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Bloomberg Markets

When drug makers' profits Outweigh Penalties

By David Evans
Bloomberg News
Sunday, March 21, 2010

Prosecutor Michael Loucks remembers clearly when attorneys for Pfizer, the world's largest drug company, looked across the table and promised it wouldn't break the law again. ¶ It was January 2004, and the lawyers were negotiating in a conference room on the ninth floor of the federal courthouse in Boston, where Loucks was head of the health-care fraud unit of the U.S. Attorney's Office. One of Pfizer's units had been pushing doctors to prescribe an epilepsy drug called Neurontin for uses the Food and Drug Administration had never approved. ¶ In the agreement the lawyers eventually hammered out, the Pfizer unit, Warner-Lambert, pleaded guilty to two felony counts of marketing a drug for unapproved uses. New York-based Pfizer agreed to pay $430 million in criminal fines and civil penalties, and the company's lawyers assured Loucks and three other prosecutors that Pfizer and its units would stop promoting drugs for unauthorized purposes. ¶ What Loucks, who was acting U.S. attorney in Boston until November, didn't know until years later was that Pfizer managers were breaking that pledge not to practice off-label marketing even before the ink was dry on their plea.

On the morning of Sept. 2, 2009, another Pfizer unit, Pharmacia & Upjohn, agreed to plead guilty to the same crime. This time, Pfizer executives had been instructing more than 100 salespeople to promote Bextra -- a drug approved only for the relief of arthritis and menstrual discomfort -- for treatment of acute pain of all kinds.

For this new felony, Pfizer paid the largest criminal fine in U.S. history: $1.19 billion. On the same day, it paid $1 billion to settle civil cases involving the off-label promotion of Bextra and three other drugs with the United States and 49 states.

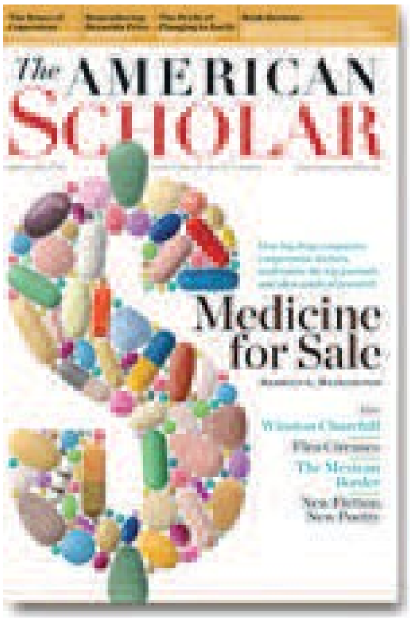
"At the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct in 2004, Pfizer was itself in its other operations violating those very same laws," Loucks, 54, says. "They've repeatedly marketed drugs for things they knew they couldn't demonstrate efficacy for. That's clearly criminal."

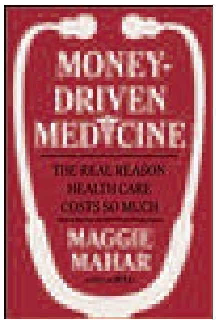
The penalties Pfizer paid for promoting Bextra off-label were the latest chapter in the drug's benighted history. The FDA found Bextra to be so dangerous that Pfizer took it off the market for all uses in 2005.

Across the United States, pharmaceutical companies have pleaded guilty to criminal charges or paid penalties in civil cases when the Justice Department finds that they deceptively marketed drugs for unapproved uses, putting millions of people at risk of chest infections, heart attacks, suicidal impulses or death.

It used to be legal for companies to promote drugs in the United States for any use. Congress banned the practice in 1962, requiring pharmaceutical companies to first prove their drugs were safe and effective for specific uses.

If the law is clear, why do drug companies keep breaking it? The answer lies in economics. Pharmaceutical companies spend about $1 billion to develop and test a new drug. To recoup their investment, the companies want doctors to prescribe their drugs as widely as possible.





Since May 2004, Pfizer, Eli Lilly, Bristol-Myers Squibb and four other drug companies have paid a total of $7 billion in fines and penalties. Six of the companies admitted in court that they marketed medicines for unapproved uses. In September 2007, New York-based Bristol-Myers paid $515 million -- without admitting or denying wrongdoing -- to federal and state governments in a civil lawsuit brought by the Justice Department. The six other companies pleaded guilty in criminal cases.

In January 2009, Indianapolis-based Lilly, the largest U.S. psychiatric drugmaker, pleaded guilty and paid $1.42 billion in fines and penalties to settle charges that it had for at least four years illegally marketed Zyprexa, a drug approved for the treatment of schizophrenia, as a remedy for dementia in elderly patients.

In five company-sponsored clinical trials, 31 people out of 1,184 participants died after taking the drug for dementia -- twice the death rate for those taking a placebo, according to an article in the Journal of the American Medical Association.

"Marketing departments of many drug companies don't respect any boundaries of professionalism or the law," says Jerry Avorn, a professor at Harvard Medical School. "The Pfizer and Lilly cases involved the illegal promotion of drugs that have been shown to cause substantial harm and death to patients."

Profits make penalties seem trivial, and Profits drive the companies to attack all that stand in their way