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JOHNSON & JOHNSON TO PAY MORE THAN \$2.2 BILLION TO RESOLVE FRAUD AND MISBRANDING ALLEGATIONS

Settlement is largest amount paid over misbranding and unapproved use of single drug

PHILADELPHIA – Health care giant Johnson & Johnson (J&J) will pay over \$2.2 billion to resolve criminal and civil liability that included the promotion of the atypical anti-psychotic drugs Risperdal and Invega for uses not approved as safe and effective by the Food and Drug Administration (FDA). Of the \$2.2 billion, J&J is paying \$1.673 billion to resolve allegations of off-label marketing for Risperdal and Invega, as well as the alleged payment of kickbacks to physicians involving Risperdal. The resolution – the largest in U.S. history involving a single drug (Risperdal) and the third-largest health care fraud settlement involving one company – is the result of whistleblower lawsuits filed in the Eastern District of Pennsylvania. It was announced today by the Department of Justice and United States Attorney Zane David Memeger.

Criminal Information: Risperdal was originally approved only to treat the management of the manifestations of psychotic disorders. On March 3, 2002, the approved use was narrowed to treatment of schizophrenia only. According to a criminal information filed today, Janssen Pharmaceuticals, Inc., a J&J subsidiary, introduced Risperdal for a new, unapproved use, rendering the product misbranded. In a plea agreement resolving these charges, Janssen admits that between March 3, 2002, and December 31, 2003, it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated disturbances exhibited by elderly, non-schizophrenic dementia patients. Under the terms of the plea agreement, Janssen will pay a total of \$400 million, including a criminal fine of \$334 million and forfeiture of \$66 million. Janssen has agreed to plead guilty to introducing a misbranded drug into interstate commerce.

Civil Complaint: In its Complaint, the United States alleges that between January 1999 and December 2005, Janssen marketed Risperdal for unapproved uses to control and treat behavioral disturbances and conduct disorders in the nation's most vulnerable patients: elderly nursing home residents, children, and individuals with mental disabilities. Between 2006 and 2009, the government alleges that Janssen marketed the sale and use of Invega – which was approved to treat schizophrenia – for conditions for which it was not approved. J&J and Janssen caused false claims to be submitted to federal healthcare programs by promoting these drugs for off-label uses that federal healthcare programs did not cover, making false and misleading statements about the safety and efficacy of Risperdal, and paying kickbacks to physicians to prescribe Risperdal. The government's complaint also contains allegations that Janssen paid speaker fees to doctors to influence them to write more prescriptions for Risperdal. Sales representatives allegedly told the doctors that if they wanted to receive payments for speaking, they needed to increase their Risperdal prescriptions. For this conduct, J&J is paying \$1.273 billion in civil penalties. J&J paid \$118 million to the State of Texas in March 2012 to resolve similar allegations involving both state and federal dollars, bringing the total civil settlement to \$1.391 billion.

The Federal Food, Drug and Cosmetic Act (FDCA) requires a pharmaceutical company to specify the intended uses of a product in its new drug application to the FDA. Once approved, a drug may not be introduced into interstate commerce for unapproved or “off-label” uses. A manufacturer’s promotional activities of a drug for a use not approved by the FDA are evidence of its intent to distribute the drug for a new, unapproved use, also known as “misbranding.” In its complaint, the government alleges that the FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be “misleading.”

“The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust,” said Attorney General Eric Holder. “This multibillion-dollar resolution demonstrates the Justice Department’s firm commitment to preventing and combating all forms of health care fraud. And it proves our determination to hold accountable any corporation that breaks the law and enriches its bottom line at the expense of the American people.”

“J&J’s promotion of Risperdal for unapproved uses threatened the most vulnerable populations of our society – children, the elderly, and those with developmental disabilities,” said Memeger. “This historic settlement sends the message that drug manufacturers who place profits over patient care will face severe criminal and civil penalties.”

Off-Label Promotion to the Elderly

The civil complaint further alleges that from 1999 through 2005, despite the FDA warnings, Janssen aggressively marketed Risperdal to control behavioral disturbances in dementia patients through an “ElderCare sales force” designed to target nursing homes and doctors who treated the elderly. In business plans, Janssen’s goal was to “[m]aximize and grow RISPERDAL’s market leadership in geriatrics and long term care.” The company touted Risperdal as having “proven efficacy” and “an excellent safety and tolerability profile” in geriatric patients. The complaint further alleges that J&J and Janssen were aware that Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but that the company downplayed these risks. For example, a J&J study showed a significant risk of strokes and other adverse events in elderly dementia patients taking Risperdal. Janssen pooled the study data with other studies resulting in a lower overall risk of adverse events.

