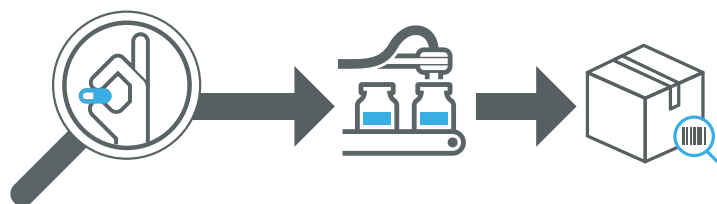
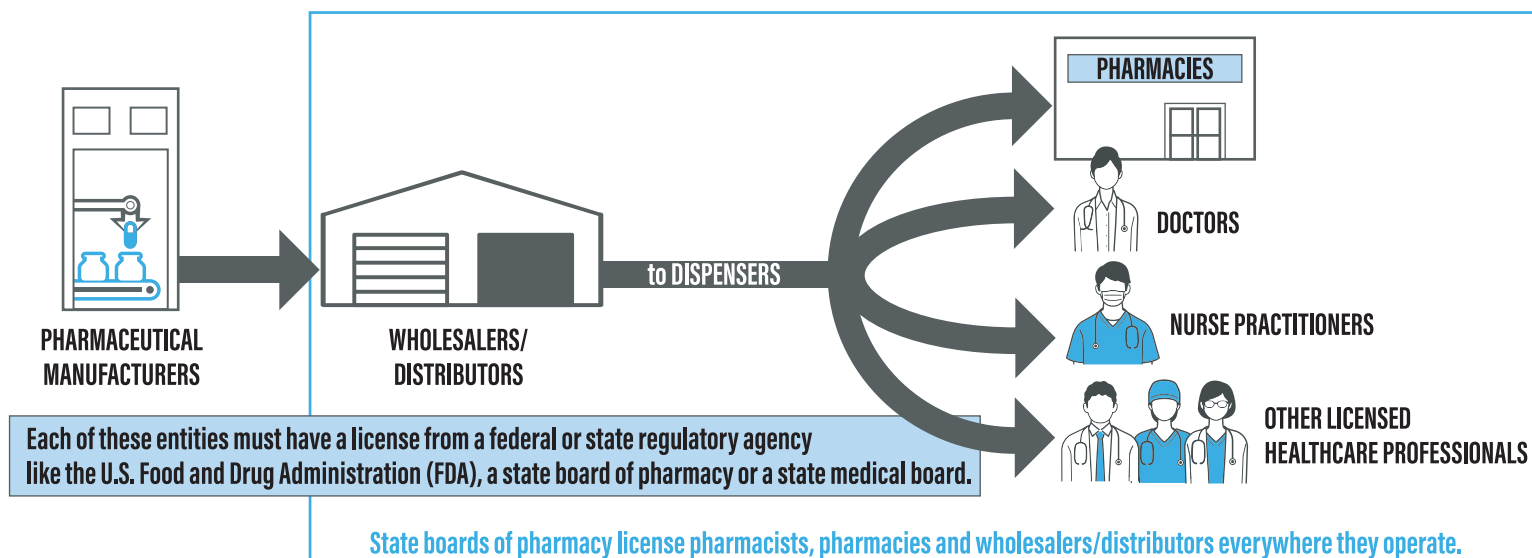


Protect Your Patients and Your Practice

Reports suggest that counterfeit medicine trafficking is one of the world's fastest-growing criminal enterprises. This is not only a problem in under-resourced countries: it is also a problem in industrialized countries like the U.S.

To appropriately address this problem, we need to understand how America's secure drug supply chain works:



Every entity in this supply chain is licensed by a U.S. entity, either state or federal, to ensure that they are compliant with all patient safety requirements.

In addition, the Drug Supply Chain Security Act requires a serial number to be placed on every package when it's manufactured, so that it can be traced all the way to the pharmacy shelf.



Pharmacies and wholesalers must be located within the U.S., where state regulators license and inspect them. The FDA licenses manufacturers, sending staff to inspect them whether they are inside or outside the U.S.

This is critical because the world has many manufacturing facilities outside of the United States which don't meet FDA standards, and few other countries are as well-resourced as the U.S.



Patients: Beware Of The Black Market

Criminals target consumers through fake online pharmacies, using marketing messages that suggest they are selling FDA-approved medicine from “safe” countries like Canada. Instead, they routinely ship substandard medicine manufactured in foreign facilities that aren’t FDA-inspected. The medicines and their packaging can look nearly identical to the real medicines, making them hard to detect. And it’s almost impossible to prosecute foreign nationals for this crime, so the problem continues to grow.

Physicians: Beware Of The Black Market

Criminals also target physicians by claiming their products are the same as U.S. medicines, just made for another country. Even if it’s the same medicine (*and often it’s just a credible counterfeit*), section 331 of the Food, Drugs and Cosmetic Act (FDCA) prohibits the receipt of prescription medicine from outside America’s drug supply chain, whether the supplier is a foreign company or a domestic one that is not licensed in the state where the sale is made. In the past 20 years, **clever scams have duped physicians and hurt American patients in almost all therapeutic areas.** Hundreds of physicians have found themselves in legal and financial trouble for purchasing medicine that isn’t FDA-approved or came from a wholesaler without the correct license.

The same provision means:

- **physicians may only purchase medicine for patients from wholesalers licensed in the state in which they practice**
- **section 353 of the FDCA requires a wholesaler to have a board of pharmacy license for every state where they sell medicine.**

Education of physicians and their office staff is important in addressing this growing issue.

Every state maintains a site to verify that a wholesaler or a pharmacy is appropriately licensed, so you can check for yourself. Find the link to your state’s site here:

 <https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses>

? What happens when a physician purchases and dispenses medicine bought from unlicensed wholesalers?

A dermatologist bought over \$1 million in black market Botox from a series of online pharmacies that were not licensed by the California Board of Pharmacy. *She was prosecuted and pleaded guilty to a misdemeanor personally and a felony for her practice.*

A Tennessee physician pleaded guilty to buying and dispensing \$2 million in non-FDA-approved oncology drugs to his patients. He and his partners paid \$4.25 million fines. *He was sentenced to two years in jail and the state medical board revoked his license.*