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Protecting Drug Supply Chain Security

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Millions of Americans take prescription drugs every day while assuming that those drugs are what they purport to be, that they have not been tampered with, and certainly that they are not counterfeit. The validity of those assumptions is increasingly tested and challenged, if not undermined, by a drug supply chain that circles the globe and by the involvement of multiple parties standing between the manufacturer and the consumer. The 2013 Drug Supply Chain Security Act (DSCSA) amends the Federal Food, Drug, and Cosmetic Act and clarifies the obligations of the parties in this chain.

Supply chain integrity necessarily implies an ability to identify, track, and trace drugs. The current regulatory capacity to do this at scale, given the volume of products, is limited. The DSCSA outlines steps for building an electronic, interoperable system to increase this capacity over the next decade. In the meantime, however, and in pursuit of less heroic objectives, the Food and Drug Administration (FDA) published a **draft guidance document** on June 10, 2014 to implement the provisions of the DSCSA. The provisions require manufacturers, repackagers, wholesale distributors, or dispensers (all "trading partners" in DSCSA parlance) to identify "suspect" drug products and to notify FDA and their "trading partners" of these findings. Suspect drug products, as defined by the DSCSA, are those products "for which there is reason to believe" the product:

- "is potentially counterfeit, diverted, or stolen;"
- "is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;"
- "is potentially the subject of a fraudulent transaction;" or
- the catchall, "appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans."

The draft guidance document provides, for example, a non-exhaustive list of illustrative scenarios that could significantly increase the likelihood of a suspect product entering the supply chain. Examples include purchasing a product from a new source, purchasing a product on the Internet from an unknown source, and purchasing a product from a source with a prior negative history of engaging in transactions with suspect products. Similarly, the guidance identifies red flags to help spot suspicious products as soon as possible, such as a product name that differs from the FDA-approved drug name and the use of foreign language labels with little or no English.

The relevance of this guidance document is at least twofold. First, there is a shared interest on the part of all responsible prescription drug trading partners in the end product – which the consumer receives and consumes – being safe, pure, and authentic. Though some of the guidance may seem obvious, it is helpful in meeting those goals because it is based on FDA's experience and is relevant to concerns raised by global supply chains. Second, no later than January 1, 2015, trading partners must have systems in place to determine if a product is a suspect product and, if so, to quarantine the product and conduct an investigation to determine if the product is illegitimate. The guidance speaks directly to this second point, and it informs industry what FDA expects the elements of these systems to be.

The draft guidance is open for public comment for 60 days starting June 10, 2014. All prescription drug trading partners should give the document a close reading and consider submitting comments, paying particular attention to the section on procedures FDA intends to require regarding industry's obligations to notify and communicate with FDA about suspect products. FDA makes explicit its view that although guidance documents are generally advisory and non-binding, the section of this guidance (once issued final) with respect to how trading partners terminate notifications of illegitimate products will be binding.