September 2013

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

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

The Drug Quality and Security Act contains two titles. Title I, "The Compounding Quality Act," distinguishes between traditional compounders and outsourcing facilities. It clarifies a uniform set of rules for outsourcing facilities while preserving the states' primary role in traditional pharmacy regulation. Title II, "The Drug Supply Chain Security Act," provides a uniform, national drug tracking and tracing framework to track prescription drugs from the manufacturer to the pharmacy and raises the standards for prescription drug wholesalers across the U.S.

TITLE I –DRUG COMPOUNDING

Section 101: Short Title: "Compounding Quality Act"

Section 102: Outsourcing Facilities

This section establishes a new section 503B to the Federal Food, Drug, and Cosmetic Act (FFDCA) that provides an option for a facility engaged in compounding of sterile drugs to register with the Food and Drug Administration (FDA) as an outsourcing facility. A facility qualifying as an outsourcing facility will be exempt from adequate directions for use (Sec. 502(f)(1)), the new drug provisions (Sec. 505), and Sec. 582, the drug tracing provisions added in Title II, and is not required to receive prescriptions.

An outsourcing facility must:

- Give a licensed pharmacist direct oversight over the drugs compounded;
- Compound only drugs from bulk ingredients that appear on a list developed by the Secretary. This list will be developed through a notice published in the Federal Register following a 60 day comment period, and must take into consideration clinical need;
- Register as an outsourcing facility. FDA will make available on their website a list of the name of each outsourcing facility along with the state where the facility is located, whether the facility compounds from bulk drug substances, and whether drugs compounded from bulk are sterile or non-sterile;
- Report to the Secretary upon registering, and every 6 months thereafter, the drugs sold in the previous 6 months;
- Be inspected by FDA according to a risk-based inspection schedule, and pay annual fees to support;
- Report serious adverse event experiences within 15 days and conduct follow up investigation and reporting similar to current drug manufacturers;
- Label products with a statement identifying it as a compounded drug and other specified information about the drug.

Drugs removed from the market for safety and effectiveness reasons may not be compounded.

Copies of marketed FDA-approved drugs may not be compounded by an outsourcing facility except in the case of a drug shortage. Products subject to Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use can only be compounded under these exceptions if the compounder shows the Secretary it utilizes controls that are comparable to those in the REMS.

Compounded drugs may only be sold by the outsourcing facility that compounded the drug, and all must be labeled "not for resale." An outsourcing facility may or may not be a licensed pharmacy. If an outsourcing facility maintains its pharmacy license, FDA is responsible for overseeing all drugs compounded in that facility.

An outsourcing facility would pay an annual establishment fee and, if necessary, a reinspection fee to defray the cost of compounding oversight (e.g. inspections).

The fee is $15,000 per year with an inflation adjustment. Small businesses, defined as compounding manufacturers with under $1,000,000 in annual gross revenue, pay one-third of that fee. FDA would then adjust the fee for the larger facilities based on the number of small businesses. Fees can only be used for the inspection and regulation of compounding manufacturers.

The Secretary will provide an annual report to Congress on the fees collected from registration and reinspections, a description of the hiring and placement of new staff, the use of fee resources to support inspecting compounding manufacturers, and the number of inspections completed in that fiscal year.

Section 103: Penalties

This section would add prohibited acts for failing to report events or pay fees, reselling drugs labeled "not for resale," and falsifying prescriptions. A drug would be misbranded if the advertising or misbranding was false or misleading.

Section 104: Regulations

This section would require the Secretary to follow the formal rulemaking process when promulgating regulations to implement this title.

Section 105: Enhanced Communication

This section would require the Secretary to facilitate meaningful communication between the agency and the state boards of pharmacy about concerns raised or actions taken against compounding pharmacies.

Section 106: Severability

This section would amend section 503A of the FFDCA by removing the unconstitutional provisions which led to a circuit court split and contributed to FDA's inability to take decisive action against entities like New England Compounding Center (NECC). In doing so, traditional pharmacy compounding will continue to be regulated according to section 503A nationwide and remain exempt from certain provisions of the FFDCA relating to drug manufacturing.

Section 107: GAO Study

This section would request GAO submit a report on pharmacy compounding to Congress within three years of the date of enactment, including examining the volume of compounding that occurs, a review of state law and policies, an assessment of available tools for purchasers to know compliance status of compounders, and an evaluation of the communication between FDA and State Boards of Pharmacy.

TITLE II – DRUG SUPPLY CHAIN SECURITY

Section 201: Short Title: "The Drug Supply Chain Security Act"

Section 202: Pharmaceutical Distribution Supply Chain

Section 581: Definitions

This section adds a new section to the FFDCA. This section sets forth definitions for the Drug Supply Chain Security Act (Act).

Section 582: Requirements

This new section in the FFDCA sets forth product tracing requirements for "downstream" pharmaceutical supply chain members: drug manufacturers, repackagers, wholesale distributors, and dispensers. These entities will be required to pass certain information and representations about pharmaceutical transactions when there is a change of ownership. Entities in the supply chain may only accept product if this information is provided. These entities will also engage in verification and notification activities in circumstances pertaining to suspect and illegitimate product. Once product is serialized, manufacturers, repackagers, and wholesale distributors will respond to requests to verify product at the unit level in circumstances pertaining to suspect and illegitimate product and must also verify product at the unit level for saleable returns.

