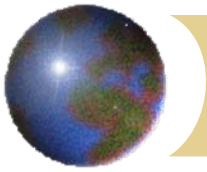


**American Enterprise Institute
Conference: The Global Impact of Fake
Medicine**

**June 10, 2009
Washington, D.C.**

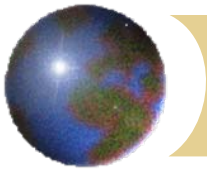
**Topic: The Impact of the Globalization of the
Pharmaceutical Industry on the Counterfeit and
Substandard Medicines Problem**

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



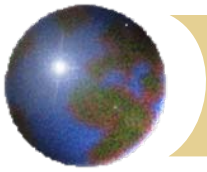
Outline

- Introduction
- The impact of globalization of the pharmaceutical industry
- The substandard and counterfeit medicines global problems
- DOC activities
- Possible solutions
- Summary and conclusions



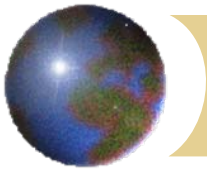
Introduction

- U.S. Department of Commerce (DOC) is the advocate for business in the U.S. government and DOC's international trade role is to promote U.S. trade by strengthening industry competitiveness and reducing trade barriers
- I direct the Office of Health and Consumer Goods and my office focuses on medical devices, pharmaceuticals, biotechnology, and a wide array of consumer goods products
- An outcome of the globalization of the pharmaceutical industry is a significant increase in substandard and counterfeit medicines
- A related significant global problem is the growth of counterfeit medicines



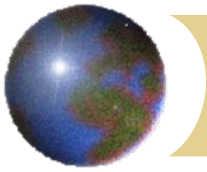
Introduction (cont'd)

- During the past several years DOC has been very active in the global battle to stop the spread of counterfeit medicines and we work very closely with U.S. FDA and industry in our activities
- We are also currently exploring drug quality issues, such as the global substandard medicines problem, and ways that DOC can work with industry and regulators to address this problem
- Although we do not have reliable data, experts agree that the amount of counterfeit and substandard medicines on the global market is increasing each year



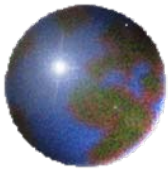
Introduction (cont'd)

- Factors leading to this increase in counterfeit and substandard medicines includes:
 - An increasing number of criminals, and sophistication of criminals producing counterfeit medicines
 - High profit level (profit levels for counterfeit medicines are significantly larger than for narcotics)
 - The internet provides an easy and lucrative marketing vehicle for counterfeiters to distribute counterfeit medicines
 - Lack of penalties and coordinated law enforcement and prosecution activities have created conditions for counterfeiting to grow

