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Pfizer's $2.3 Billion Settlement Today Is Largest Pharmaceutical *Qui Tam* Settlement in History and Includes Allegations of Illicitly Promoting Antibiotic As Clinically Superior When Its Own FDA-Approved Label Said Otherwise; First-Ever *Qui Tam* Whistleblower Settlement of Its Type

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PHILADELPHIA– Pfizer Inc. ignored a 2005 FDA Warning Letter to stop promoting its antibiotic Zyvox® as clinically superior to the significantly less expensive, generic vancomycin when its own FDA-approved label indicated otherwise. The drug giant also defrauded federal and state taxpayers by marketing Zyvox off-label, according to a *qui tam* whistleblower complaint filed by Sheller, P.C. attorneys and other documents unsealed with today's $2.3 billion Pfizer settlement.

The $2.3 billion settlement included off-label marketing allegations for the withdrawn arthritis drug Bextra®, which was included in the Sheller complaint. Zyvox (linezolid) is an antibacterial agent that is approved by the FDA to treat certain types of infections, including nosocomial pneumonia and complicated skin and skin structure infections ("CSSSIs") due to methicillin resistant Staphylococcus aureus ("MRSA"). Worldwide sales of Zyvox totaled $1.115 billion in 2008.

The largest pharmaceutical *qui tam* settlement in history, the $2.3 billion settlement was announced today by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts.

Stephen A. Sheller, Esq., name partner of the Philadelphia firm, earlier this year represented a relator, the legal term for a whistleblower, in the largest single-drug whistleblower case in U.S. history when Eli Lilly & Company paid $1.4 billion to settle Zyprexa® off-label marketing allegations. The Sheller firm's lawyers have previously represented several other whistleblowers in successful lawsuits.

Approximately $4.4 billion worth of Pfizer's Zyvox was sold from 2000 to 2008, according to the company's annual reports. Explosive sales increases averaged close to 200 percent per year. They also caused public health concerns of drug resistance and immunity, according to court and public documents.

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"The widespread off-label promotion of Zyvox by Pfizer for non-FDA approved purposes poses a grave public risk because it increases the risk that linezolid resistant eterococci will develop and also increases the risk that more Zyvox resistant bacterial strains will develop," according to Sheller's complaint.

In a 2007 letter to physicians, the New York State Health Department warned that, "Overuse of [Zyvox] will accelerate the development of resistance and limit its overall effectiveness."

"Let's hope this case helps put the brakes on the overuse of Zyvox so the New York State Health Department's warning doesn't come true and patients can continue to be treated effectively for the specific uses for which this drug is effective and approved," said James J. Pepper, Esq., of Sheller, P.C. who also represents the relator.

In its July 2005 Warning Letter, the FDA stated that Pfizer's ad misbranded Zyvox, made misleading and unsubstantiated implied superiority claims, and omitted important safety information. Although it paid lip service to the FDA in response to the letter, Pfizer continued to make claims to physicians that Zyvox was superior to vancomycin, according to Pepper. Zyvox costs approximately tens times as much as the generic vancomycin.

"Our client had a tremendous amount of information about the illegal marketing behind Zyvox that proved invaluable in making the case. We investigated his allegations and then filed a complaint under seal in federal court. As a result of what he observed and the careful cooperation our office had with federal and state authorities, he's been able to return millions of ill-gotten gains to taxpayers," said Brian J. McCormick, Esq., of Sheller, P.C. who also represents the relator.

Among the off-label promotion by Pfizer for Zyvox, according to the complaint:

- Promoting Zyvox for the treatment of catheter related skin infections and concomitant bloodstream infections associated with catheter related skin infections. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.
- Promoting Zyvox for the treatment of surgical site infections or as a prophylaxis for the prevention of surgical site infections. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.
- Promoting Zyvox as clinically superior to vancomycin. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.
- Promoting Zyvox as effective for all infections caused by MRSA including community acquired MRSA. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.
- Promoting Zyvox as an appropriate choice "anywhere on the treatment continuum" regardless of the infection. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.
- Promoting Zyvox as appropriate empiric therapy for all bacterial infections even though it has no effect on gram negative infections and only partial effect on polymicrobial

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infections. The promotion of Zyvox as appropriate empiric therapy for all infections constitutes an off-label promotion.

The government also discovered that Pfizer offered and paid illegal compensation to health care professionals to induce them to promote and prescribe Zyvox in violation of federal kickback laws.

"What Pfizer did with Zyvox was outrageous," Sheller said. "They effectively ignored a corporate integrity agreement with the federal government following an earlier 2004 off-label settlement."

"Our client showed tremendous courage when he came to us," Sheller said. "He knew what Pfizer was doing was wrong and wanted to do something about it. Without him, and the egregious promotion discovered in the investigation of our case I don't believe the government's case against Pfizer on Zyvox could have been made."

Under the FCA, so-called "*qui tam*" actions, a term derived from English Common Law meaning "he who sues on behalf of the king as well as himself," allow private citizens with knowledge of fraud to help the Government recover ill-gotten gains and additional civil penalties. The FCA allows the Government to collect up to three times the amount it was defrauded, in addition to civil penalties between $5,500 and $11,000 per false claim. Whistleblowers usually have received rewards representing 15 to 25 percent of *qui tam* recoveries, according to Sheller, whose law firm represents relators across the country.

Qui tam whistleblower cases recently settled by Sheller, P.C. have returned more than $1.5 billion to the U.S. and states' treasuries.

Sheller praised the work of Assistant U.S. Attorney Sara Bloom of the District of Massachusetts.

Sheller, McCormick and Pepper of Sheller, P.C. served as lead counsel in the case. Steven Brooks and Robert Hillman of Deutsch, Williams, Brooks, DeRensis & Holland, P.C., Boston, Massachusetts served as local counsel for the case.

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U.S. ex. rel. Ronald Rainero v. Pfizer, Inc.;
District of Massachusetts, Case No: 07-CA-11728;

For more information about Sheller, P.C. and its attorneys, visit www.sheller.com.

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