Department of Justice

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Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa

$515 Million Criminal Fine Is Largest Individual Corporate Criminal Fine in History; Civil Settlement up to $800 Million

American pharmaceutical giant Eli Lilly and Company today agreed to plead guilty and pay $1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration (FDA), the Department of Justice announced today. This resolution includes a criminal fine of $515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind. Eli Lilly will also pay up to $800 million in a civil settlement with the federal government and the states.

Eli Lilly agreed to enter a global resolution with the United States to resolve criminal and civil allegations that it promoted its antipsychotic drug Zyprexa for uses not approved by the FDA, the Department said. Such unapproved uses are also known as "off-label" uses because they are not included in the drug's FDA approved product label.

Assistant Attorney General for the Civil Division Gregory G. Katsas and acting U.S. Attorney for the Eastern District of Pennsylvania Laurie Magid today announced the filing of a criminal information against Eli Lilly for promoting Zyprexa for uses not approved by the FDA. Eli Lilly, headquartered in Indianapolis, is charged in the information with promoting Zyprexa for such off-label or unapproved uses as treatment for dementia, including Alzheimer's dementia, in elderly people.

The company has signed a plea agreement admitting its guilt to a misdemeanor criminal charge. Eli Lilly also signed a civil settlement to resolve civil claims that by marketing Zyprexa for unapproved uses, it caused false claims for payment to be submitted to federal insurance programs such as Medicaid, TRICARE and the Federal Employee Health Benefits Program, none of which provided coverage for such off-label uses.

The plea agreement provides that Eli Lilly will pay a criminal fine of $515 million and forfeit assets of $100 million. The civil settlement agreement provides that Eli Lilly will pay up to an additional $800 million to the federal government and the states to resolve civil allegations originally brought in four separate lawsuits under the *qui tam* provisions of the federal False Claims Act. The federal share of the civil settlement amount is $438 million. Under the terms of the civil settlement, Eli Lilly will pay up to $361 million to those states that opt to participate in the agreement.

Under the Food, Drug, and Cosmetic Act (FDCA), a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.

The FDA originally approved Zyprexa, also known by the chemical name olanzapine, in Sept. 1996 for the treatment of manifestations of psychotic disorders. In March 2000, FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder. In Nov. 2000, FDA approved Zyprexa for the short term treatment of schizophrenia in place of the management of the manifestations of psychotic disorders. Also in Nov. 2000, FDA approved Zyprexa for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months. Zyprexa has never been approved for the treatment of dementia or Alzheimer's dementia.

The criminal information, filed in the Eastern District of Pennsylvania, alleges that from Sept. 1999 through at least Nov. 2003, Eli Lilly promoted Zyprexa for the treatment of agitation, aggression, hostility, dementia, Alzheimer's dementia, depression and generalized sleep disorder. The information alleges that Eli Lilly's management created marketing materials promoting Zyprexa for off-label uses, trained its sales force to disregard the law and directed its sales personnel to promote Zyprexa for off-label uses.

The information alleges that beginning in 1999, Eli Lilly expended significant resources to promote Zyprexa in nursing homes and assisted-living facilities, primarily through its long-term care sales force. Eli Lilly sought to convince doctors to prescribe Zyprexa to treat patients with disorders such as dementia, Alzheimer's dementia, depression, anxiety, and sleep problems, and behavioral symptoms such as agitation, aggression, and hostility.

The information further alleges that the FDA never approved Zyprexa for the treatment of dementia, Alzheimer's dementia, psychosis associated with Alzheimer's disease, or the cognitive deficits associated with dementia.

The information also alleges that building on its unlawful promotion and success in the long-term care market, Eli Lilly executives decided to market Zyprexa to primary-care physicians. In Oct. 2000, Eli Lilly began this off-label marketing campaign targeting primary care physicians, even though the company knew that there was virtually no approved use for Zyprexa in the primary-care market. Eli Lilly trained its primary-care physician sales representatives to promote Zyprexa by focusing on symptoms, rather than Zyprexa's FDA approved indications.

The *qui tam* lawsuits alleged that between Sept. 1999 and the end of 2005, Eli Lilly promoted Zyprexa for use in patients of all ages and for the treatment of anxiety, irritability, depression, nausea, Alzheimer's and other mood disorders. The *qui tam* lawsuits also alleged that the company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

"Off-label promotion of pharmaceutical drugs is a serious crime because it undermines the FDA's role in protecting the American public by determining that a drug is safe and effective for a particular use before it is marketed," said Gregory G. Katsas, Assistant Attorney General for the Civil Division. "This settlement demonstrates the Department's ongoing diligence in prosecuting cases involving violations of the Food, Drug, and Cosmetic Act, and recovering taxpayer dollars used to pay for drugs sold as a result of off-label marketing campaigns."

