



Protecting Consumers from Unsafe & Fraudulent Products *Implementing Better Alternatives to IP Enforcement Measures*

Overview

- Public safety should be protected through public safety frameworks, not through regimes designed primarily to protect exclusive commercial rights.
- Interagency and international efforts best protect public health by focusing squarely and specifically on fraudulently mislabeled, adulterated and unlicensed medicines, as well as substandards and other quality failures, rather than intellectual property.

Suggested Policies

Increase Quality Regulation

- Strengthen drug regulatory authorities like the FDA in the U.S. and abroad.
- Strengthen consumer protection agencies in the U.S. and abroad.
- Increase post-marketing pharmacovigilance & testing, including support for training and equipment.

International Law Enforcement Cooperation

- Continue support of targeted international law enforcement cooperation efforts that identify criminal operations producing fake medicines.

Determine Prevalence of Drug Quality Problems

- Create reliable empirical data on the prevalence of a variety of quality problems in the market.
- Use data to determine an efficient allocation of resources.
- Institute statutory disclosure requirements for private companies to disclose any information they have about potentially dangerous, mislabeled medicines on the market.

Promote robust, price-lowering competition

- Lower prices will decrease demand for infringing goods since high prices drive counterfeit markets.

De-link R&D Costs from Manufacturing Costs

- Possible funding of R&D through prize funds.