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Report Details Fraud and Abuse by Pharmaceutical Companies

Steven Fox

September 12, 2011 — Since 1996, \$12 billion has been recovered from pharmaceutical companies in the United States for legal cases stemming from fraud and abuse, according to a new research article. More than three quarters of the 31 cases prosecuted were initiated by whistle-blowers, usually current or former employees.

"Settlements and fines resolving allegations of fraudulent marketing practices accounted for the largest recoveries," write Charles Bennett, MD, PhD, MPP, from the South Carolina College of Pharmacy, Columbia, and colleagues. The study was published in the September 12 issue of the *Archives of Internal Medicine*.

The investigators reported that from 1996 to 2000, only a single healthcare-related case was prosecuted, resulting in a recovery of \$8 million. From 2001 to 2005, 15 cases were brought, and \$3.9 billion was recovered. From 2006 to 2010, another 15 cases were prosecuted, and \$8.1 billion was recovered.

Nearly all the prosecutions arose from marketing violations. Off-label or fraudulent marketing and misbranding practices were charged in 15 cases. Billing fraud was responsible for 17 cases, and kick-backs triggered 1.

The group analyzed data on cases prosecuted under the most common law invoked in healthcare fraud prosecution, the so-called False Claims Act. The law permits private citizens to file antifraud actions on behalf of the government and allows them to share in proceeds recovered. The legal term *qui tam* refers to such actions, and a *qui tam* relator is a person who brings such a suit.

The False Claims Act also imposes liability up to triple damages, as well as civil penalties up to \$11,000 for each instance when pharmaceutical companies submit false claims to the government.

Previous research by other investigators showed that during the period from 1996 to 2005, whistle-blower cases involving pharmaceutical company fraud were responsible for recovering \$3.6 billion in funds. That total involved 13 fraud cases.

Even though these cases accounted for just 3% of the total number of federal fraud cases involving healthcare companies, the amount collected totaled 40% of all federal fraud financial recoveries from companies, regardless of industry, the authors noted.

In this report, the authors updated statistics for healthcare fraud, analyzing Lexis/Nexis news data from 1996 through 2010, regardless of whether or not cases were initiated by whistle-blowers.

One company was named in 3 cases, and 3 companies were named in 2 cases each.

The largest recovery was from Pfizer, at \$2.3 billion, which accounted for nearly a fifth of the total amount recovered during the entire study period. That action was brought in 2009 and centered on charges of illegal marketing, misbranding, and payment of kickbacks to physicians for prescribing the COX-2 inhibitor valdecoxib (*Bextra*), which is no longer marketed.

The second-largest recovery, also during 2009, was \$1.4 billion, paid by Eli Lilly and Company. That was for off-label marketing of olanzapine (*Zyprexa*). The FDA had approved the drug for use in bipolar disorder and severe schizophrenia, but Lilly reportedly encouraged off-label use for children who were under foster care, for elderly people, and for people with insomnia.

Another \$750 million came from GlaxoSmithKline in 2010. That was for selling contaminated drugs from a manufacturing plant in Puerto Rico.

Whistle-blower cases accounted for 77% of the cases, and total dollars recovered in those cases added up to \$836 million.

"*Qui tam* relators, usually employees or former employees of pharmaceutical corporations, are the primary information source for fraud investigations," the authors write. "With awards as high as \$102 million being awarded to *qui tam* relators, and *qui tam* relators having initiated 77% of pharmaceutical cases, their central role in identifying fraudulent pharmaceutical marketing practices is likely to expand."

The authors said that with the role of government in healthcare growing, it is likely that investigations of pharmaceutical makers will continue to result in substantial financial recoveries.

However, they added, "Our findings raise concern that despite these recoveries, industry-wide changes in the way pharmaceutical corporations conduct marketing activities are needed."

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