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

Wyeth Pharmaceuticals Inc., a pharmaceutical company acquired by Pfizer, Inc. in 2009, has agreed to pay $490.9 million to resolve its criminal and civil liability arising from the unlawful marketing of the prescription drug Rapamune for uses not approved as safe and effective by the U.S. Food and Drug Administration (FDA), the Justice Department announced today. Rapamune is an “immunosuppressive” drug that prevents the body’s immune system from rejecting a transplanted organ.

“FDA’s drug approval process ensures companies market their products for uses proven safe and effective,” said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department’s Civil Division. “We will hold accountable those who put patients’ health at risk in pursuit of financial gain.”

The Federal Food, Drug and Cosmetic Act (FDCA) requires a company such as Wyeth 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 until the company receives FDA approval for the new intended uses. In 1999, Wyeth received approval from the FDA for Rapamune use in renal (kidney) transplant patients. However, the information alleges, Wyeth trained its national Rapamune sales force to promote the use of the drug in non-renal transplant patients. Wyeth provided the sales force with training materials regarding non-renal transplant use and trained them on how to use these materials in presentations to transplant physicians. Then, Wyeth encouraged sales force members, through financial incentives, to target all transplant patient populations to increase Rapamune sales.

“Wyeth's conduct put profits ahead of the health and safety of a highly vulnerable patient population dependent on life-sustaining therapy,” said Antoinette V. Henry, Special Agent in Charge, Metro-Washington Field Office, FDA Office of Criminal Investigations. “FDA OCI is committed to working with the Department of Justice and our law enforcement counterparts to protect public health.”

Wyeth has pleaded guilty to a criminal information charging it with a misbranding violation under the Federal Food, Drug and Cosmetic Act (FDCA). The resolution includes a criminal fine and forfeiture totaling $233.5 million. Under a plea agreement, which has been accepted by the U.S. District Court in Oklahoma City, Wyeth has agreed to pay a criminal fine of $157.58 million and forfeit assets of $76 million.

The resolution also includes civil settlements with the federal government and the states totaling $257.4 million. Wyeth has agreed to settle its potential civil liability in connection with its off-label marketing of Rapamune. The government 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. These unapproved uses included non-renal transplants, conversion use (switching a patient from another immunosuppressant to Rapamune) and using Rapamune in combination with other immunosuppressive agents not listed on the label. The government alleged that this conduct resulted in the submission of false claims to government health care programs. Of the amounts to resolve the civil claims, Wyeth will pay $230,112,596 to the federal government and $27,287,404 to the states.

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Pfizer is currently subject to a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services' Office of Inspector General that it entered in connection with another matter in 2009, shortly before acquiring Wyeth. 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.

“We are committed to enforcing the laws protecting public health, taxpayers and government health programs, and to promoting effective compliance programs,” said Daniel R. Levinson, Inspector General, Department of Health and Human Services. “Our integrity agreement with Pfizer, which acquired Wyeth, includes required risk assessments, a confidential disclosure program, and auditing and monitoring to help prospectively identify improper marketing.”

The civil settlement resolves two lawsuits pending in federal court in the Western District of Oklahoma 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 share in any recovery. The first action was filed by a former Rapamune sales representative, Marlene Sandler, and a pharmacist, Scott Paris. The second action was filed by a former Rapamune sales representative, Mark Campbell. The whistleblowers’ share of the civil settlement has not been resolved.

“The success obtained in this case is an excellent example of how we address the threats to our nation’s health care system; the importance of the public reporting of fraud, waste, or abuse; and the significant results that can be obtained through multiple agencies cooperating in investigations,” said James E. Finch, Special Agent in Charge of the Oklahoma City Division of the FBI.

The criminal case was handled by the U.S. Attorney’s Office for the Western District of Oklahoma (USAO) and the Justice Department’s Civil Division, Consumer Protection Branch. The civil settlement was handled by USAO and the Justice Department’s Civil Division, Commercial Litigation Branch. The Department of Health and Human Services’ (HHS) Office of Counsel to the Inspector General; the HHS Office of General Counsel, Center for Medicare and Medicaid Services; the FDA’s Office of Chief Counsel; and the National Association of Medicaid Fraud Control Units. These matters were investigated by the FBI; the FDA’s Office of Criminal Investigation; HHS’ Office of Inspector General, Office of Investigations and Office of Audit Services; the Defense Criminal Investigative Service; the Office of Personnel Management’s Office of Inspector General and Office of Audit Services; the Department of Veterans’ Affairs’ Office of Inspector General; and TRICARE Program Integrity.

Except for conduct admitted in connection with the criminal plea, the claims settled by the civil agreement are allegations only, and there has been no determination of civil liability. The civil lawsuits are captioned United States ex rel. Sandler et al v. Wyeth Pharmaceuticals, Inc., Case No. 05-6609 (E.D. Pa.) and United States ex rel. Campbell v. Wyeth, Inc., Case No. 07-00051 (W.D. Okla.).