

Significant Drug & Device Settlements

❖ Astellas Pharmaceuticals US Inc. (April 2014)

- Pharmaceutical company Astellas Pharma US Inc. will pay \$7.3 million to resolve allegations that it violated the False Claims Act in connection with its marketing and promotion of the drug Mycamine for pediatric use, the Justice Department announced today. Astellas Pharma US Inc., located in Northbrook, Ill., manufactures and sells pharmaceutical drugs, including Mycamine.
- The settlement resolves allegations that, between 2005 and 2010, Astellas knowingly marketed and promoted the sale of Mycamine for pediatric use, which was not a medically accepted indication and, therefore, not covered by federal health care programs. During this time period, the FDA approved Mycamine to treat adult patients suffering from serious and invasive infections caused by the fungus Candida, including infections in the esophagus, the blood and the abdomen, and to prevent Candida infections in adults undergoing stem cell transplants. From 2005 through June 2013, however, Mycamine was not approved to treat pediatric patients for any use.

❖ Endo Pharmaceuticals/Endo Health Solutions (February 2014)

- \$192.7M settlement to resolve the criminal and civil liability from Endo Health Solutions, and its subsidiary Endo Pharmaceuticals, marketing of the drug Lidoderm for unapproved uses.
- During the period of 2002 to 2006, Lidoderm was only approved for relief of pain associated with post-herpetic neuralgia (PHN). The alleged information states that Lidoderm was distributed nationwide and misbranded due to lack of sufficient use directions for the treatment of non-PHN related pain. These uses were never approved by the FDA.

❖ Ethicon Inc (December 2013)

- \$1.25M to settle a civil money penalty action against Advanced Sterilization Products (ASP), which is a division of Ethicon, Inc. a Johnson & Johnson Company. Two ASP executives alleged that ASP manufactured and distributed adulterated and misbranded sterilization monitoring products. ASP knew that it did not have

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sufficient data for the stated shelf life on the label of the Sterrad Cyclesure 24 Biological Indicators, but continued to ship the product with inaccurate expiration dates to the customers. The product is used to monitor and confirm the effectiveness of the sterilization process in ASP's Sterrad sterilizers.

❖ Janssen Pharmaceuticals/ Johnson & Johnson (November 2013)

- \$400M criminal fine for misbranding the drug, Risperdal. A Johnson and Johnson company, JPI, must also pay \$1.25 billion under a separate civil settlement concerning the same drug. The combined settlement fee to resolve the misbranding allegations and filing false claims are more than \$1.67 billion. Risperdal was FDA approved in 2002 for the treatment of schizophrenia and in 2003 for the treatment of acute mania and mixed episodes of Bipolar 1 Disorder.
- In 2002, JPI marketed the drug for agitation associated with dementia in the elderly, which was unapproved by the FDA. Additionally, JPI marketed Risperdal for behavior challenges in children, when it was not until late 2006 Risperdal was approved for use in children.

❖ C.R. Bard (ProSeed Inc.) (May 2013)

- \$48.3M to settle False Claims Act allegations that the company and its wholly owned subsidiary, ProSeed Inc., provided illegal remuneration to hospital customers and physicians to induce them to purchase brachytherapy seeds, a radiation treatment for cancer. The action was brought by a *qui tam* relator who was a former Bard manager. The Complaint alleged that the company paid illegal remuneration in the form of grants, guaranteed minimum rebates, conference fees, marketing assistance, and /or free medical equipment. In addition, it was alleged that the company overcharged customers for the radioactive seeds and told hospital customers to pass along the inflated charges to Medicare, resulting in false reimbursement claims.
- In addition to the settlement, Bard paid agreed to pay an additional \$2.2M to enhance its corporate compliance program but no CIA was included in the settlement.

