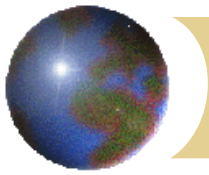


**2007 FIP World Congress of Pharmacy and
Pharmaceutical Sciences
September 3, 2007
Beijing, China**

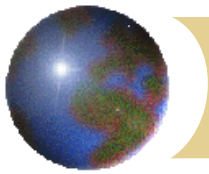
**Topic: International Trade Issues Related to Counterfeit
Medicines and the Need for Global Cooperation**

Jeffrey Gren, Director
Office of Health and Consumer Goods
U.S. Department of Commerce



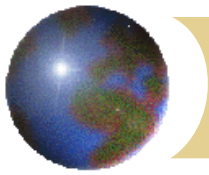
Outline

- Definitions of Counterfeit Medicines
- Why an International Trade Problem
- Pharmaceutical Security Institute
2006 Situation Report
- Impact of Industry Trends
- Solutions
- Summary and Conclusions



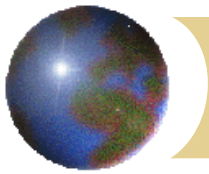
Drug Counterfeiters

- Currently, the drug counterfeiters are winning and for the past decade, each year there were more counterfeit medicines being consumed than the previous year
- I look forward to the day when this trend is reversed



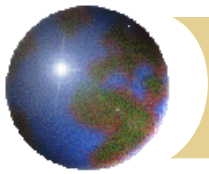
Definitions

WHO: A medicine, which is **deliberately** and **fraudulently** mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.



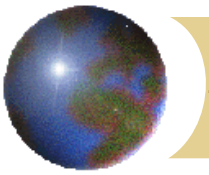
Definitions

- Counterfeit drugs are a subset of Substandard drugs
- Substandard drugs: medicines manufactured below established standards of safety, quality and efficacy
- Different definitions in different countries
 - China – “Fake”
 - India – “Spurious”
 - Cause harm or do not work



Definitions

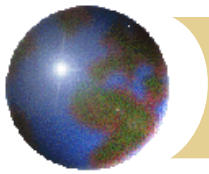
- Correct combination and concentration of active pharmaceutical ingredients (APIs) and excipients does NOT equal safe drugs
- Our view at DOC is that all drugs deliberately and fraudulently mislabeled with respect to identity and source are **counterfeit and unsafe**



Definitions

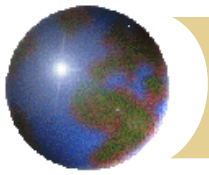
Why Unsafe?

- Does not meet regulatory requirements for bioequivalence
- No clinical trials ensuring safety for human consumption
- Does not conform to GMP, Pharmaequivalence or Bioequivalence
- May contain contaminants such as heavy metals, pesticide, etc.



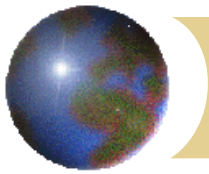
Why an international trade problem?

- Intellectual Property Rights (IPR) violation
- Manufacturers lose revenue
 - \$75 billion in global sales by 2010 (The Center for Medicines in the Public Interest in the U.S.)
 - WHO: an increase of more than 90% from 2005
- Violates WTO and Free Trade Agreements



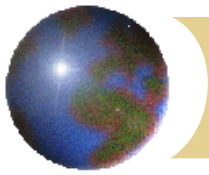
Why an international trade problem?

- Global problem causing injury and death
- Contributes to drug resistance
- Loss of trust in the public health system
- Loss of confidence in brand names
- Loss of tax revenue



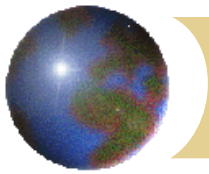
Why an international trade problem?

- Expenditure of resources combating counterfeit medicines – law enforcement, customs, justice, regulatory, etc.
- Counterfeit medicines can also cause a loss of trust in the public health system and drug regulatory systems



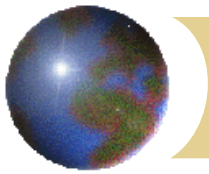
Why an international trade problem?

- Combating Counterfeit Drugs, “Drug counterfeiters not only defraud customers, they also deny ill patients the therapies that can alleviate suffering and save lives”
- According to the U.S. Food and Drug Administration February 2004 report, there are numerous documented, heart wrenching stories of human suffering and death due to counterfeit medicines



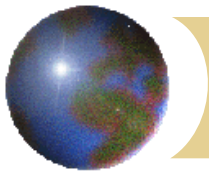
Lack of Statistics

- No reliable statistics to measure full global impact
- 10-20 years ago most counterfeits had no APIs
- Now increasing number of counterfeit products contain real APIs
- Although there are counterfeit APIs, many counterfeit drugs are made with real APIs
- Developing markets have higher incidence:
 - Africa, Asia, Eastern Europe, Russia, and Latin America citizens regularly encounter counterfeit drugs



