

Pfizer's \$2.3 Billion Settlement Leaves Victims in the lurch

Thursday, 03 September 2009

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The level of corruption that the pharmaceutical industry engages in--with assistance by prominent academic physicians who prostitute their academic credentials for cash--is beyond compare in its impact on undermining public health and depleting healthcare budgets.

The Justice Department announced that it has reached a settlement with Pfizer, who agreed to pay \$2.3 billion penalty to settle civil and criminal charges for its illegal promotion practices related to the drugs, Bextra and Lyrica (approved for pain), Geodon (approved for schizophrenia and acute manic depression in adults), and Zyvox (antibiotic to treat infection). It is the largest fine ever levied for fraud in the Medicare and Medicaid programs...

According to The New York Times, Obama administration officials — criticized by Republicans on Capitol Hill for failing to crack down on fraud in the government's health programs — sought to highlight the case by having Health and Human Services Secretary Kathleen Sebelius make the announcement.

However, The New York Post reports, "In an unusual twist, the head of the Justice Department, Attorney General Eric Holder, did not participate in the record settlement, because he had represented Pfizer on these issues while in private practice."

Pfizer, the world's largest drug manufacturer has the dubious distinction of being a corporate "repeat offender"-- rogue pharmaceutical corporations knowingly and deliberately put patients' lives at risk by violating federal law prohibiting the marketing of prescription drugs for uses that have not been tested and approved by the FDA.

New York State Attorney General, Andrew Cuomo, said:

"Pfizer ripped off New Yorkers and taxpayers across the country to pad its bottom line. Pfizer's corrupt practices went so far as sending physicians on exotic junkets as well as wining and dining health care professionals to persuade them to prescribe the company's drugs for patients in taxpayer-funded programs."

According to the Geodon whistleblower suit filed by Dr. Stefan Kruszeuski, and unsealed yesterday, Pfizer illegally promoted the sale and use of Geodon for a variety of off-label conditions, including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism, posttraumatic stress disorder, and for pediatric, adolescent and geriatric patients.

According to Dr. Kruszeuski's attorneys, Kenney, Egan, McCafferty & Young,

"Pfizer targeted pediatrics and adolescents to expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide." Kenney stated that, "Pfizer regularly paid generous speaking fees to these child psychiatrists to give what were basically promotional lectures about the benefits of Geodon to their peers, who were naturally also child psychiatrists, despite the fact the drug is not FDA-approved or medically indicated to treat children at all. The purpose and intent of paying so many child psychiatrists is clear -- to gain a foothold within the fastest growing market for antipsychotics -- children. The practice of expansive off-label use is dangerous, particularly in children because the drug has not been evaluated for its safety for the unique physiological make up of children."

Furthermore, Pfizer's marketing campaign also urged doctors to switch patients on other allegedly more dangerous atypical antipsychotics, such as Zyprexa, Seroquel and Risperdal, to Geodon. According to Kenney, Pfizer's switching campaign "endangered patients by ignoring or materially understating Geodon's serious, and even life threatening, side effects. Among Geodon's most dangerous side effects is its potential to affect the heart's rhythm, a condition known as QT prolongation. If the QT interval is increased excessively, conditions are created whereby unstable heart rhythms can intercede and disrupt the normal, regular rhythm essential for heart function." According to Kenney, "such ventricular rhythm disturbances greatly increase the risk of sudden cardiac death."

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.

According to the Zyvox Qui Tam whistleblower complaint filed by the Sheller, P.C. Law Firm, Pfizer 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.

The complaint charges: "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 enterococci will develop and also increases the risk that more Zyvox resistant bacterial strains will develop."

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

Pfizer spokesman Chris Loder confirmed Wednesday that the \$2.3 billion charge to the company's earnings had been taken in the fourth quarter of 2008. In other words, \$2.3 billion in criminal penalties are inconsequential to Pfizer--the penalties have already been absorbed by profits from its criminal marketing practices. Indeed, the company reported profits....!

