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Feds to pharma: Fraud cases are in our crosshairs

Companies set internal controls to ensure regulatory compliance

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By Jared Kaltwasser

Last year, **Margaret A. Hamburg,** the new commissioner of the Food and Drug Administration, gave a speech at the Food and Drug Law Institute, in Washington, and delivered a clear message: "A strong FDA enforces the law," she said.

Pharmaceutical industry executives didn't need to read between the lines. Hamburg's speech, and a number of high-profile, high-cost pharmaceutical industry settlements, have many in the industry redoubling their compliance efforts.

Paul J. Fishman, the U.S. Attorney for New Jersey, has made health care fraud a key point of emphasis in his tenure, reorganizing the office to create a Health Care and Government Fraud Unit that resulted in increased resources being devoted to fraud and abuse throughout the health care industry.

"Obviously, one of our goals is to root out fraud in the industry and make it clear to people that they will get caught," Fishman said.
David Stone, managing partner at the law firm of **Stone & Magnanini LLP**, in the Short Hills section of Millburn, said in some cases, drug companies have an economic incentive to violate FDA rules.

"It's very hard to get approval for a drug at the FDA," he said. After clinical trials, "it's not uncommon to get a narrow approval for a drug, where it can only be used for a small market. There's tremendous financial pressure on these drug companies to expand those markets beyond the on-label market."

Stone recently represented a whistle-blower in a case against Forest Pharmaceuticals, in which the drugmaker paid a $313 million settlement for off-label marketing.
Jack Garvey, principal at Compliance Architects, in Robbinsville, said industry shifts also have complicated compliance.

"The industry has transformed from being vertically integrated — everything inside — to a much more distributed model," he said.
Garvey said drug companies need to make sure any contractors or business partners also are in compliance.

Carlos Ortiz, a former federal prosecutor who now heads the Foreign Corrupt Practices Act team at Newark-based law firm LeClairRyan, said the government also keeps a watchful eye overseas.

"In many countries around the world, doctors and physicians who work for government hospitals are considered government officials under the FCPA," he said. So companies doing business overseas need to realize that giving those doctors perks or sponsoring trips to conferences could be considered bribery.
Garvey said companies found to be in violation of federal regulations face consequences beyond a simple fine.

"There are real, tangible impacts — not just the direct cost, but the indirect costs of the complete distraction of the business model, and in addition, the loss of shareholder value," Garvey said.

Stone said companies who reach a settlement with the government also may be forced to sign corporate integrity agreements with sometimes-onerous compliance requirements.

But executives who allow fraud or violations can face personal fines — or worse, Stone said.
"They really have kind of served notice that we are going after conduct, and the way we're going after conduct is we're going to pursue you criminally," Stone said.
But compliance isn't exactly cheap, either, Garvey said.

"Compliance with FDA regulations and expectations is the price of admission to their company's business model of manufacturing and selling these high-margin health care products," he said.

Garvey said the first step to compliance is facing facts.
"The first step is for executives to get engaged and start asking the right questions, and demand unvarnished, no-spin answers," he said.
Ortiz said companies should thoroughly train their staff and keep good records of their compliance policies and efforts. Companies should also vet business partners here and abroad.

If a company is found to be violating the law, "one of the questions you'll get is, 'How did this happen?'" he said. "If your answer is we had controls in place, and this guy just found a way around it, Justice looks at that and says, as a company, you're doing the right thing."

Stone, who also advises pharmaceutical companies, said another good idea is to "have a very well-thought-out and clearly articulated whistle-blower program, where people in the company can go to a neutral source and, without being punished for it, give a report of conduct that might be unlawful, so you can address it."

Ortiz noted the recently passed Dodd-Frank Act sets up new incentives — including financial rewards — for whistle-blowers who alert federal authorities to violations. Fishman said companies also have an incentive to self-report violations.

"If a company discovers wrongdoing and comes forward with that information, it will clearly fare better in the investigative process and will get credit from us for having done that," Fishman said.

Fishman's office has reached out to a number of industry groups, insurers and attorneys to discuss health care fraud and exchange information. Last month, he spoke at Seton Hall's Center for Health and Pharmaceutical Law and Policy.

Kendra Martello, assistant general counsel at the Pharmaceutical Research and Manufacturers of America, said along with the government's new emphasis on enforcement, they've also emphasized transparency. One outgrowth of that is a new warning letter close-out process, whereby the FDA publishes close-out letters online when a company remediates a violation.

"In the past, if there were issues with a company that were identified with a warning letter, there was no mechanism for the FDA to let the public know those issues were resolved," Martello said.

Garvey said while compliance is expensive, good compliance strategies should be constructed in a way that is most beneficial to the bottom line.

"The best compliance systems are business-supportive, but meet the expectations" of regulators, he said. "It takes a lot of thinking and a lot of planning."

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