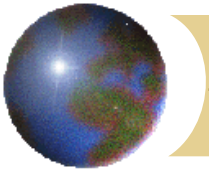
Lack of Statistics

- A single global figure is misleading
- Latest estimates jointly elaborated by WHO, the OECD, and the Pharmaceutical Security Institute show:
 - More than 30% of medicines in some areas of Latin America, South East Asia and Sub-Saharan Africa are counterfeit
 - Emerging economies - the proportion is estimated at 10%; however, in many of the former Soviet republics it can be as high as 20%
 - Wealthy countries with strong regulatory mechanisms - counterfeits account for less than 1% of the market value, but 50% of Internet sales are counterfeit

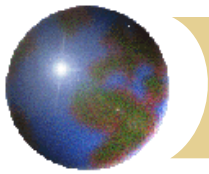


Why do people buy counterfeit medicines?

- Indonesian study: consumers will buy counterfeit consumer goods, such as, handbags and watches, but will not knowingly buy counterfeit medicines
- Consumers buy counterfeit medicines because they do not know they are buying counterfeits
- Many times counterfeits are sold for a lower price than the real medicine, however, this is not always the case (i.e., Thailand)

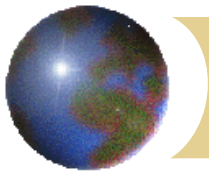


*The most expensive
drug is the one that
does not work!!*



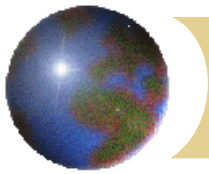
Why an international trade problem?

- Two Types: Organized Crime Operations v. Smaller Scale Counterfeiters?
 - Manufacturing counterfeit drugs has become extremely profitable
 - Organized crime has moved from narcotics into counterfeiting
 - The penalty for producing counterfeit drugs is far less than the penalties for illegal narcotics



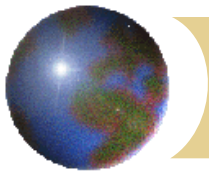
Why an international trade problem?

- To illustrate the high profits in counterfeit medicines
- The profit margin for \$1,000 invested in ingredients to produce heroin is \$3,000 or 200%
- The profit margin for \$1,000 invested to produce a widely counterfeit drug is \$30,000 or 2000%



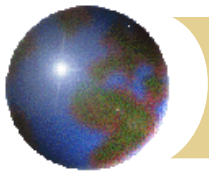
PSI 2006 Situation Report

- Pharmaceutical crime is increasing worldwide
- Counterfeiting, the most common type of incident, increased by 32% in 2006
- Number of countries linked to incidents remained consistent – 100
- Law enforcement successes in targeting the counterfeit manufacturers and those transporting illegal pharmaceuticals



PSI 2006 Situation Report (contd.)

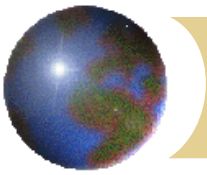
- Illegal Diversion – When a genuine pharmaceutical product is approved and intended for sale in one country, but is then illegally intercepted and sold in another country
- Often done using false statements or declarations. Sometimes the drugs sold in the unintended country are not approved by that country's regulatory authorities



PSI 2006 Situation Report (contd.)

Definitions:

