

*Periodically, we will send you a **concise** update on current events in the healthcare compliance arena **as it relates specifically to pharmaceutical and medical device manufacturers** that may have an impact upon your business and operating procedures. These news items and analyses are intended for informational purposes only.*



As previously reported, it appears that the FDA has grown weary of the protracted warning letter process and now is looking at the Park Doctrine for enforcement, under which it can prosecute corporate executives for violations of the Food, Drug, and Cosmetic Act.

The FDA, aware of its weak public perception, is actively investigating again using its criminal prosecutory authority aggressively under the Park Doctrine. The Park doctrine allows the government to seek a misdemeanor conviction against company officials for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA)—even if a corporate official was unaware of the violation—if the official was in a position of authority to prevent or correct the violation and did not do so.

Eric Blumberg, FDA's deputy chief counsel for litigation, told an industry gathering in April that the agency would go after executives at companies that seem to be flouting the FDA's rules. "Very soon, and I have no one particular in mind, some corporate executive is going to be the first in a long line ... So it's going to happen. Do what you can and do the right thing before we find out about it," Blumberg said.

Additionally, FDA Commissioner Margaret Hamburg wrote to Sen. Chuck Grassley, R-Iowa, in March to say that the agency intends to consider "the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable."

"The FDA has generally avoided resorting to court to enforce their actions," said Lewis Grossman, professor of law at American University, and an expert in food and drug law. That wasn't always the case. According to Grossman, the agency brought more than 600 criminal prosecutions against companies in 1939, but that the number plummeted to about 16 in 1989.

David Rosen, who worked at the FDA for 14 years and is now with the law firm Foley & Lardner, agreed. "The FDA is developing a tougher compliance attitude because companies are ignoring warnings from the FDA. It appears the agency does want to send a clearer message to people now."

While a misdemeanor prosecution may seem trivial, it could lead to an individual being named to the OIG Exclusion List, thereby inhibiting current and future employment in any industry receiving payment from the government for goods and/or services.

As always, if you have any questions, comments, or concerns we can be reached at sreardo23@centurylink.net or at (908) 370-4085.