Wyeth Pharmaceuticals Will Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses

Sara M. Lord

On July 30, 2013, the Justice Department and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) announced that Wyeth Pharmaceuticals Inc. will pay $490.9 million to settle criminal and civil claims arising from the unlawful marketing of the prescription drug Rapamune. In 1999, Wyeth received approval from the Food and Drug Administration to market Rapamune, an immunosuppressive drug that prevents the body's immune system from rejecting a transplanted organ, for use in renal (kidney) transplant patients. The criminal and civil settlements address Wyeth's promotion of the drug for unapproved use in non-renal transplant patients.

The settlements relate to two qui tam lawsuits, one filed in the Eastern District of Pennsylvania in 2005 and a second filed in the Western District of Oklahoma in 2007. The Justice Department initially declined to intervene in the Pennsylvania case in 2006, and the whistleblowers filed a second amended complaint in May 2010. In June 2010, the House Committee on Oversight and Government Reform announced a probe into Wyeth's marketing of Rapamune. On Sept. 21, 2010, the Justice Department intervened in the case and transferred it to the U.S. District Court for the Western District of Oklahoma, where the second qui tam lawsuit had been filed, and an investigation was initiated with regard to the whistleblowers' claims.

In 2009, Wyeth was acquired by Pfizer, Inc., for approximately $68 billion. Pfizer had already disclosed the $490.9 million settlement on a preliminary basis in a November 2012 securities filing. The joint announcement by the Justice Department and HHS came after U.S. District Judge Vicki Miles-LaGrange, of the Western District of Oklahoma (Oklahoma City) unsealed the final court papers documenting the settlements. Shortly before it acquired Wyeth, Pfizer had entered into a Corporate Integrity Agreement (CIA) with HHS in connection with another matter. As the joint press release noted, the CIA covers former Wyeth employees who now perform sales and marketing functions at Pfizer. Under the CIA, Pfizer is subject to exclusion from federal health care programs, including Medicare and Medicaid, for a material breach of the CIA, and the company is subject to monetary penalties for less significant breaches.

In resolution of the criminal charges, Wyeth has pleaded guilty to a criminal information charging a misbranding violation under the Federal Food, Drug and Cosmetic Act (FDCA). According to the information that was filed, Wyeth trained its national Rapamune sales force to promote the use of the drug for all transplant patients, including by providing training materials regarding non-renal transplant use, and offering financial incentives to target all transplant patient populations.

Under the plea agreement, Wyeth will pay a total of $233.5 million in criminal fines and forfeitures. Of this amount, $157.58 million will be paid in fines, while the company will forfeit assets of $76 million.

The civil settlement resolves the two lawsuits that were pending under the whistleblower, provisions of the False Claims Act in the Western District of Oklahoma. The qui tam lawsuits alleged that Wyeth violated the False Claims Act, from 1998 through 2009, by promoting Rapamune for unapproved uses, some of which were not medically accepted indications and, therefore, were not covered by Medicare, Medicaid and other federal health care programs. The government alleged that this conduct resulted in the submission of false claims to government health care programs.

The resolution of the civil cases also includes settlements with the federal government and the states totaling $257.4 million. Of these amounts, Wyeth will pay $230,112,596 to the federal government and $27,287,404 to the states. The whistleblowers' share of the settlement has not yet been determined.

Authors and Contributors

Sara M. Lord
Partner, DC Office
202.677.4054
sara.lord@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with 160 attorneys in Atlanta, Washington, DC and Miami, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street NW
Suite 2100
Atlanta, GA 30363

Miami Office
Two South Biscayne Boulevard
One Biscayne Tower 2690
Miami, FL 33131

Washington, DC Office
1775 Pennsylvania Ave., NW,
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**