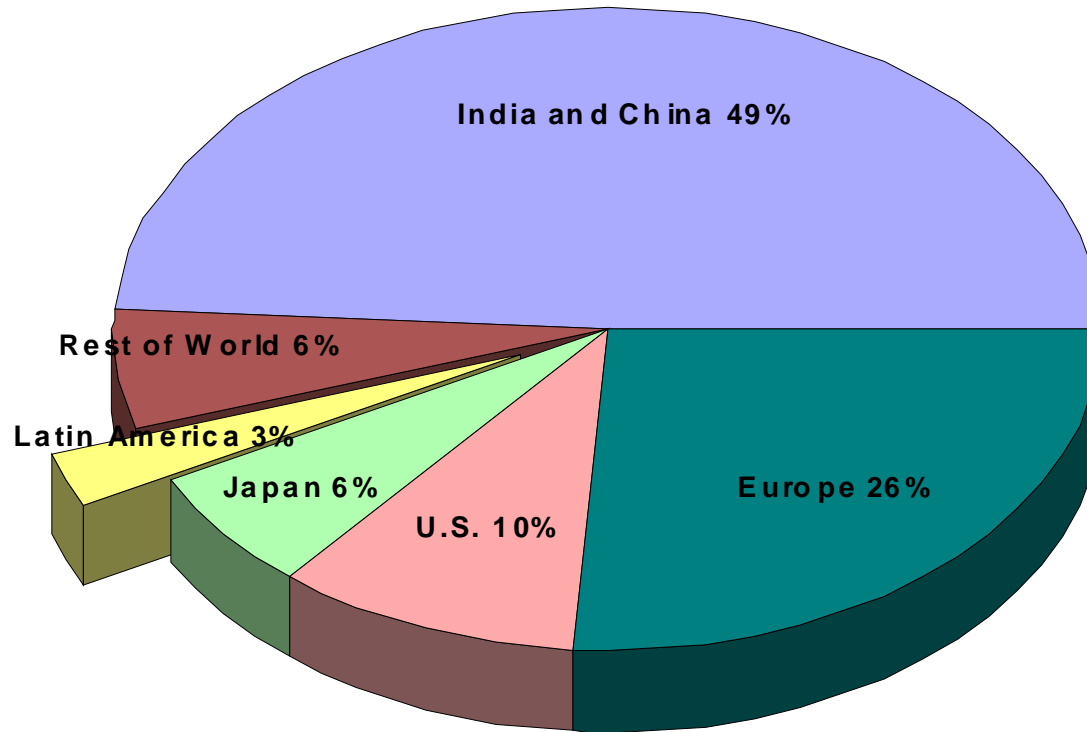


Introduction (cont'd)

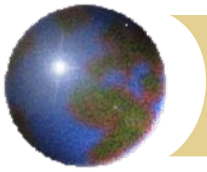
- The globalization of the pharmaceutical industry has contributed to the ready supply of APIs to counterfeiters
- The globalization of the pharmaceutical industry has also contributed to the growth of substandard medicines, as manufacturing of APIs and finished dosage forms shifts from developed to lesser developed countries



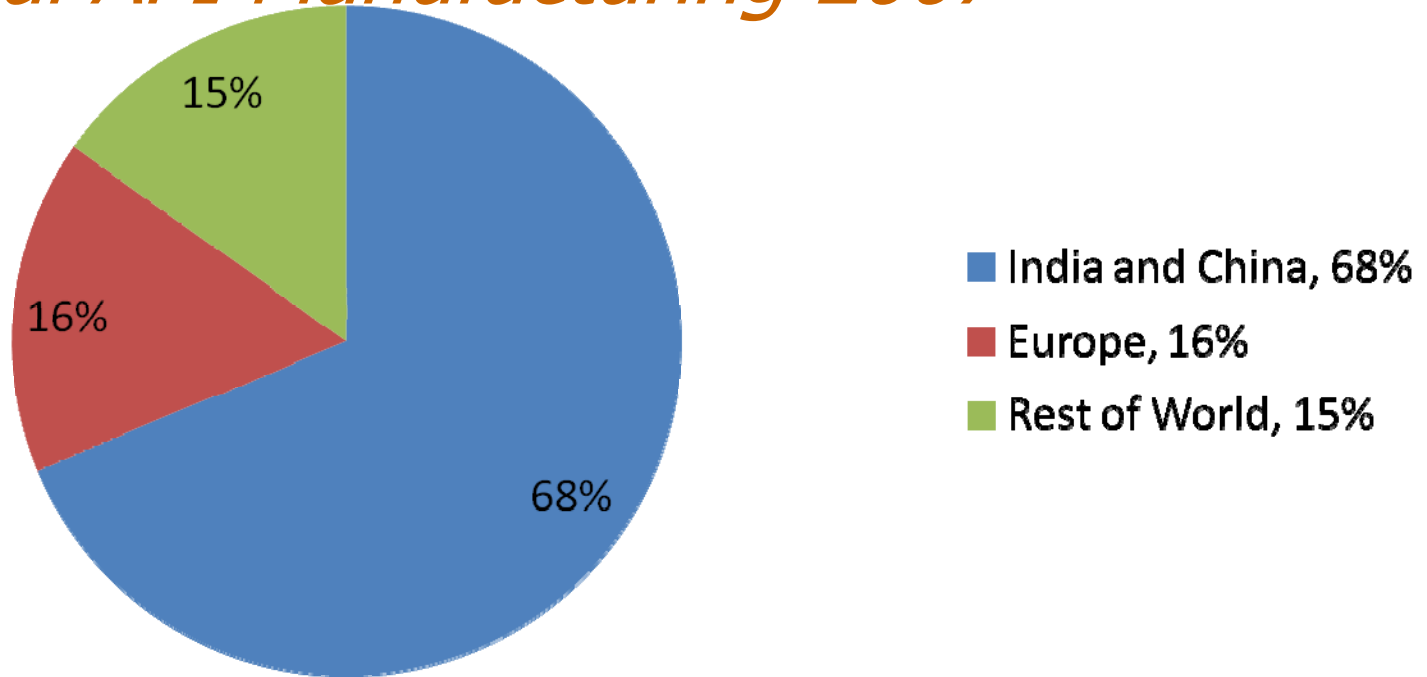
Impact of Globalization of the Pharmaceutical Industry: Global API Manufacturing - 2004



