

Idaho Statesman, Thursday, June 2, 2011 – by The AP (2 pages)

In shift, feds target top execs for health fraud

It's getting personal now. In a shift still evolving, federal enforcers are targeting individual executives in health care fraud cases that used to be aimed at impersonal corporations.

The new tactic is raising the anxiety level - and risks - for corporate honchos at drug companies, medical device manufacturers, nursing home chains and other major health care enterprises that deal with Medicare and Medicaid.

Previously, if a company got caught, its lawyers in many cases would be able to negotiate a financial settlement. The company would write the government a check for a number followed by lots of zeroes and promise not to break the rules again. Often the cost would just get passed on to customers.

Now, on top of fines paid by a company, senior executives can face criminal charges even if they weren't involved in the scheme but could have stopped it had they known. Furthermore, they can also be banned from doing business with government health programs, a career-ending consequence.

Many in industry see the more aggressive strategy as government overkill, meting out radical punishment to individuals whose guilt prosecutors would be hard pressed to prove to a jury.

The feds say they got frustrated with repeat violations and decided to start using enforcement tools that were already on the books but had been allowed to languish. By some estimates, health care fraud costs taxpayers \$60 billion a year, galling when Medicare faces insolvency.

"When you look at the history of health care enforcement, we've seen a number of Fortune 500 companies that have been caught not once, not twice, but sometimes three times violating the trust of the American people, submitting false claims, paying kickbacks to doctors, marketing drugs which have not been tested for safety and efficacy," said Lewis Morris, chief counsel for the inspector general of the Health and Human Services Department.

"To our way of thinking, the men and women in the corporate suite aren't getting it," Morris continued. "If writing a check for \$200 million isn't enough to have a company change its ways, then maybe we have got to have the individuals who are responsible for this held accountable. The behavior of a company starts at the top."

Lawyers who represent drug companies say the change has definitely caused a stir, but the end result is far from certain.

"People are alarmed," said Brien O'Connor, a partner in the Boston office of Ropes & Gray. "They want to know what facts and circumstances would cause the Justice Department to indict someone who hadn't even known about the misconduct. They are doing all they can to achieve compliance."

Others say high-powered corporate targets won't go meekly.

"If the government does continue to press its campaign against individuals, we will see the limits of the government's theories tested," said Paul Kalb, who heads the health care group at the law firm of Sidley Austin in Washington. "In my mind, there is a very important open question as to whether individuals can be held criminally culpable or lose their jobs simply by virtue of their status."

Although the Obama administration has increased scrutiny of corporate America generally, this shift in health care enforcement seems to have come up from the ranks, government and corporate attorneys say.

Investigators and lawyers at the HHS inspector general's office, the Justice Department and the Food and Drug Administration started moving more or less independently toward holding executives accountable. Morris outlined the inspector general's position in congressional testimony this spring, saying his office will use its power judiciously.

A test case is playing out with an 83-year-old drug company chief executive, Howard Solomon of New York City-based Forest Laboratories. Forest makes antidepressants, blood pressure drugs and other medications. Last month, the inspector general's office notified Forest that Solomon could potentially be banned from doing business with federal programs.

The power to ban or "exclude" an individual rests with the inspector general. It's routinely applied to low-level violators, but rarely to people of Solomon's rank. In the industry, they call it the "death penalty."

Last year, a Forest subsidiary pleaded guilty to criminal charges as part of a settlement with the Justice Department in which the company also agreed to pay \$313 million to resolve long-running investigations. Prosecutors charged that Forest deliberately ignored an FDA warning to stop distributing an unapproved thyroid drug, promoted the use of an antidepressant in treating children although it was only approved for adults and misled FDA inspectors making a quality check at a manufacturing plant.

The company said it had considered the case closed. But then came the inspector general's letter.

"No one has ever alleged that Mr. Solomon has done anything wrong and excluding him would be completely unjustified," Herschel Weinstein, Forest's general counsel, said in a statement. "In prior cases where a senior executive has been excluded, that individual has been accused of wrongdoing and ultimately has either been convicted of or (pleaded) guilty to a crime."

Forest is fighting the move to ban Solomon. The inspector general's office refused to comment on the case, and no final decision has been made. In congressional testimony, Morris said that when there is evidence an executive knew or should have known about misconduct, the inspector general "will operate with a presumption in favor of exclusion of that executive."

Separate from the inspector general's power to ban, the FDA has resurrected something called the "Park Doctrine," which makes it easier for prosecutors to bring criminal charges against an executive.

The doctrine, stemming from a 1970s Supreme Court case, allows the government to charge corporate officers in the chain of command with a criminal misdemeanor. They could face up to a year in prison and fines if they had the authority and responsibility to prevent, detect or resolve misconduct affecting the public welfare but failed to do so.

It's making an entire industry nervous.

