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RxLegal

The Drug Quality and Security Act

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A national spotlight was shone on the safety of compounded pharmaceutical products with the 2012 multistate outbreak of fungal meningitis and other infections due to contaminated steroid injections produced by the New England Compounding Center (NECC) in Framingham, Massachusetts.[1] To date, 751 cases and 64 deaths in 20 states have been linked to tainted NECC steroid injections. As a direct result of this outbreak, Congress passed the Drug Quality and Security Act, which was signed into law by President Obama in November 2013.[2-4] The Drug Quality and Security Act consists of 2 Titles: Title I covers drug compounding and Title II relates to drug supply chain security.[4]

There are 2 major compounding-related changes to current law within Title I of the Drug Quality and Security Act. One change involves Section 503A of the Food, Drug, and Cosmetics Act (FDCA).[2,4] Section 503A creates a "safe harbor" for traditional pharmacy compounding performed for a specific patient prescription and generally overseen by state boards of pharmacy.[2,3] This section exempts this type of compounding from FDCA requirements including compliance with current good manufacturing practices (cGMP), appropriate labeling, and US Food and Drug Administration (FDA) approval prior to marketing.[2] The Drug Quality and Security Act removes wording regarding a prohibition on advertising of compounded products from Section 503A that was deemed to be unconstitutional by the Supreme Court in 2002.[2,4] By deleting these unconstitutional provisions, the Act "removes uncertainty regarding the validity" of 503A.[2]

Another major new provision is the creation of a novel section of the FDCA, Section 503B.[2,5] Under Section 503B, a pharmaceutical compounder can voluntarily register on an annual basis with the FDA as an "outsourcing facility." An outsourcing facility must adhere to cGMP, but does not need to receive FDA approval for its compounded products prior to marketing and can qualify for exemptions regarding labeling products with adequate directions for use.[2] In addition, outsourcing facilities:

- are not required to be licensed pharmacies,
- must compound under the supervision of a licensed pharmacist or physician,
- may or may not obtain patient-specific prescriptions,
- may use only drugs from a bulk ingredients list,
- are not allowed to compound products already commercially available unless the products are on shortage,
- must undergo regular FDA inspections on a risk-based schedule,
- must submit information about products compounded within the facility to the FDA every 6 months,
- must report product-related adverse events to the FDA,
- and must pay an annual fee of $15,000 to the FDA to cover inspection costs.[2,4,5]

Pharmaceutical compounders who choose not to register with the FDA as an outsourcing facility, and are not traditional compounders under 503A, are subject to the same requirements as conventional manufacturers under the FDCA.[4] As of May 28, 2014, 42 compounding centers have registered as outsourcing facilities.[6] The FDA is encouraging health care systems and providers to buy compounded medications from registered outsourcing facilities when needed.[4]

Title II of the Drug Quality and Security Act has received less attention thanTitle 1. This Title focuses on drug supply chain security. Specifically, Title II mandates the development of a national "track and trace"

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the temptation of living life outside of their ethical framework.

We urge all leaders to remember the impact they have on their pharmacy staff and patients in the delivery of care in an ethical and respectful manner. Leaders must understand how their actions can impact the lives of those with whom they work.[6] By basing each decision and action on their ethical structure, pharmacy leaders can establish a legacy that is focused on personal integrity, patient care, organizational improvement, employee development, and individual growth.

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electronic system for prescription medications.[7] The goal of this legislation is to protect consumers from potentially harmful drug exposures such as those experienced with the NECC crisis. Implementation of this system over the next 10 years should allow for verification of the legitimacy of a drug product identifier down to the individual package level, enhance detection of illegitimate drug products in the supply chain, and improve drug product recall mechanisms. Pharmaceutical manufactures, wholesale distributors, and drug repackagers and dispensers will all be involved in the development of this system over the coming decade.

Although full implementation of the Drug Quality and Security Act will take years, unresolved questions remain regarding legislative intent, and gaps in the Act have been identified, this law is an important step forward in improving the safety of the national drug supply.

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