

Fake Drug: Causes and Consequences

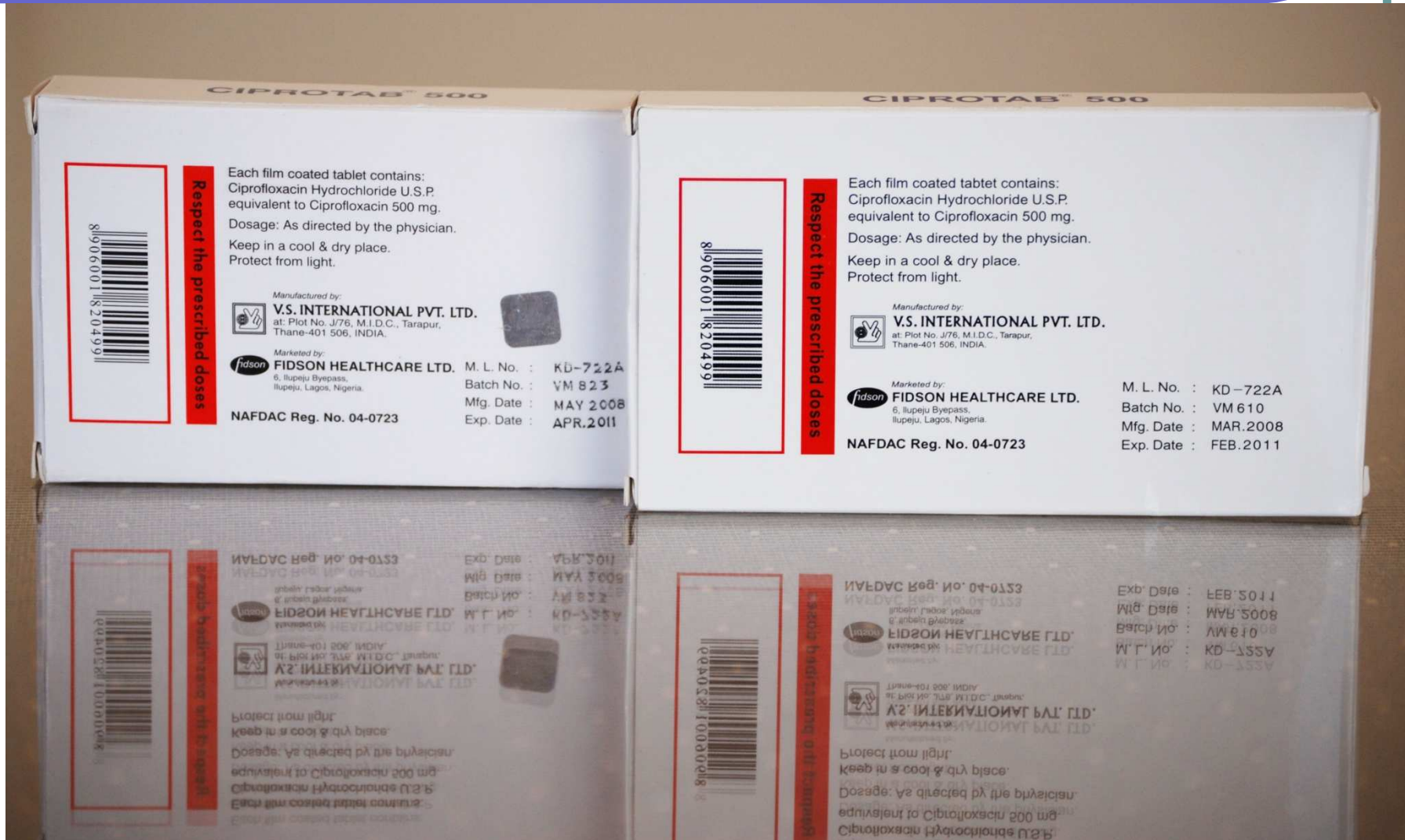
Harvard Medical School, 3rd March 2010

Roger Bate (rbate@aei.org)

