

COUNTERFEITING DRUGS IS MURDER

- CURRENT NATIONAL LEGISLATIVE RESPONSES

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Background

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Drug counterfeiting is big business:

- 8-15% of global pharmaceutical sales is counterfeit
- no continent is immune
(except, perhaps, Antarctica)

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Pharmaceuticals World Market



US\$ 620 Billion

IMSHealth, April 2007

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Counterfeit Drugs

COUNTERFEIT DRUGS IS HUGE BUSINESS

If Global Pharma Market is
US\$ 620 billion, then:

- 8% of the market
- US\$ 50 billion
- 15% of the market
- US\$ 93 billion

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Counterfeit Drugs


Partnership for Safe Medicines:

US\$ 75 billion
by 2010



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Counterfeit Drugs



Under-Developed World
Drugs of Need

- Anti-malarials
- Anti-biotics
- Anti-HIV/AIDS

Developed World
Lifestyle Drugs + Costly Drugs

- Erectile Dysfunction
- Anabolic Steroids
- Highly Expensive therapies

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Internet Sales

Legit Online Mail Order Steroid Suppliers

Medications and Steroids for sale - Never get seized again!



This website is NOT monitored or assessed by any government organization.

NO PRESCRIPTION NEEDED!

Order prescription medicine at a fraction of the cost!

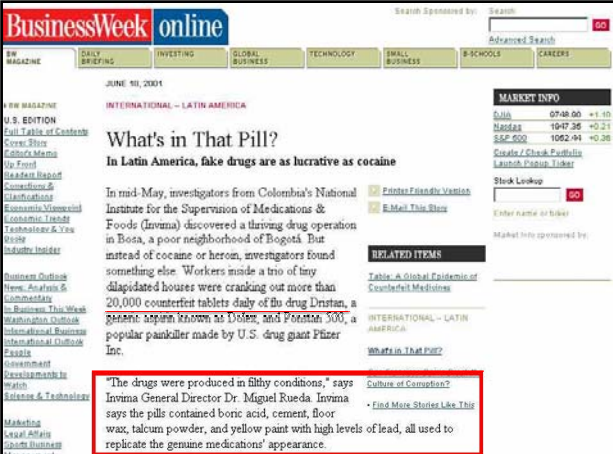
WEIGHT LOSS

Winstrol
Xenical
Clenbuterol
Cytomel
Phentermine

OTHER MEDICATIONS

The suppliers have PROVEN themselves over and over again!

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What's in That Pill?

In Latin America, fake drugs are as lucrative as cocaine

In mid-May, investigators from Colombia's National Institute for the Supervision of Medications & Foods (Invima) discovered a thriving drug operation in Bosa, a poor neighborhood of Bogotá. But instead of cocaine or heroin, investigators found something else. Workers made a trio of lumpy dilapidated houses were cranking out more than 20,000 counterfeit tablets daily of the drug Dristan, a generic version known as Dister, and Foramin 500, a popular painkiller made by U.S. drug giant Pfizer Inc.

"The drugs were produced in filthy conditions," says Invima General Director Dr. Miguel Rueda. Invima says the pills contained boric acid, cement, floor wax, talcum powder, and yellow paint with high levels of lead, all used to replicate the genuine medications' appearance.

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Drug Counterfeiting is Murder

Mass Murder
- API Sales

Panama 2006

- Diethylene Glycol (ex-China) substituted for Glycerin
- Over 300 people dead
- Over 5,000 injured



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Counterfeit Trail



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A Poison's Path

How a toxic industrial solvent from China made its way into medication in Panama, killing at least 100 people.

1 2 3 4 5 6 NEXT >



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The Papertrail
The certificates falsely stated that the toxic supply was 99.5 percent pure glycerin. Each new broker put its own name on the certificate, obscuring the provenance of the syrup.

Original certificate of analysis

品名	规格	数量	单位
1. 丙酮	工业级	2.5	吨
2. 丙酮 (99.5%)	工业级	2.5	吨
3. 丙酮 (99.5%)	工业级	2.5	吨
4. 丙酮 (99.5%)	工业级	2.5	吨
5. 丙酮 (99.5%)	工业级	2.5	吨
6. 丙酮	工业级	2.5	吨



Who Is the Murderer?

- Chinese TD-Glycerin Manufacturer
- Wholesalers / Brokers
- Panamanian Pharmaceutical Company

NOBODY NEED HAVE DIED!

