

Holding Big Pharma's Feet to the Fire

A new Public Citizen report shows state and federal governments, more than ever, are holding the drug industry accountable for fraudulent behavior. By Jake Parent

Pharmaceutical companies are still the largest defrauders of the federal government, but states are now collecting a record amount in fines levied against such companies, a new Public Citizen study has found.

In an era of ever-tighter Medicaid budgets, many states have recovered just as much, if not more, money from this litigation as they spent on all Medicaid fraud enforcement since 2006.

According to the report, "Pharmaceutical Industry Criminal and Civil Penalties: An Update," more settlements are being announced between state and federal governments and the drug industry than ever before, with financial penalties on the rise. Already, 2012 has seen the highest financial penalties assessed against the pharmaceutical industry in a single year, with \$6.6 billion

recovered through mid-July by both the federal government and states.

The federal government also has settled almost as many cases and recovered more in financial penalties from the drug industry in the past 3½ years as it had in the previous 18 years combined. Three pharmaceutical companies – GlaxoSmithKline (GSK), Johnson & Johnson and Abbott – were responsible for two-thirds of the financial penalties paid to the federal and state governments during the most recent period (Nov. 2, 2010, through July 18, 2012) covered by the report.

In Public Citizen's findings, overcharging health programs – mainly in the form of drug pricing fraud against state Medicaid programs – was the most common violation, while the unlawful promotion of drugs was associated with the largest penalties.

Reaching settlements, recouping funds for cash-strapped states

Medicaid fraud cases against pharmaceutical companies have been on the rise over the past two decades. Public Citizen's original, landmark 2010 study on pharmaceutical fraud found that such cases had skyrocketed since 1990 as prescription drug spending in the U.S. increased from \$40 billion in 1990 to more than \$234 billion by 2008.

The rise in settlements is likely due both to an increase in the scale of fraud committed by the drug industry and, more importantly, increased enforcement of current laws, such as the False Claims Act, to crack down on the wrongdoing. Since 1991, 239 settlements have been reached between pharmaceutical companies and federal or state governments, for a total of \$30.2 billion.

During that time, 27 states have prosecuted companies on their own and reached at least one settlement with a pharmaceutical company. Kentucky has had the most such single-state settlements (17) while Texas has had the highest number of single-state settlements resulting from actions initiated by private whistleblowers (six). In just the past two years, state governments have collected more than \$2 billion from Medicaid fraud cases.

Seventeen states recouped the equivalent or more of their entire Medicaid fraud enforcement budgets with money from these settlements.

Arkansas, South Carolina, Alabama and Hawaii recovered the most relative to their enforcement budgets, recouping between \$12 and \$84 for every dollar spent on Medicaid fraud enforcement.



Pharmaceutical Company Penalties: Worst Offenders, 1991-2012*

Company	Total Financial Penalties	Percent of Total	Number of Settlements
GlaxoSmithKline	\$7.56 billion	25.1%	20
Pfizer	\$2.96 billion	9.8%	15
Johnson & Johnson	\$2.33 billion	7.7%	14
Merck	\$1.86 billion	6.2%	27
Abbott	\$1.82 billion	6.0%	12
Eli Lilly	\$1.71 billion	5.7%	13
Schering-Plough	\$1.34 billion	4.4%	7
AstraZeneca	\$954 million	3.2%	7
TAP Pharmaceutical Products	\$875 million	2.9%	1
Novartis	\$793 million	2.6%	12
Bristol-Myers Squibb	\$789 million	2.6%	12
Mylan	\$707 million	2.3%	19
Serono	\$704 million	2.3%	1
Purdue	\$620 million	2.1%	2
Allergan	\$600 million	2.0%	1
Daichi Sankyo	\$500 million	1.7%	3
Cephalon	\$425 million	1.4%	1
Boehringer Ingelheim	\$329 million	1.1%	14
Forest Laboratories	\$315 million	1.0%	4
Sanofi	\$313 million	1.0%	10
Other	\$1.88 billion	6.2%	108
Total	\$29.38 billion	97.3%	303

Source: Public Citizen's "Pharmaceutical Industry Criminal and Civil Penalties: An Update"

*Information is through July 18, 2012. The total number of settlements listed here is greater than the total number of settlements during this period of time (239), because some settlements involved more than one company. Also, the percent of the total, which is based on \$30.174 billion in overall penalties, does not equal 100 percent because of the inability to determine an individual company's share in a settlement, in some cases. If a listed parent company is nonexistent now, the name at the time of the most recent settlement was used.

"What this new report unequivocally shows is that those states that have chosen to hold the pharmaceutical industry accountable have largely seen their enforcement efforts pay for themselves," said Dr. Sammy Almashat, a researcher with Public Citizen's Health Research Group and the study's author.

This uptick in settled federal cases was largely a product of increased use of provisions in the False Claims Act, which is meant to hold companies responsible for defrauding the federal government. In 2012, GSK agreed to pay \$3 billion to the federal government to resolve allegations that it had illegally marketed multiple medications and had offered paid incentives, or kickbacks, for doctors to prescribe their drugs. It was the largest single fine paid by a drug company to settle health fraud allegations.

Investigations initiated by whistleblowers were responsible for most federal settlements (75 percent) and financial penalties (78 percent) during the most recent period studied.

In fact, almost half the whistleblower-prompted federal and state settlements during this time were made possible by a single whistleblower, Ven-A-Care pharmacy in Key West, Fla. Ven-A-Care's owners tipped off the government after realizing that several of the drug manufacturers they did business with were selling the medications with unjustifiably high markups.

Changing the industry's perception of fraud

Although some of these settlement amounts seem astronomical, many drug companies may consider the settlements a cost of doing business; the total amount paid in fraud cases by pharmaceutical companies over the past 20 years represents just two-thirds of the profits made by the 10 largest drug companies in 2010 alone.

Stronger federal legislation could help make companies think twice before committing fraud, Almashat said. At

this point, however, only a few lawmakers have sought to take on the powerful pharmaceutical lobby and increase sanctions for defrauding the government.

One attempt was an amendment proposed by Sen. Bernie Sanders (I-Vt.) to a Food and Drug Administration bill in May that would have taken away exclusive marketing rights — potentially worth billions of dollars — if a company was found to be at fault for fraud involving a particular drug.

The amendment fell victim to what Sanders labeled the muscle of the pharmaceutical industry, ultimately receiving only nine votes.

"The bottom line is that the pharmaceutical industry is making money hand over fist while it systematically defrauds taxpayers, all the while individuals in the United States (let alone the developed world) are not getting the medicines they need because they cannot afford them," Sanders said in a statement regarding the proposed amendment.

One other legislative path sug-

gested by the report is to create a blacklist for companies that commit fraud.

Any firm on this list could be barred from receiving payments from Medicare and Medicaid, thus preventing access to large portions of the market for their products. So far, no such legislation has been introduced.

Finally, Public Citizen recommends that criminal charges be levied against executives who knowingly allow fraudulent activities to occur. Until some additional level of enforcement is put into place, it's likely that drug companies will continue to see the cost of paying out fraud settlements as worth it.

"It's obvious these companies will continue their fraudulent practices as long as it makes business sense for them to do so," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "Legislation and more rigorous enforcement are needed to protect taxpayer money and patient safety."

To read the report, please visit <http://bit.ly/UwHWtO>.