Total Global Number of API Manufacturers Sites approximately 2,000

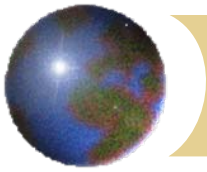


Impact of Globalization of the Pharmaceutical Industry (cont'd) Global API Manufacturing 2007



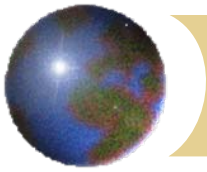
Total Global Number of API Manufacturers Sites
approximately 1,144

*Source: Newport Horizon Sourcing, October 2007



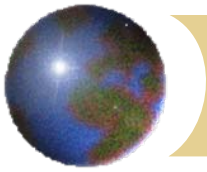
Impact of Globalization of the Pharmaceutical Industry (cont'd)

- Global API production was estimated at \$70 billion in 2008
- China and India account for approximately 60% of this production
- China and India are estimated to account for 80% of global API production within the next 10 to 20 years
- Italy and Spain are also major producers of API, but expectations are that their global percentage will decline



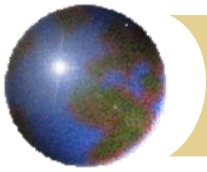
Impact of Globalization of the Pharmaceutical Industry (cont'd)

- 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
- 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



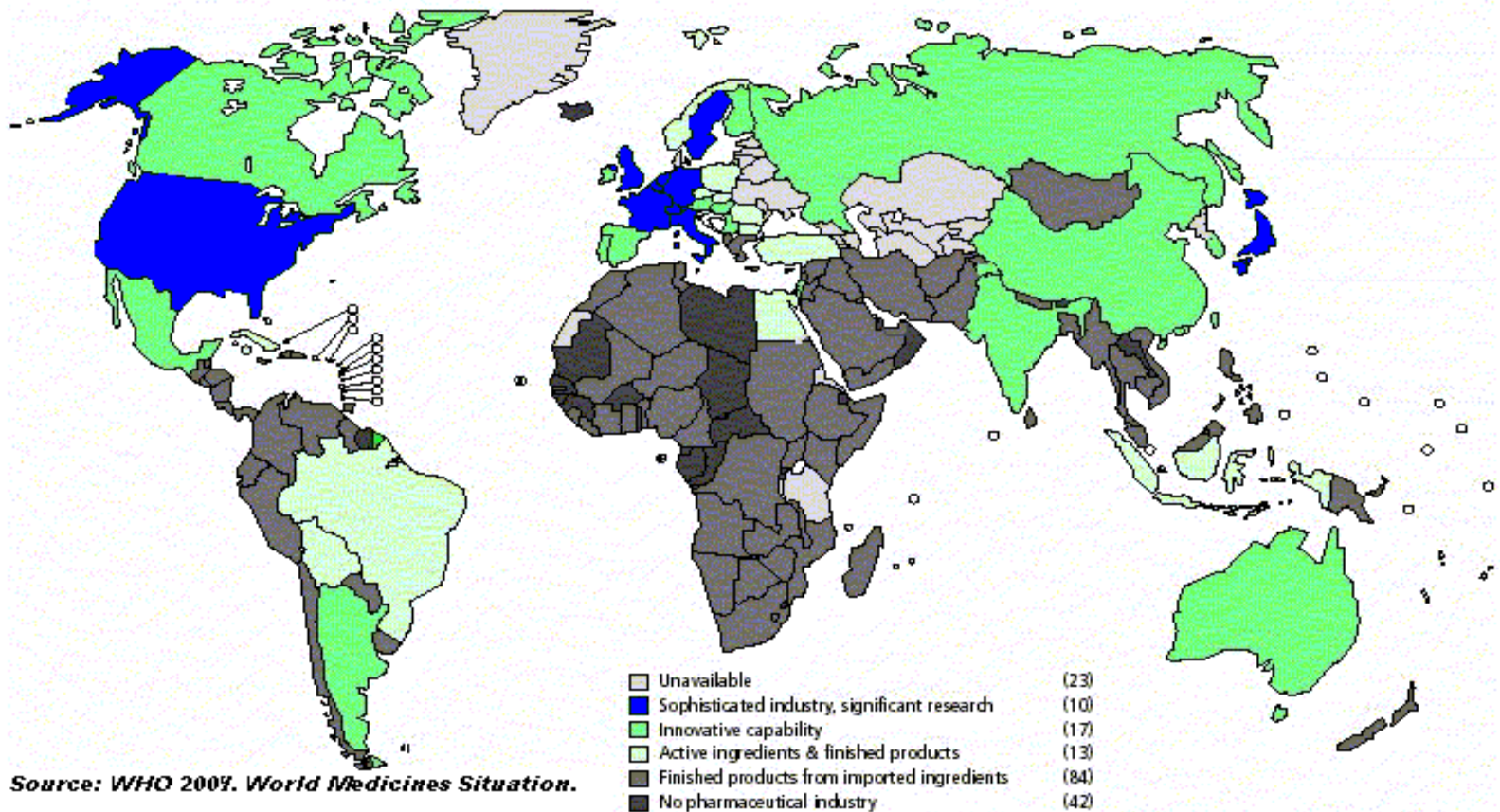
Industry Trends: Generic Production

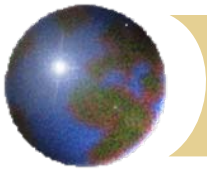
- Generic production is growing at a faster rate than innovator drug production
