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Inspections, Compliance, Enforcement, and Criminal Investigations

November 4, 2013: Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations



Food and Drug Administration Office of Criminal Investigations

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Allegations Include Off-label Marketing and Kickbacks to Doctors and Pharmacists

WASHINGTON - Global health care giant Johnson & Johnson (J&J) and its subsidiaries will pay more than \$2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor, including promotion for uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider. The global resolution is one of the largest health care fraud settlements in U.S. history, including criminal fines and forfeiture totaling \$485 million and civil settlements with the federal government and states totaling \$1.72 billion.

“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.”

The resolution includes criminal fines and forfeiture for violations of the law and civil settlements based on the False Claims Act arising out of multiple investigations of the company and its subsidiaries.

“When companies put profit over patients’ health and misuse taxpayer dollars, we demand accountability,” said Associate Attorney General Tony West. “In addition to significant monetary sanctions, we will ensure that non-monetary measures are in place to facilitate change in corporate behavior and help ensure the playing field is level for all market participants.”

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). This agreement is designed to increase accountability and transparency and prevent future fraud and abuse.

“As patients and consumers, we have a right to rely upon the claims drug companies make about their products,” said Assistant Attorney General for the Justice Department’s Civil Division Stuart F. Delery. “And, as taxpayers, we have a right to ensure that federal health care dollars are spent appropriately. That is why this Administration has continued to pursue aggressively – with all of our available law enforcement tools -- those companies that corrupt our health care system.”

J&J Subsidiary Janssen Pleads Guilty to Misbranding Antipsychotic Drug

In a criminal information filed today in the Eastern District of Pennsylvania, the government charged that, from March 3, 2002, through Dec. 31, 2003, Janssen Pharmaceuticals Inc., a J&J subsidiary, introduced the antipsychotic drug Risperdal into interstate commerce for an unapproved use, rendering the product misbranded. For most of this time period, Risperdal was approved only to treat schizophrenia. The information alleges that Janssen’s sales representatives promoted Risperdal to physicians and other prescribers who treated elderly dementia patients by urging the prescribers to use Risperdal to treat symptoms such as anxiety, agitation, depression, hostility and confusion. The information alleges that the company created written sales aids for use by Janssen’s ElderCare sales force that emphasized symptoms and minimized any mention of the FDA-approved use, treatment of schizophrenia. The company also provided incentives for off-label promotion and intended use by basing sales representatives’ bonuses on total sales of Risperdal in their sales areas, not just sales for FDA-approved uses.

In a plea agreement resolving these charges, Janssen admitted that it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral 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’s guilty plea will not be final until accepted by the U.S. District Court.

The Federal Food, Drug, and Cosmetic Act (FDCA) protects the health and safety of the public by ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bear true, complete and accurate information. Under the FDCA, a pharmaceutical company must specify the intended uses of a drug in its new drug application to the FDA. Before approval, the FDA must determine that the drug is safe and effective for those specified uses. Once the drug is approved, if the company intends a different use and then introduces the drug into interstate commerce for that new, unapproved use, the drug becomes misbranded. The unapproved use is also known as an “off-label” use because it is not included in the drug’s FDA-approved labeling.

“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,” said Director of the FDA’s Office of Criminal Investigations John Roth. “Today’s settlement demonstrates the government’s continued focus on pharmaceutical companies that put profits ahead of the public’s health. 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.”

J&J and Janssen Settle Civil Allegations of Targeting Vulnerable Patients with the Drugs Risperdal and Invega for Off-Label Uses

In a related civil complaint filed today in the Eastern District of Pennsylvania, the United States alleges that Janssen marketed Risperdal to control the behaviors and conduct of the nation's most vulnerable patients: elderly nursing home residents, children and individuals with mental disabilities. The government alleges that J&J and Janssen caused false claims to be submitted to federal health care programs by promoting Risperdal for off-label uses that federal health care programs did not cover, making false and misleading statements about the safety and efficacy of Risperdal and paying kickbacks to physicians to prescribe Risperdal.

“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 U.S. Attorney for the Eastern District of Pennsylvania Zane Memeger. “This historic settlement sends the message that drug manufacturers who place profits over patient care will face severe criminal and civil penalties.”