When a company repeatedly engages in criminal actions, illegally promoting FDA-licensed controlled substances for uses NOT licensed--it puts people's lives at risk. The FDA has the legal authority to take decisive action so as to prevent rogue companies, such as Pfizer, from continuing to sell drugs that the company illegally promoted.

What prevents the government from delicensing drug products that companies criminally promoted for unapproved, unsafe uses?

Peter Rost, former Pfizer vice-president who blew the whistle on its illegal marketing of the growth hormone, has the most complete dossier on Pfizer's activities and legal settlements on his blog.

Of note: \$102 million of the settlement money will be shared by six corporate whistleblowers.

Under the False Claims Act, so-called "qui tam" whistleblower 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...

Left out in the cold are the ultimate victims of Pfizer's criminal activities: why is no one representing the individuals who suffered serious ill effects from the illegally marketed unsafe drugs in the settlement negotiations?

Posted by Vera Sharav

Associated Press

Pfizer to pay record \$2.3B penalty over promotions

By DEVLIN BARRETT

WASHINGTON — Pfizer Inc., the world's largest drug maker, will pay a record \$2.3 billion civil and criminal penalty over unlawful prescription drug promotions.

Announcing the settlement Wednesday, the Justice Department said that it included the largest criminal fine in U.S. history — \$1.2 billion. The agreement also included a criminal forfeiture of \$105 million.

Authorities called Pfizer a repeat offender, noting it is the fourth such settlement of government charges in the last decade. They said the government will monitor the company's conduct for the next five years to rein in the abuses.

To promote the drugs, authorities said Pfizer invited doctors to consultant meetings at resort locations, paying their expenses and providing perks.

"They were entertained with golf, massages, and other activities," said Mike Loucks, the U.S. attorney in Massachusetts.

Loucks said that even as Pfizer was negotiating deals on past misconduct, they were continuing to violate the very same laws with other drugs.

Six corporate whistleblowers who first brought the misconduct to light will share \$102 million of the settlement money.

FBI Assistant Director Kevin Perkins praised the whistleblowers who decided to "speak out against a corporate giant that was blatantly violating the law and misleading the public through false marketing claims."

Associate Attorney General Thomas Perelli said the settlement illustrates ways the department "can help the American public at a time when budgets are tight and health care costs are rising."

The overall settlement is the largest ever paid by a drug company for alleged violations of federal drug rules.

The government said the company promoted four prescription drugs, including the pain killer Bextra, as treatments for medical conditions different than those the drugs had been approved for by federal regulators.

Use of drugs for so-called "off-label" medical conditions is not uncommon, but drug manufacturers are prohibited from marketing drugs for uses that have not been approved by the Food and Drug Administration.

Bextra, one of a class of painkillers known as Cox-2 inhibitors, was pulled from the U.S. market in 2005 amid mounting evidence it raised the risk of heart attack, stroke and death.

A Pfizer subsidiary, Pharmacia and Upjohn Inc., which was acquired in 2003, has entered an agreement to plead guilty to one count of felony misbranding. The criminal case applied only to Bextra.

The \$1 billion in civil penalties was related to Bextra and a number of other medicines. A portion of the civil penalty will be distributed to 49 states and the District of Columbia, according to agreements with each state's Medicaid program.

"These agreements bring final closure to significant legal matters and help to enhance our focus on what we do best — discovering, developing and delivering innovative medicines to treat patients dealing with some of the world's most debilitating diseases," said Amy W. Schulman, senior vice president and general counsel of Pfizer.

Justice officials discussed details of the deal at a news conference with FBI, federal prosecutors, and Health and Human Services Department officials.

In financial filings in January, the company had indicated that it would pay \$2.3 billion over allegations it had marketed the pain reliever Bextra and possibly other drugs for medical conditions different than their approved use. The civil settlement announced Wednesday also covered Pfizer's promotions of three other drugs: blockbuster nerve pain and epilepsy treatment Lyrica, schizophrenia medicine Geodon, antibiotic Zyvox and nine other medicines. Pfizer said the agreement with the Justice Department resolves the investigation into promotion of all those drugs, plus several related whistleblower lawsuits.

