

ALERTS AND UPDATES

FDA to Increase Criminal Prosecution of Corporate Officials in the Pharmaceutical Industry

March 11, 2010

In a recently released letter to U.S. Sen. Chuck Grassley (R-Iowa), the Government Accountability Office (GAO) reported the results of its study into the Food and Drug Administration's (FDA) criminal investigation of individuals and companies through the FDA's Office of Criminal Investigations (OCI). OCI currently has 223 staff members, 180 of which are criminal investigators often hired from other federal law-enforcement agencies.

The GAO study originated from concerns raised by members of Congress that, while OCI's budget and staff have grown significantly over the past 10 years, OCI has operated with little accountability to FDA management. Among other things, GAO was asked to examine FDA's oversight of OCI investigations as well as OCI's funding, staffing and workload.

The GAO made recommendations with which FDA agreed, including: (1) implementation of a regular assessment by the FDA of the OCI field offices; and (2) establishment by the FDA of standard performance measures to monitor OCI's investigations and to assess program results against these measures.

These actions are likely to lead to a greater focus by the FDA on OCI. This may then increase the number of OCI prosecutions of pharmaceutical company executives under the *Park* doctrine of strict liability—a result that members of Congress, including Senator Grassley, have been seeking. The *Park* doctrine provides that management can be held criminally liable for a company's violations of the federal Food, Drug, and Cosmetic Act (FDCA) even if management was unaware of the violation. A March 4, 2010, *Wall Street Journal* article discussing the GAO report cited an unnamed FDA official in support of this conclusion:

A FDA official said the agency has the authority to prosecute corporate executives for criminal actions within their companies under a provision called "strict liability." He said the government doesn't have to show intent to defraud in order to get a conviction. He added that the provision is an important tool that hasn't been used much in recent years.

The GAO report and congressional oversight indicate that the FDA may apply this provision more frequently. Such a change may place increased emphasis on companies to ensure they have a robust corporate-compliance program in place to help identify potential violations of the FDCA internally.

For Further Information

If you would like a copy of the GAO report or have other questions about this *Alert*, please contact [Frederick \(Rick\) R. Ball](#), any of the [lawyers](#) in the [White-Collar Criminal Defense, Corporate Investigations and Regulatory Compliance Practice Group](#), any of the [health law lawyers](#) in the [Pharmaceutical & Biotechnology](#) industry group or the attorney in the firm with whom you are regularly in contact.