

**Bloomberg – Business Week**

# **Jail Time for Executives Might Stop Drug Crimes**

Commentary by Ann Woolner

March 17 (Bloomberg) -- If a surgeon cuts open your chest and implants a device meant to shock your heart into beating regularly, you are counting on the thing not short-circuiting.

You assume every aspect of its manufacture, each change in the process, has been reviewed and approved by proper authorities. If malfunctions turn up, surely the company will so report.

And if it fudges on notification, gets caught, admits a crime and pays a whopping fine, you figure the maker surely would never again let its reporting lapse.

Alas.

This week Boston Scientific Corp. halted sales of implantable defibrillators because it hadn't told the U.S. Food and Drug Administration of changes in its manufacturing process.

Not to worry. There is no reason to fear the manufacturing changes made the devices dangerous, the company assures us.

But it's hard to trust an entire industry that keeps promising to do better and doesn't. We badly want to believe those who make medical devices and drugs because they hold lives in their hands.

Boston Scientific disclosed its reporting lapses this week, little more than four months after pleading guilty to two misdemeanors stemming from, guess what? Reporting lapses.

In the earlier case, prosecutors said an outfit the company bought, Guidant, hid malfunctions it had known about for three years. Some of its defibrillators were short-circuiting, and at least one patient died. Boston Scientific is slated to pay a fine of almost \$300 million for that, on top of \$240 million to settle related civil complaints.

Doing Better

Maybe the parent company is trying to do better than Guidant did. Boston Scientific says it suspended defibrillator sales voluntarily this week when it discovered a reporting lapse. There is no evidence the latest notification failure hid a problem with the product, as happened before.

The unease stems from context. Pharmaceutical and medical device companies repeatedly signal they just don't seem to care what the law says if they can find a way around it.

Internal documents show Johnson & Johnson planning a push for \$302 million in geriatric sales for a drug after the FDA had said that for the elderly, the medication wasn't as helpful and carried more risks than the company had claimed, Bloomberg reported earlier this month. The New Brunswick, New Jersey-based company denies wrongdoing.

Examples abound that these companies keep breaking rules and violating laws to make and market their products, no matter how many times they are caught, fined and forced to promise to go straight.

### Off-Label Use

One insider at Warner-Lambert -- now part of Pfizer Inc. -- worried about promoting children's use of a drug for a purpose the FDA hadn't approved. His sales manager told him not to fret about off-label uses.

"It'll never get back to us," the manager said, according to Bloomberg Markets magazine.

The biggest fine ever imposed in U.S. history, \$2.3 billion against recidivist Pfizer, represented a mere 14 percent of the revenue stream from selling the drugs at issue over seven years.

So immune to criminal sanctions was the New York-based company that it launched its off-label Bextra campaign at the same time the company was pleading guilty to doing precisely the same thing with other drugs. The anti-inflammatory medication was later yanked from the market because of increased risk of heart attacks and stroke.

What's to be done?

The government can essentially kill a company by pushing for the parent firm to be barred from government work, which would include Medicaid and Medicare.

### Teaching a Lesson

That would teach the company a lesson. But it would also hurt the millions of people who depend, in Pfizer's case, on products from Accupril to treat congestive heart failure to Zyvox when you have certain pneumonias or infections.

And then there are those thousands of company employees who do good, honest work and who would suddenly find themselves in already massive unemployment lines.

And yet, companies count on selling drugs to patients that can't benefit from the medications and may be harmed by them. An estimated 15 percent of sales were prescribed for off-label uses.

Through the years, companies have admitted to paying doctors kickbacks for meeting with sales people who promote off-label uses and to sponsoring golf vacations and Caribbean respites for prescribing physicians.

The challenge is to find a way to make it not worthwhile to break the rules.

### Executives Behind Bars

Throwing a few company executives in jail might do the trick. On occasion, sales managers and physicians have been prosecuted.

As for top managers at pharmaceuticals, six have been convicted or pleaded guilty, mostly for misbranding or promoting off-label uses, according to the Justice Department.

Winning felony convictions is tough to pull off because you have to prove they had specific intent to commit fraud. As with any white-collar crime, that is tricky.

But there is a way around that obstacle, and the FDA announced this month that it would go that route to focus on pharmaceutical executives, the Wall Street Journal reported.

The Food and Drug Act allows misdemeanor convictions without proof of intent to do wrong.

That is an awesome power and it can be easily abused. The timing of the FDA announcement suggests that it's a response to critics in Congress and a brutal Government Accountability Office report that the division operates without scrutiny or, well, accountability.

And yet, used for the right cases, the misdemeanor prosecution of an executive or two who set up incentives for the sales force to push drugs illegally and withhold information about devices from regulators just might do the trick.

Nothing else has yet.