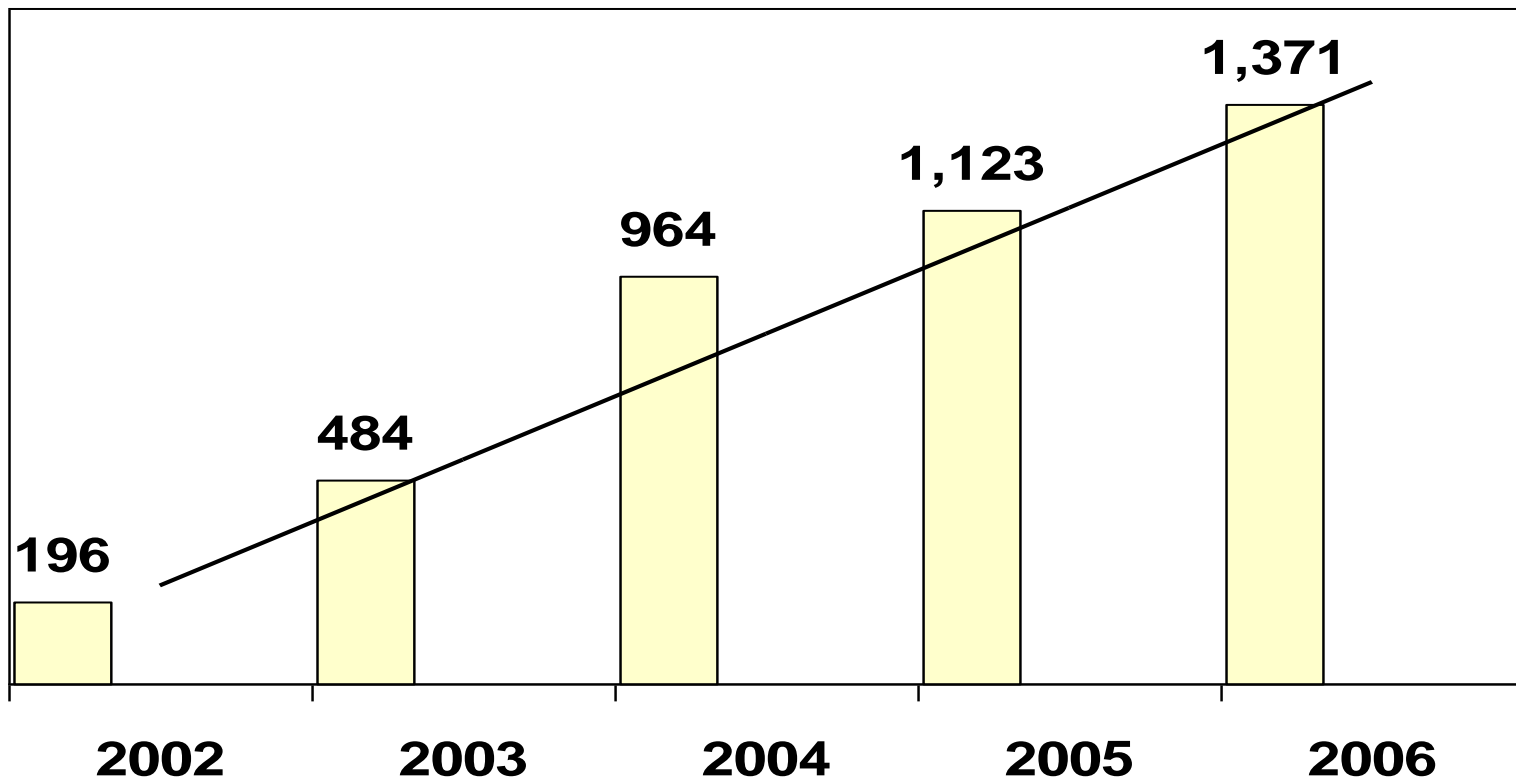
- Pharmaceutical Theft – Theft of finished dosage form medicines any where in the distribution chain, such as at the site of production, freight forward distribution center, warehouses, pharmacies, or hospitals
- Incident – A discreet event triggered by discovery of counterfeit, illegally diverted or stolen pharmaceutical



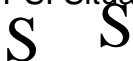
PSI 2006 Situation Report (contd.)

