

# Pfizer pays extra for Bextra

Drugmaker learns the hard way the painful price of cutting corners

Even if the Obama administration falls short on health-care reform, a recent landmark plea agreement and settlement could make 2009 the year of health-care enforcement. Among the thousands of federal crimes on the books, few observers would guess the one responsible for the highest criminal fines in our history would be the Food, Drug and Cosmetic Act.



## POINT OF VIEW

Pete Anderson

On Sept. 2, the Department of Justice announced a historic settlement between the federal government and pharmaceutical giant Pfizer Inc. (along with its subsidiaries Pharmacia and Upjohn Co. Inc.), over a pattern of fraudulent marketing of drugs.

Pfizer's payment of \$2.3 billion (that's with a "b") arose from a global settlement that included civil and criminal components.

More specifically, Pfizer's criminal fine and forfeiture of \$1.3 billion was part of its guilty plea to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra, an anti-inflammatory drug, with the intent to defraud or mislead. Under the act, a company is required to specify the intended uses of a product when it submits a drug application to the Food and Drug Administration. If the drug is approved, it cannot be marketed or promoted for any "off-label" or unapproved uses.

On the civil side, Pfizer will pay \$1 billion to settle allegations under the civil False Claims Act. The company's alleged promotion of four drugs caused false claims (or requests for payments) to be sent into state and federal health-care programs for uses that were not medically approved and not covered.

The civil settlement also resolves allegations Pfizer paid kickbacks to doctors to encourage them to prescribe the drugs.

Another element of the settlement was a

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corporate-integrity agreement, which outlines procedures and audits to prevent and detect similar violations from recurring. It includes a way for doctors to report questionable conduct by Pfizer sales representatives.

Many aspects of the Pfizer plea and settlement are common to other federal fraud investigations. The prescription for this investigation included the following active ingredients:

- A lengthy pattern of fraudulent misrepresentations;
- A huge increase in sales and profits or ill-gotten gains arising from these lies;
- A half-dozen whistleblowers to stir in specifics for prosecutors and regulators; and
- A blend of parallel investigations from state and federal regulatory agencies, each responsible for different aspects of the improper conduct.

But what if everyone else is doing it? Apparently, promoting off-label drug use to physicians is a common practice. Unfortunately, this fact is no defense. No matter how common or widespread the practices may be within an industry, this is a disaster waiting to happen, and will eventually give rise to an aggressive enforcement campaign.

As Pfizer now knows, it's far better to prevent and detect than simply to react, respond and pay.

There's a unique aspect to the Pfizer plea. Unlike many recent federal criminal-enforcement initiatives, this case involved no criminal charges against executives. Despite the record-setting criminal fine, Justice did not force anyone to take the fall and face jail time. It's

undisputed the underlying conduct for these alleged corporate crimes was approved by particular executives.

While such a decision rests within the broad discretion of federal prosecutors, the lack of individual charges appears inconsistent with government policy. The U.S. Attorney's Manual, the official playbook for federal prosecutors, states: "Only rarely should provable individual culpability not be pursued, particularly if it relates to high-level corporate officers, even in the face of an offer of a corporate guilty plea or some other disposition of the charges against the corporation."

Some onlookers might be surprised this case was pursued criminally. But such a reaction stems from outdated notions still swirling around the boardrooms of many regulated businesses. This view holds federal criminal prosecutions are only brought against "bad" companies that are run by "evil-hearted" people.

Enlightened business leaders in every industry can get pain relief from Pfizer — not from its products, but by carefully noting the broad scope of criminal liability and the harsh consequences of its business practices.

The proper prescription for avoiding Pfizer's heartburn is to make a priority of compliance.

This includes setting up a compliance plan with standards and procedures and possibly a hotline; designating a high-level executive to serve as the compliance officer; conducting background checks for employees; engaging in regular training, monitoring and audits; responding to allegations of improper conduct and continually improving the program; and enforcing standards consistently.

That's how a proactive company can spell relief.

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