BITTER PILLS FOR PHARMA

After criticism that huge fines are not dissuading drug firms from engaging in fraudulent business practices, the US is turning to more radical enforcement measures. **Melanie Newman** reports

It was the biggest fine ever imposed in America, the largest healthcare fraud settlement in Department of Justice history, and the largest civil fraud settlement ever paid by a drug company. It was, said Kevin Perkins, assistant director of the Federal Bureau of Investigation's criminal investigative division "a clear message" to drug companies that they would not be allowed to "peddle their prescriptions or products for uses beyond their intended—and federal government-approved—purpose."

Pfizer had just agreed to be fined a record $2.3bn (£1.5bn; €1.8bn) for illegally promoting four drugs—valdecoxib, ziprasidone, linezolid, and pregabalin—for uses that the US Food and Drug Administration had not approved.[1] The company was also accused of paying incentives or "kickbacks" to doctors to prescribe the drugs, a charge that was also resolved under the terms of the settlement. Both practices are considered fraudulent in the US, because they mean government healthcare programmes are paying for drugs that may not work effectively or are unnecessary.

On the day after the fine was announced, the *New York Times* pointed out that $2.3bn amounted to less than three weeks of Pfizer's sales.[2] And US authorities admitted that Pfizer was illegally marketing its drugs at the same time as it was negotiating settlement terms for a similar, previous offence.

Repeat offending and unenforceable penalties

In 2004 Pfizer agreed to pay $420m to settle charges that its newly acquired subsidiary, Warner-Lambert, had marketed an epilepsy drug, gabapentin, for unapproved purposes. The company's lawyers assured prosecutors that Pfizer and all its subsidiaries would cease this practice immediately. But at the same time its sales representatives were marketing the anti-inflammatory drug valdecoxib, which was approved for arthritis and menstrual pain, for other, unapproved conditions.

And Pfizer is not alone in failing to change its behaviour in response to large fines. AstraZeneca paid out $520m in 2010 to settle civil charges of illegally marketing its anti-psychotic drug quetiapine.[3] Seven years earlier it had been fined $355m for criminal and civil charges relating to the same offence—this time involving the prostate cancer drug gosarelin.[4]

So why are the fines not working? Critics argue that for the multibillion dollar drug industry, even such hefty fines are not hard pills to swallow. The penalties, they say, are treated as just another cost of doing business. Worse, as the companies make up their lost profits by hiking future drug prices, it is actually the public that ends up paying for them.

Patrick Burns, communications director at the campaigning organisation Taxpayers Against Fraud, which helps whistleblowers to expose fraud against the government, complains that the fines have had little effect beyond "moving a few numbers on the New York stock exchange." Pfizer made around $180bn out of the 12 drugs that were the subject of the federal investigation, he points out. "They paid $2.3bn—that's a good business plan."

He adds: "We're shooting 22s—little bullets — into the arse of a rhino. They're roaring a little, running a little, and then they're going back to business. If we're going to affect change, we have to increase the calibre of the bullet."

By settling the case, and thereby avoiding criminal conviction by a court, Pfizer also side stepped a rule that companies convicted of major fraud against the government should be barred from working for government programmes. Under a section of the US Social Security Act that came into force in 1996, any organisation convicted of healthcare fraud at state or federal level must be excluded from Medicare and state healthcare programmes. The law is one of a series of statutes introduced to strengthen the Department of Health's ability to punish fraud.

Although Pfizer settled the case, the government could still have debarred the company. But the company's lawyers managed to wriggle free of these commercially damaging restrictions. A Pfizer subsidiary was permitted to plead guilty to the criminal charges,[5] leaving the parent company free to continue working for the government.

Mr Burns says that "The problem with that portion of the law is that Pfizer's too big to fail. There are too many people that use Pfizer drugs."

Lewis Morris, chief lawyer at the US Department of Health and Human Services, suggests that's true. "A big drug company hires tens of thousands of people, provides life saving drugs, it's a critical component of the health system. Cutting them out of the market and depriving patients of drugs, putting a lot of innocent employees on the street—that's not a very attractive option."

New sanctions

But all this could be about to change, with major consequences for the drug industry. The government, reveals Mr Morris, is now turning to more radical measures that will make the stock market and the shareholders sit up.

"In the drug industry we have a case that is moving to final resolution where we are going to be requiring a subsidiary, and all its assets, to be sold off to a third party," he says. "The parent company can no longer own that part of the company."

It's a radical move but one that the department has used before in a different area. In 2006 the Tenet Healthcare chain settled several civil fraud allegations for $900m.[6] "We found that in two different instances a particular hospital had paid kickbacks to doctors and had provided medically unnecessary cardiac services to patients. As part of resolving the allegations with the parent company, those two hospitals had to be sold off to an independent third party," Mr Morris says.

"Five years ago [before the Tenet case] people would have said you're never going to get a hospital [chain] to sell off an asset, you're never going to be able to force that kind of change."

