

DRUG & PHARMACY ALERT

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U.S. Senate Approves the Drug Quality and Security Act

On November 18, 2013, the U.S. Senate, by voice vote, passed the Drug Quality and Security Act (the "Act") (H.R. 3204), marking the culmination of a nearly decade-long effort by many in the drug and pharmacy industry to clarify and strengthen both the regulatory framework for compounding pharmacies and the security of the pharmaceutical supply chain. The U.S. House of Representatives passed the measure in September and President Obama is expected to sign the Act into law shortly.

According to the Senate Floor Statement of Senator Carl Levin (D-Mich.) on H.R. 3204, the Drug Quality and Security Act aims to address a regulatory "grey area" by clarifying the responsibilities of the FDA with regard to the oversight of mass compounded pharmaceuticals. The Act defines the distinction between traditional compounding and compounding manufacturers that make large volumes of drugs without individual prescriptions. As noted by Senator Levin:

Under this bill, mass compounding pharmacies can choose to register as "outsourcing" facilities that would be subject to new FDA regulatory oversight similar to that of other pharmaceutical manufactures. And, in an effort to provide patients with better information about compounded drugs, this legislation calls for detailed labeling of compounded drugs and directs the FDA to make available on their website a list of FDA-regulated facilities.

The Act also establishes important requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain. It creates uniform national standards for supply chain security, preempting state and local requirements related to tracing drugs through the distribution system. The new "track-and-trace" requirements are intended to prevent counterfeit or contaminated drugs from entering the market downstream in the supply chain and to allow faster recall of bad products. The track-and-trace system gradually phases in over a period of 10 years, with specific deadlines for all of those operating within the distribution supply chain. At the time of full implementation, each package of drugs will be electronically traceable throughout the supply chain.

The Drug Quality and Security Act has far-reaching implications across the drug and pharmacy industry. Please contact **Ned Milenkovich** at 312.582.1676 or nmilenkovich@ralaw.com for further information.