

Making a Killing

The Deadly Implications of Counterfeit
Drug Trafficking

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The harm of bad drugs

- An estimated 200,000 people die every year from malaria because of poorly produced and delivered drugs (WHO).
- 50,000 people were inoculated with fake vaccines during a meningitis epidemic in Niger in 1995. Over 2,500 died (WHO).
- At least Brazilian 10 women were left pregnant after taking faulty contraceptive pills.
- Marcia Bergeron, first North American killed by fakes. 81 deaths attributed to contaminated/counterfeit heparin

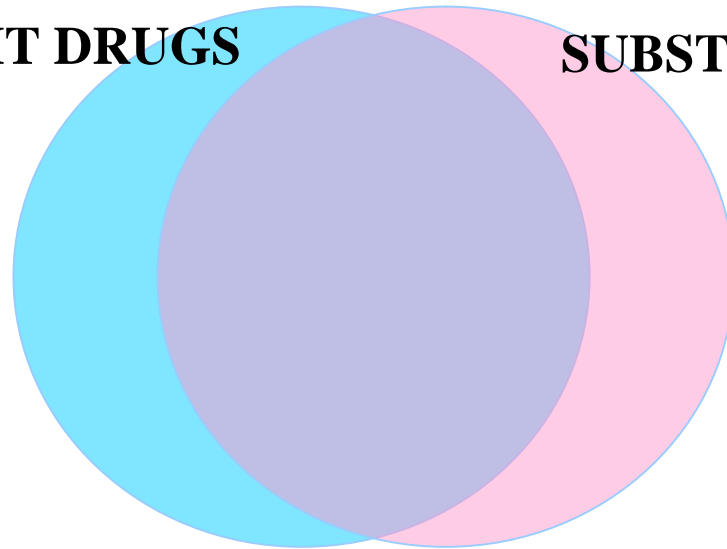
What is a counterfeit drug?

- No consistent, universally agreed-upon definition exists, making regulation and enforcement difficult.
- 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 vs. Substandard drugs

COUNTERFEIT DRUGS

*Willfully
mislabeled
as to
identity or
source*



SUBSTANDARD DRUGS

*Low quality (old,
insufficient
ingredients,
incorrect ratio of
ingredients, wrong
ingredients)*

Why is counterfeiting a problem?

- Public health threat:
 - Direct: Fake drugs containing harmful ingredients (e.g. heavy metals)
 - Indirect: Drugs with inadequate or wrong active ingredients have no curative power
 - Wider Impacts: 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.
- Intellectual property/brand integrity threat
 - Threatens long-term innovation and development

The Global Face of Counterfeiting

COUNTRY/ REGION	WHO/IMPAC T ESTIMATE
United States	<1%
Europe	<1%
United Kingdom	<1%

COUNTRY/ REGION	WHO/IMPACT ESTIMATE
Russia	10%
CIS	20%
China	8%
Indonesia	25%
India	20%
Nigeria	16%
Kenya	30%
Lebanon	35%
Cambodia	13%

The Global Face of Counterfeiting I

Developed countries

- Perhaps 1% of drug products are counterfeit; most of these tend to enter the system through the internet.
- Counterfeiters target “lifestyle drugs” such as Viagra and Cialis, expensive products with high returns that can be easily marketed over the internet.
- Despite a few widely-publicized cases (Lipitor and faulty diabetes strips) enforced regulation and educated wholesalers and retailers have kept most counterfeits from infiltrating the system.
- Smugglers and counterfeiters, wildlife products, arms, narcotics and now life-saving therapeutic drugs.

The Global Face of Counterfeiting II

Developing countries

- In the worst affected countries in Africa, Latin America, and Asia more than 30 percent of medicines sold are counterfeit.
- As well as lifestyle drugs, counterfeiters target life-saving medicines like antiretrovirals for HIV/AIDS, treatments for tuberculosis and malaria, and antibiotics. For patients with malaria and many bacterial infections, consuming fake drugs can lead to death in a matter of days.

Why is there an increase in poor quality drugs?

