THOMAS & ASSOCIATES
AND
DURRELL LAW OFFICE

Elan & Eisai Whistleblower Cases Settle for $203 Million and $11 Million

Law Firms Assist Successful Prosecution of Off-label Marketing Cases

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BOSTON – WEDNESDAY, DECEMBER 15, 2010 – Attorneys Robert M. Thomas, Jr. and Suzanne E. Durrell are pleased to announce a substantial whistleblower recovery for their client in a case originally filed in 2004 against pharmaceutical companies Elan Corp. and Eisai, Inc. The case involved allegations of improper "off-label" marketing of the anti-seizure drug Zonegran, first by Irish pharmaceutical manufacturer Elan Corp., then later by Japanese pharmaceutical company Eisai, Inc., which bought the rights to the drug from Elan in 2004.

In the Elan settlement, which was announced today, the company has agreed to plead guilty to introducing misbranded drugs into interstate commerce, in violation of the federal Food Drug and Cosmetic Act and pay criminal fines and forfeitures of just over $100 million. Elan is also paying $102,890,517 plus interest, in civil damages as a result of improper billings to federal and state health insurance programs. The criminal and civil settlements combined exceed $203 million. Eisai Inc. has separately agreed to pay $11 million in civil damages to the federal and state governments for the period of time the off-label marketing continued after it acquired the rights to the drug. There is no criminal case against Eisai, Inc., which came to terms with the government several months ago, but whose case remained under seal until today.

"Today's settlements are the latest in a long line of off-label prosecutions under the False Claims Act, including several involving anti-seizure, anti-pain, and anti-epilepsy medications. We can expect these kinds of results to continue as long as the industry turns a blind eye to off-label marketing by their sales forces," Thomas and Durrell said. "We are proud to have played

a part in holding companies accountable when they cross the line and put patients' safety at risk by promoting unapproved uses of drugs."

The complaint alleged that the defendant companies marketed Zonegran, which was approved only for reducing seizures, for weight loss and mood stabilization as well. The drug was not and is not approved for either of those uses. The increase in drug prescriptions resulting from this off-label marketing not only caused improper billings to the federal and state governments, but it also undercut the authority of the U.S. Food and Drug Administration, which determines the safety and efficacy of drug products and approves (and limits) their uses.

In 2004, Warner Lambert settled off-label claims about the anti-epileptic drug Neurontin for $430 million. In 2008, Cephalon settled off-label claims about the drug Gabitril, which was approved for anxiety, pain, and insomnia, for $425 million. In 2009, Pfizer paid a civil fine of one billion dollars in settlement of off-label claims concerning several of its products, including Lyrica, which was approved for epilepsy. In April of 2010, Ortho-McNeil settled off-label claims concerning the anti-seizure drug Topomax for $81 million. In September 2010, Novartis settled off-label claims concerning the anti-seizure drug Trileptal for $422 million. "There's a pattern here," said Thomas, "and it will continue until the personal and financial costs become greater than the economic benefits of engaging in the behavior. We are, and will continue to be, part of the process that increases those costs."

Federal and State False Claims Acts allow private citizens with detailed knowledge of fraud to bring an action on behalf of the governments and to assist in the recovery of the governments' stolen dollars. These statutes allow the government to recover three times the amount it was defrauded, in addition to civil penalties of $5,500 to $11,000 per false claim. In the Elan case, the company will pay the federal government over $101 million to settle the criminal allegations. The civil settlement of over $102 million will be divided between the federal government, which will receive over $ 59 million and the states, which will receive over $ 43 million, as a result of the states' losses in connection with the Medicaid programs.

The settlement was achieved through the coordinated efforts of the U.S. Justice Department, state attorneys general and other law enforcement entities including Medicaid Fraud Control Units, and the Office of Inspector General of the U.S. Department of Health and Human Services. Assistant U.S. Attorneys Anton Giedt and Mary Beth Carmody, and Department of Justice attorney Brian McCabe were primarily responsible for investigating the initial allegations and moving the case forward to completion. Robert Patten, Assistant Attorney General for the Commonwealth of Massachusetts

played a critical role in coordinating the Attorney General's offices of the fifty states, on behalf of the National Association of Medicaid Fraud Control Units.

Thomas and Durrell also hailed the work of Attorney Rory Delaney, whose substantial contributions to the case, when he was employed by Thomas & Associates, were instrumental in the result achieved today.

Bob Thomas and Suzanne Durrell have been involved in several substantial whistleblower settlements, including Serono Labs ($704 million) in 2005, Pfizer ($2.3 billion) in 2009, and Forest Labs ($330 million) earlier this year.

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