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PHARMACEUTICAL COMPANIES TO PAY \$214.5 MILLION TO RESOLVE ALLEGATIONS OF OFF-LABEL PROMOTION OF EPILEPSY DRUG

BOSTON, Mass. – Irish pharmaceutical manufacturer Elan Corporation, PLC (Elan) and its U.S. subsidiary, Elan Pharmaceuticals, Inc. (EPI) have agreed to pay over \$203.5 million to resolve criminal and civil liability arising from the illegal promotion of the epilepsy drug Zonegran, the Justice Department announced today. In a separate civil settlement, Japanese drug marketer Eisai, Inc. which purchased the drug from Elan, has already paid \$11 million to resolve civil liability for off-label marketing of Zonegran.

Pursuant to the agreement, EPI has agreed to plead guilty to an information charging it with misdemeanor misbranding of Zonegran, in violation of the Food, Drug and Cosmetic Act. Zonegran was approved by the Food and Drug Administration (FDA) as an adjunctive therapy for the treatment of partial seizures in epilepsy for adults over the age of 16, and was not approved for any other uses. Elan promoted the sale of Zonegran for a wide variety of improper off-label uses for example, psychiatric disorders including mood stabilization for mania and bipolar disorder; migraine headaches; chronic daily headaches; eating disorders; obesity/weight loss; movement disorders (i.e. Parkinson's Disease); monotherapy (not using it in combination therapy but alone); and for a variety of seizures in children under the age of 16. Elan's off-label marketing efforts targeted non-epilepsy prescribers and the company paid illegal kickbacks to physicians in an effort to persuade them to prescribe Zonegran for these off-label uses. Under the terms of the plea agreement, Elan has agreed to pay a criminal fine of \$97,050,266 and plead guilty to a misdemeanor violation of the Food Drug and Cosmetic Act. EPI will also forfeit \$3.6 million in substituted assets.

In addition, Elan has agreed to pay \$102,890,517 to resolve civil allegations under the False Claims Act that the company illegally promoted Zonegran and caused false claims to be submitted to government healthcare programs for a variety of uses that were not medically accepted indications and therefore not covered by those programs. The federal share of the civil settlement is \$59,491,477, and the state Medicaid share of the civil settlement is \$43,399,040.

The civil settlement resolves a whistleblower lawsuit filed under the *qui tam* provisions of the False Claims Act that is pending in the District of Massachusetts: *United States ex rel. Chartock, et al. v. Elan Corporation, PLC, et al.* Civil Action No. 04-11594-RWZ. As part of today's resolution, the whistleblower will receive payments totaling more than \$10 million from the federal share of the civil recovery.

Also as part of the settlement, Elan has agreed to enter into a corporate integrity

agreement with the Office of Inspector General of the Department of Health and Human Services that provides for procedures and reviews to be put in place, in order to avoid and promptly detect conduct similar to that which gave rise to this matter.

Under the settlement with Eisai, entered into in June, that company paid \$11 million to resolve civil allegations under the False Claims Act that the company illegally promoted Zonegran and caused false claims to be submitted to government healthcare programs for uses that were not medically accepted indications and therefore not covered by those programs. The federal share of the civil settlement is \$6,341,751, and the state Medicaid share of the civil settlement is \$4,658,249. Eisai purchased the drug and its sales force from Elan in 2004. While Eisai retained the sales force and took steps to stop illegal marketing of the drug, some off-label marketing continued and Eisai benefitted from the previous off-label marketing by Elan.

The civil settlement with Eisai also resolves allegations in *United States ex rel. Chartock, et al. v. Elan Corporation, PLC, et al.* Civil Action No. 04-11594-RWZ. As part of today's resolution, the whistleblower has received payments totaling more than \$1 million from the federal share of the civil recovery.

"Off-label promotion of pharmaceutical products undermines the FDA's important role in protecting the American public by determining whether a drug is safe and effective for a particular use before it is marketed," said Tony West, Assistant Attorney General. "Such illegal conduct by pharmaceutical companies also costs the government billions of dollars, and these civil settlements and the criminal plea agreement by Elan demonstrate that such conduct will not be tolerated."

"This global resolution reflects the government's continued commitment to combating pharmaceutical fraud in all its forms, especially where it effects the safe use of potent drugs being prescribed to children. We will continue to aggressively investigate and prosecute companies who intentionally put patient safety at risk in order to turn a profit," said United States Attorney Carmen M. Ortiz.

"Our priority is to protect taxpayer-funded government health care programs and beneficiaries," said Daniel R. Levinson, Inspector General of the Department of Health and Human Services. "If Elan -- or any of its subsidiaries - intends in the future to actively promote drugs reimbursed by Federal health care programs, the company has agreed to accept even stricter amendments to the formal compliance program signed with OIG today."

"Today's announcement signals the government's commitment to investigate and prosecute companies that violate the law and choose to put their profits ahead of the public health," said Acting Director Thomas Doyle of FDA's Office of Criminal Investigations. "The FDA will continue to pursue criminal resolutions when pharmaceutical companies undermine the drug approval process by promoting drugs for uses not approved by the FDA as safe and effective."

This settlement is part of the government's emphasis on combating health care

fraud. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover approximately \$2.2 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 have topped \$5.8 billion. The District of Massachusetts has recovered over \$4 billion in civil and criminal penalties in the last two years alone.

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Justice Department's Office of Consumer Litigation. The civil settlements were reached by the U.S. Attorney's Office and the Commercial Litigation Branch of the Justice Department's Civil Division. The Corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services. Assistance was provided by the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

The investigation was led by Assistant United States Attorneys Mary Elizabeth Carmody of Ortiz's Healthcare Fraud Unit and Anton P. Giedt of Ortiz's Civil Division, and Department of Justice Trial Attorney Brian McCabe from the Frauds Section of the Justice Department's Civil Division, with assistance from Patrick H. Hearn, Department of Justice Trial Attorney, Office of Consumer Litigation and Steven J. Tave, Associate Chief Counsel for Enforcement, U.S. Food & Drug Administration, Food & Drug Division, Office of General Counsel. Attorneys Mary Riordan and Geeta Kaveti of the Office of Counsel to the Inspector General, Office of Inspector General, Office of General Counsel, United States Department of Health and Human Services, provided assistance in the resolution of both cases. The cases against Elan and Eisai were investigated by Special Agents from the United States Food & Drug Administration, Office of Criminal Investigations; the United States Department of Health and Human Services, Office of Inspector General; the Federal Bureau of Investigation; and the Department of Veterans Affairs, Office of Inspector General.

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