FDA TO INITIATE LIMITED REGULATION OF COMPOUNDING PHARMACIES

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Just over one year after New England Compounding Center's (NECC) tainted epidural steroid injections caused an outbreak of fungal meningitis that infected over 750 patients in 20 states and resulted in the deaths of 64 people, the U.S. Senate on October 18, 2013, passed the Drug Quality and Security Act (DQSA), which President Obama is expected to sign in the coming days.

At the time of the meningitis outbreak, the U.S. Food and Drug Administration (FDA) was criticized for not acting quickly enough to shut down the company that was obviously producing dangerous drugs. As a consequence, FDA asked Congress to clarify its authority over compounding pharmacies.

Clarification was required because the traditional role of compounding pharmacies had evolved over time. Historically, compounding pharmacies produced custom doses of specialized drugs pursuant to a doctor's prescription and were regulated by the states' boards of pharmacy. But in the past two decades, many compounding pharmacies had pushed the limits of this activity by producing dozens or hundreds of doses prior to receiving a prescription from a doctor. To FDA, this started looking like drug manufacturing, but without any of the very stringent quality controls such as Current Good Manufacturing Practices (CGMPs) that are required of pharmaceutical manufacturers. It is this lack of quality control that directly led to the fungal contaminations that resulted in 64 deaths in the NECC case.

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The DQSA is not as comprehensive as FDA would have wanted. The DQSA will put larger compounding pharmacies, known as "outsourcing facilities," under FDA oversight, but only if they agree to be inspected. The bill would also bar larger compounding pharmacies from copying drugs approved by the FDA and marketed by other pharmaceutical companies. Additionally, the bill will establish an electronic "track and trace" system to protect the safety of the nation's pharmaceutical supply chain.

What is clear is that FDA has taken an important first step in protecting American patients from the subset of companies that would place profits over patient safety. No doubt FDA will continue to focus on compounding pharmacies and these businesses will realize that understanding and implementing CGMP's and other well-known QA/QC concepts will be a necessity in the future in order to avoid becoming a victim of FDA's vast enforcement authority.