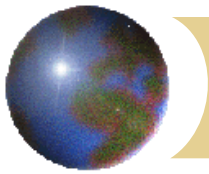
Five Year Trend Line

Total Number of Incidents by Year: 2002 - 2006



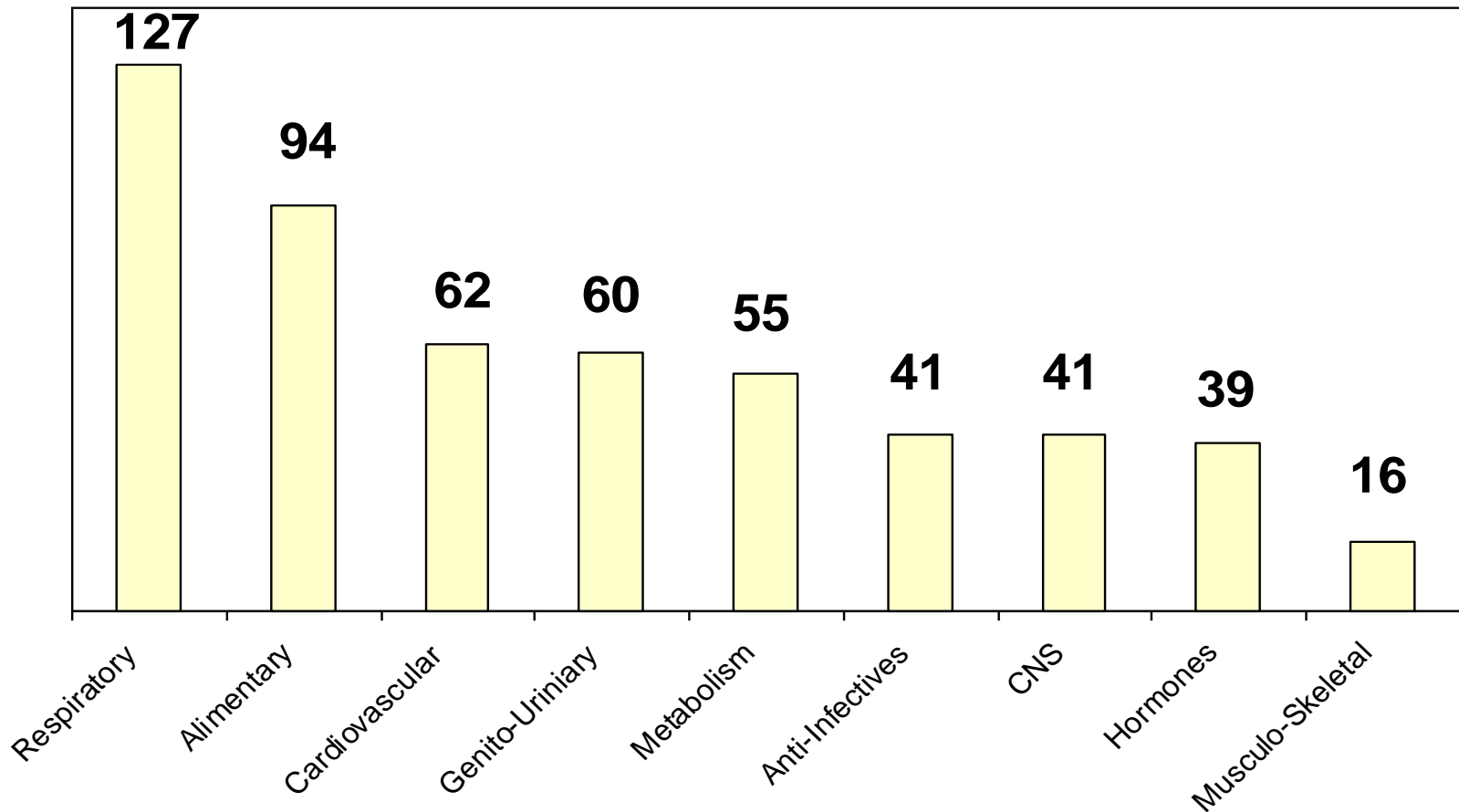
Source: PSI Situation Report 2006



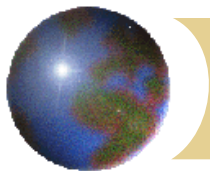


PSI 2006 Situation Report (contd.)

Therapeutic Categories Counterfeit Incidents: 2002 - 2006



Source: PSI Situation Report 2006

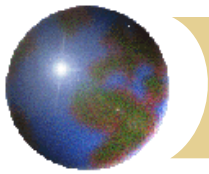


PSI 2006 Situation Report (contd.)

Top Ten Countries Arrests: 2006

Country	Point of Sale	Transporting	Distributor	MFG	Theft	Total
China	5	4	55	119	0	183
Brazil	12	81	16	4	9	122
South Korea	0	5	25	40	0	70
Taiwan	30	0	17	13	0	60
Israel	37	2	6	0	0	45
India	4	0	7	17	0	28
Thailand	17	6	2	0	0	25
United States	10	3	9	1	1	24
El Salvador	11	4	2	0	0	17
Peru	9	6	1	1	0	17

Source: 2006 PSI Situation Report

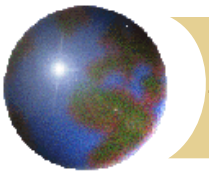


PSI 2006 Situation Report (contd.)

