

# **Combating Pharmaceutical Counterfeiting**

**Second Global Congress for Combating Counterfeiting, Lyon, France  
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**Answers That Matter.**

# Presentation Outline

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- 1. Overview and Scope of Pharmaceutical Counterfeiting**
- 2. Risks Posed by Counterfeit Pharmaceuticals**
- 3. How To Address The Problem? – Lilly's Approach**

# The Counterfeiters - Overview

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Counterfeiters are criminals and opportunists, operate globally and have little regard for public health.

Counterfeiters are becoming increasingly sophisticated although some produce product in filthy conditions.

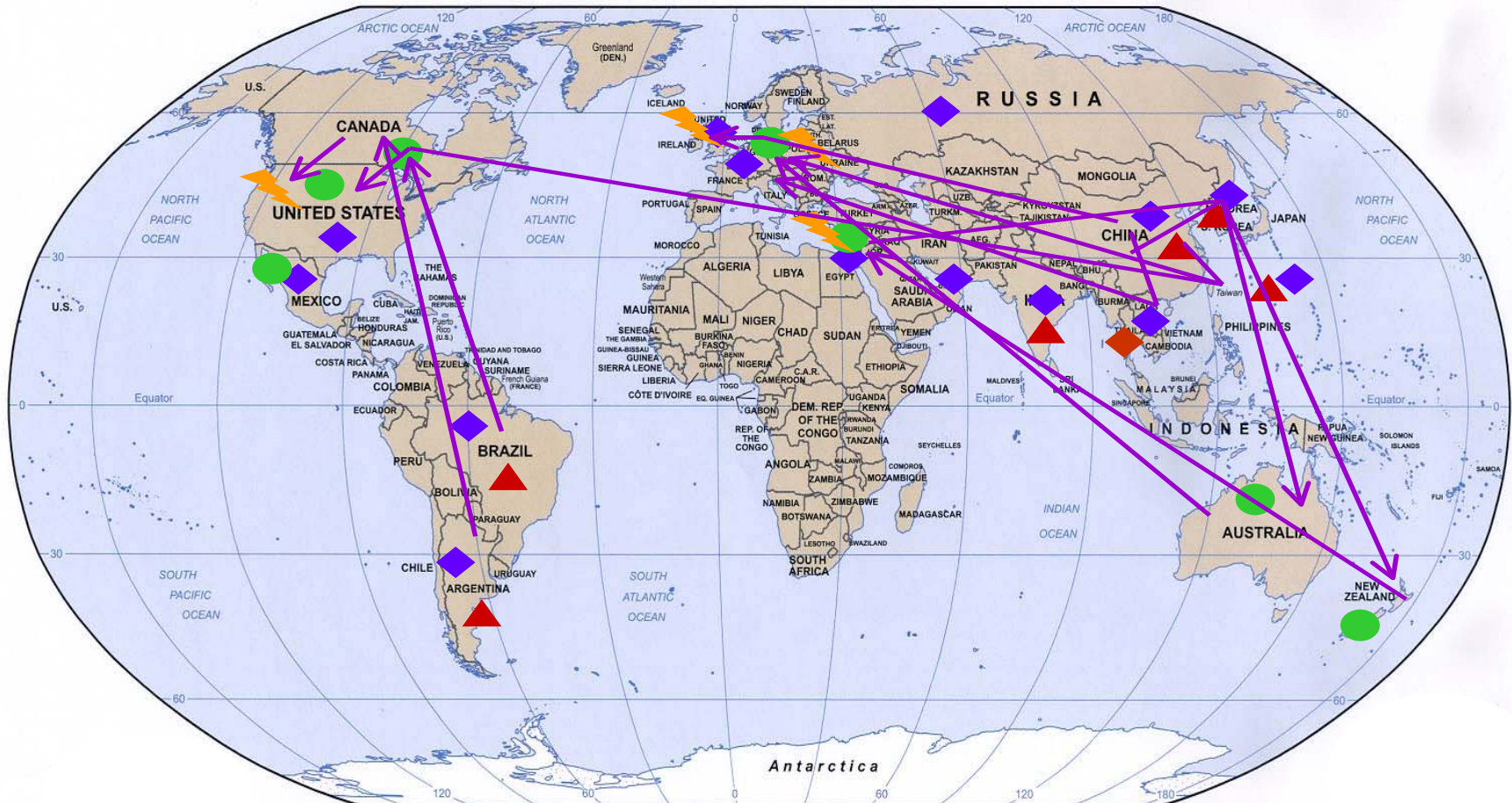
Counterfeit products are distributed through multiple distribution channels – mainly paths of least resistance, limited law enforcement, and free trade zones.