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 FDA cautioned Janssen that behavioral disturbances in elderly dementia patients were not necessarily manifestations of psychotic disorders and might even be “appropriate responses to the deplorable conditions under which some demented patients are housed, thus raising an ethical question regarding the use of an antipsychotic medication for inappropriate behavioral control.”

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 companies downplayed these risks. For example, when a J&J study of Risperdal showed a significant risk of strokes and other adverse events in elderly dementia patients, the complaint alleges that Janssen combined the study data with other studies to make it appear that there was a lower overall risk of adverse events. A year after J&J had received the results of a second study confirming the increased safety risk for elderly patients taking Risperdal, but had not published the data, one physician who worked on the study cautioned Janssen that “[a]t this point, so long after [the study] has been completed ... we must be concerned that this gives the strong appearance that Janssen is purposely withholding the findings.”

The complaint also alleges that Janssen knew that 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 complaint alleges that 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.

The complaint alleges that, despite the FDA warnings and increased health risks, from 1999 through 2005, 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.

In addition to promoting Risperdal for elderly dementia patients, from 1999 through 2005, Janssen allegedly promoted the antipsychotic drug for use in children and individuals with mental disabilities. The complaint alleges that 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 the drug's market share with child/adolescent patients. 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, oppositional defiant disorder, obsessive-compulsive 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 government's complaint also contains allegations that Janssen paid speaker fees to doctors to influence them to write prescriptions for Risperdal. Sales representatives allegedly told these doctors that if they wanted to receive payments for speaking, they needed to increase their Risperdal prescriptions.

In addition to allegations relating to Risperdal, today's settlement also resolves allegations relating to Invega, a newer antipsychotic drug also sold by Janssen. Although Invega was approved only for the treatment of schizophrenia and schizoaffective disorder, the government alleges that, from 2006 through 2009, J&J and Janssen marketed the drug for off-label indications and made false and misleading statements about its safety and efficacy.

As part of the global resolution, J&J and Janssen have agreed to pay a total of \$1.391 billion to resolve the false claims allegedly resulting from their off-label marketing and kickbacks for Risperdal and Invega. This total includes \$1.273 billion to be paid as part of the resolution announced today, as well as \$118 million that J&J and Janssen paid to the state of Texas in March 2012 to resolve similar allegations relating to Risperdal. Because Medicaid is a joint federal-state program, J&J's conduct caused losses to both the federal and state governments. The additional payment made by J&J as part of today's settlement will be shared between the federal and state governments, with the federal government recovering \$749 million, and the states recovering \$524 million. The federal government and Texas each received \$59 million from the Texas settlement.

Kickbacks to Nursing Home Pharmacies

The civil settlement also resolves allegations that, in furtherance of their efforts to target elderly dementia patients in nursing homes, J&J and Janssen paid kickbacks to Omnicare Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients. In a complaint filed in the District of Massachusetts in January 2010, the United States alleged that J&J paid millions of dollars in kickbacks to Omnicare under the guise of market share rebate payments, data-purchase agreements, "grants" and "educational funding." These kickbacks were intended to induce Omnicare and its hundreds of consultant pharmacists to engage in "active intervention programs" to promote the use of Risperdal and other J&J drugs in nursing homes. Omnicare's consultant pharmacists regularly reviewed nursing home patients' medical charts and made recommendations to physicians on what drugs should be prescribed for those patients. Although consultant pharmacists purported to provide "independent" recommendations based on their clinical judgment, J&J viewed the pharmacists as an "extension of [J&J's] sales force."

J&J and Janssen have agreed to pay \$149 million to resolve the government's contention that these kickbacks caused Omnicare to submit false claims to federal health care programs. The federal share of this

settlement is \$132 million, and the five participating states' total share is \$17 million. In 2009, Omnicare paid \$98 million to resolve its civil liability for claims that it accepted kickbacks from J&J and Janssen, along with certain other conduct.

“Consultant pharmacists can play an important role in protecting nursing home residents from the use of antipsychotic drugs as chemical restraints,” said U.S. Attorney for the District of Massachusetts Carmen Ortiz. “This settlement is a reminder that the recommendations of consultant pharmacists should be based on their independent clinical judgment and should not be the product of money paid by drug companies.”