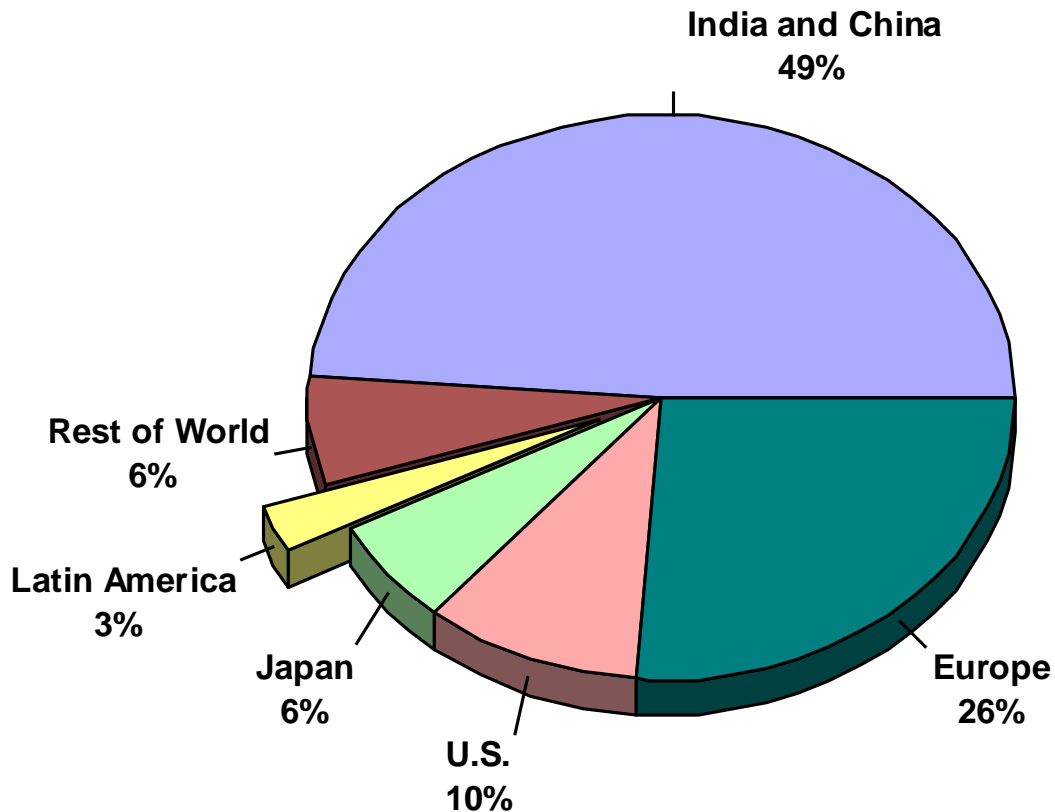
Top Ten Ranked Reported Incidents: 2006

Country	Counterfeiting	Diversion	Theft	Total Incidents
China	233	7	0	240
Russia	162	3	1	166
United States	74	31	6	111
Brazil	47	35	22	104
India	94	5	1	100
Uzbekistan	79	0	0	79
South Korea	72	0	0	72
Germany	64	4	0	68
Peru	63	4	0	67
United Kingdom	38	8	3	49

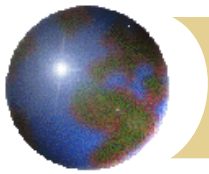
Source: 2006 PSI Situation Report



Industry Trends Impacting the Problem: Global API Manufacturing - 2004

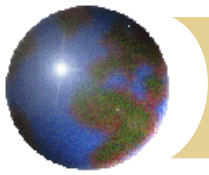


Total Global Number of API Manufacturers Sites nearly 2,000



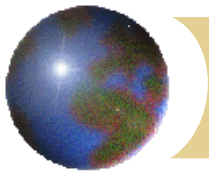
Industry Trends Impacting the Problem: APIs

- IMS Health: India will be the dominant country for API production for the next 20 years, and over the next 50 years China will become more dominant for API production
- Global API production is expected to grow by 42% between 2003 and 2008.
- China API production is projected to increase by 125% by 2010



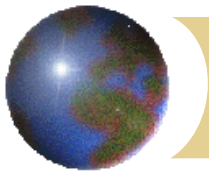
Industry Trends Impacting the Problem: APIs (contd.)

- Currently most API manufacturing in India and China is for the generic drug market, but this will change over time due to:
 - lower developmental costs
 - complex synthesis capabilities
 - shifting pharmaceutical drug production
 - regulatory compliance and adherence to GMP and GCP



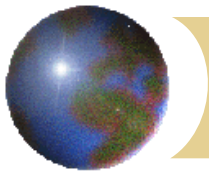
Industry Trends Impacting the Problem: The Generic Trend

- Generic production is growing at a faster rate than innovative drug production
- Shift in the global production of generic drugs – – countries/regions with significant growth of generic production include India, China, Southeast Asia, Brazil, Middle East, Russia, Mexico