- Low marginal cost, high marginal returns
 - Weak rules preventing fakes; poor enforcement of extant rules on good quality production.
 - low penalties for producers and traffickers
 - Product high demand means high prices
- Enabled by:
 - Complex supply chains in West and opaque ones in poorer nations
 - Corruption, low risk of capture and limited punishment
 - Ignorance of many in supply chain

To India: Aligarh Market



Delhi Palace Market Kiosk



Counterfeit Operations



Counterfeit Operations



Enforcement



Table 1: Testing results by formulation* and country purchased for TLC and dissolution
(total failed either dissolution or TLC/total treatments tested)

	Ghana	Kenya	Nigeria	Rwanda	Tanzania	Uganda	Total
SP	50% (3/6)	38% (6/16)	50% (1/2)	50% (3/6)	27% (3/11)	33% (3/9)	38% (19/50)
AQ	33% (2/6)	50% (4/8)	25% (1/4)	-	100% (2/2)	56% (5/9)	48% (14/29)
Mefloquine	0% (0/1)	-	50% (1/2)	-	0% (0/3)	27% (3/11)	24% (4/17)
Artesunate	38% (3/8)	0% (0/4)	33% (2/6)	-	31 (4/13)	33% (6/18)	31% (15/49)
Artemether	0% (0/3)	100% (1/1)	-	-	-	29% (2/7)	27% (3/11)
DHA	40% (2/5)	56% (5/9)	100% (1/1)	-	50% (2/4)	67% (2/3)	55% (12/22)
Artemether-lumefantrine fixed-dose combination	38% (3/8)	0% (0/4)	14% (1/7)	0% (0/3)	0% (0/1)	22% (2/9)	19% (6/32)
Total	35% (13/37)	38% (16/42)	32% (7/22)	33% (3/9)	32% (11/34)	35% (23/66)	35% (73/210)

*Co-packaged ACTs are listed as individual monotherapies

SOURCE: Roger Bate, Philip Coticelli, Richard Tren, Amir Attaran, "Antimalarial drug quality in the most severely malarious parts of Africa – a six country study," unpublished study.

Artesunate monotherapies



Table 2: Testing results by region of manufacture
(*manufacturer information not available for 3 tested samples)

Region of manufacture	Total Samples Failing TLC or Dissolution	Total Samples Tested	Percent Failed
Africa	30	63	48%
Asia	29	90	32%
Europe	12	50	24%
U.S.	0	4	0%

- Collectively, Africa and Asia are responsible for 83% (59/71) of the failed drugs observed in the study.

SOURCE: Roger Bate, Philip Coticelli, Richard Tren, Amir Attaran, "Antimalarial drug quality in the most severely malarious parts of Africa – a six country study," unpublished study.

What can be done? INTERNATIONAL

- **International:**

- IMPACT can increase awareness of the dangers of counterfeit medical products and serve as a forum for anti-counterfeiting initiatives. Along with Interpol, it can provide technical advice to nation-states.
- Donor agencies must ensure that they are not purchasing or distributing substandard medicines. They should also pair drug distribution with educational initiatives on the proper use, storage, and prescription of drugs, such as antimalarials.
- Policymakers should encourage appropriate technology to create a transparent and verifiable chain of custody from the point of production to the point of sale as well as encouraging self-regulation within the supply chain by endorsing reputable, independent regulatory organizations.

What can be done? NATIONAL

- National:
 - Developing countries should lower tariffs on imports, open up trade and protect patents. It will encourage companies determined to protect their brands to work within poorer nations (e.g. Novartis, Pfizer in India).
 - European countries should reevaluate European Union parallel trade.
 - FDA, USP or other third party private entity should investigate internet pharmacies and provide stamp of approval to good entities.
 - Stricter regulation on drug wholesalers
 - Drug companies must alert both the public and law enforcement officials of counterfeit versions of their own drugs when they discover them. By fostering an environment of openness, pharmaceutical companies will help ensure a safe drug supply and keep the trust of their customers

What can be done? INDIVIDUAL

- **Individual:**

- Consumers should educate themselves about the consequences—for their own health, for the health of the community, and for the likelihood of future innovative drugs—of purchasing drugs outside of the standard supply chain.
- Consumers must demand that drug companies and public agencies educate the public, buttressing the last-resort defense against the spread of fakes and making it possible for individuals to take charge of this aspect of their health care.

A Silver Lining

