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JUSTICE NEWS

Deputy Attorney General James M. Cole Speaks at the GSK Press Conference

Washington, D.C. ~ Monday, July 2, 2012

Good afternoon. We are here today to discuss the latest development in the Administration's continuing fight against health care fraud. It's my privilege to be joined by Bill Corr, Deputy Secretary for the Department of Health and Human Services; Stuart Delery, Acting Assistant Attorney General for the Civil Division; Daniel Levinson, Inspector General for the Department of Health and Human Services; Carmen Ortiz, the United States Attorney for the District of Massachusetts; Deborah Autor, Deputy Commissioner for Global Regulatory Operations and Policy at the Food and Drug Administration; John Walsh, the United States Attorney for the District of Colorado; and Kevin Perkins, Acting Executive Assistant Director of the FBI.

Today, I am pleased to announce that the Justice Department and our law enforcement partners have reached a historic \$3 billion resolution with the pharmaceutical manufacturer GlaxoSmithKline, LLC, to resolve multiple investigations into the company's sales, marketing, and pricing practices. This action constitutes the largest health care fraud settlement in United States history. It underscores our robust commitment to protecting the American people from the scourge of health care fraud. And it proves the effectiveness of the strong relationships we've forged with our partners to help ensure the health and safety of the American people, and to safeguard the integrity of our health care system.

Under the agreements announced today, GSK will plead guilty to criminal charges and pay \$1 billion in criminal fines and forfeitures for illegally marketing and promoting the drugs Paxil and Wellbutrin for uses not approved by the FDA – including the treatment of children for depression, and the treatment of other patients for ailments ranging from obesity, to anxiety, to addiction and ADHD – and for failing to report important clinical data about the drug Avandia to the Food and Drug Administration. GSK will pay an additional \$2 billion to resolve civil allegations that it caused false claims to be submitted to federal health care programs for these and other drugs as a result of the company's illegal promotional practices and payments to physicians. This settlement also resolves a civil investigation of the company's alleged underpayment of rebates that were required under the Medicaid Drug Rebate Program.

Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores this Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud. At every level, we are determined to stop practices that jeopardize patients' health; harm taxpayers; and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law.

Since May 2009 – when Attorney General Eric Holder and HHS Secretary Kathleen Sebelius announced the creation of the Health Care Fraud Prevention and Enforcement Action Team – or HEAT – this fight has been a Cabinet-level priority. Over the last three years, the Justice Department has recovered a total of more than \$10.2 billion in settlements, judgments, fines, restitution and forfeiture in health care fraud matters. And our Medicare Strike Forces have brought criminal charges against more than 800 defendants seeking to defraud Medicare.

These results – and the groundbreaking resolution we announce today – are extraordinary. They've been made possible by close and seamless coordination between state and agency partners, both here in Washington and throughout the country. And they demonstrate the fierce determination – shared by every official, attorney, and investigator who has contributed to these efforts – to be relentless in pursuit of those who break the law; to stop those who would endanger the health and safety of the American people; and to hold accountable those who violate the public trust by committing waste, fraud, or abuse.

Let me be clear: we will not tolerate health care fraud. And, in every instance where we uncover it, we will use all available tools to hold those responsible to account.

Before I turn the podium over to our next speaker, I want to acknowledge our colleagues and partners at the Department of Health and Human Services; its Office of Inspector General; the Federal Bureau of Investigation; the Food Drug and Administration; the Massachusetts Medicaid Fraud Control Unit; and all of our other federal and state partners who have made invaluable contributions to this effort.

I'd also like to thank Carmen Ortiz, the United States Attorney for the District of Massachusetts – along with her outstanding staff – for all they've done to make this historic settlement possible, and for their longstanding commitment to eradicating health care fraud. Thank you also to John Walsh, the United States Attorney for the District of Colorado, and his office for their significant contributions to the investigation into GSK's off-label promotion. And finally, I'd like to express my gratitude for the hard work of the Justice Department's Civil Division – and the teams in both the Commercial Litigation Branch and the Consumer Protection Branch – whose efforts have proved instrumental in advancing both this investigation and other important ones like it.

At this time, it's my pleasure to introduce Deputy Secretary Bill Corr.



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