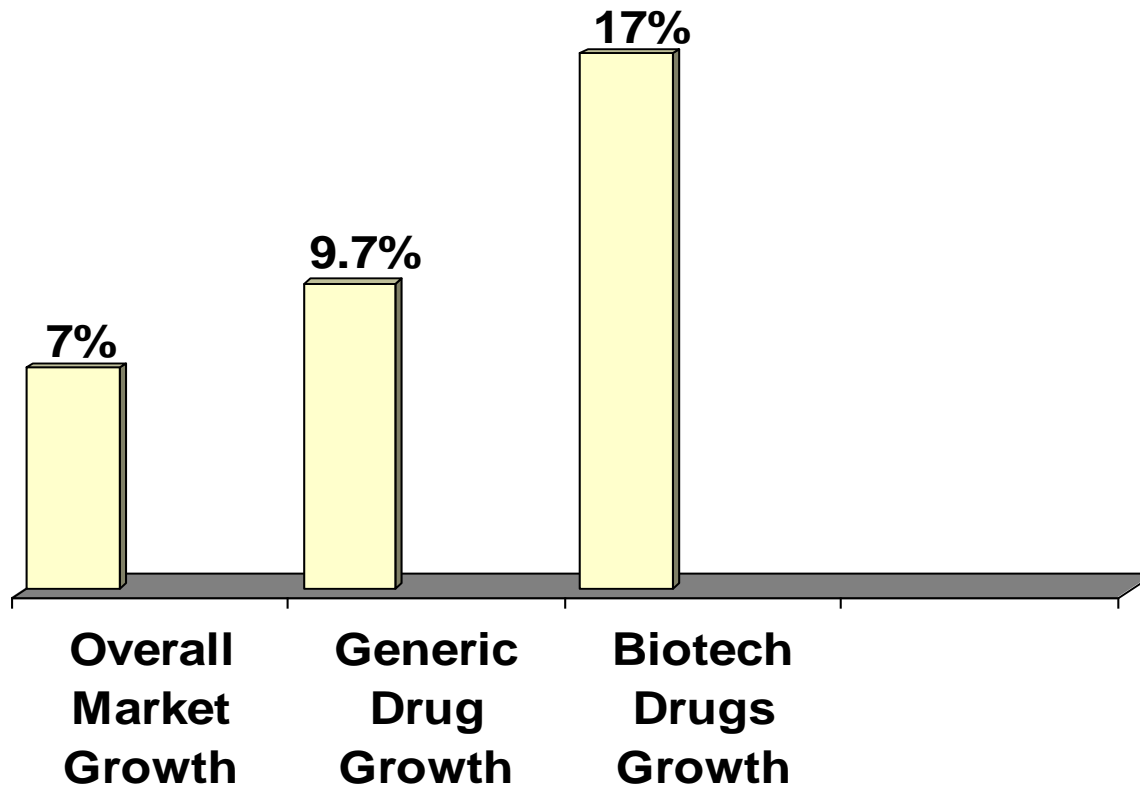


Industry Trends Impacting the Problem: The Generic Trend (cont'd)

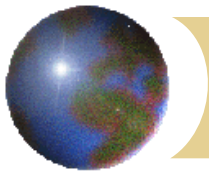
- The shift in generic drug and API production away from the developed markets (U.S., Europe and Japan) adds to the problem of counterfeit drugs, since the regulatory regimes and standards established by pharmacopeias, are much weaker away from the U.S., Europe, and Japan