Under terms of the settlement, Pfizer must pay \$1 billion to compensate Medicaid, Medicare, and other federal health care programs. Some of that money will be shared among the states: New York, for example, will receive \$66 million, according to the state's attorney general, Andrew Cuomo.

"Pfizer ripped off New Yorkers and taxpayers across the country to pad its bottom line," Cuomo said. "Pfizer's corrupt practices went so far as sending physicians on exotic junkets as well as wining and dining health care professionals to

persuade them to prescribe the company's drugs for patients in taxpayer-funded programs."

Pfizer spokesman Chris Loder confirmed Wednesday that the \$2.3 billion charge to the company's earnings had been taken in the fourth quarter of 2008.

"No additional charge to the company's earnings will be recorded in connection with this settlement," he said.

In her statement, Schulman said: "We regret certain actions taken in the past, but are proud of the action we've taken to strengthen our internal controls and pioneer new procedures so that we not only comply with state and federal laws, but also meet the high standards that patients, physicians and the public expect from a leading worldwide company dedicated to healing and better health."

"Corporate integrity is an absolute priority for Pfizer," she said, "and we will continue to take appropriate actions to further enhance our compliance practices and strengthen public trust in our company."

When Pfizer originally disclosed the settlement figure, it also announced plans to acquire rival Wyeth for \$68 billion. That deal, which would bolster Pfizer's position as the world's top drug maker by revenue, is expected to close before year's end.

Shares of Pfizer dropped 14 cents to \$16.24 in midday trading.

AP Business Writer Linda A. Johnson in Trenton, N.J. contributed to this report.

THE NEW YORK Times

Pfizer Pays \$2.3 Billion to Settle Marketing Case

By GARDINER HARRIS

WASHINGTON — Top aides in the Obama administration announced a \$2.3 billion settlement on Wednesday with the pharmaceutical giant Pfizer Inc. over the company's illegal promotion of its now-withdrawn painkiller, Bextra.

It is the largest fine ever levied for fraud in the Medicare and Medicaid programs, and Obama administration officials — criticized by Republicans on Capitol Hill for failing to crack down on fraud in the government's health programs — sought to highlight the case by having Health and Human Services Secretary Kathleen Sebelius make the announcement. The agreement also includes some promotional practices involving other Pfizer drugs — Zyxov, Geodon and Lyrica.

The settlement had been expected. Pfizer, which is acquiring a rival Wyeth, had reported in January that it had taken a

\$2.3 billion charge to resolve claims involving Bextra and other drugs.

Marketing fraud cases against pharmaceutical companies have become almost routine, with almost every major drug maker being accused of giving kickbacks to doctors or shortchanging the Medicaid program on prices. Prosecutors said that they have become so alarmed by the growing criminality in the industry that they have begun hiking fines into the billions of dollars and will soon start charging doctors individually as well.

Under the agreement with the Department of Justice, Pfizer will pay a \$1.3 billion criminal penalty related to Bextra and \$1 billion in civil fines related to a number of medicines. In addition, a Pfizer subsidiary, Pharmacia & Upjohn Company, will plead guilty to violating the Food, Drug, and Cosmetic Act for its promotion of Bextra.

In January, prosecutors announced that they would fine Eli Lilly \$1.4 billion for its illegal marketing efforts on behalf of Zyprexa, an antipsychotic.

Although the fine amounts began to soar during the Bush administration, top administration officials rarely touted the cases or appeared during news conferences about them. The Zyprexa case was announced by federal prosecutors in Philadelphia.

Ms. Sebelius's decision to make the Pfizer announcement in a news conference in Washington suggests that the political environment for the pharmaceutical industry has become more treacherous — despite the industry's commitment to save the government \$80 billion as part of efforts to change the health care system.

In addition, Pfizer has reached agreements with attorneys general in 42 states and the District of Columbia to settle state claims related to its promotional practices concerning Geodon. The company will pay \$33 million to the settling states and will take a charge in that amount to third-quarter 2009 earnings.