

BIG PHARMA'S CRIME SPREE

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BIG PHARMA'S CRIME SPREE is a riveting report by David Evans in the current issue of Bloomberg Markets Magazine relying on recent criminal legal settlements. It leaves no doubt about the fact that Big Pharma's business practices are defined by criminal activities. Finding cures is not even remotely a consideration by pharmaceutical executives, as it would present a financial conflict of interest.

Shorter online version :

"Across the U.S., pharmaceutical companies have been pleading guilty to criminal charges or paying penalties in civil cases when the U.S. Department of Justice finds that they deceptively marketed drugs for unapproved uses, putting millions of people at risk of chest infections, heart attacks, suicidal impulses or death. Since May 2004,

Pfizer, Eli Lilly & Co., Bristol-Myers Squibb Co. 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."

"About 15% of drug sales in the U.S. are for unapproved uses without adequate evidence the medicines work."

The widespread off-label promotion of drugs for untested, unapproved uses is a manifestation of a health-care system that is dysfunctional as it is costly. Americans are paying exorbitant prices for drugs that put their lives at increased risk of death. Indeed, a conservative estimate by the Institute of Medicine (2000) is 106,000 preventable deaths from non-error adverse prescription drug effects.

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.

The evidence is inescapable: "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. Indeed, rather than having a deterrent effect, the number of Big Pharma high profile criminal settlements is increasing and the settlements are getting bigger.

Bloomberg documents how companies such as Pfizer and Eli Lilly—each has been prosecuted repeatedly for the same crimes—are, if anything, emboldened as repeat offenders—ignoring FDA admonitions, as well as promises made to the Department of Justice not to break the law.

In January, 2004, "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 prosecutor Michael Loucks and three other prosecutors that Pfizer and its units would stop promoting drugs for unauthorized purposes. What Loucks, who's now acting U.S. attorney in Boston, didn't know until years later was that Pfizer managers were breaking that pledge not to practice so-called off-label marketing even before the ink was dry on their plea."

"Jeff Kindler, who became Pfizer's general counsel in 2002, supervised the lawyers who made the promises to prosecutors. By 2004, Kindler increased the compliance budget 12-fold."

"What Pfizer's lawyers didn't tell the prosecutors was that Pfizer was at that moment running an off-label marketing promotion using more than 100 of its salespeople" who were pitching Bextra for pain, a use the FDA explicitly forbade Pfizer to promote! In 2001, the FDA had rejected Pfizer's application to market Bextra for pain because in clinical trials the drug had shown it could cause heart damage and death.

In her guilty plea (March 30, 2009), Mary Holloway, a Pfizer regional sales manager for the Northeastern US, acknowledged that her team promoted Bextra to doctors without disclosing the risks, and also acknowledged that her team "had solicited hospitals to create protocols to buy Bextra for the unapproved purpose of acute pain relief. Her representatives didn't mention the increased risk of heart attacks in their marketing..."

Kindler became chief executive officer in 2006. In Pfizer's ethics guide, he says stories about misbehaving companies and executives abound. "Pfizer truly stands apart," he says. "I am proud of our record."

Instead of being held accountable for criminal marketing practices Pfizer and its corporate divisions engaged in, on Oct. 1, Kindler was elected to the board of the Federal Reserve Bank of New York.

ESCALATING PENALTIES

Includes criminal fines and civil penalties. Source: Court records

RAP SHEET

Pharmaceutical companies paid about \$7 billion in fines or penalties for illegal off-label marketing during the past five years. Here are some of the biggest.

COMPANY	DATE OF PENALTY	DRUG(S)	Amount MILLIONS
Pfizer	September 2009	Bextra, others	\$2,300.
Lilly	January 2009	Zyprexa	1,415.
Serono	October 2005	Serostim	704.
Purdue	May 2007	Oxycontin	634.
Cephalon	September 2008	Actiq, Gabitril, Provigil	425.
Schering-Plough	August 2006	Temodar, Intron A	435.
Pfizer (Warner-Lambert)	May 2004	Neurontin	430.

Source: Bloomberg / Federal court records

The amounts of Eli Lilly's fines and penalties have soared during the past 25 years.

\$25,000 APRIL 1985: Pleads guilty to 25 misdemeanors for misbranding Orflex.

