope.

And because so many depend on the products you discover, produce and distribute—often at the most vulnerable times in their lives—you enjoy a public trust where so many depend on the integrity of the claims you make about the products you sell. To the extent we encourage, condone or ignore health care fraud, we undermine that trust. So I want to encourage you to work with us by emphasizing and enforcing compliance; by implementing best practices; by educating your workforces; and by learning from past mistakes.

Working together to combat fraud, we can keep and enhance that public trust. We can bring down the costs of health care. We can ensure the integrity of our public health care programs and we can help create a system that works well and efficiently for all of us.