Entities across the supply chain also must promptly respond to requests for information from the Secretary, or another state or federal official, in the event of a recall or investigation of suspect or illegitimate product and to keep records of investigations of suspect and illegitimate product. However, rather than imposing one-size-fits-all requirements, requirements are tailored to the supply chain members to reflect the different and unique roles that each sector plays in the pharmaceutical distribution supply chain. Four years after the date of enactment of this Act, manufacturers will provide transaction information, transaction history, and transaction statements in an electronic format to their trading partners. To further strengthen pharmaceutical supply chain security, starting January 2015, the trading partners of drug manufacturers, repackagers, wholesale distributors, and dispensers must be properly registered or licensed.

The timeline for serializing product and accepting and transferring only serialized product is phased in: manufacturers are responsible for these requirements four years after the date of enactment of this Act; repackagers in five years; wholesale distributors and third-party logistics providers in six years; and dispensers in seven years. This section also sets forth how grandfathered product will be addressed, both with respect to serialization and tracing requirements.

Section 203: Enhanced Drug Distribution Security

Section 582: Requirements

This section further amends Section 582, as added by this Act, to require interoperable, electronic unit level product tracing ten years after the date of enactment of this Act. This section lays out an appropriate pathway to achieve unit-level traceability. The unit-level product tracing requirements are tied to guidance issued by the Secretary on unit level product tracing and standards for interoperable data exchange, which are informed by public meetings and pilot projects. Specific procedures for the issuance and revision of such guidance are set forth in this section.

The Secretary is required to contract with a private, independent consulting firm to conduct an assessment of the feasibility of unit level product tracing requirements on dispensers with 25 or fewer full-time employees. The Secretary, taking into consideration this assessment, shall provide for alternative methods of compliance, including establishing a process by which a dispenser may obtain a waiver from any of the requirements if the Secretary determines that such requirements would result in undue economic hardship. The Secretary is also required to establish one or more pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. The transaction history requirements sunset ten years after the date of enactment of the Act, when the interoperable, electronic unit level product tracing requirements begin.

Section 204: National Licensure Standards for Prescription Drug Wholesale Distributors

Section 503(e)/Section 583: Licensure Standards

This section amends Section 503(e) of the FFDCA to raise wholesale distributor licensure standards nationwide under current law by regulation. Starting January 2015, any person who owns or operates an establishment that engages in wholesale distribution shall report to the Secretary, on an annual basis, regarding each state by which the person is licensed and the name and address of each facility at which the person conducts business. The Secretary shall then establish a database that identifies each wholesale distributor by name, contact information, and the state where the wholesale distributor is licensed and make this database available on the Internet website of the Food and Drug Administration. If a state chooses not to license a wholesale distributor to the standards set forth in the newly added Section 583 of the FFDCA, the Secretary shall license qualified wholesale distributors in that state and collect reasonable fees to cover the costs of this licensing program. This section also makes clear that a third-party logistics provider is not required to obtain a license as a wholesale distributor. The amendments made in Section 4 go into effect January 2015.

Section 205: National Licensure Standards for Third-Party Logistics Providers; Uniform National Policy

Section 584: National Licensure Standards for Third-Party Logistics Providers

This section sets forth third-party logistics provider licensure standards in the FFDCA. Beginning one year after the date of enactment of the Act, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis, regarding the state by which the facility is licensed and the name and address of the facility. If a state chooses not to establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider and collect reasonable fees to cover the costs of administering a federal licensing program for entities in such states. The Secretary is required to issue regulations regarding the standards, including establishing a process by which a third-party accreditation program approved by the Secretary, shall upon request by a third-party logistics provider, issue a license to a third-party logistics provider that meets the requirements set forth in this Act. If the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements, the Secretary shall issue a license to a third-party logistics provider consistent with this section.

Section 585: Uniform National Policy

This section makes explicit that, beginning on the date of enactment of this Act, the product tracing requirements set forth in this Act preempt state product tracing requirements, including paper or electronic pedigree systems. This section also makes clear that, beginning on the date of enactment of this Act, no state may establish or continue any standards, requirements, or regulations with respect to

wholesale prescription drug distributor or third-party logistics provider licensure requirements inconsistent with, less stringent than, directly related to, or covered by the standards and requirements set forth in Sections 503(e) and 584. This section makes clear that pre-emption of product tracing shall not be construed to pre-empt state requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in this Act.

Section 206: Penalties

This section amends Section 301(t) of the FFDCA to add failure to comply with the requirements under Sections 582 and 584 as prohibited acts. It also amends Section 502 to make a product misbranded if it fails to bear a product identifier as required under Section 582.

Section 207: Conforming Amendment

This section makes a conforming amendment to Section 303(b)(1)(D) to update the cross cite in current law to wholesale distributor licensure requirements in Section 503(e).

Section 208: Savings Clause

This section makes clear that except as provided in the amendments made to wholesale distributor licensure requirements in Section 4(a) and the penalties in Section 6(a), nothing in this Act (including the amendments made by this Act) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act under any provision of such Act or the Public Health Service Act.