- If Panamanian company had followed GMPs:
 - ◆ audited source supplier
 - ◆ sampled/identity tested incoming chemicals

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Drug Counterfeiting is Murder

Mass Murder
- API Sales

Panama 2006+2007

- Diethylene Glycol (ex-China) substituted for Glycerin
- Over 300 people dead
- Over 5,000 injured

Individual Murder
- Internet Sales of Dosage Form

Vancouver 2006

- Marcia Bergeron
- Took Zolpidem tablets (Ambien® - sleep aid)
- Died of overdose of **aluminium**, found as contaminant of remaining tablets
- Ambien not registered for legal sale in Canada

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Center for Combating Counterfeit Drug

Current situation of Counterfeit Drug Problem in Thailand

Counterfeit Drug found in Thailand

Diane
Esperson
Garamycin
Locasalen
Postnor
Primolut N
Viagra

Counterfeit/ Unregistered veterinary Drug

Amoxi-coli
Cefotax (Cephalosporin)
Cortexona retard
Enrofloxacin-50
Ivermec (Ivermectin)
Kanamycin-250 label
Norfloxin-150 (Norfloxacin)
Tiamulin-100
Tylosulfat

Counterfeit/ Unregistered Psycholeptic Products

Halcion 0.5 mg
Ionamin 30
Obedrex
Rohypnol 2 mg
Ultralev 0.25 mg

This FDA Website
<http://www.fda.moph.go.th>

Counterfeit Drugs smuggled between Cambodia- Thailand: 2007

http://www.app1.fda.moph.go.th/drug/eng/zone_counterfeit/cd_borderline/page_01.asp

Pictures of counterfeit drug collected around the border line between Thailand and Cambodia.
(Click to enlarge)

Chloramphenicol Capsules_(BRAINNY).jpg

Chloramphenicol Capsules_(MATER).jpg

PARAC.jpg

PENICILLIN V POTASSIUM.jpg

PENICILLIN V, CAPSULES.jpg

Puridoxine Hydrochloride.jpg

TETRACYCLINE HYDROCHLORIDE.jpg

Thiamine HCL.jpg

Vitamin-C.jpg

Unregistered/ Smuggling Sildenafil citrate founded in Thailand

Arause

Edgria 100 mg

Dana 1 ea Viagra

350 mg

BAOJINIA

Caplet 150 mg

CP viagra 250 mg

HAI NAN JIU JIU YAO YE YOU XIAN GONG SI

HUGE YIBAI

JINGZHUANWEIYI WANG

JU WU BA 400 mg

LANG YI HAO 145 mg

LONGBAO

MIAOGE 200 mg

MIAOGE 500 mg

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Counterfeit Companies

Trade name : Chloramphenicol
I.N.N : Chloramphenicol
Packaging : 100 tab/bottle
Batch N° : Unknown
Reg N° : Unknown
Mfg date : 9-1-02
Exp date : 9-1-07
Claimed Source : Brainy Pharmaceutical
Real Source : Unknown

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Counterfeit Packaging



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Counterfeit Holograms



Can Counterfeit RFID tags be far behind?

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Counterfeit Documentation



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Street Market - West Africa



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Anti-Counterfeit Measures ???



What value technology:
color shifting inks, holograms, RFID tags, etc?

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Sources of Counterfeit Drugs



Prime Sources of Counterfeits

China - APIs
India - Finished Dosages
Russia - Finished Dosages

Who Are The Major Counterfeiters

Multi-National Criminal Gangs
International Terrorist Groups

Vanuatu - Finished Dosages

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Legislation

FIP Anti-Counterfeit Task Force

Questions:

- What is current world-wide legislation?
- Can we foster a world-wide adaptable "model legislation"

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Legislative Survey

- 216 Countries
- 6,200,000,000 people (6.2 billion)
- Pareto Analysis (80-20 rule):
 - ◆ 43 countries account for
 - ◆ 5/6 of world population
- Survey performed on 50 most populous nations world-wide

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Study of Global National Counterfeit Drug Legislation

Study Methodology

- **University of Illinois at Chicago, College of Pharmacy**
 - ◆ P2 Year, Class of 2008
 - ◆ 198 Students, from 39 countries, fluent in over 40 languages
 - ◆ Professor Ron Koch
- **DePaul University, Chicago, College of Law**
 - ◆ School of Health Law
 - ◆ Camille Gourdet, JD, under direction of
 - ◆ Dr. Michele Goodwin, JD
- **Sponsors: BMS, Eli Lilly, Pfizer, WHO**
 - ◆ Dr. Jane Nicholson, FIP Anti-Task Force Chair
- **Project Coordination: Michael H. Anisfeld**

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Survey Conclusions

- Most nations treat drug counterfeiting as an Intellectual Property (IP) matter, or regard drug counterfeiting as a trademark infringement issue
- Most nations treat drug counterfeiting with same severity as counterfeiting of Gucci handbags
- Most nations treat drug counterfeiting with less severity than counterfeiting software (*digital rights legislation*)
- No uniform definition of drug counterfeiting: country-by-country variation
- Only 16 of 50 of the world's most populous countries have legislation specifically mentioning drugs as part of counterfeit legislation

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Counterfeit Drug Definitions

- **WHO**
A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.
- **World Bank**
Counterfeits are drugs that are deliberately made as fake copies of original branded or generic drugs, imitating design, colors and other visible features.

