Prescription Interdiction

Pharmaceutical firms aren't supposed to push their drugs for non-approved uses. But the profits are easily worth a few penalties. By Meghan McCarthy

Mass production: Drug companies prefer sales to compliance.

GlaxoSmithKline, the mammoth pharmaceutical company based in Britain, blasted out an odd press release in January 2011. It said that it anticipated $3.4 billion in U.S. legal costs. The stock briefly plunged. But 17 months later, after GSK finalized its settlement with Washington for fraudulently marketing drugs, among other charges—the largest such settlement in U.S. history—its stock actually rose a few points. The reason? The agreement cost the company $3 billion, 12 percent less than it feared. Shareholders made money from its legal woes.

In the world of pharmaceuticals, billion-dollar profits aren't unusual. Now billion-dollar settlements are becoming more common, often because the manufacturers push doctors to prescribe drugs for uses the Food and Drug Administration hasn't blessed. Pfizer's Neurontin, for example, a medication approved to treat seizures, made 94 percent of its $2.27 billion in 2002 revenue from off-label prescriptions to combat conditions ranging from bipolar disorder to pain. (Doctors are allowed to prescribe whatever drugs they want, but pharmaceutical companies aren't supposed to encourage them.) According to Public Citizen, 75 percent of the $19.8 billion in penalties levied on pharmaceuticals since 1990 occurred between 2006 and 2010. It's not that the drugmakers don't know the risks; they've just decided that the rewards outweigh them.

In addition to paying big fines, pharmaceutical companies that settle with the feds often sign agreements to stop illegal practices. But business opportunities keep luring them to violate the law. GlaxoSmithKline generated about $43 billion in revenue in 2011, according to its annual report, for a profit of $12 billion. That $3 billion charge wasn't peanuts, but it was a tolerable loss. Which may explain why, even though the company signed a seven-year "corporate integrity agreement" in 2003, some offenses occurred while it was still on probation.

GSK isn't the only company to land repeated fines after promising good behavior. Pfizer paid $2.3 billion in 2009, which was then the biggest settlement in history, for illegally pushing several drugs, including Bextra, an anti-inflammatory medication; Geodon, an antipsychotic; Zyvox, an antibiotic; and Lyrica, an antiepileptic drug. Then it entered into its *third* corporate-integrity agreement with the government. Schering-Plough paid three separate fines in 2002, 2004, and 2006, totalling $1.28 billion.

The government is aware of the problem. "Providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business," Lewis Morris, chief counsel in the Health and Human Services Department's inspector general's office, told Congress last year. "As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue." But there's only so much regulatory officials can do. After all, the drugmakers provide patients with life-saving medicines, so officials can't exactly toss them out of Medicare and Medicaid.

Without any credible threat of harm to corporations' bottom lines, the penalties are toothless, says Sidney Wolfe, director of the health research group at Public Citizen. "The message from the government is that crime does pay, because these companies are engaged in criminal and civil violations, they pay their money, and they do it again," he says.

Lawyers at HHS think they've devised a way to make it harder for pharmaceutical manufacturers to skirt the law and simply pay penalties. The recent GSK agreement requires the board of directors to annually review how it is complying with the law and to post on the company's website information on payments to doctors. The agreement also includes two provisions never used before in drug settlements, says Mary Riordan, a senior counsel in the department IG's office: First, GSK agreed to compensate its sales force based on the quality of services offered to doctors instead of sales volume. Second, the company will recoup bonuses or company stock for up to three years from executives caught engaging in illegal behavior. "This is very different from what we have done before," Riordan says. The effort aims at "the heart of the financial incentives motivating sales representatives and executives."

Still, potential profits are so immense that even these penalties may not scare drugmakers straight. So Reps. Wally Herger, R-Calif., and Pete Stark, D-Calif., have introduced a bill to boost HHS's enforcement power. Today, the department can ban company executives from working with Medicare and Medicaid if, by the time the government gets around to charging them, they are in the same job in which they broke the law. But because employees move too often for this measure to work well, the Herger-Stark proposal would allow HHS to ban executives from working with Medicare and Medicaid if they are convicted, regardless of where they currently work—a death knell for anyone in the health industry.

This time, GSK expressed contrition and promised to learn from its mistakes. "We've gotten the message, and the changes that we've made in how we conduct our business demonstrate that we are committed to ensuring the appropriate promotion of our medicines," spokesman Kevin Colgan says. But until Congress enacts truly tough punishments into law, paying big penalties may just continue to be standard operating procedure. ■

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