Off-Label Promotion to Children

In addition to promoting Risperdal for elderly dementia patients, Janssen allegedly promoted the antipsychotic drug for use in children and individuals with mental disabilities from 1999 through 2005. J&J and Janssen knew that Risperdal posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production. Nonetheless, one of Janssen’s Key Base Business Goals was to grow and protect share in the child/adolescent market. Janssen instructed its sales representatives to call on child psychiatrists as well as mental health facilities that primarily treated children and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, obsessive-compulsive disorder, oppositional defiant disorder and autism. Until late 2006, Risperdal was not approved for use in children for any purpose, and the FDA repeatedly warned the company against promoting it for use in children.

The complaint also alleges that Janssen knew patients taking Risperdal had an increased risk of developing diabetes, but nonetheless promoted Risperdal as “uncompromised by safety concerns (does not cause diabetes).” When Janssen received the initial results of studies indicating that Risperdal posed the same diabetes risk as other antipsychotics, the company retained outside consultants to re-analyze the

study results and ultimately published articles stating that Risperdal was actually associated with a lower risk of developing diabetes.

Non-monetary Provisions and Corporate Integrity Agreement

In addition to imposing substantial monetary sanctions, the resolution will subject J&J to stringent requirements under a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The agreement is designed to increase accountability and transparency and prevent future fraud and abuse.

The CIA includes provisions requiring J&J to implement major changes to the way its pharmaceutical affiliates do business. Among other things, the CIA requires J&J to change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. J&J may recoup monies from executives who are current employees and those who have left the company. The CIA also requires J&J's pharmaceutical businesses to implement and maintain transparency regarding its research practices, publication policies, and payments to physicians. On an annual basis, management employees, including senior executives and certain members of J&J's independent Board of Directors, must certify compliance with provisions of the CIA. J&J must submit detailed annual reports to HHS-OIG about its compliance program and its business operations.

“OIG will work aggressively with our law enforcement partners to hold companies accountable for marketing and promotion activities that violate laws intended to protect the public,” said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. “Our compliance agreement with Johnson & Johnson increases individual accountability for board members, sales representatives, company executives and management. The agreement also contains strong monitoring and reporting provisions to help ensure that the public is protected from future unlawful and potentially harmful off-label marketing.”

“When pharmaceutical companies interfere with the FDA’s mission of ensuring that drugs are safe and effective for the American public, they undermine the doctor-patient relationship and put the health and safety of patients at risk. Today’s settlement demonstrates the government’s continued focus on pharmaceutical companies that put profits ahead of the public’s health,” said John Roth, director of the Food and Drug Administration’s Office of Criminal Investigations. “The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the drug approval process and recklessly promote drugs for uses that have not been proven to be safe and effective.”

“Any illegal healthcare scheme to increase profit over the protection of unsuspecting patients is shameful,” said Special Agent-in-Charge Craig W. Rupert, Defense Criminal Investigative Service. “This illegal activity harms patients and negatively affects the delivery of healthcare to more than nine million Department of Defense military members, retirees, and their families. This settlement demonstrates DCIS’ continuing commitment to investigate those who abuse government healthcare programs and who disregard appropriate corporate governance at the expense of patients.”

“Unfortunately, there are those who take advantage of the healthcare system by seeking reimbursement for services and products that they are not entitled to,” said Monica Weyler, Special Agent in Charge of the Eastern Area Field Office for U.S. Postal Service Office of Inspector General. “We want to thank our law enforcement partners for their efforts in preventing fraud, waste, and abuse within the Postal Service.”

This civil settlement described above resolves four lawsuits pending in federal court in the Eastern District of Pennsylvania under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. As part of today's resolution, the whistleblowers in those cases will share \$112 million from the federal share of the settlement amount.

This matter was investigated by the Health and Human Services-Office of Inspector General, the Food and Drug Administration's Office of Criminal Investigations, the Defense Criminal Investigative Service of the Department of Defense, the Office of the Inspector General for the U.S. Postal Service. Assistance was provided by the National Association of Medicaid Fraud Control Units.

The criminal case is being prosecuted by Assistant U.S. Attorneys Albert Glenn and Scott Cullen; the civil case is being prosecuted by Assistant U.S. Attorneys Charlene Keller Fullmer and Mary Catherine Frye.

Court documents related to the entire global settlement can be viewed online at <http://www.justice.gov/opa/jj-pc-docs.html>.

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