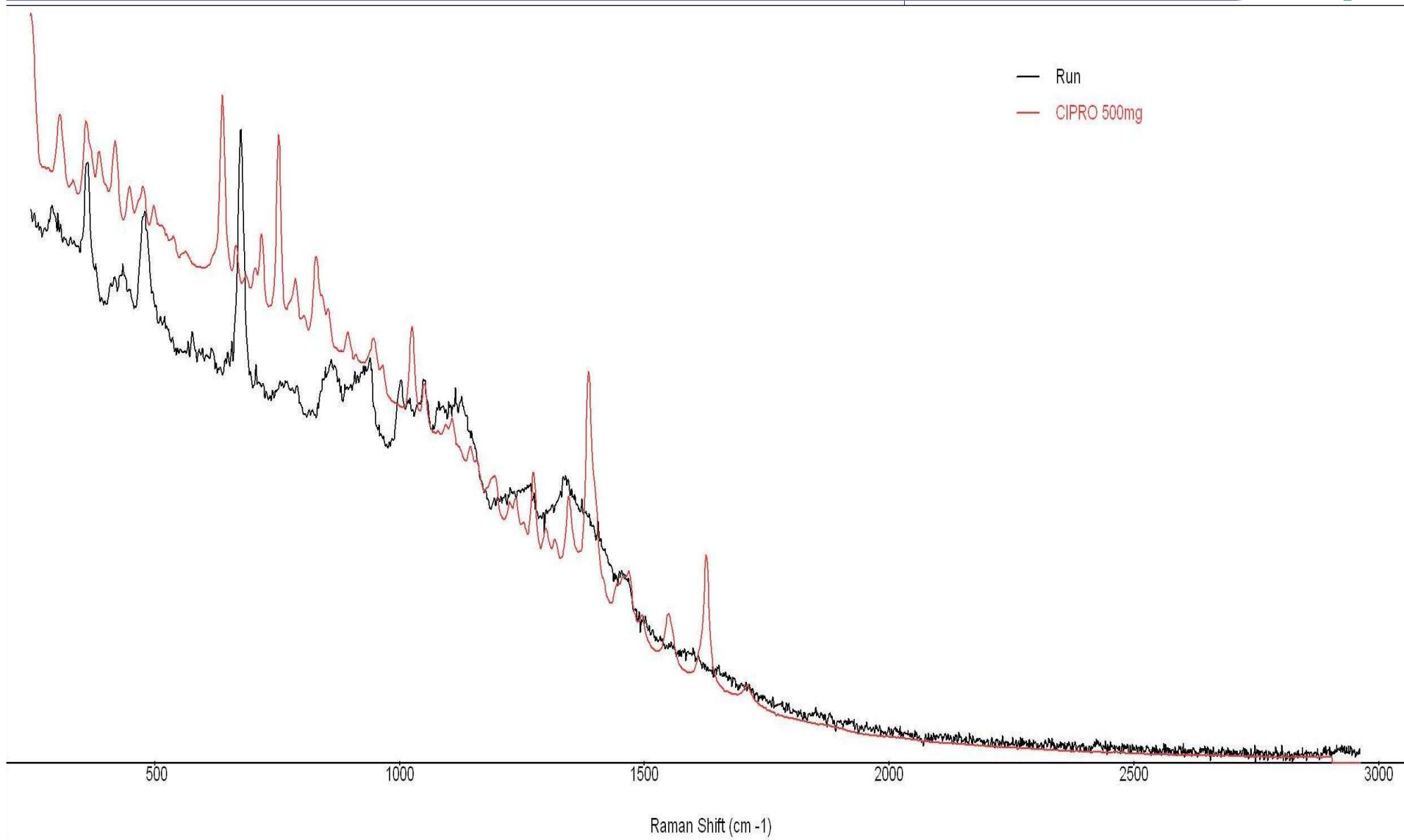
Faking an Indian Brand



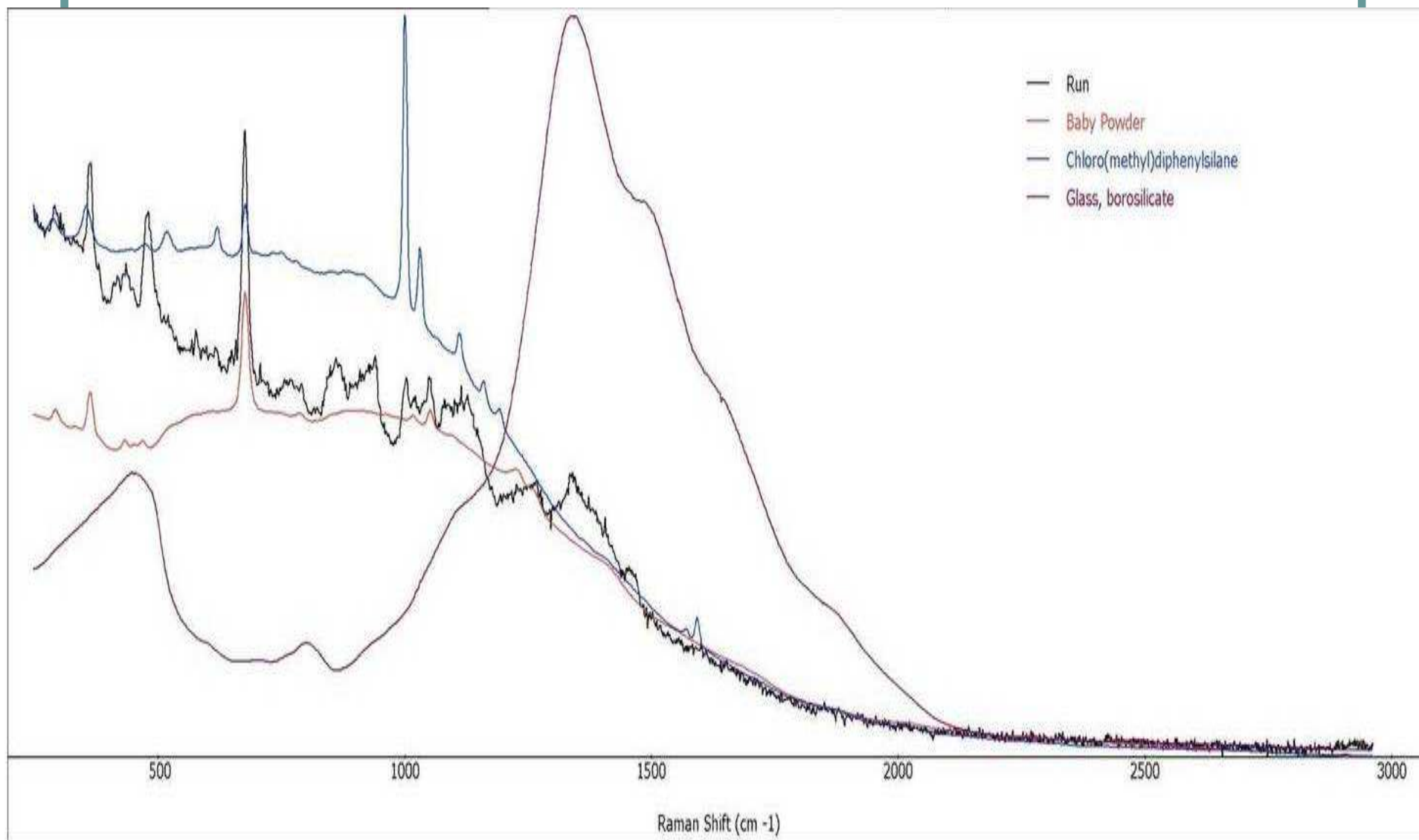
Fake Cipro on Right



Real v Fake Raman Spectra



Fake Cipro components



Counterfeit Operations



Counterfeit Operations



Counterfeit Operations



Counterfeit Operations



Why is counterfeiting a problem?

- **Public health threat:**
 - Direct: Fake drugs containing harmful ingredients (e.g. heavy metals, bacteria, fungi, OSCS/Heparin)
 - Indirect: Drugs with inadequate or wrong active ingredients have no curative power (e.g. thousands of malaria deaths)
 - Long run: Drugs with only *some* of the correct ingredients can cause a patient to develop resistance to that particular drug, making it harder for the patient (and potentially the population as a whole) to be treated with effective medicines later on (drugs for TB, HIV, malaria badly affected).
- **Intellectual property/brand integrity threat**
 - Threatens long-term innovation and development

Why do counterfeiters flourish?

- Low marginal cost, high demand and high marginal returns
 - Historically weak rules against fakes
 - Low penalties for producers, traffickers and packagers
 - Poor enforcement of rules
 - Corruption lowers capture rates in many places
- Enabled by:
 - Complex and opaque supply chains, with many parties ignorant of good practice
 - Confusion over what products are counterfeit

What exactly is a counterfeit drug?

