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### **U.S. Subsidiary of Belgian Pharmaceutical Manufacturer Pleads Guilty to Off-Label Promotion; Company to Pay More Than \$34 Million**

*UCB Inc. Promoted Anti-Epileptic Drug Keppra for Off-Label Uses*

**U.S. Department of Justice**

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**Office of Public Affairs**

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WASHINGTON—The U.S. subsidiary of Belgian pharmaceutical manufacturer UCB S.A. pleaded guilty today to the off-label promotion of its epilepsy drug Keppra and will pay more than \$34 million to resolve criminal and civil liability arising out of its illegal conduct, the Justice Department announced today.

Under the terms of the plea agreement before the U.S. Court for the District of Columbia, UCB Inc., which has its headquarters in Smyrna, Ga., pleaded guilty to a misdemeanor in connection with the company's misbranding of Keppra, in violation of the Food, Drug and Cosmetic Act. Keppra was approved by the Food and Drug Administration (FDA) as an anti-epileptic drug, for the treatment of seizures in adults and children suffering from epilepsy. Keppra is not approved for the treatment of migraine, headache, psychiatric conditions or pain conditions. Once approved by the FDA, a manufacturer may not market or promote a drug for any use not specified in the FDA-approved product label. These uses are also known as unapproved or "off-label" uses.

The government alleged that UCB promoted the sale of Keppra for off-label use in the treatment of migraine by generating and disseminating posters representing that Keppra was safe and effective for treating migraine based on purportedly independent investigator-initiated studies. The posters did not disclose UCB's sponsorship of these studies or that UCB's own clinical trial had failed to demonstrate that Keppra was effective in treating migraine.

UCB will pay a \$7.55 million criminal fine for the misbranding of Keppra and an asset forfeiture of \$1.078 million.

In addition, UCB will pay \$25.7 million to resolve civil allegations under the False Claims Act that the company illegally promoted Keppra and caused false claims to be submitted to government healthcare programs for a variety of off-label uses that were not medically accepted indications and therefore not covered by those programs, including headache, migraine, pain, bipolar, mood disorders and anxiety. The federal share of the civil settlement is \$15,871,208, and the state Medicaid share of the civil settlement is \$9,893,322.

"UCB put its pursuit of profits ahead of its obligations to patients," said Ronald C. Machen Jr., U.S. Attorney for the District of Columbia. "Today's guilty plea and UCB's \$34 million payout should remind drug companies that try to cleverly design off-label marketing schemes that we will not allow them to compromise patient safety."

"Patients have a right to know that the drugs they are prescribed have been approved by the FDA as safe and effective for a particular use," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "Off-label promotion of pharmaceuticals undermines the FDA's important role in protecting the public and is a drain on taxpayer dollars."

"This settlement demonstrates the ongoing efforts to pursue violations of the False Claims Act and recover taxpayer dollars for Medicaid and other federal health care programs," noted Dwight C. Holton, U.S. Attorney for the District of Oregon. "Our office will continue to work with whistleblowers and law enforcement to stop health care fraud."

The civil settlement resolves two whistleblower lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act that are pending in Washington, D.C., and Oregon: United States ex rel. Root v. UCB, Civil Action No. 1:07-cv-1056, and United States ex rel. Maly v. UCB, Inc., Civil Action No. 1:08-cv-1161. As part of today's resolution, the whistleblowers will receive payments totaling more than \$2.8 million from the federal share of the civil recovery.

Also as part of the resolution accepted by the court, UCB has entered into an expansive corporate integrity agreement (CIA) with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and

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Patients have a right to be prescribed drugs based on sound medical judgment — not on drug company payoffs or off-label promotions,” said Daniel R. Levinson, Inspector General of the Department of Health & Human Services. “Taxpayers shouldn’t have to pay for unlawful conduct.”

“Today’s guilty plea and settlement is evidence of the government’s continued commitment to hold pharmaceutical companies accountable when they undermine the drug approval process by promoting drugs for uses not approved by the FDA as safe and effective,” said Acting Director Kathleen Martin-Weis of FDA’s Office of Criminal Investigations. “We will continue to join forces with the Department of Justice and our law enforcement counterparts to seek this kind of criminal resolution when pharmaceutical companies put profits ahead of the public health and safety.”

The criminal case was handled by the U.S. Attorney’s Office for the District of Columbia and the Justice Department’s Office of Consumer Protection Litigation.

The civil settlement was reached by the U.S. Attorney’s Offices for the District of Columbia and the District of Oregon and the Commercial Litigation Branch of the Justice Department’s Civil Division. The CIA was negotiated by the Office of Inspector General of the Department of Health and Human Services. The investigation was conducted by the Department of Veterans Affairs Office of Inspector General, the FBI’s Washington Field Office and FDA Office of Criminal Investigations. Assistance was provided by the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

This resolution is part of the government’s emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than \$5.7 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department’s total recoveries in False Claims Act cases since January 2009 are over \$7.3 billion.

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