Industry Trends Impacting the Problem: Growth in Pharmaceutical Segments

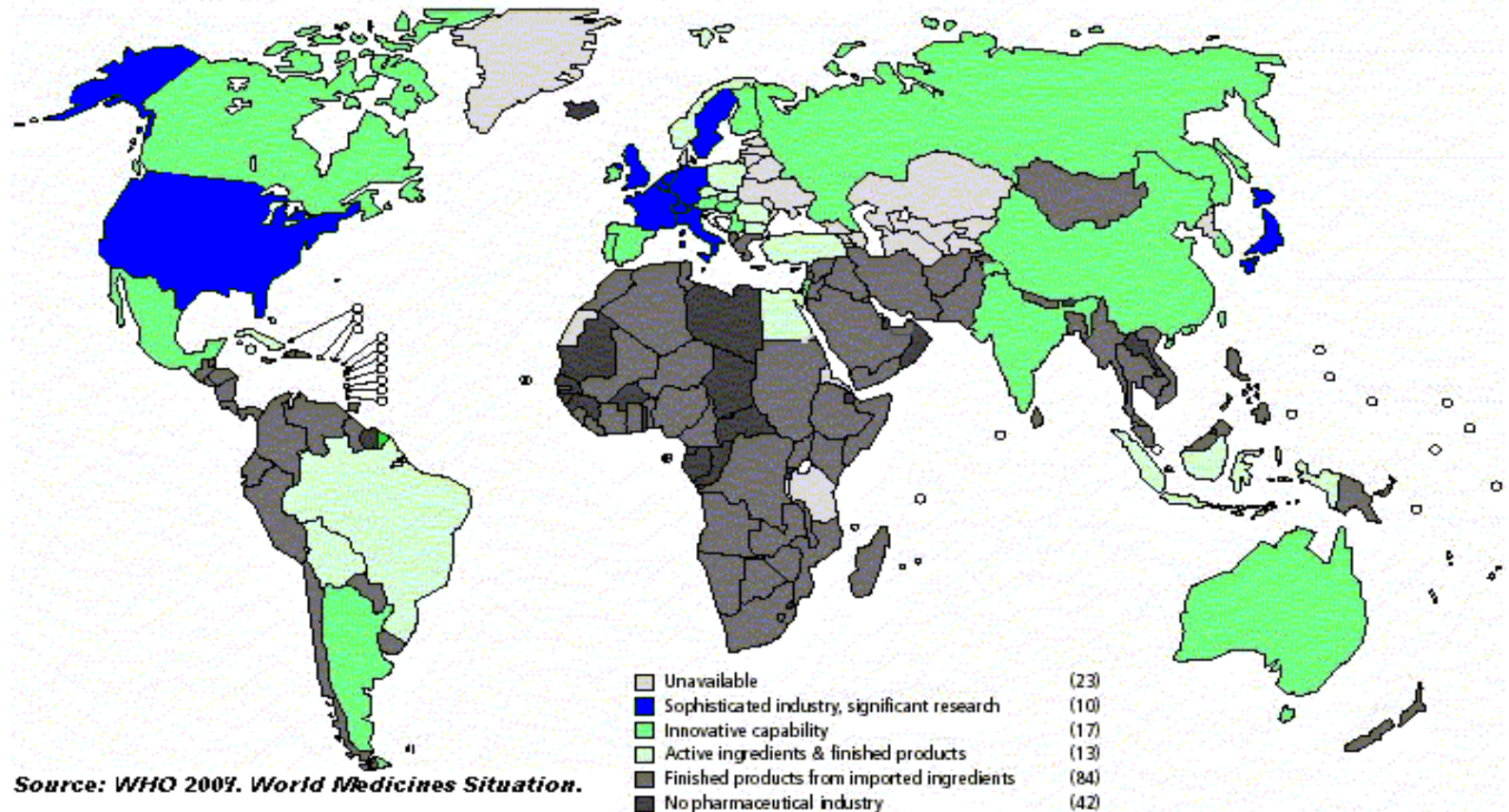


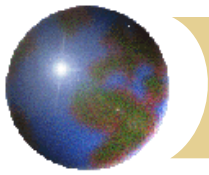
Source: IMS Health MIDAS - 2005



Industry Trends Impacting the Problem: Global Pharmaceutical Manufacturing

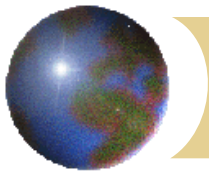
Local pharmaceutical production capacity varies greatly among countries





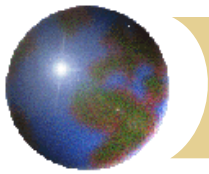
Solutions

- Protecting the integrity of the supply chain
- Need for global cooperation to stop counterfeit medicines and catch the counterfeits
- Cooperation health officials, customs, law enforcement and industry
- WHO IMPACT



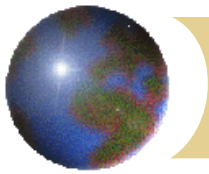
Solutions: Protecting the integrity of the drug supply chain

- Development of drug supply chain guidelines to prevent distribution of counterfeit medicines
- Problem varies greatly among countries
- Countries with weak regulatory regimes, and lack of pharmaceutical standards enforcement are impacted most severely



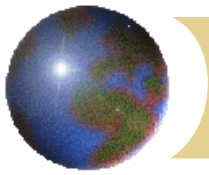
Solutions: Protecting the integrity of the drug supply chain

- FDA 2004 report: “In some countries the counterfeiting of drugs is endemic – with some patients having a better chance of getting a fake medication than a real one.”
- WHO 2005 Report on The Safety of Medicines: “In wealthier countries, new expensive medicines are frequently counterfeited, such as cholesterol lowering medicines, drugs used for treatment of growth hormone deficiency and for cancer.
- In developing countries the most counterfeited medicines are those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS.”



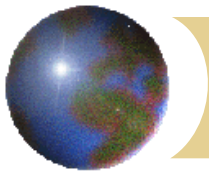
Solutions: Protecting the integrity of the drug supply chain

- Verification programs, reliance on standards, monographs, track and trace (RFID) technologies, and authentication technologies
 - Radio frequency identification (RFID) tagging of products by manufacturers, wholesalers and retailers is a reliable product tracking and tracing technology
 - Authentication technologies include measures such as color shifting inks, holograms, fingerprints, tangents, and chemical markers embedded in a drug or its label
- Establishment of global harmonized standards for pharmaceutical ingredients (APIs and excipients),
 - Pharmacopeias Discussion Group (PDG) of the pharmaceutical International Conference on Harmonization (ICH)



Solutions: Protecting the integrity of the drug supply chain

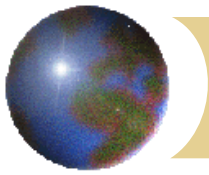
- The area of the pharmaceutical supply chain that is most vulnerable to counterfeits is with the secondary wholesalers and not through transactions between legitimate manufactures and the primary distributor
- Therefore, wholesalers can also contribute to the fight against counterfeiting by securing the source of products in the supply chain



Solutions: Protecting the integrity of the drug supply chain

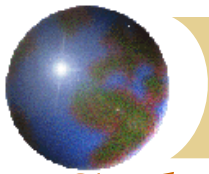
How can Wholesalers contribute:

- Assuring that printed packaging materials provided by external printers can not be diverted
- All excess, rejected, returned or expired packages need to be properly disposed of
- Bulk finished product and packaging materials need to be securely stored to prevent their diversion
- Insure that all third parties involved in packaging are properly controlled



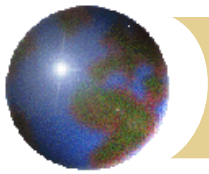
Solutions: Communication

- Establish government “certified pharmacy programs” in countries with significant amount of counterfeit drugs in the drug supply chain
- Educate consumer and health professionals to better recognize counterfeit medicines
- Improved market surveillance through close monitoring of adverse events



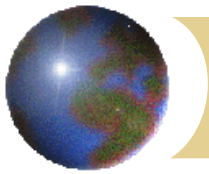
Solutions: Need for global cooperation to stop counterfeit medicines and catch the counterfeiters

