The Spreading Plague of Counterfeiting

Harvey Bale

Director General

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

PSF Assembly

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Rising Tide of a Counterfeiting Pandemic

*"The evil of fake medicines is **worse** than the combined scourges of malaria, HIV/AIDS, and armed robbery."*

Dr. Dora Akunyili, Chef

National Agency for Food and Drug Administration and Control of Nigeria

(Reported in ***The Pharmaceutical Journal***, 4 October 2003, p.453)

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Regional Variations

No precise figure for the extent of counterfeit medicines is possible – probably is in the range of 2 percent, but this would *distort* the picture of the problem:

- US, EU, Japan, Canada < 1%
- Russia - 12%
- India - 16%
- SE Asia - 10%
- Latin America – 10 to 30%
- Africa – up to 50%

Definition(s) of Counterfeiting

We are not discussing generic versions of patented medicines legally manufactured: local laws dictate this, consistent with international rules.

(India, Argentina, least-developed countries)

Definition(s) of Counterfeiting

World Health Organization

A counterfeit medicine is one which is deliberately and fraudulently *mislabeled* with respect to *identity and/ or source*.

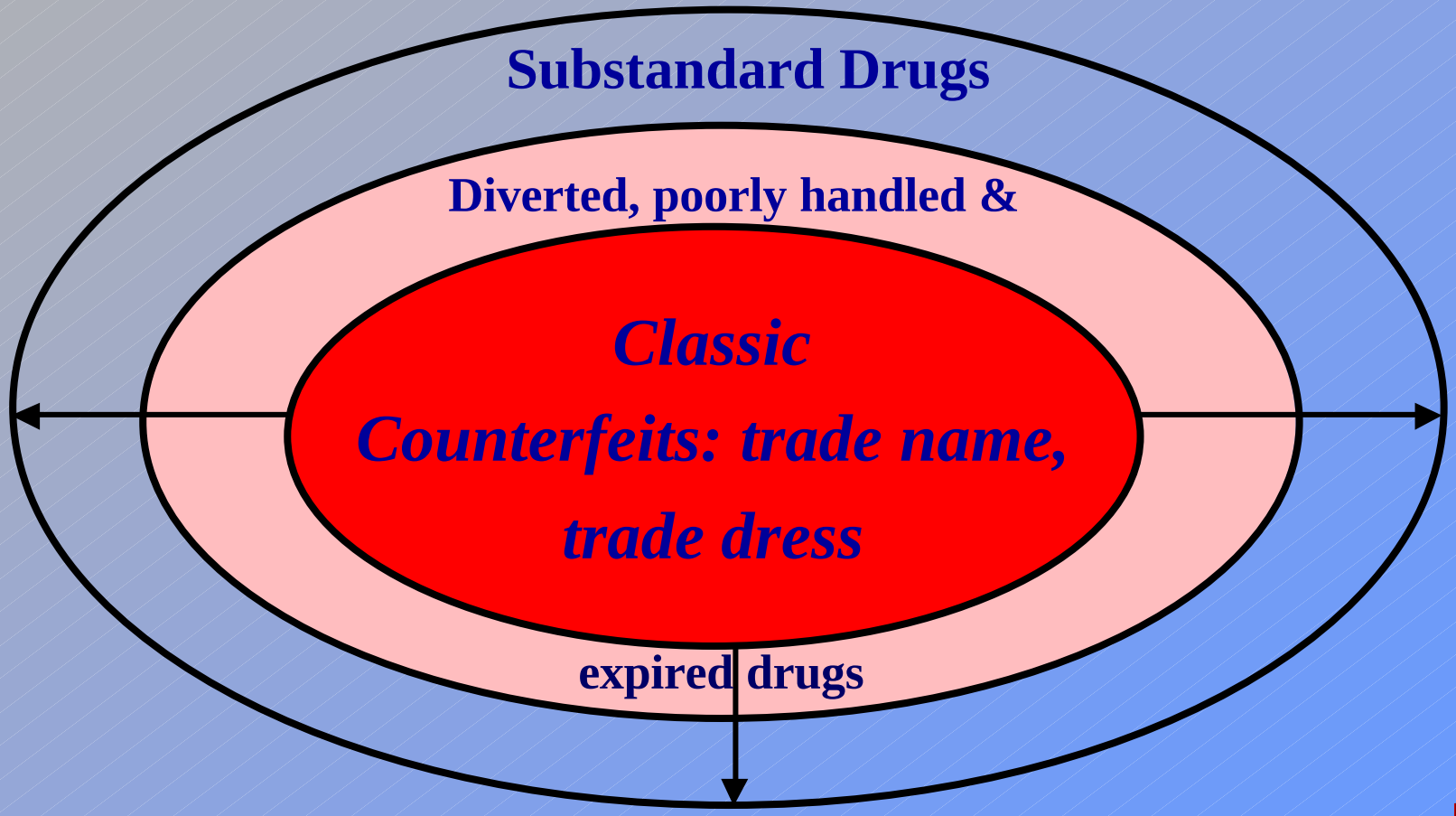
Counterfeiting of medicines can apply to both branded and generic products. Generally, counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with in correct quantities of activities ingredients or with fake packaging

Definition(s) of Counterfeiting

Nigerian Definition is Broader

1. Deceptive clones with same amount of active ingredients
2. Clones with insufficient, different or no active ingredients
3. Expired or soon-to-be expired medicines re-labeled to mask dates
4. Ineffective or toxic herbal medicines
5. Medicines lacking manufacturer's name and address
6. Medicines nor registered with the Nigerian NAFDAC

Substandard, