

## **Attorney General Eric Holder's Prepared Remarks At Johnson & Johnson Press Conference**

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REMARKS AS PREPARED FOR DELIVERY BY ATTORNEY GENERAL  
ERIC HOLDER AT THE JOHNSON & JOHNSON PRESS CONFERENCE

WASHINGTON, D.C.

Good morning – and thank you all for being here. I am joined by Associate Attorney General [Tony] West; Assistant Attorney General for the Civil Division [Stuart] Delery; U.S. Attorney for the Eastern District of Pennsylvania [Zane] Memeger; U.S. Attorney for the District of Massachusetts [Carmen] Ortiz; First Assistant U.S. Attorney for the Northern District of California [Brian] Stretch; and Deputy Inspector General for Investigations at the Department of Health and Human Services [Gary] Cantrell.

We are here to announce that Johnson & Johnson and three of its subsidiaries have agreed to pay more than \$2.2 billion to resolve criminal and civil claims <sup>[1]</sup> that they marketed prescription drugs for uses that were never approved as safe and effective – and that they paid kickbacks to both physicians and pharmacies for prescribing and promoting these drugs. Through these alleged actions, these companies lined their pockets at the expense of American taxpayers, patients, and the private insurance industry. They drove up costs for everyone in the health care system and negatively impacted the long-term solvency of essential health care programs like Medicare.

This global settlement resolves multiple investigations involving the antipsychotic drugs Risperdal and Invega – as well as the heart drug Natrecor and other Johnson & Johnson products. The settlement also addresses allegations of conduct that recklessly put at risk the health of some of the most vulnerable members of our society – including young children, the elderly, and the disabled.

In the criminal information filed today, we allege that Johnson & Johnson subsidiary Janssen Pharmaceuticals Incorporated violated the Federal Food, Drug, and Cosmetic Act by introducing Risperdal into the market for unapproved uses. In its plea agreement, Janssen admits that it promoted this drug to health care providers for the treatment of psychotic symptoms and associated behaviors exhibited by elderly, non-schizophrenic patients who suffered from dementia – even though the drug was approved only to treat schizophrenia.

In separately filed civil complaints, we further allege that both Johnson & Johnson and Janssen Pharmaceuticals promoted Risperdal and Invega to doctors – and to nursing homes – as a way to control behavioral disturbances in elderly dementia patients, children, and the mentally disabled. The companies allegedly downplayed the serious health risks associated with Risperdal – including the risk of stroke in elderly patients – and even paid doctors to induce them to prescribe the drugs. As part of this scheme, the companies allegedly paid kickbacks to the nation's largest long-term care pharmacy, whose pharmacists were supposed to be the gatekeepers to provide an independent review of patient medications. Instead, at the companies' behest, the pharmacists allegedly recommended Risperdal for nursing home patients who exhibited behavioral symptoms associated with Alzheimer's Disease and dementia. This alleged conduct resulted in government health care programs paying millions of dollars in false claims for these drugs.

To resolve allegations stemming from the improper promotion of Risperdal, Janssen Pharmaceuticals will plead guilty to misbranding Risperdal – and has agreed to pay \$400 million in criminal fines and forfeitures. Johnson & Johnson and Janssen Pharmaceuticals have further agreed to pay over \$1.2 billion to resolve their civil liability under the False Claims Act. And Johnson & Johnson will pay an additional \$149 million to resolve claims relating to alleged kickbacks to a long-term care pharmacy.

In addition to these claims, we allege that Johnson & Johnson and its subsidiary, Scios Incorporated, promoted the heart failure drug Natrecor for off-label uses that caused patients to submit to costly infusions of the drug – without credible scientific evidence that it would have any health benefit for those patients. In a separate matter that was resolved in 2009, Scios pleaded guilty to misbranding Natrecor and paid a criminal fine of \$85 million. To resolve current allegations associated with the settlement we announce today, the companies have agreed to pay an additional \$184 million.

This significant settlement was made possible by the relentless investigative and enforcement efforts of dedicated men and women serving as part of the Health Care Fraud Prevention and Enforcement Action Team – or, HEAT – which Health and Human Services Secretary Kathleen Sebelius and I launched more than four years ago to recover taxpayer dollars, to keep the American people safe, and to aggressively pursue fraud and misconduct whenever and wherever it is found.

Put simply, this alleged conduct is shameful and it is unacceptable. It displayed a reckless indifference to the safety of the American people. And it constituted a clear abuse of the public trust, showing a blatant disregard for systems and laws designed to protect public health.

As our filings make clear, these are not victimless crimes. Americans trust that the medications prescribed for their parents and grandparents, for their children, and for themselves are selected because they are in the patient's best interest. Laws enacted by Congress – and the enforcement efforts of the Food and Drug Administration – provide important safeguards to ensure that drugs are approved for uses that have been demonstrated as safe and effective. Efforts by drug companies to introduce their drugs into interstate commerce for unapproved uses subvert those laws. Likewise, the payment of kickbacks undermines the independent medical judgment of health care providers. It creates financial incentives to increase the use of certain drugs, potentially putting the health of some patients at risk. Every time pharmaceutical companies engage in this type of conduct, they corrupt medical decisions by health care providers, jeopardize the public health, and take money out of taxpayers' pockets.

This settlement demonstrates that the Departments of Justice and Health and Human Services – working alongside a variety of federal, state, and local partners – will not tolerate such activities. No company is above the law. And my colleagues and I are determined to keep moving forward – guided by the facts and the law, and using every tool, resource, and authority at our disposal – to hold these corporations accountable, to safeguard the American people, and to prevent this conduct from happening in the future.

This announcement marks another step forward in our strategic, comprehensive, and effective approach to fraud prevention. We can all be encouraged by the actions that have been taken – and the results we've obtained – in recent years. But we cannot yet be satisfied. And that's why, here in Washington and across the country, this critical work will continue.

I'd like to thank everyone who made this settlement possible. In particular, I want to recognize the leaders, prosecutors, trial attorneys, investigators, and staff of the Civil

Division here in Washington – as well as our United States Attorney’s Offices in Philadelphia, Boston, and San Francisco. I am grateful for the committed efforts of our partners at the Department of Health and Human Services – particularly in the Office of the Inspector General – as well as the Food and Drug Administration and many other federal agencies that contributed to this outcome. And I want to thank each of the state Attorneys General and Medicaid Fraud Control units across this country who contributed to this investigation.

I would be happy to take a few questions at this time.

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