- The production of counterfeit drugs has grown at an alarming rate in recent years, however, data is difficult to obtain since the extent of counterfeit drugs is hard to measure
- The growth of counterfeit drugs is a global problem that requires global cooperation to regulate and to stop the flow of pharmaceutical substances
- Risk of doing nothing – prevalence of counterfeit medicines **will** continue to grow



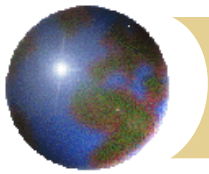
Solutions: Partnership for Safe Medicines

- “Partnership for Safe Medicines” is a coalition of patients, physicians, pharmacists, universities, industry, and other professional organizations, committed to protecting the public from counterfeit medicines
- Avoid – Detect – Report
- SafeMeds Alert System: www.safemedicines.org
- Countries can sign up to participate



Solutions: Need for global cooperation to stop counterfeit medicines and catch counterfeiters

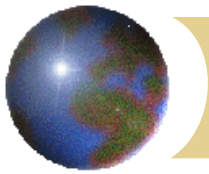
- There are two aspects to this problem:
 - 1) Counterfeits within a country's borders
 - Cooperation between regulators, customs, law enforcement, and the judicial system, at both the national and local (state or provincial) levels
 - Need to regulate and control the use of APIs



Solutions: Need for global cooperation to stop counterfeit medicines and catch counterfeiters (contd.)

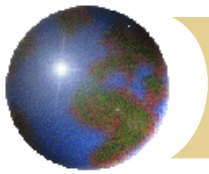
2) Import/Export of Counterfeit products:

- Bulk APIs are shipped from one country to another country for the purpose of producing counterfeit drugs
- To control this movement of pharmaceutical substances (APIs and excipients) for the illegal purpose of producing counterfeit drugs requires health, customs, law enforcement, and industry from various countries to work together



Solution: Need for global cooperation to stop counterfeit medicines and catch the counterfeiters (contd.)

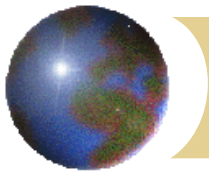
- For example, if an API, such as sildenafil citrate, that may be used to produce a counterfeit Viagra is shipped from China to Thailand, China customs should inform Thailand customs
- In turn, Thailand customs could work with Thailand law enforcement to track down the shipping location of the sildenafil citrate, and investigate if this is a legitimate production, or an illegal counterfeit operation
- If it is an illegal counterfeit operation, then Thailand authorities could shut down the plant and arrest the counterfeiters



Solutions: DOC International Activities

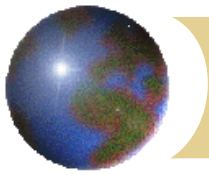
- India – U.S.-India High Technology Government Cooperation Group, Biotechnology and Life Sciences Working Group, and the activities of the U.S. India Business Council

- China – U.S.-China Joint Commission on Commerce and Trade (JCCT) and bulk API activities



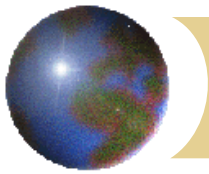
Solutions: DOC International Activities (contd.)

- APEC Funded Anti-counterfeit Health Product Seminars - U.S. FDA, working with DOC and other U.S. Government Agencies, the Singapore Health Science Authority and industry will organize a series of Asia APEC funded capacity building seminars to stop the spread of counterfeit health products
- STOP!: Strategy Targeting Organized Piracy - 1-866-999-HALT or www.stopfakes.gov



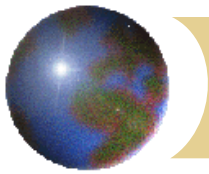
Summary and Conclusions

- During my presentation I have discussed the international trade issues related to the global counterfeit drug problem
- After covering definitions of counterfeit drugs, I outlined why counterfeit drugs are considered a trade problem
- I discussed who are the counterfeiters and methods to protect in integrity of the drug supply chain



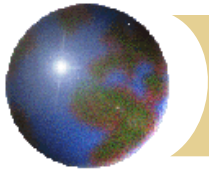
Summary and Conclusions (contd.)

- I also outlined global shifts in the production of pharmaceutical substances and generic drugs and why this adds to the global counterfeit drug problem
- I also outlined U.S. DOC programs and activities related to counterfeit drugs
- I provided an outline of the WHO International Medical Products Anti-counterfeiting Task Force (IMPACT) activities



Summary and Conclusions (contd.)

- In conclusion, the only way the rapid growth of counterfeit medicines will be stopped is through global cooperation among health, customs, law enforcement officials, and industry representatives from major countries of the world to catch and arrest counterfeiters
- Progress is being made, but a focused global approach is needed
- I look forward to the day when we can announce there are less counterfeiting medicines in the world than there were a year earlier



Thank You!

Jeffrey Gren, Director

Office of Health and Consumer Goods

U.S. Department of Commerce

Phone: 202-482-2587

Email: Jeffrey.Gren@mail.doc.gov

Website: www.export.gov/health