- Shift in the global production of generic drugs – countries/regions with significant growth of generic production include India, China, South East Asia, Brazil, Middle East, Russia, Mexico
- According to IMS, India is currently producing about 70% of the global generic medicines
- India has roughly 20,000 licensed drug manufacturers and IMS predicted Indian generic industry will grow to \$70 billion by 2008
- With no product patent protection until implementation of TRIPS, Indian drug producers made copies of innovator medicines using alternative production procedures and marketed them throughout the world



Impact of Globalization of the Pharmaceutical Industry

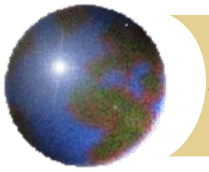
Local pharmaceutical production capacity varies greatly among countries





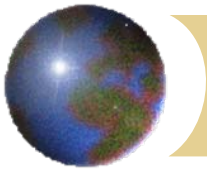
Impact of Globalization on the Pharmaceutical Industry (cont'd)

- As I mentioned earlier, the shift in API and finished dosage form production away from the developed markets contributes to the counterfeit and substandard medicines problem
- The regulatory regimes and standards established by pharmacopeias are much weaker in developing and least developed countries
- With the increase of API production in India and China, and a lack of regulatory enforcement, APIs have become readily available to counterfeiters in various locations around the world