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❖ Amgen (Apr. 2013)

- \$24.9M to settle allegations that the company violated the False Claims Act by paying kickbacks to long term care pharmacy providers in return for conducting “therapeutic interchange” programs, designed to switch Medicare and Medicaid beneficiaries from a competitor drug to its drug, Aranesp. The settlement resolved allegations that Amgen paid kickbacks to long term care pharmacy providers which took the form of performance-based rebates. As part of the exchange program, the government alleged that Amgen distributed materials to consultant pharmacists and nursing home staff encouraging the use of Aranesp for patients for whom Aranesp would not have been indicated. The civil settlement was based on a *qui tam* case action filed in the District of South Carolina. The federal government will get \$17.8M, with the remainder to be split among several states, including the District of Columbia.

❖ Eli Lilly (Dec. 2012)

- \$29.4M to resolve FCPA civil charges brought by the SEC, based on an investigation that began in 2003. The settlement, which relates to certain activities of Lilly subsidiaries in Brazil, China, Poland, and Russia from 1994 through 2009, ordered the company to pay \$29.4M, including disgorgement of \$13.9M, prejudgment interest of \$6.7M and a penalty of \$8.7M. In addition, without admitting or denying the allegations, the settlement included a 60 day review of the company’s internal controls and compliance program related to the FCPA by an independent compliance consultant. DOJ’s investigation remains open and ongoing.

❖ Janssen Pharmaceuticals/Johnson & Johnson (Aug. 2012)

- \$181M to settle allegations by 36 states and the District of Columbia related to its promotional and marketing practices of the antipsychotic medication Risperdal. The settlement was part of a consent decree entered into by the company and was not an admission of wrongdoing or violation of any law or regulation. As part of the settlement, Janssen agreed that it would not promote any of its antipsychotic

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medications for off-label uses nor make any false or misleading claims related to the products.

❖ **Pfizer (Aug. 2012)**

- \$60M to settle allegations that its employees bribed doctors and other foreign officials in China, Italy, Russia, Croatia, and other Eastern European countries in violation of the Foreign Corrupt Practices Act. The settlement resolved alleged FCPA violations by Wyeth which Pfizer acquired in 2009, with Pfizer and Wyeth paying approximately \$45M to the SEC. Additionally, Pfizer's subsidiary, Pfizer HCP Corp, agreed to pay a \$15M fine and entered a deferred prosecution agreement. There was no indication that anyone at Pfizer's corporate headquarters knew of the conduct, which was voluntarily self-reported by Pfizer.
- 2 year CIA.

❖ **GlaxoSmithKline (June 2012)**

- \$3B to settle civil and criminal charges relating to its branding, safety disclosures, and price reporting of several drugs. GSK agreed to pay \$1.8B to resolve criminal and civil allegations for off-label marketing, and more than \$1B for alleged False Claims Act violations relating to antidepressants Paxil and Wellbutrin as well as other drugs. The company agreed to pay a \$243M criminal fine for failing to report safety data to the FDA regarding Avandia, a diabetes drug. GSK also agreed to pay \$657M to resolve allegations about its statements concerning Avandia's safety and efficacy. The company also agreed to pay \$300M for allegedly failing to report its best prices for certain drugs to Medicaid.

❖ **Abbott Laboratories (May 2012)**

- \$1.5B to settle criminal and civil allegations of off-label marketing of Depakote. Abbott Laboratories has agreed to pay \$800M to resolve federal and state civil allegations that its illegal marketing practices and remuneration caused false claims to be submitted to government health care programs and that Abbott offered and paid illegal remuneration to induce health care providers and pharmacy providers

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to promote or prescribe Depokote. It was also alleged that the company unduly influenced the content of CME programs in violation of the Federal Anti- kickback Statute. The company also agreed to pay a \$700M criminal fine and to plead guilty to one misdemeanor count of misbranding by promoting Depakote for off-label uses. The civil settlement was based on four *qui tam* cases filed by former Abbott sales representatives.

- 5 year CIA.

❖ McKesson (Apr. 2012)

- \$190M to resolve False Claims Act allegations into inflated pricing information for a large number of prescription drugs reimbursed by the Medicaid program. As part of its average wholesale price litigation efforts, DOJ alleged that the company defrauded the Medicaid program by falsely reporting inflated wholesale drug prices, causing the government to set higher reimbursement rates.

❖ Janssen/Johnson & Johnson (Jan. 2012)

- \$158M to the state of Texas to settle allegations of off-label marketing of Risperdal.