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:

Pharmaceutical manufacturers
-> Wholesalers/Distributors
->Dispensers

Each of these entities must have a license from a federal or state regulatory agency like the U.S. Food and Drug Administration (FDA), a state board of pharmacy or a state medical board.

State boards of pharmacy license pharmacists, pharmacies and wholesalers/distributors everywhere they operate.

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.

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