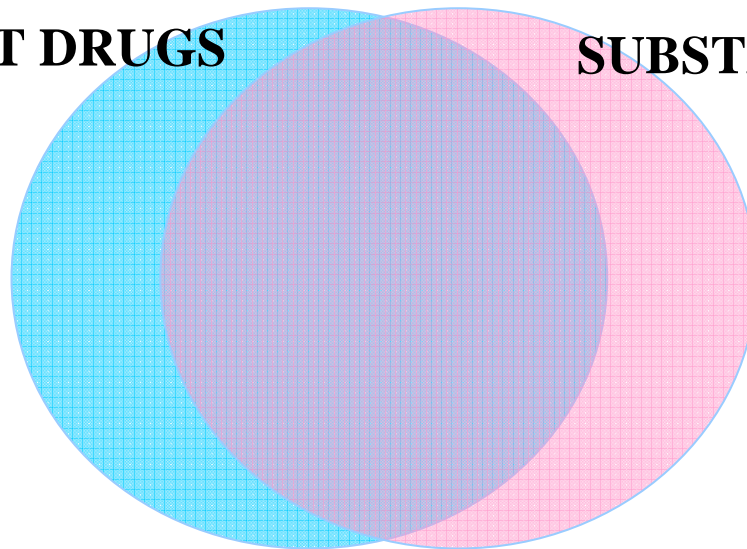
- WHO's definition:

“A counterfeit drug is a drug that has been **deliberately and fraudulently mislabeled** with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and...may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

Counterfeit and Substandard drugs

COUNTERFEIT DRUGS

Willfully mislabeled as to identity or source, but not always a trademark violation



SUBSTANDARD DRUGS

Well-made drugs that are old or poorly stored, badly-made drugs

Non-counterfeit substandard drugs – some developing country estimates

COUNTERFEIT DRUGS

Willfully mislabeled as to identity or source, often, but not always, a trademark violation

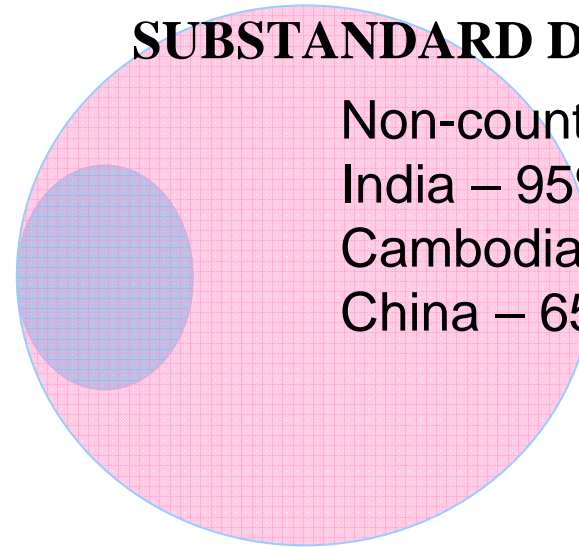
SUBSTANDARD DRUGS

Non-counterfeit

India – 95%

Cambodia - 25%

China – 65%



New Definitions

- **Authorized/Registered Products**

Good standard

Substandard

- **Not authorized/non-registered products**

Good standard

Good standard and labeling/trademark violation

Substandard

Efforts to improve drug quality

- USP –DQI/PQM
- MeTA/World Bank
- WHO/IMPACT
- US Commerce Department/FDA/APEC
- Federal Governments in Beijing/Delhi
- NAFDAC
- Western Pharma Companies

Problems limiting success

- EU Drug Seizures
- Stalling at WHA
- Kenyan anti-counterfeit law
- Corporate/brand secrecy and safety issues
- State opposition to federal efforts in India and China (PLA?)
- Poverty/illiteracy/corruption (MRAs?)

What more can be done to combat counterfeiting?

- Budgets to enforce legislation banning counterfeit products (assist customs and MRAs)
- Increase enforcement efforts (including technical monitoring at ports and within country...more important than increasing penalties)
- Improve education of intermediaries/pharmacists in how to spot counterfeit products
- Reward whistleblowers
- Product tracking (simplify supply chains?), assess API more rigorously

Fake Viagra Spectrum