Off-Label Promotion of the Heart Failure Drug Natrecor

The civil settlement announced today also resolves allegations that J&J and another of its subsidiaries, Scios Inc., caused false and fraudulent claims to be submitted to federal health care programs for the heart failure drug Natrecor. In August 2001, the FDA approved Natrecor to treat patients with acutely decompensated congestive heart failure who have shortness of breath at rest or with minimal activity. This approval was based on a study involving hospitalized patients experiencing severe heart failure who received infusions of Natrecor over an average 36-hour period.

In a civil complaint filed in 2009 in the Northern District of California, the government alleged that, shortly after Natrecor was approved, Scios launched an aggressive campaign to market the drug for scheduled, serial outpatient infusions for patients with less severe heart failure – a use not included in the FDA-approved label and not covered by federal health care programs. These infusions generally involved visits to an outpatient clinic or doctor's office for four- to six-hour infusions one or two times per week for several weeks or months.

The government's complaint alleged that Scios had no sound scientific evidence supporting the medical necessity of these outpatient infusions and misleadingly used a small pilot study to encourage the serial outpatient use of the drug. Among other things, Scios sponsored an extensive speaker program through which doctors were paid to tout the purported benefits of serial outpatient use of Natrecor. Scios also urged doctors and hospitals to set up outpatient clinics specifically to administer the serial outpatient infusions, in some cases providing funds to defray the costs of setting up the clinics, and supplied providers with extensive resources and support for billing Medicare for the outpatient infusions.

As part of today's resolution, J&J and Scios have agreed to pay the federal government \$184 million to resolve their civil liability for the alleged false claims to federal health care programs resulting from their off-label marketing of Natrecor. In October 2011, Scios pleaded guilty to a misdemeanor FDCA violation and paid a criminal fine of \$85 million for introducing Natrecor into interstate commerce for an off-label use.

“This case is an example of a drug company encouraging doctors to use a drug in a way that was unsupported by valid scientific evidence,” said First Assistant U.S. Attorney for the Northern District of California Brian Stretch. “We are committed to ensuring that federal health care programs do not pay for such inappropriate uses, and that pharmaceutical companies market their drugs only for uses that have been proven safe and effective.”

Non-Monetary Provisions of the Global Resolution and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, J&J has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). 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 from those who have left the company. The CIA also requires J&J's pharmaceutical businesses to implement and maintain transparency regarding their 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 that violate laws intended to protect the public," said Inspector General of the U.S. Department of Health and Human Services Daniel R. Levinson. "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."

Coordinated Investigative Effort Spans Federal and State Law Enforcement

This resolution marks the culmination of an extensive, coordinated investigation by federal and state law enforcement partners that is the hallmark of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaborations to fight fraud. Announced in May 2009 by Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius, the HEAT initiative has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation.

The criminal cases against Janssen and Scios were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania and the Northern District of California and the Civil Division's Consumer Protection Branch. The civil settlements were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania, the Northern District of California and the District of Massachusetts and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division, the FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

This matter was investigated by HHS-OIG, the Department of Defense's Defense Criminal Investigative Service, the FDA's Office of Criminal Investigations, the Office of Personnel Management's Office of Inspector General, the Department of Veterans Affairs, the Department of Labor, TRICARE Program Integrity, the U.S. Postal Inspection Service's Office of the Inspector General and the FBI.

One of the most powerful tools in the fight against Medicare and Medicaid financial fraud is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$16.7 billion through False Claims Act cases, with more than \$11.9 billion of that amount recovered in cases

involving fraud against federal health care programs.

The department enforces the FDCA by prosecuting those who illegally distribute unapproved, misbranded and adulterated drugs and medical devices in violation of the Act. Since 2009, fines, penalties and forfeitures that have been imposed in connection with such FDCA violations have totaled more than \$6 billion.

The civil settlements described above resolve multiple lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the government and to share in any recovery. From the federal government's share of the civil settlements announced today, the whistleblowers in the Eastern District of Pennsylvania will receive \$112 million, the whistleblowers in the District of Massachusetts will receive \$27.7 million and the whistleblower in the Northern District of California will receive \$28 million. Except to the extent that J&J subsidiaries have pleaded guilty or agreed to plead guilty to the criminal charges discussed above, the claims settled by the civil settlements are allegations only, and there has been no determination of liability.

Court documents related to today's settlement can be viewed online at www.justice.gov/opa/jj-pc-docs.html.²

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