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Counterfeit Drug Definitions

- **Russia**
The good, labels, packages of those goods on which the trademark, or a confusingly similar sign, are used shall be regarded as counterfeits.
Article 4 of Law of the Russian Federation #3520-1 On Trademarks, Service Marks and Appellations of Origin of Goods 1992
- **Mexico**
Trademark is "any visible sign adopted by a manufacturer, merchant or service provider to identify its goods or services and distinguish them from others of their same kind of class in the market place". Trademarks shall not be copied by others.
Article 88 of Industrial Property Law, 1958

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Counterfeit Drug Definitions

- **Philippines**
 - i. A drug is deliberately and fraudulently mislabeled with respect to identity and/or source, or has fake packaging
 - ii. A drug contains no amount of, or a different active ingredient, or less than 80% of the active ingredient it purports to possess, as distinguished from an adulterated drug including loss of efficacy due to expiration
 - iii. A drug refilled in containers by unauthorized persons if the legitimate labels, or marks, are used

GI • bepharm Special Law on Counterfeit Drugs, Rep. Act No. 8203 (1996) 39



Counterfeit Drug Definitions

- **China**
A drug is a counterfeit drug in any of the following cases:
 1. the ingredients in the drug are different from those specified by the national drug standards; or
 2. a non-drug substance is simulated as a drug, or one drug is simulated as another.
- A drug shall be treated as a counterfeit drug in any of the following cases:
 1. its use is prohibited by the regulations of the drug regulatory department under the State Council;
 2. it is produced or imported without approval, or marketed without being tested, as required by this Law;
 3. it is deteriorated;
 4. it is contaminated;
 5. it is produced by using drug substances without approval number as required by this Law; or
 6. the indications indicated are beyond the specified scope.

GI • bepharm Article 48 of The Drug Administration Law, PRC No. 45 (2001) 40



Outdated Counterfeit Drug Legislation

Most national anti-counterfeit legislation, where it exists, is at least 50 years old

United Kingdom Legislation:

- ◆ Weights and Measures Act - 1824
- ◆ Trade Description Act - 1968

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Enforcement Priorities

Trade Mark
Infringement

Or

MURDER



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Enforcement Problems

- Lack of sufficient inspectors
- Lack of trained inspectors/analysts
- Low inspector/analyst salaries
 - ◆ Bribery
 - ◆ Corruption
- Lack of sufficient funds for laboratories and effective surveillance
- Lack of sufficient international coordination and cooperation

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Outdated/Unrealistic Penalties

- India - 10,000 Rupees or 5 years jail
- United States - 1 year jail

New Hope:
 – tougher proposed legislation

India – death penalty
United States – 20 years jail
France:
 7.5m € fine + life imprisonment

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Need Paradigm Shift

- All legislations are national and are focused on local trade mark infringement; in the main using outdated legislation
- Not designed to deal with international crime perpetrated by sophisticated multi-national criminal and multi-national terrorist gangs
- Counterfeiters are technologically savvy, and very nimble

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Paradigm Shift - Proposals

- Need Single uniform world-wide definition of counterfeit drug
 - ◆ WHO (IMPACT) needs to formulate proposed national anti-counterfeit "model legislation", including suggested maximum penalties
- Treat drug counterfeiting as murder, rather than trade mark infringement
 - ◆ Suggest institute sever penalties:
 - ✦ Murder for original counterfeiter/mastermind
 - ✦ Manslaughter for passer of counterfeits (at all links in the distribution chain)

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Drug Counterfeiting

- In 2010 will be US\$ 75 billion annual business (US\$ 88 million a day)
- In 2010 the global income generated from drug counterfeiting will be bigger than the GNP of the 80 poorest countries combined (1/3 of world).
- Causes an unknown numbers of deaths; - those drug counterfeit deaths reported are the tip of the iceberg

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Drug Legislation Survey

Copies of FIP Drug Legislation Survey
are available from

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