\$36,000,000 DECEMBER 2005: Pleads guilty to one misdemeanor count for misbranding Evista.

\$1,415,000,000 JANUARY 2009: Pleads guilty to one misdemeanor count for misbranding Zyprexa.

But those fines are tiny compared to the revenues from criminally marketed sales:

Eli Lilly Zyprexa sales from criminal marketing yielded the company \$36 billion from 2000 to 2008.

And Pfizer's recent \$2.3 billion settlement in fines and penalties for the illegal marketing of Bextra, Geodon, Zyvox and Lyrica pales in comparison to the \$16.8 billion the company garnered from its criminal marketing of these drugs. Indeed, the total penalties Pfizer has paid in settlements--\$2.75 billion, since 2004--is but 1% of the company's revenue of \$245 billion from 2004 to 2008.

Dr. Avorn points out that "The Pfizer and Lilly cases involved the illegal promotion of drugs that have been shown to cause substantial harm and death to patients."

Despite the fact that in five company-sponsored clinical trials, 31 people out of 1,184 participants died after taking Zyprexa for dementia--twice the death rate for those taking a placebo--Lilly aggressively marketed the drug for off-label use in children and the elderly.

Even more shameful than the pharmaceutical industry's blatant criminal practices, drug companies "find ready and willing partners in physicians" who wantonly prescribe dangerous drugs for untested, off-label uses for cash kickbacks.

Bloomberg reports that "Pfizer's marketing program offered doctors up to \$1,000 a day to allow a Pfizer salesperson to spend time with the physician and his patients." If profits "uber alles" is the overriding goal, and human casualties are viewed as so much shrapnel, then Big Pharma has been hugely successful--billions in sales and hundreds of thousands buried.

In 2004, Neurontin sales reached \$2.12 billion-- according the prosecutors' sentencing memo, 94% of those sales came from off-label use.

Much like the large financial institutions, Big Pharma companies are shielded by the rationale, "too big to fail." The government is reluctant to use the ultimate sanction which would put an end to criminal marketing--namely, a felony conviction that would render a company's drugs ineligible for reimbursement by state health programs and the federal government.

However, "a legal fig leaf" allows a parent company (such as Pfizer) to continue to receive government federal reimbursement for hazardous drugs that have been criminally marketed--even as one after another of the company's subsidiaries has pleaded guilty.

Pfizer and its executives have thus successfully avoided criminal culpability while paying the settlements but maintaining

that it was not responsible for the illegal actions of the dozens of companies it acquired--actions that continued after Pfizer acquired them:

Bloomberg reports:

"From 1995 to 2005, Pfizer purchased more than 20 companies. Since 2004, companies that are now Pfizer divisions have pleaded guilty to off-label marketing of two drugs. Pfizer continued off-label promotions for these medications after buying the firms, according to Pfizer's Sept. 2 guilty plea and FDA correspondence with Pfizer.

Pfizer first stepped into an off-label scheme in 1999, when it offered to buy Morris Plains, New Jersey-based Warner-Lambert Co. Prosecutors charged that Warner-Lambert marketed Neurontin off-label between 1995 and 1999. Warner-Lambert admitted doing so for one year in a May 2004 guilty plea for which Pfizer paid \$430 million in fines and penalties."

Despite all this, "Pfizer maintains its good standing with such agencies because its subsidiaries, Warner-Lambert and Pharmacia-Upjohn, and not the corporation itself, entered the guilty pleas to felony charges."

While Big Pharma executives have evaded justice, Scott Harkonen, one former CEO of a small company, InterMune, has been convicted of illegal marketing of its only drug, Actimmune, for uses not approved by the FDA. He's out on bail, awaiting sentencing.

"As prosecutors continue to uncover patterns of deceit in off-label marketing by pharmaceutical companies, millions of patients across the nation remain in the dark."

Doctors have become pill pushers who blindly prescribe the latest, most expensive medications based on deceptive marketing by drug company salesmen.

The result is documented in hundreds of thousands of preventable drug-induced deaths, and unsustainable healthcare expenditure. What's especially disturbing is that nowhere in the proposed healthcare reform bills are life-threatening crimes by pharmaceutical companies in collusion with doctors who abuse their medical prescribing licenses even addressed.

Expanded Bloomberg Market Magazine version with tables, side-bars, upon request

Posted by Vera Hassner Sharav