

# FDA Law Update

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## FDA Looks to Boost Criminal Prosecutions

In the wake of a scathing March 4<sup>th</sup> GAO Report, FDA has informed Congress that it will boost criminal prosecutions of pharmaceutical and food industry executives. [\[1\]](#) Although the Agency's Office of Criminal Investigation (OCI) can prosecute 'responsible corporate officials,' according to the GAO Report OCI has failed to exercise this enforcement tool to achieve FDA priorities and has underperformed comparable agencies in bringing misdemeanor prosecutions.

The Report determined that OCI instead operates independent from broader FDA priorities and with little accountability to top FDA officials. As the authors noted, "FDA's oversight of OCI's investigations of individuals and companies external to FDA is limited." In her letter to Senator Charles Grassley (R-Iowa), FDA Commissioner Margaret Hamburg acknowledged that OCI and FDA's various centers must improve their communication. If they do not, OCI will continue to operate outside the context of emerging Agency policies and priorities, and OCI's prosecution trends cannot inform FDA policies or support appropriate allocation resources for inspections, civil enforcement, and risk communication.

Industry insiders find the lack of OCI accountability and oversight especially troubling during FDA's public campaign for increased transparency. Meanwhile, FDA has allowed OCI to lag comparable federal agencies in developing performance standards; indeed, the GAO reports that OCI has failed to complete 70% of required assessments. Although Hamburg promises greater communication between OCI and high-level FDA administrators, there is no small gap to bridge.

Although the Report focused principally on improved communication, accountability, and oversight, what caught the press's attention is the prospect of increased misdemeanor prosecutions. No surprise. The American public has not forgotten last year's rash of adulterated imports, and the public has a keen interest in FDA-regulated products.

Prudently, however, FDA does not expect to see widespread and aggressive criminal prosecutions in all areas. Instead, stepped up criminal enforcement will likely more specifically target issues concerning counterfeiting, diversion, tampering, and adulteration: key Agency priorities. Under the FDCA's strict-liability provisions, fraudulent information is fraud; misdemeanor prosecutions can proceed without proof of intent to defraud.

Commissioner Hamburg expects revised OCI policies and procedures to incorporate some newly developed criteria for selecting cases to prosecute.

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[1] GAO, “Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations,” 29 January 2010, released 4 March 2010. Available <http://gao.gov/products/GAO-10-221>