FDA ALERT

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FDA Quickly Leverages its Jurisdiction over Compounding Pharmacies

Within one week of President Obama's signing a law that will give the U.S. Food and Drug Administration (FDA) partial jurisdiction over compounding pharmacies, the FDA has taken important action that will effectively change how the industry is regulated.

On November 27, 2013, President Obama signed into law the Drug Quality and Security Act (the "Act"). Under the Act, compounding pharmacies that ship compounded drugs across state lines will be designated as "outsourcing facilities." These "outsourcing facilities" can choose to voluntarily register with FDA. Compounding pharmacies that choose to pay a fee and register with FDA as "outsourcing facilities" will be subject to FDA oversight, inspections of their facilities and compounded products, and be required to manufacture according to the FDA's current Good Manufacturing Practices (cGMPs).

On December 2, 2013, FDA issued three draft guidances to help compounding pharmacies comply with the new law. The guidance entitled *Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetics Act* outlines procedures for registering as an outsourcing facility. The guidance entitled *Interim Product Reporting for Human Drug Compounding Outsourcing Faculties Under Section 503B of the Federal Food, Drug and Cosmetics Act* outlines, among other things, the timeline in which outsourcing facilities just report the drugs they have compounded in the previous six months. The third guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetics Act* withdraws a prior compounding pharmacy guidance and reiterates that FDA expects state boards of pharmacy to continue their oversight and regulation of the practice of pharmacy. It also provides clarity with regard to compounding pharmacies that do not register with FDA as outsourcing facilities. Finally, the guidance states that FDA will give highest enforcement priority to compounded drugs and Food, Drug, and Cosmetic Act violations that pose the greatest health risk.

The obvious question is: Why would any compounding pharmacy choose to **voluntarily** register with FDA and be subject to a seemingly onerous regulatory burden when they can remain under the less onerous state regulations?

This is the "leverage" portion. There are two important reasons why compounding pharmacies will seek to be regulated by FDA. The first reason is found in FDA Commissioner Margaret Hamburg's November 2, 2013, official FDA blog post, in which she states: "*If compounders register with FDA as outsources, hospitals and other health care providers will be able to provide their patients with drugs that were compounded in facilities that were subject to FDA oversight and federal requirements for current good manufacturing practices…we will be encouraging healthcare providers and health networks to consider purchasing compounded products from facilities that are registered with FDA and subject to risk based inspections."*

Commissioner Hamburg reiterated this position at a press conference on December 2, 2013, where she stated that, *"[w]e hope that all the [compounding pharmacies] that are making high-risk products will be registering with us...We hope this will be the* ***standard of practice*** *for where providers will seek these kinds of medicines for their patients.*"

Consequently, compounding pharmacies will likely seek FDA registration that subjects them to more stringent regulatory requirements because: (1) FDA will encourage hospitals and other health care providers to purchase compounded drugs only from such registered facilities; and (2) FDA is likely to succeed in establishing that only FDA-regulated facilities meet the "standard of practice" for high-risk compounded products.

With regard to the compounding pharmacies identified as “outsourcing facilities,” there is no doubt FDA will continue using all tools available to the agency either to bring those operations within its jurisdiction or to put them out of business.

If you have questions regarding FDA’s new requirements for compounding pharmacies or other FDA-related questions, please contact **Edgar Asebey-Birkholm,** Food & Drug Practice Group Manager at 954.759.2754 or easebey@ralaw.com or any of the following Roetzel attorneys:

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