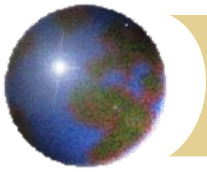
Counterfeit vs. Substandard Drugs

- Notably, there is a significant difference between counterfeit and substandard drugs
- WHO's website defines counterfeit drug as "a drug that is deliberately mislabeled with respect to identity and or source"
- Counterfeit drugs are produced by criminals and meet the "fraudulent and the deliberate" aspects of the WHO definition of counterfeit medicines
- Substandard drugs are made by manufacturers, are registered, and do not meet established standards of safety, quality and efficacy
- Substandard drugs are not included in the WHO website definition of counterfeit drugs



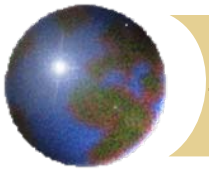
Counterfeit vs. Substandard Drugs (cont'd)

- However, neither counterfeit nor substandard medicines generally meet regulatory requirements such as cGMPs, bioequivalence, or pharmaceutical equivalence
- The public health impact of substandard and counterfeit medicines is the same since both can have correct APIs, wrong APIs, no APIs or less than effective APIs



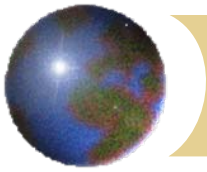
Counterfeit vs. Substandard Drugs

- In our view all counterfeit and substandard medicines have the potential to cause unnecessary harm to patients and are unsafe
- The substandard and counterfeit medicines problem varies significantly among countries and regions
- Countries and regions with weak regulatory oversight are more likely to have a significant amount of substandard and counterfeit medicines on their market



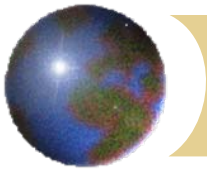
Counterfeit vs. Substandard

- The consequences of the use of counterfeit or substandard medicines is the same:
 - Direct harm to patients
 - Therapeutic failure
 - Weakens public confidence in health system
 - Affects reputation of the supply chain



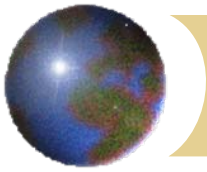
Counterfeit vs. Substandard Drugs (cont'd)

- As I said earlier, there are no reliable statistics to measure global impact of counterfeit and substandard medicines
- There is a need to develop good reliable data on the extent of counterfeit medicines in global markets
- 10-20 years ago most counterfeit medicines had no APIs
- Now an increasing number of counterfeit medicines contain real APIs



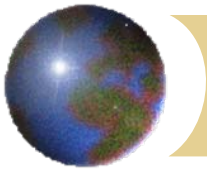
Counterfeit vs. Substandard Drugs (cont'd)

- Developed countries with strong regulatory oversight are estimated to have less than 1-2% of the drug supply as counterfeit. However, 1-2% of the U.S. or EU drug supply is a huge number
- Internet sales of drugs is a huge problem – a recent study cites that 63% of drugs purchased on the Internet are counterfeit and all are illegal
- Much of the world (SE Asia, Africa, China, Latin America) has a high incidence (possibly over 50%) of the drug supply counterfeit or substandard



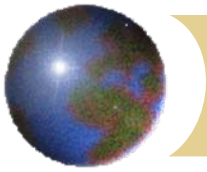
Counterfeit vs. Substandard Drugs (cont'd)

- A US Pharmacopeia 2004 study of counterfeit medicines in SE Asia countries documents that selected drugs tested 25 - 75 substandard or counterfeit
- According to an Indonesian Study, consumers will buy counterfeit consumer goods, such as, handbags and watches, but will not knowingly buy counterfeit medicines



Counterfeit Vs. Substandard Drugs

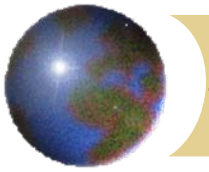
*The most expensive
drug is the one that
does not work!!*



