

## JUSTICE NEWS

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## **Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations**

### ***Former President and Three District Managers Also Face Criminal Charges***

Warner Chilcott U.S. Sales LLC, a subsidiary of pharmaceutical manufacturer Warner Chilcott PLC, has agreed to plead guilty to a felony charge of health care fraud, the Justice Department announced today. The plea agreement is part of a global settlement with the United States in which Warner Chilcott has agreed to pay \$125 million to resolve its criminal and civil liability arising from the company's illegal marketing of the drugs Actonel<sup>®</sup>, Asacol<sup>®</sup>, Atelvia<sup>®</sup>, Doryx<sup>®</sup>, Enablex<sup>®</sup>, Estrace<sup>®</sup> and Loestrin<sup>®</sup>. Prior to today's guilty plea by Warner Chilcott, several individuals also pleaded guilty or were charged in connection with the company's illegal activities.

Warner Chilcott agreed to plead guilty in the District of Massachusetts to criminal charges that the company committed a felony violation by paying kickbacks to physicians throughout the United States to induce them to prescribe its drugs, manipulating prior authorizations to induce insurance companies to pay for prescriptions of Atelvia<sup>®</sup> that the insurers may not have otherwise paid for and making unsubstantiated marketing claims for the drug Actonel<sup>®</sup>.

Earlier today, an indictment was unsealed in the District of Massachusetts charging former Warner Chilcott President W. Carl Reichel, 57, of Chester, New Jersey, with one count of conspiring to pay kickbacks to physicians. Reichel was arrested today in Boston and will make an initial appearance at 2:30 p.m. before U.S. District Court Magistrate Judge Jennifer C. Boal.

"The Justice Department is committed to protecting the integrity of physician prescribing decisions and ensuring that financial arrangements in the healthcare marketplace comply with the law," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "The Department will continue to hold companies and responsible individuals accountable when they use improper incentives, like those alleged here, to promote their products."

"Doctors' medical judgment should be based on what is best for the patient, and not clouded by expensive meals and other pharmaceutical company kickbacks," said U.S. Attorney Carmen M. Ortiz for the District of Massachusetts. "Pharmaceutical company executives and employees should not be involved with treatment decisions or submissions to a patient's insurance company. Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."

In a criminal information filed today in the District of Massachusetts, the government charged that, between 2009 and 2013, Warner Chilcott, through its employees acting at the direction of members of the company's management team, knowingly and willfully paid remuneration to physicians in order to induce those physicians to prescribe Warner Chilcott drugs. Under the law, it is illegal to offer or pay remuneration to physicians to induce them to refer individuals to pharmacies for the dispensing of drugs for which payments are made in whole or in part under a federal health care program. The information alleges that Warner Chilcott employees, at the direction of company management, provided payments, meals and other remuneration associated with so-called "Medical Education Events," which included dinners, lunches and receptions. These events, which were often held at expensive restaurants, often contained minimal or no educational component and were instead used to pay prescribing physicians in an attempt to gain a "competitive advantage" over other companies. Warner Chilcott also enlisted high-prescribing physicians as "speakers" for the company. In fact, the "speakers" often did not actually speak about any clinical or scientific topics, and, instead, the payments were primarily intended to induce prescriptions. For instance, Warner Chilcott informed "speakers" who were not prescribing at a high volume that they would not be paid for subsequent events unless their prescribing habits increased.

In addition, the information alleges that from 2011 to 2013, Warner Chilcott employees knowingly and willfully submitted false, inaccurate, or misleading prior authorization requests and other coverage requests to federal health care programs for the osteoporosis medications Atelvia<sup>®</sup> and Actonel<sup>®</sup>. The false, inaccurate and misleading information was provided to certain insurance companies in order to overcome formulary restrictions that favored less expensive osteoporosis drugs. For instance, Warner Chilcott was aware that many insurers only paid for Atelvia<sup>®</sup> if a physician submitted an individualized request explaining why the patient could not be treated with less-expensive medications approved to treat the same conditions. As detailed in the information, Warner Chilcott sales representatives filled out numerous prior authorizations for Atelvia<sup>®</sup>, using "canned" medical justifications which often were inconsistent with the patients' medical conditions. In some instances, according to the information, Warner Chilcott sales representatives submitted these prior authorizations directly to insurance companies, holding themselves out to be physicians. In other cases, sales representatives coached physicians and staff about which medical justifications would result in an approved prior authorization, whether or not the justification was true for a particular patient.

