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CLIENT ALERT

Congressional Report Critical of FDA Enforcement Protocol

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On June 15th, 2012, the U.S. House Committee on Oversight and Government Reform, led by Chairman Darrel Issa, released a sharply worded staff report entitled "FDA's Contribution to the Drug Shortage Crisis." The report's harsh criticism of FDA, which comes on the heels of an Executive Order, Government Accounting Office report, FDA draft Guidance, and proposed legislation that all address the growing problem of drug shortages, underscores that this topic will continue to be a political hot potato for the foreseeable future.

The House report attributes the rise in drug shortages to caps imposed on drug reimbursements by the Medicare Modernization Act, signed into law in 2003 by President Bush, and FDA's more aggressive enforcement posture toward drug manufacturers, particularly manufacturers of generic injectable medications. It finds that such manufacturers, undertaking efforts to upgrade facilities in the face of threatened FDA enforcement actions, have reduced their manufacturing capacity by 30%, thereby restricting the supply of critical cancer and other life-saving drugs. The report criticizes FDA for not taking into account the substantial impact of heightened enforcement activity on the supply of critical drugs.

All drug manufacturers should be aware if drugs in their product portfolio are in shortage or at risk of being in shortage. In addition to possible future reporting obligations, companies should consider what a shortage might mean if confronted with an FDA enforcement action. If the agency moves to take control of compliance problems before shortages becomes acute, manufacturers of drugs in shortage could find themselves targets of even more aggressive enforcement actions. Agency-proposed consent decrees for manufacturers of drugs in shortage could include more onerous terms, requiring disgorgement of profits or compelling manufacturers to prioritize less profitable, or even unprofitable, product lines. Alternatively, manufacturers of drugs in shortage may hold more leverage in negotiations with the agency to limit or even avoid temporary shut-downs.

Given the partisan tone of the report, it is unlikely to have meaningful impact on current FDA enforcement activity. We are advising our clients to continue to be vigilant about their compliance efforts in this environment. We are also developing innovative strategies for responding to FDA concerns that are tailored to the agency's current compliance expectations.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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