

# Breaking NEWS

## The Largest Pharma Fraud Whistleblower Case in U.S. History Totaling \$1.4 Billion

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### Sheller, P.C.

1528 Walnut Street, Third Floor  
Philadelphia, PA 19102  
www.Sheller.com

#### Media Contacts:

Stephen A. Sheller, Esq.  
SASheller@sheller.com  
215-790-7300 Ofc 215-301-9999 Cell

Brian J. McCormick, Jr., Esq.  
BJMcCormick@Sheller.com  
215-790-7325 Ofc 215-687-7965 Cell

### Philadelphia Attorney Stephen Sheller's Whistleblower Clients Help Government Recover \$1.4 Billion Record Settlement and Criminal Fine in Eli Lilly & Company Zyprexa<sup>®</sup> Marketing Case

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Lead Attorney Filed Complaint in 2003 Representing Six Whistleblowers

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PHILADELPHIA – Pharmaceutical giant Eli Lilly & Company (“Lilly”) will pay federal and state governments more than \$1.4 billion to remedy a wide-ranging, off-label marketing scheme for its prescription drug, Zyprexa<sup>®</sup>. This settlement is the largest *qui tam* settlement in the history of the False Claims Act.

Stephen A. Sheller, a well-known mass tort and class action lawyer from Philadelphia, filed the first Complaint in the case in February 2003, bringing the off-label drug allegations to the government under seal as required by law. Today, after six years, the Department of Justice settled with Lilly the allegations that six former Lilly drug marketing representative whistleblowers brought to Sheller.

Lilly will pay more than \$1.4 billion for its illegal off-label marketing of the antipsychotic drug, the U.S. Attorney's Office for the Eastern District of Pennsylvania announced. Zyprexa is Lilly's top-selling drug with worldwide sales of nearly \$40 billion since its approval in 1996.

In today's settlement, Lilly will pay \$800 million in civil penalties and plead guilty to criminal charges, paying an additional \$600 million fine. The six whistleblowers who brought the Complaint against the drug company will share in approximately 18 percent of the federal and qualifying states' recoveries, Sheller said.

Related complaints filed by other law firms in 2005, 2006 and 2007 were ultimately consolidated into Sheller's first-filed Complaint.

“The reason the settlement and fine are record-breaking is because Eli Lilly perpetrated an outrageous fraud on the American government and taxpayers” said Sheller.

The whistleblowers represented by Sheller, two with 27 or more years' service at Lilly, expressed concern through proper channels about Lilly's improper marketing practices. All six whistleblowers were eventually fired or forced to resign. One sales representative, who also is a pharmacist, contacted the company hotline regarding unethical sales practices but received no response, according to the Complaint.

Zyprexa is approved by the U.S. Food and Drug Administration ("FDA") for very limited conditions – schizophrenia and a specific type of bipolar disorder. Under FDA rules, prescription drug manufacturers and marketers may only promote their products for approved uses.

To boost sales, Eli Lilly marketed Zyprexa for numerous off-label uses including Alzheimer's, depression and dementia according to Sheller's Complaint.

Eli Lilly's off-label sales strategies were very effective. The government's investigation found that a substantial amount of Zyprexa sales were for off-label uses, particularly in children and the elderly.

For years, Lilly has been accused of influencing doctors to prescribe Zyprexa to treat disruptive children and tranquilize nursing home patients. The FDA has not approved the drug for children or the elderly and the side effects of the drug are significant: inducing heart failure and pneumonia in the elderly and increasing the risk of significant weight gain and diabetes in children.

According to the Sheller Complaint, some of the tactics used by Eli Lilly to push Zyprexa sales beyond the drug's approved use were:

- During off-label lectures and audio conferences for physicians Lilly sales people posed as persons in the audience who were interested in Zyprexa's expanded use and asked "planted questions;"
- While knowing the significant risk for weight gain posed by Zyprexa, Lilly minimized the connection between Zyprexa and weight gain in a widely disseminated videotape called "The Myth of Diabetes" which used "allegedly scientific studies of questionable integrity as well as the haphazard reporting of adverse events;"
- Providing evidence that, in the summer of 2003, Lilly management ordered the destruction of sales literature with misleading information, "core sales aids, flip charts and acetates;" and
- Promoting the sublingual version of Zyprexa, called "Zydis," by claiming that it did not have the same weight-gain effects as Zyprexa.

Federal and state False Claims Acts allow private individuals to sue companies that knowingly defraud national or state governments. They also protect whistleblowers from demotion, suspension, harassment and discrimination for cooperating with the investigation of their employer.

"I applaud the courage of these whistleblowers. They came forth at personal and professional risk to protect the American people and expose corporate fraud," Sheller said.

Sheller also lauded the cooperation among federal prosecutors, investigators, the National Association of Medicaid Fraud Control Units and whistleblowers' attorneys that led to today's settlement. "The collaborative efforts we all took to bring this case to a conclusion is an affirmation of

how experienced whistleblower lawyers can work with authorities to reach a satisfactory conclusion,” Sheller said.

Acting United States Attorney Laurie Magid and Civil Division Assistant U.S. Attorneys Joseph Trautwein, Virginia Gibson, Peg Hutchison and Kathy Votaw of the Eastern District of Pennsylvania managed and oversaw the investigation. The criminal case was managed by Linda Hoffa, Criminal Division Chief. Sheller was effusive in his praise for the government attorneys, “The U.S. Attorneys’ Office in Philadelphia did exemplary work on this case. As a citizen, I was thrilled to see such an effective team.”

Joining Sheller in the case are attorneys Gary Farmer, Esq. of Rothstein Rosenfeldt Adler in Fort Lauderdale, Florida and Philadelphia attorney Michael Mustokoff, Esq. of Duane Morris.

The settlement is detailed in a 37-page Settlement Agreement, as well as in a Corporate Integrity Agreement executed by Lilly and the Office of Inspector General of the Department of Health and Human Services.

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#### **About Sheller, P.C.**

Sheller P.C. (<http://www.Sheller.com>) is among the preeminent plaintiff and *qui tam* whistleblower law firms in the United States. Stephen A. Sheller, Esq., Managing Partner, has been an effective advocate for victims for nearly three decades. Sheller has litigated groundbreaking cases ranging from premises liability and automobile litigation to defective drugs, products liability and whistleblower lawsuits. The firm also practices in complex mass tort and commercial litigation involving business disputes and consumer fraud. Mr. Sheller began the Palm Beach County, Florida litigation involving the 2000 U.S. Presidential election and the “butterfly ballots” which launched him into national media prominence as a lead attorney challenging the voting count. Sheller frequently appears on “The American Law Journal,” the television talk program on the law that airs on The Comcast Network.

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The American Law Journal  
Valerie Jones  
757-627-8200

PRforLAW, LLC  
Richard Lavinthal  
215-736-0198