Counterfeiters have entered the legitimate distribution channels (e.g. UK, Netherlands, and U.S.).

The Internet is a key enabler in connecting counterfeiters with one another and with unwitting patients.

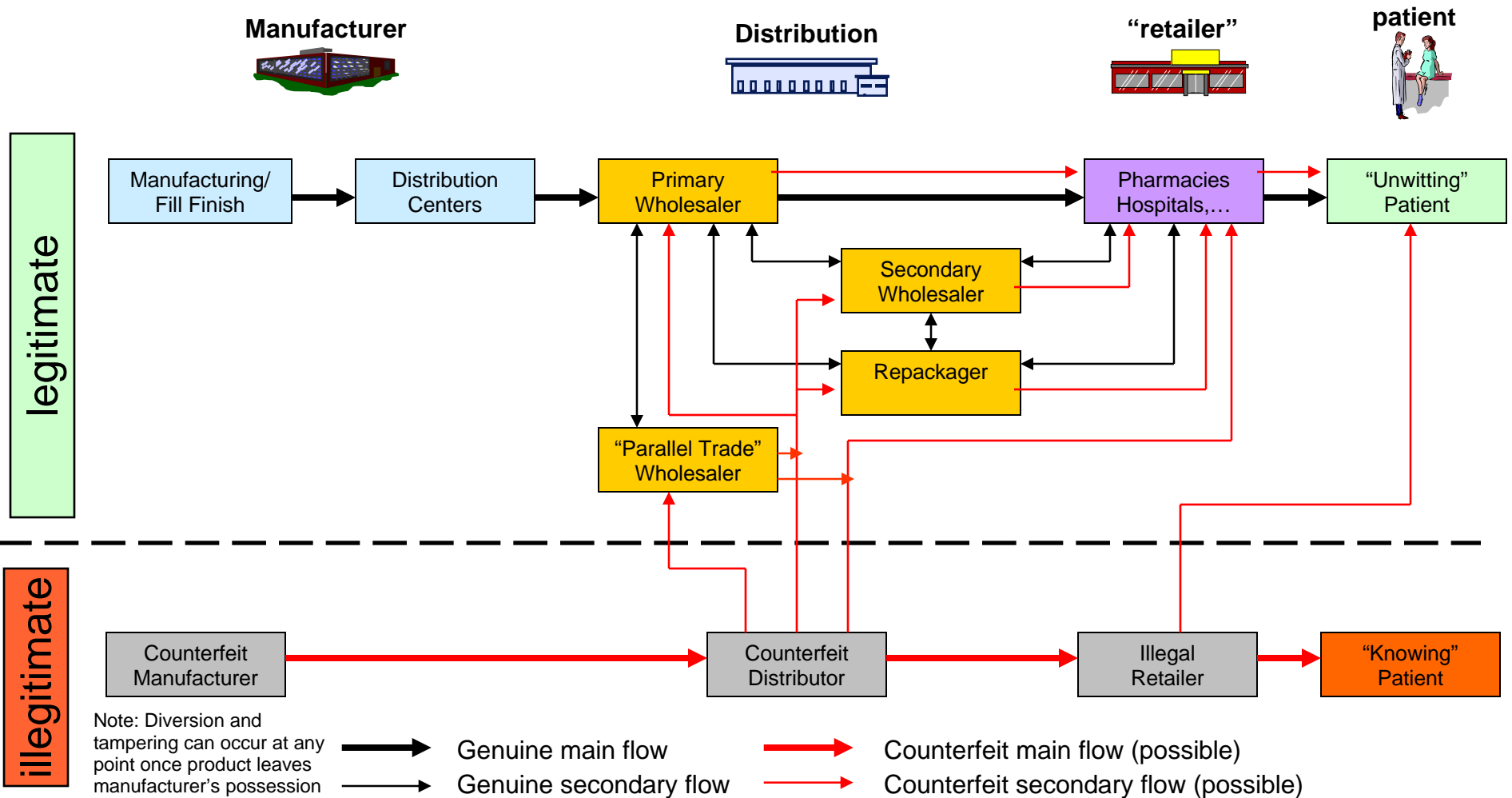
# Manufacture and Distribution of Counterfeit Product from East to West

The Drug Counterfeiting Network Is Globally Integrated



- ▲ Producers
- ◆ Fill/finishers
- Flow-through
- ⚡ Destination

# Possible Inflow of Counterfeits to the Legitimate Distribution Channel



# Estimated Level of Pharmaceutical Counterfeits

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Counterfeits estimated to 5% to 12% of medicines sold globally, found in most countries.

