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## **Criminal Enforcement Will Become Even More Aggressive for the Pharmaceutical and Medical Device Industries**

Through a series of recent public statements, the government has indicated that it will ratchet up investigations and criminal prosecutions of the pharmaceutical and medical device industries. Substantial additional resources have been allocated and deployed to pursue more investigations and to expand the types of conduct that will be subject to intense scrutiny. Also, a theory of strict criminal liability will be used more frequently to secure convictions. The conclusion is unmistakable – pharmaceutical and medical device companies and individuals associated with those industries will be subject to even greater risk.

In May 2009, the government announced the formation of the Health Care Fraud Prevention and Enforcement Action Team – which operates under the acronym HEAT. The program sharply increased the number of investigators hired by the FBI, HHS and DOJ. Many of those investigators are now in place and will provide the resources to significantly increase the number of investigations and prosecutions.

In June 2010, government officials discussed the use of these enhanced capabilities. The pharmaceutical industry will continue to be an important target. Over the last few years, the government has secured numerous settlements for hundreds of millions of dollars each in off-label promotion investigations, and the government will not abandon an area which has proved to be so fruitful.

But the focus of investigation will expand and the government also will direct substantial attention to the medical device industry and will even include companies involved in the production and sale of biologics. In particular, the government will review the conduct of companies operating under the authority of Section 510(k) notification.

The government has concluded that many companies involved in the medical device industry have not dedicated sufficient resources and attention to compliance efforts. In part, this might be due to a substantial number of mid-sized competitors that are more cost conscious than large pharmaceutical companies. In particular, the government believes that sales practices in this type of environment are not always well controlled, and often include incentives that encourage questionable conduct. Sales compensation that relies on a high percentage of commission will often attract the government's attention.

The government's increased and expanded investigatory focus will be supported by the use of aggressive theories of prosecution. In March 2010, the FDA Commissioner, Margaret Hamburg, directed a letter to Senator Grassley. The letter was intended as a response to a GAO report that criticized FDA's oversight of criminal investigations. Commissioner Hamburg promised to "hold responsible corporate officials accountable" by increasing "the appropriate use of misdemeanor prosecutions."

Commissioner Hamburg's response invoked a theory of strict criminal liability that is limited to a few regulatory statutes. Under this theory, an individual can be held criminally liable without participation in or even knowledge of a violation. It is only necessary that the individual had a "responsible relation" to the questionable conduct.

In essence, this describes every individual who had the power to prevent or detect misconduct but failed. The Supreme Court has stated: "The Act imposes not only a positive duty to seek out and remedy violations when they occur, but also, and primarily, a duty to implement measures that will insure that violations will not occur." Of course, companies also will be prosecuted under this theory because they can be held vicariously liable for the perceived transgressions of their employees.

The theory of strict criminal liability applies to any of the "prohibited acts" listed in the FDA statute, and provides the government with enormous prosecutorial discretion. Thus, a change in enforcement policy can be implemented by the government relatively quickly and directly. It is only necessary for the government to make more aggressive prosecutorial decisions.

Despite its broad application, the strict liability theory can support severe sanctions. An individual can be incarcerated for as much as one year. Companies and individuals can be required to pay monetary fines calculated at twice the pecuniary

gain or loss caused by the violative conduct. For a product with any significant sales, the fine can become astronomical. Moreover, HHS can use the conviction to prevent participation in government-funded programs. Recently, former executives of a large pharmaceutical company were debarred for 15 years under this approach.

The government's warnings of a more aggressive criminal enforcement program suggest that companies would be well served to review their internal compliance programs. An effective program can help to promote an environment of regulatory compliance and prevent violations. If questionable conduct does occur, evidence of a diligent and well-designed compliance program can help to persuade the government that criminal prosecution is neither justified nor warranted. Where the government can exercise virtually unlimited prosecutorial discretion, this can be an important defense consideration.

In the final analysis, if an investigation is commenced the company should consider consultation with experienced and knowledgeable legal counsel immediately. Often, decisions made at the beginning of an investigation have a profound effect on its eventual outcome.

At this point, the message is clear – companies and individuals will be subjected to even more investigations and heightened risk.

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