Confiscation of the company's patents is another penalty under consideration. If a company abuses a patent by marketing a drug for a purpose it has not be approved or tested for, why should it continue to benefit from the exclusivity that you get as a brand name?" Mr Morris asks.

The company would be allowed to keep the drug but it would have to compete as a generic. "That would have an enormous impact on the financial bottom line, and we think it would probably cause some of these executives to think twice about illegally marketing drugs."

Accountability

Even this, argues Burns, will not be enough unless executives are held personally accountable for their companies' wrongdoing. "The

pain has to be personal," says Mr Burns. "The US invaded Iraq for regime change, we invaded Afghanistan for regime change, we took over General Motors and forced a change at the top of the company . . . it's time we started to force a change at the top of certain healthcare corporations. We need to say: get rid of your chief executive, your finance officer, your compliance officer, or you are done with us."

Mr Morris says the department is planning to make more use of a strict liability rule to hold executives to account. He explains: "This responsible corporate official doctrine will allow us to go to a chief executive and say 'I don't even need to have proof that you specifically hatched this scheme. You could have stopped it. You had the responsibility and the authority to stop it and you didn't, so you have to leave the company."

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Executives found guilty will be banned from working for the state, and their sacking could be a condition of the company's negotiated settlement.

Officials have already used this approach in a handful of cases. In 2007 the president, chief legal officer, and former chief medical officer of drug company Purdue Frederick pleaded guilty to charges of misbranding prescription painkiller OxyContin (modified release oxycodone) as part of a $634.5m settlement after the company had claimed that the drug was less addictive and less likely to be abused than rival medications.

"That was strict liability—they did not admit to any personal engagement in the fraudulent conduct," Mr Morris says. "Nonetheless, they were convicted of misdemeanour and excluded from our programme for 12 years."

Consumer advocates have called for executives to be given jail terms. But Mr Morris argues that the criminal burden of proof is hard to meet. In white collar crime responsibility for illegal acts is usually spread across many individuals at all levels in the organisation: there is rarely one person who has made a critical decision on which the prosecutors can hang their case.

Another of the department's relatively new lines of attack is to pursue individual doctors suspected of receiving kickbacks from industry in return for prescribing or using certain practices.

"A kickback can be as crass as twenty dollar bills in an envelope or something more subtle—perhaps putting the doctor on an advisory committee where she doesn't do any work but gets paid $20 000 or taking the doctor on all expenses paid trip to Phoenix, Arizona, in the winter," Mr Morris says.

The medical profession is waking up to its responsibilities here. This July, Harvard Medical School banned its faculty from accepting industry sponsored travel and meals and from giving sponsored speeches. And in March, Stanford University extended its conflict policy to ban all adjunct faculty (volunteer teaching staff) from participating in drug company speakers' bureaus.

But enforcement is equally important, Morris says. And although the department has traditionally focused on the company offering the kickback, it is now turning its attention to the recipients—the doctors.

When a company is charged with paying kickbacks to doctors, the authorities won't accept a settlement unless the company cooperates with a secondary investigation into the doctors concerned.

"The company has to turn over the call notes . . . we'll know which doctors said to a drug rep, 'If you don't give me that $50 000 consulting agreement I'm moving all my artificial hip patients to your competitor,'" says Mr Morris.

The Department of Health's Office of the Inspector General, where Mr Morris is chief counsel, has the right to impose a $50 000 penalty for every kickback received plus three times the amount of the kickback and exclude the doctor from working for the state again.

Like drug companies, doctors usually settle the cases rather than allow them to continue to the exclusion stage. They still have to pay a substantial fine, but the department monitors their behaviour rather than throwing them out of state programmes.

This February Florida based surgeon Harvey Montijo agreed to pay $650 000 after the Department of Health and Human Services alleged he "solicited and received remuneration in the form of consulting payments from two medical device manufactures in exchange for using their orthopedic hip and knee products."[7]

Will this combination of new measures convince companies, executives, and doctors that illegal behaviour is just too risky, even though the profits to be made are so huge?

It's too soon to tell, as many of the fines currently being dished out are for offences that happened four or five years ago. But Mr Burns isn't convinced the deterrent is strong enough yet.

"In medieval times people used to put the bodies of criminals in cages and hang them to rot outside the town," he says. "You would see the bones and you'd know that if you committed a crime there, you weren't going to be slapped around, you were going to be done. That's the message we need to send to the people who are green-lighting the fraud, who think that fraud is a good business plan."

Melanie Newman reporter, Bureau of Investigative Journalism, City University, London EC1V7HD, UK (www.tbij.com) melanienewman@tbij.com

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The Bureau of Investigative Journalism's documentary on the drug industry is available at http://thebureauinvestigates.com/2010/08/11/documentary-reveals-the-unhealthy-profits-of-the-pharmaceutical-industry/.

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