U.S. estimated to have low(est) level of counterfeits (<1%), while developing countries estimated to have highest level (up to 50%).

In developed countries, counterfeit drugs include high volume and/or high cost and “lifestyle” drugs.

In developing countries, a wide variety of drugs is likely to be counterfeited.

Overall, counterfeiting is getting worse. The Center for Medicines in the Public Interest projects counterfeit sales \$75 billion in 2010, a 92% increase from 2005

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# Reported US Counterfeit Cases in 2005\*

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- Missouri - Indictments of 3 businesses and 11 individuals in \$42M conspiracy with multiple drugs, leading to recall of 18M cholesterol lowering tablets
- Texas – 1 individual indicted for importation/distribution of ED and cholesterol lowering drugs. Chinese authorities arrested 11 individuals
- Florida – 2 individuals sentenced to 2 year jail terms for counterfeiting anti-psychotic drugs and illegal distribution
- California – 1 individual indicted for importation and manufacture of \$5M counterfeit ED drugs
- California/Florida – 1 individual sentenced to 4 year prison term and 14 being prosecuted for large international internet conspiracy involving variety of drugs linked to Mexico and Asia
- Texas – 1 individual arrested for alleged counterfeit flu vaccine
- Nov 1 2005 Congressional hearing on Counterfeit drugs in US - Randall Lutter FDA  
[www.fda.gov/ola/2005/counterfeit1101.html](http://www.fda.gov/ola/2005/counterfeit1101.html)

# Counterfeiter's Manufacturing Facilities

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# Counterfeiter's Labeling Equipment

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# Example of a Counterfeit Cialis®



Cialis is a LillyICOS JV product

# Example of Counterfeit Viagra®

Counterfeit Viagra found in two California pharmacies, June 2004:



Counterfeit products can be very sophisticated in their appearance and packaging

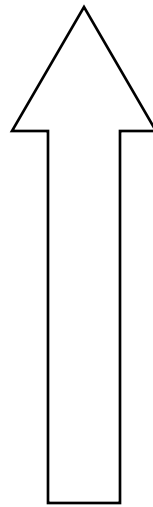
Note: Viagra is a registered trademark of Pfizer Inc.

# Risks Posed by Counterfeit Pharmaceuticals

## What are the Top Two?

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**#1 Patient Safety**



**#2 See Risk #1**

## **Risks Posed (Cont'd)**

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- **Brand Equity (corporate/ product)**
- Product Recall Costs
- Lost Sales