Finally, the information alleges that Warner Chilcott employees were instructed by members of the company's management team to make unsubstantiated superiority claims when marketing the drug Actonel<sup>®</sup>. The management team instructed the sales representatives to tell physicians that Actonel<sup>®</sup> was superior to other bisphosphonates due to its supposedly unique "mechanism of action." According to the information, Warner Chilcott managers also encouraged sales representatives to use props to visually support this false claim, including pouring water and syrup onto two sponges while telling physicians that Actonel, like water, penetrated and exited the bone more quickly than its competitors, represented by the syrup. Warner Chilcott management directed the sales representatives to make the superiority claim even though the claim was not supported by clinical evidence.

Under the terms of the plea agreement, Warner Chilcott will pay a criminal fine of \$22.94 million.

Warner Chilcott also entered into a civil settlement agreement under which it agreed to pay \$102.06 million to the federal government and the states to resolve claims arising from its conduct, which allegedly caused false claims to be submitted to government health care programs. The civil settlement resolved allegations that Warner Chilcott violated the federal Ant-Kickback Statute by paying illegal remuneration to prescribing physicians in connection with the so-called "Medical Education Events" and speaker programs and caused the submission of false prior authorization requests for Atelvia<sup>®</sup> and Actonel<sup>®</sup>. The federal share of the civil settlement is approximately \$91.5 million, and the state Medicaid share of the civil settlement is approximately \$10.6 million.

Prior to today's guilty plea by Warner Chilcott and civil settlement, several individuals were either criminally charged

or pleaded guilty to various offenses related to the company's alleged conduct. Two former district managers, Jeffrey Podolsky, 49, of East Meadow, New York, and Timothy Garcia, 35, of Los Gatos, California, previously pleaded guilty to various charges, including conspiracy to commit health care fraud and violations of the Health Insurance Portability and Accountability Act (HIPAA). A third former district manager, Landon Eckles, 30, of Huntersville, North Carolina, was criminally charged earlier this month for alleged HIPAA violations relating to the alleged prior authorization scheme. Last week a Springfield, Massachusetts physician, Rita Luthra, M.D., 64, of Longmeadow, Massachusetts, was charged with, among other things, allegedly accepting free meals and speaker fees from Warner Chilcott in return for prescribing its osteoporosis drugs.

"Placing financial gain above the legitimate needs of patients is deplorable," said Inspector General Daniel R. Levinson of the U.S. Department of Health and Human Services (HHS). "Paying kickbacks and even providing instructions on how to defraud Medicare are practices that will not be tolerated."

"Pharmaceutical companies and their employees have a significant responsibility to sell and market drugs in an ethical and legal manner," said Special Agent in Charge Harold H. Shaw of the FBI's Boston Field Office. "This settlement and the related indictments reflect the commitment of the FBI and our government partners to aggressively investigate companies and individuals who fail that responsibility and seek to profit from fraudulent activities."

The civil settlement resolves a lawsuit filed under the whistleblower provisions of the False Claims Act, which permit private individuals to sue on behalf of the government for false claims and to share in any recovery. The civil lawsuit was filed in the District of Massachusetts and is captioned *United States ex rel. Alexander, et al. v. Warner Chilcott plc, et al.*, Civil Action No. 11-CA-1121 (D. Mass.). As part of today's resolution, the whistleblowers will receive approximately \$22.9 million from the federal share of the civil recovery.

The criminal case was prosecuted by the U.S. Attorney's Office of the District of Massachusetts and the Civil Division's Consumer Protection Branch. The civil settlement was handled by the U.S. Attorney's Office of the District of Massachusetts and the Civil Division's Commercial Litigation Branch. Assistance was provided by the FDA's Office of Chief Counsel, HHS Office of Counsel to the Inspector General, and the National Association of Medicaid Fraud Control Units. This matter was investigated by the FBI, HHS Office of the Inspector General, the Department of Defense's Defense Criminal Investigative Service, the FDA's Office of Criminal Investigations, the Department of Veterans Affairs and the Office of Personnel Management's Office of Inspector General.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. 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 this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$26.2 billion through False Claims Act cases, with more than \$16.4 billion of that amount recovered in cases involving fraud against federal health care programs.

Except for the conduct admitted in connection with the criminal plea, the claims resolved by the civil agreement are allegations only, and there has been no determination of civil liability.

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Civil Division

**Topic:**

Consumer Protection

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