



March 8, 2010

**GAO Criticism of FDA's Office of  
Criminal Investigations Could Lead to  
Increased Criminal Prosecutions for Executives**

On March 4, 2010, the Government Accountability Office (GAO) issued a new report (Report) sharply criticizing the FDA's Office of Criminal Investigations (OCI). Senator Charles Grassley (R-IA) previously raised concerns about OCI's and the Office of Internal Affairs' (OIA) procedures for conducting and coordinating investigations, the adequacy of FDA oversight of these offices, and the level of funding and staffing for these offices in comparison to other FDA activities. The OCI conducts and coordinates criminal investigations for the agency and in conjunction with the Department of Justice and other enforcement authorities, including investigations relating to the manufacture and sale of counterfeit drugs and the illegal marketing of drugs. OIA, which is organizationally part of OCI, conducts internal investigations of allegations of misconduct, criminal activity, or other violations of applicable laws or regulations by FDA employees. Congress' apparent concern with FDA's oversight of OCI is ironic, given that OCI was established by Congress to operate independent of FDA.

After conducting a review of FDA's oversight of OCI and OIA investigations, policies and procedures and resources for OCI and OIA investigations, GAO found that FDA's oversight of OCI and OIA investigations has been too limited. GAO concluded that FDA management cannot have reasonable assurance that OCI and OIA investigative policies and procedures are routinely followed and that deficiencies are promptly resolved when identified. In addition, FDA management cannot determine whether OCI's criminal investigative program is achieving its goals because OCI has not developed sufficient performance measures. According to the GAO, FDA's lax oversight of OCI and OIA investigations and inability to effectively evaluate OCI's performance frustrate FDA's efforts to strategically manage OCI's criminal investigative program to ensure its successful operation.

In a response to the GAO's Report, FDA officials largely agreed with the GAO's recommendations to strengthen FDA's oversight of criminal and other investigations and described the steps it would take to implement them, including (1) allocating additional

For more information, contact:

**Seth H. Lundy**  
+1 (202) 626 2924  
slundy@kslaw.com

**Ed Basile**  
+1 (202) 626 2903  
ebasile@kslaw.com

**Mark Brown**  
+1 (202) 626 5443  
mbrown@kslaw.com

**Dan Donovan**  
+1 (202) 661 7815  
ddonovan@kslaw.com

**C. Scott Strickland**  
+1 (202) 626 9247  
cstrickland@kslaw.com

**King & Spalding**  
**Washington, D.C.**  
1700 Pennsylvania Avenue, NW  
Washington, D.C. 20006-4707  
Phone: +1 (202) 737 0500  
Fax: +1 (202) 626 3737

[www.kslaw.com](http://www.kslaw.com)



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resources to comply with the time frames established in OCI's existing policy for conducting regular assessments of OCI's field offices; (2) developing a new written policy for conducting regularly scheduled assessments of OIA; and (3) developing performance measures to determine the extent to which OCI is achieving its desired results, as part of a new FDA-wide initiative.

### **Implications for Pharmaceutical and Food Industry Executives**

In a separate letter to Sen. Grassley, FDA indicated that it has formed a committee comprised of senior leadership to examine opportunities and develop recommendations to enhance coordination and strategic alignment between OCI and other FDA components. According to FDA's letter, this internal committee has recommended that OCI "increase the appropriate use of misdemeanor prosecutions, which allows responsible corporate officials to be held accountable and is a valuable enforcement tool." To further this end, FDA is currently developing criteria for consideration in the selection of misdemeanor prosecution cases that will be incorporated into revised policies and procedures covering the appropriate use of misdemeanor prosecutions targeting corporate officials.

It is believed that this renewed focus on enforcement and the criminal office's performance will likely result in increased prosecutions of pharmaceutical, medical device and food industry executives moving forward. Given the tenor of the GAO's Report, it is also likely that Congress will continue its scrutiny of OCI and the FDA's oversight of this office, further intensifying pressure both to successfully prosecute high-profile cases and to demonstrate increased misdemeanor convictions coming out of those cases. As much of the focus seems to be on off-label promotion of drugs and devices and of food contaminants, companies should continue to pay close attention to these areas. Of particular note is the apparent intention to not only increase prosecutions, but specifically to increase misdemeanor prosecution of individual industry executives with responsibilities for the products and foods at issue.

King & Spalding will continue to monitor FDA's response to the GAO Report as well as the activities of Senator Grassley and the Senate Finance Committee. Please contact us with any questions or if we can assist with targeted analysis of the GAO Report.

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