Bipartisan Agreement Reached on Legislation Granting FDA Greater Authority to Regulate Drug Compounders

Wednesday, October 2, 2013

Last week, Democrat and Republican leaders of both houses of Congress agreed to the terms of a bill that would give the U.S. Food and Drug Administration (FDA) greater authority to regulate drug compounding and would revamp the way drugs are tracked from the manufacturer to the pharmacy. The House of Representatives voted in favor of the bill shortly after the agreement was announced. The bipartisan agreement comes at a time when compromise between the two major political parties has been rare and fights over the federal budget and raising the “debt ceiling” have become commonplace. Congress’s failure to agree on a spending bill has resulted in the first government shutdown since 1995-1996.

The Drug Quality and Security Act (Act) would give the FDA oversight authority over large-volume compounders who elect to register as outsourcing facilities. The FDA’s oversight of such compounders would be similar to the manner in which the FDA regulates traditional drug manufacturers. Those compounders that elect to remain as traditional pharmacies would continue to be regulated by state boards of pharmacy.

The Act would also create a uniform framework to track drugs from the manufacturer to the pharmacy and would supersede the current “patchwork of state prescription-drug tracing laws.” Federal officials believe the uniform tracking framework will limit the number of counterfeit or stolen drugs that reach consumers.

This legislation follows a July 2013 Government Accountability Office (GAO) report which concluded that the FDA needed more explicit authority and reliable data to improve its oversight of drug compounding.

Last year, at least 64 people were killed and 750 people were injured following a meningitis outbreak tied to the New England Compounding Center. Federal officials contend that the legislation will help prevent a future public health crisis similar to last year’s meningitis outbreak.

Although the Act would not require drug compounders to register with the FDA, it does create an incentive to register, and will give hospitals and physicians confidence that they are getting drugs from an FDA-approved source if the compounder is registered.

Organizations in the pharmaceutical supply chain should both monitor the bill’s progress in Congress and understand FDA’s expanded oversight role if the bill is enacted.

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