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Drug deals

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In the past two years alone, a handful of the biggest players in the pharmaceuticals industry, each with operations in New Jersey, have agreed to pay nearly \$1.5 billion to settle allegations of shady business dealings.

The charges have included paying kickbacks to lure potential customers, knowingly touting faulty goods, and misleading investors with fraudulent earnings reports.

The major reason companies are apparently willing to cut corners has been well documented: With profit growth and stock prices sliding in recent years, the companies are under intense pressure from Wall Street to find new blockbuster products to replace old ones whose market shares are being eaten away by generic competition.

The stunning amounts in some recent settlements, and the frequency with which they are announced, beg the question of just who benefits when companies worth many billions of dollars write checks to resolve accusations of bad behavior.

Equally important is the issue of whether this is the best way to punish companies and deter future shenanigans.

"It's an imperfect attempt to deal with a stunningly complex issue," said James E. Tierney, director of the National State Attorneys General Program at Columbia Law School.

Settlements are "sadly necessary" in an industry described by Tierney, a former attorney general of Maine, as lightly regulated.

When government agencies with limited budgets take on hugely profitable companies, settlements are often the most efficient way to resolve allegations of wrongdoing while avoiding lengthy and costly trials, Tierney explained.

To the average person, many of these cases appear similar. But there are important differences.

There are civil allegations, such as those tentatively settled in May by Medco Health Solutions for \$163 million. The Franklin Lakes-based pharmacy benefits manager was charged by federal prosecutors with defrauding patients and seeking kickbacks from pharmaceutical houses to favor their drugs.

The agreement must still be approved by a judge.

Then there are criminal allegations, like those settled last year by Bristol-Myers Squibb Co. The drug maker agreed to pay \$300 million and to adopt significant structural reforms for cooking its books to defraud investors.

Two former executives still face criminal charges related to the allegations.

John J. Carney, former chief of the health care and securities fraud unit for the U.S. Attorney's Office in Newark, said prosecutors decide whether to file civil or criminal charges based primarily on whether they can

prove intent.

Civil charges generally are filed when the allegations stem from negligent or reckless conduct, he said. Criminal charges occur when prosecutors believe the accused "knowingly and willfully" committed crimes.

"The evidence and the mental state of the accused are the two biggest drivers of whether a case will go criminal or civil," Carney said.

Also important is that the burden of proof in civil cases is 51 percent. In criminal cases, meanwhile, the burden is much higher, or "beyond a reasonable doubt," which explains why many more civil cases are filed against corporations than criminal.

Schering-Plough Corp. pulled off a rarity in 2004, settling criminal and civil charges stemming from the same set of accusations.

Schering's sales and marketing unit agreed to plead guilty to criminal charges and pay a fine of \$52.5 million for paying a kickback to an HMO to keep the allergy drug Claritin on its formulary, or the list of drugs approved by the HMO.

At the same time, the parent company agreed to pay \$293 million to settle civil charges that it gave secret discounts on Claritin to two large managed-care companies to keep them as clients.

But Schering failed to provide similar discounts to Medicaid, causing the government program to pay a much higher price, which federal prosecutors viewed as fraud.

As part of the settlement, Schering entered into an agreement with the U.S. Department of Health and Human Services to reform its business practices.

In many cases brought by the Securities and Exchange Commission, the government agency charged with protecting investors, companies are allowed to reach settlements without admitting or denying wrongdoing.

Companies settling SEC charges frequently seek that phrase because it protects them from additional lawsuits down the road, legal experts explained. And the SEC, with its limited budget, allows the phrase because the agency is content to obtain a large fine and at the same time stop the company in question from doing whatever brought the charges in the first place.

"The ability to settle without admitting liability is an important facilitator in reaching settlements," noted Edward Hartnett, a Seton Hall Law School professor

In general, large settlements allow for a resolution in which everyone involved can walk away claiming at least a partial victory.

The companies are able to put the allegations behind them; the prosecutors, regulatory agencies or plaintiffs' attorneys who brought the allegations can file them in their win column; and an array of groups, including shareholders, consumers, whistle-blowers and patients, benefit from the money paid out by the companies.

Consider the \$300 million Bristol-Myers settlement: The money is earmarked to "compensate present and former" Bristol-Myers shareholders, according to the agreement. And although Bristol-Myers was forced to agree to wide-ranging reforms, the company is still making drugs, still turning a profit and its chief executive, Peter Dolan, still has his job.

Finally, U.S. Attorney Christopher J. Christie was able to take credit – and bask in the publicity – for the successful prosecution of a well-known company gone astray.

And Wall Street loves settlements.

"What Wall Street hates more than anything else is uncertainty, so the faster a company can conclude the matter, the better," said Les Funtleyder, a health care analyst for Miller Tabak & Co. in New York.

Settlements are also a good way to get allegations of impropriety out of the headlines, said Mahmud Hassan, who heads the pharmaceutical MBA program at Rutgers University.

Lawsuits in company scandals can go on indefinitely, he said, and the attendant media coverage tends not only to weaken employees' morale but also pressure a company's stock price.

"If you put this all together, it makes sense to reach a settlement. It's not lingering in the media, so there's no lingering effect on the stock price," said Hassan.

According to the experts, there is no formula either for reaching a settlement figure or for how the money is distributed.

"The figures are negotiated, and a lot depends on the judge and the talent of the lawyers involved," said former Maine attorney general Tierney.

In civil cases filed by individuals or groups that feel they've been wronged, the money goes to members of the group of aggrieved people -- for instance, patients who claim to have been injured by a faulty medication.

And in most cases filed by state attorneys general or federal prosecutors, most of the settlement money goes back to shareholders.

But in some cases, such as the recently settled allegations against Medco, whistle-blowers who initiated the lawsuit are in line to receive a percentage of the settlement.

Derek Brandt, an Illinois attorney who represents health plans in cases against pharmaceutical benefit managers, or PBMs, such as Medco, expressed frustration at the way settlements frequently allow the facts of a case to seemingly go away once an agreement is reached.

But Brandt conceded there may be a silver lining to large settlements: Other potential litigants may catch wind of the agreement and decide to file suits of their own.

"The risk they run is that they nudge the sleeping dog," he said. "They are putting something behind them, but they run the risk that more people's eyes will be opened."

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