



September 2013

H.R. 3204, the Drug Quality and Security Act: Summary

Bipartisan, Bicameral Legislation to Address High-Risk Drug Compounding Practices and Secure the Pharmaceutical Supply Chain

Title I: Compounding Quality Act

One year ago, the meningitis outbreak caused by contaminated compounded drugs from the New England Compounding Center alerted the nation that providers and patients need sources of safe compounded drugs. In response to this crisis, the Energy and Commerce Committee held hearings and engaged with stakeholders, the Food and Drug Administration (FDA), and bipartisan and bicameral health policy leaders in order to understand the existing problems and the best options for addressing them. This legislation helps ensure that quality compounded drugs are available to patients who need them. It reflects a bicameral, bipartisan effort to address this public health crisis.

Among other highlights, the legislation:

- Distinguishes compounders engaged in traditional pharmacy practice from those making large volumes of compounded drugs without individual prescriptions. Compounders who wish to practice outside the scope of traditional pharmacy practice can register as outsourcing facilities, but those who choose to remain traditional pharmacies will continue to be regulated by State Boards of Pharmacy as they are in current law.
- Defines the FDA's role in oversight of outsourcing facilities. Outsourcing facilities would be subject to FDA oversight in much the same way as traditional manufacturers. FDA will know who these outsourcers are and what they are making, receive adverse event reports about compounded drugs, and have the authority and resources to conduct risk-based inspections. The legislation will give providers and patients the option of purchasing product from outsourcing facilities that comply with FDA quality standards.
- Offers providers and patients better information about compounded drugs. The legislation directs FDA to make a list of FDA-regulated outsourcing facilities available on FDA's website, requires detailed labeling on compounded drugs, and prohibits false and misleading advertising.
- Clarifies current federal law regarding pharmacy compounding. The legislation strikes unconstitutional provisions in current law, resolving the patchwork of current federal regulation and applying a uniform standard nationwide.

Title II: Drug Supply Chain Security Act

This legislation improves patient safety by replacing today's patchwork of state product tracing laws with a strong, uniform standard that would ultimately result in electronic, interoperable unit level product tracing for the entire country. The last comprehensive effort to establish safeguards for the drug distribution supply chain was 25 years ago. This bipartisan, bicameral draft is the result of several years of work to address the growing problem of pharmaceutical theft, counterfeiting, and diversion.

Among other highlights, the legislation:

- Develops a workable pathway to unit-level tracing in a decade. Over the course of seven years, the major sectors of the pharmaceutical supply chain, such as manufacturers, repackagers, wholesale distributors, and dispensers will all be passing and holding onto key information about each drug's distribution history. Within ten years, supply chain stakeholders will participate in electronic, interoperable product tracing.
- Strengthens licensure requirements for wholesale distributors and third-party logistics providers. Wholesale distributors will have higher standards for their licenses nationwide, and third-party logistics providers will be recognized for the first time as a part of the drug supply chain. FDA will also keep a database of wholesalers that will be available to the public through the FDA's website, allowing consumers and members of the drug supply chain to identify appropriately licensed wholesalers.
- Establishes nationwide drug serial numbers. Four years after the date of enactment, manufacturers will serialize drugs in a consistent way across the industry. This will allow for efficient tracing to respond to recalls and notices of theft and counterfeiting.