DOC Involvement / Activities

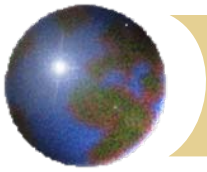
- DOC/FDA led Anti-counterfeiting Task Force
- APEC Life Science Innovation Forum activities, such as anti-counterfeit medical product Asia and Latin America seminars (with USFDA)
- U.S. - China Pharmaceutical and Medical Devices JCCT Subgroup
- US - China Anti-counterfeiting Medicines Seminar (November 2008 and planned November 2009)
- U.S. - India HCTG Biotechnology and Life Sciences Working Group

STOP!: Strategy Targeting Organized Piracy - 1-866-999-HALT or www.Stopfakes.gov



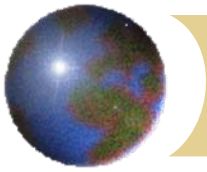
Potential Solutions (cont'd)

- WHO IMPACT initiative (counterfeit)
- “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
- Anti-counterfeiting Trade Agreement (ACTA)



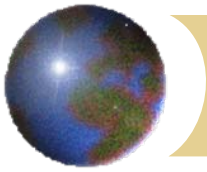
Potential Solutions (cont'd)

- Implementing the action plan and recommendations developed during the APEC Life Science Innovation Forum (LSIF) series of anti-counterfeit medical product seminars
- Major APEC LSIF findings and recommendations include:
 - Conduct a study on the extent of counterfeit medicals in the global market. This will be a difficult study since a key to conducting this study will be an agreement on a common definition of counterfeit medicines and an agreement on the methodology to conduct this study



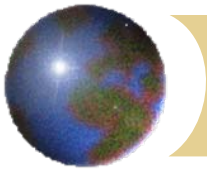
Potential Solutions (cont'd)

- Global cooperation among health regulators, customs, law enforcement and industry is needed to arrest and prosecute counterfeiters and to stop the flow of APIs used in the production of counterfeit medicines
- Establish a single point of contact within each APEC economy to facilitate the exchange of information and cooperation on criminal investigations (this is also a WHO IMPACT recommendation)



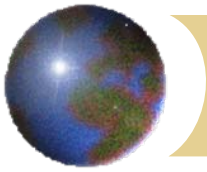
Potential Solutions (cont'd)

- Harmonize the definition of counterfeit medicines within APEC economies
- Develop a strong legal framework within APEC economies to combat counterfeit medical products and to arrest and prosecute counterfeiters
- Enhance medical training by conducting judges on the counterfeit medical products problem
- Conduct training on laboratory detection of counterfeit medicines
- Organize a workshop on the regulation of APIs and the need for global cooperation to stop the availability of APIs to counterfeiters



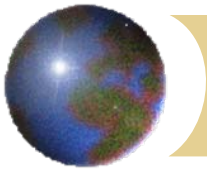
Potential Solutions (cont'd)

- Continue global harmonization efforts, including training and harmonized standards (ICH and country or region specific activities)
- Global cooperation on plant inspections/audits – no one country can do this alone
- Manufacturers need to be responsible for product quality; regulators need to enforce standards, and take action against poor performances
- Continue to focus on regional dialogues – APEC, ASEAN, PAHO, WHO, PANDRA, etc.
- Risk of doing nothing – prevalence of substandard and counterfeit medicines will continue



Summary and Conclusions

- The globalization of the pharmaceutical industry has contributed to an increase in counterfeit and substandard medicines
- The global shift in the production of API and finished dosage form medicines adds to the global problem
- Any meaningful solution requires cooperation among various stakeholders, including customs, regulators, law enforcement, judicial and industry
- Progress is being made, but a focused global approach is needed
- I look forward to the day when we can announce there are less substandard and counterfeit medicines in the world than there were the previous year



Thank You!

Jeffrey Gren, Director

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