# How to Address the Problem? - Lilly's Approach

## Anti-counterfeiting Strategic Intent

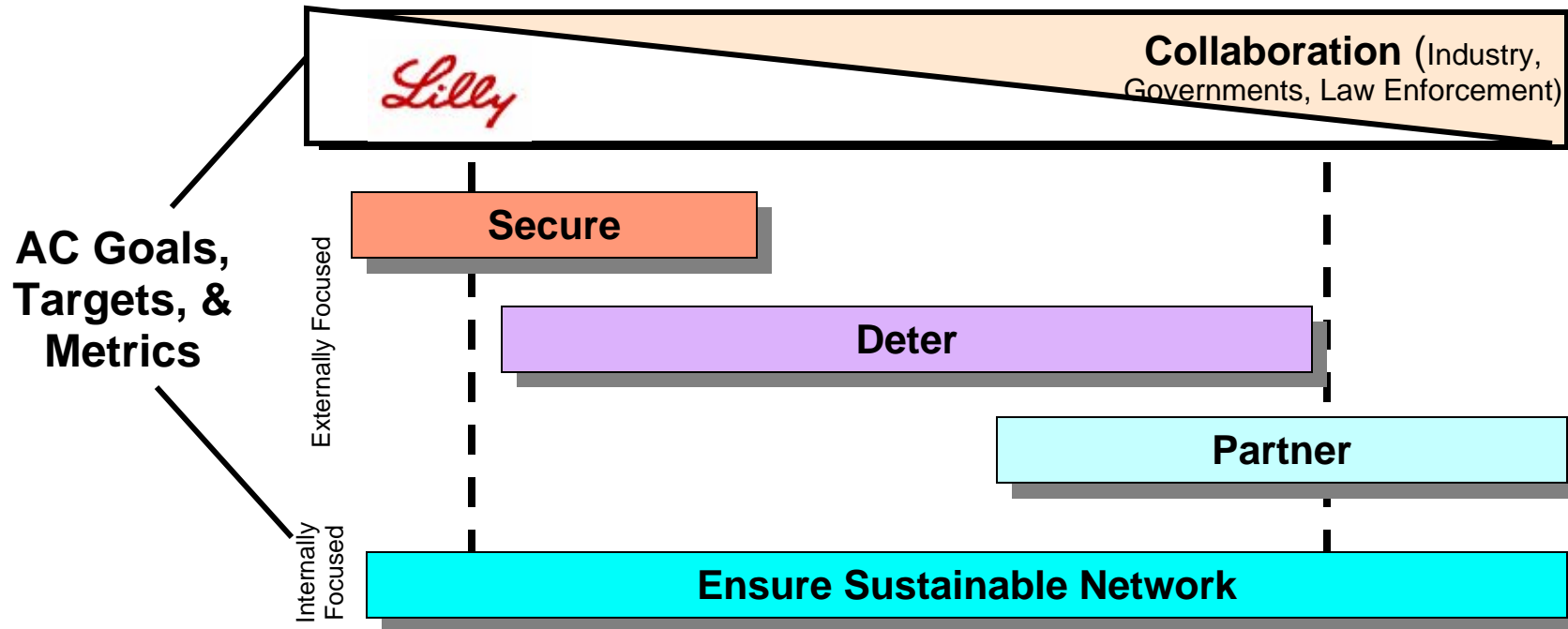
“Be a leader in protecting patient safety, consistent with the Lilly brand – reliable and trustworthy.”



## Anti-counterfeiting Goals

1. **Secure/enhance** the integrity of Lilly products through the legitimate distribution channel
2. **Deter** major counterfeiters of Lilly products through targeted investigations, litigation, prosecution, and use of technology
3. **Partner** with Government/Non-Government Organizations and Trade Associations to strengthen, enact, and enforce anti-counterfeiting laws, and to raise public awareness
4. **Ensure** a sustainable network with designated leadership to anticipate, prioritize, and effectively respond to all Lilly counterfeiting challenges

# The Four Goals



Collaboration between Lilly and various external entities is needed to effectively address counterfeiting.

# How to Address the Problem? - Lilly's Approach

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## Goal 1 : Secure/enhance supply channel

- Strengthen wholesale contracts
- Monitor and audit supply chain

## Goal 2 : Deter major counterfeiters

- Trademark recordations and Internet monitoring
- Leverage technology – overt, covert, forensics
- Security/Investigators work closely with customs, law enforcement (FDA-OCI, Interpol, PSI etc.)

# How to Address the Problem? - Lilly's Approach

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## Goal 3 : Partner for.....

- Tougher anti-counterfeiting laws and enforcement of penalties
- Public awareness
- Pedigrees to document chain of custody

## Goal 4 : Ensure sustainable network

- Governance structure
- Rapid response systems

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# Thank you

*Christopher James Shaw*

The Lilly logo is written in a red, cursive script font.

**Answers That Matter.**

# Q&A

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# Overview - Definitions

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## COUNTERFEITS\*

Counterfeit medicines are those that are deliberately and fraudulently mislabeled with respect to identify and/or source. May include products:

- with the correct ingredients but fake packaging
- with the wrong ingredients
- without active ingredients, with insufficient and/or contaminated active ingredients, or with too much active ingredients.

## DISTRIBUTION CHANNELS

**Legitimate channels** – medicines distributed within government-regulated supply chain that attempts to ensure integrity of product and packaging at every stage

**Illegitimate channels** – medicines distributed through non-regulated channels that neither guarantees product integrity nor patient safety and where financial motivation is driving factor

\*Based upon counterfeiting definition from WHO

# How to Address the Problem?

## - Cooperation with Law Enforcement

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### Global Network of Investigators

- Receive reports and samples from affiliates
- Submit samples for testing and analysis
- Investigate and liaise with law enforcement and regulatory authorities
- Coordinate with legal, e.g., IP
- Develop enforcement strategy with input from legal and testing and analysis
- Result in raids and criminal/civil action

# How To Address The Problem?

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