



SECURING AMERICA'S PHARMACEUTICAL SUPPLY CHAIN

It's time for a national track-and-trace system

The political response to the tragic heparin situation has now begun in earnest. While pointing our finger at China seems easy, it is highly misleading to link contamination of an ingredient to the equally pressing concerns of stopping counterfeit finished goods from infiltrating the legitimate pharmacy supply chain. America's approach to tracking finished drugs in the pharmaceutical supply chain needs a radical overhaul.

Thankfully, counterfeit drugs are still extremely rare in the United States. Legislators should recognize that the heparin situation does not represent the most common way in which a counterfeit drug could enter your neighborhood pharmacy. Instead, it's much more common for a counterfeit drug to slip into the system when someone buys from an unreliable secondary source or intentionally counterfeits or compromises an authentic medicine. This process has been the entry point for almost every case investigated by the FDA in which a counterfeit or adulterated drug ended up in your local pharmacy. We cannot be complacent.

Manufacturers, wholesalers, and pharmacies have already closed many gaps by voluntarily adopting new sourcing and data-sharing practices. Yet sophisticated criminals, drug traffickers, or terrorists continually attempt to compromise our drug supply chain. One recent study suggests that \$10 billion in diverted or counterfeit prescription drugs were purchased by pharmacies that bypass legitimate channels.

A national system for tracking and tracing pharmaceuticals would close these remaining gaps by requiring greater documentation across the supply chain for all purchases, significantly reducing the chance for fake drugs to sneak in. This system would also create a chain of custody history using unique serial numbers on a drug package. This technology is available today and would allow both consumers and regulators to validate that a pharmacy follows safe business practices. It would even be possible for a consumer to check up on their local pharmacy by entering the serial number on a web site.

This vision can not become a reality as long as individual state pharmacy boards retain the authority to establish unique documentation requirements for manufacturers, wholesalers and pharmacies operating within each state. This approach has created a disparate patchwork of inconsistent regulations for tracking pharmaceuticals in the U.S. supply chain. In the absence of federal standards, ambitious local politicians around the country are establishing their own incompatible systems, raising costs, reducing product availability, and lowering safety.

Florida led the charge with a 2006 law requiring wholesalers to provide a paper document showing the purchasing history for each drug. Florida's tougher rules were prompted in part by a 2003 grand jury report that documented the introduction of counterfeit drugs due to drug trading by criminals acting as lightly-regulated, licensed wholesalers.

Not to be outdone, California will require an electronic system by 2011 in which individual packages

will be tracked based on a unique identification number placed on the package by the drug's manufacturer. This number will be passed down the supply chain to wholesalers and then to your local pharmacy, allowing true visibility. However, the California Board of Pharmacy will be hard-pressed to enforce this ambitious new law with a \$10 million budget and fewer than 20 already overworked inspectors.

Alas, these two state systems neither correspond to each other nor to the myriad proposals and regulations from more than 30 other states. Amazingly, 15 states have not even proposed legislation or regulations for tracking drugs, leaving them subject to a Federal law that was passed in 1987 yet has still not been fully implemented.

We urgently need to replace these well-intentioned but disorganized, uncoordinated, and underfunded state-level mandates. These inconsistent state laws ignore the fact that today's pharmaceutical supply chain is a national business. Drugmakers sell more than 95% of their products through three large wholesalers shipping across state lines, while six out of ten prescriptions are filled by only 10 national chain and mail order pharmacies. The costs of distributing and dispensing drugs makes up almost one-quarter of U.S. retail drug spending. Complying with a grab bag of state laws does little more than add unnecessary costs without an equivalent increase in safety.

It's inaccurate to claim that the industry is moving too slowly because tracking drugs through the supply chain is much more complex than some obvious analogies might suggest. For instance, FedEx' renowned package tracking ability handles 7.5 million shipments daily within a single company, so there is no need for any industry-wide standard setting. By comparison, consumers receive 11 million prescriptions per day from more than 150,000 locations throughout the U.S. Our drug distribution network involves tens of thousands of independent companies so that uniform standards are essential if we are to avoid chaos.

A track-and-trace infrastructure will also allow much more rapid response in the event of a product safety issue. Instant national visibility will save lives by going faster than the traditional manual recall process. Individual packages could be located within minutes, permitting precise and targeted recalls from specific pharmacies that purchased the product.

America needs to stop blaming foreign suppliers for homegrown problems and get serious about stopping counterfeit drugs. A national track-and-trace system based on uniform standards will make us all safer.



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