

PHARMACEUTICAL COMMERCE

Business Strategies for
Pharma/Bio Success



CONFRONTING COUNTERFEIT DEMAND

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It's time for manufacturers to shoulder the burden of supply chain security by confronting the pharmacies and dispensers that buy counterfeits.

State and national governments had a mixed year in protecting the public from

counterfeit drugs. Florida overcompensated for years of lax enforcement by finally implementing pedigree laws. The FDA was prevented from implementing the Prescription Drug Marketing Act despite a crazy national patchwork of regulation and inconsistent state-level enforcement.

The international situation is even worse due to rampant parallel trade. Yet Senators Dorgan (D-ND) and Vitter (R-LA), among others in Congress, want to open up new gateways for counterfeits with the magic bullet of reimportation despite Canada's understandable reluctance to be our drugstore.

We've made some progress. Inventory-management agreements (IMAs) and fee-for-service agreements limit product leakage into the wholesale gray market, closing a significant entry point for counterfeiters. Drug makers must now literally pay for greater product security by purchasing data from wholesalers to monitor orders, invento-

ries, and product movement in real-time. Overseas, Pfizer, GlaxoSmithKline, and AstraZeneca have all announced plans to overhaul drug distribution in the UK, Europe's top destination for parallel imports.

Commercial-operations and trade-relations executives now need to look beyond their immediate trading partners to confront the unpleasant truth. Counterfeit sellers require counterfeit buyers. How do we stop pharmacy buyers and consumers from purchasing outside of a theoretically secure supply chain?

Unfortunately, we are many years away from a practical technology to monitor all 160,000 points of U.S. drug dispensing and make sure dispensers abide by "safe sourcing" rules. Pedigree rules only work if buyers refuse to buy outside legitimate channels.

Cardinal Health's recent settlement with the New York Attorney General [*see p. 9-ed.*]

provides a roadmap for supply chain security. The wholesaler must now gather, monitor, and analyze customer sales data to detect instances of possible diversion of prescription pharmaceuticals. This "know your customer" business reform is a tacit acknowledgment that most state pharmacy boards are not doing their job.

Unless we start getting real about this problem, then we won't really be meeting the FDA's requirements or bringing genuine security to the supply chain.

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