"When pharmaceutical companies ignore the government's process for protecting the public, they undermine the integrity of the doctor-patient relationship and place innocent people in harm's way," said acting U.S. Attorney for the Eastern District of Pennsylvania, Laurie Magid. "Off-label marketing created unnecessary risks for patients. People have an absolute right to their doctor's medical expertise, and to know that their health care provider's judgment has not be clouded by misinformation from a company trying to build its bottom line."

The global resolution includes the following agreements:

- A plea agreement signed by Eli Lilly admitting guilt to the criminal charge of misbranding. Specifically, Eli Lilly admits that between Sept. 1999 and March 31, 2001, the company promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia. Eli Lilly has agreed to pay a $515 million criminal fine and to forfeit an additional $100 million in assets.
- A civil settlement between Eli Lilly, the United States and various States, in which Eli Lilly will pay up to $800 million to the federal government and the states to resolve False Claims Act claims and related state claims by Medicaid and other federal programs and agencies including TRICARE, the Federal Employees Health Benefits Program, Department of Veterans Affairs, Bureau of Prisons and the Public Health Service Entities. The federal government will receive $438,171,544 from the civil settlement. The state Medicaid programs and the District of Columbia will share up to $361,828,456 of the civil settlement, depending on the number of states that participate in the settlement.
- The *qui tam* relators will receive $78,870,877 from the federal share of the settlement amount.
- A Corporate Integrity Agreement (CIA) between Eli Lilly and the Office of Inspector General of the Department of Health and Human Services. The five-year CIA requires, among other things, that a Board of Directors committee annually review the company's compliance program and certify its effectiveness; that certain managers annually certify that their departments or functional areas are compliant; that Eli Lilly send doctors a letter notifying them about the global settlement; and that the company post on its website

information about payments to doctors, such as honoraria, travel or lodging. Eli Lilly is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches.

"OIG's Corporate Integrity Agreement will increase the transparency of Eli Lilly's interactions with physicians and strengthen Eli Lilly's accountability for its compliance with the law," said Department of Health and Human Services Inspector General Daniel R. Levinson. "This historic resolution demonstrates the Government's commitment to improve the integrity of drug promotion activities."

In addition to the $1.415 billion criminal and civil settlement announced today, Eli Lilly previously agreed to pay $62 million to settle consumer protection lawsuits brought by 33 states. The state consumer protection settlements were announced on Oct. 7, 2008.

"Today's announcement of the filing of a criminal charge and the unprecedented terms of this settlement demonstrates the government's increasing efforts aimed at pharmaceutical companies that choose to put profits ahead of the public's health," said Special Agent-in-Charge Kim Rice of FDA's Office of Criminal Investigations. "The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the safeguards of the drug approval process and recklessly promote drugs for uses for which they have not been proven to be safe and effective."

"The illegal scheme used by Eli Lilly significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Ed Bradley, Special Agent-in-Charge, Defense Criminal Investigative Service. "This illegal activity increases patients' costs, threatens their safety and negatively affects the delivery of healthcare services to the over nine million military members, retirees and their families who rely on this system. Today's charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its partners in law enforcement to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"This case should serve as still another warning to all those who break the law in order to improve their profits," said Patrick Doyle, Special Agent-in-Charge of the Office of Inspector General for the Department of Health and Human Services in Philadelphia. "OIG, working with our law enforcement partners, will pursue and bring to justice those who would steal from vulnerable beneficiaries and the taxpayers."

The civil settlement resolves four *qui tam* actions filed in the Eastern District of Pennsylvania: *United States ex rel. Rudolf, et al., v. Eli Lilly and Company,* Civil Action No. 03-943 (E.D. Pa.)*; United States ex rel. Faltaous v. Eli Lilly and Company,* Civil Action No. 06-2909 (E.D. Pa.)*; United States ex rel. Woodward v. Dr. George B. Jerusalem, et al.,* Civil Action No. 06-5526 (E.D. Pa.)*;* and *United States ex rel. Vicente v. Eli Lilly and Company,* Civil Action No. 07-1791 (E.D. Pa.). All of those cases were filed by former Eli Lilly sales representatives.

The criminal case is being prosecuted by the U.S. Attorney's Office for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Justice Department's Civil Division. The civil settlement was reached by the U.S. Attorney's Office and the Commercial Litigation Branch of the Justice Department's Civil Division.

This matter was investigated by the FDA's Office of Criminal Investigations, the Defense Criminal Investigative Service and the Department of Health and Human Services Office of Inspector General.

Assistance was provided by representatives of FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

The Corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services.

Eli Lilly's guilty plea and sentence is not final until accepted by the U.S. District Court.

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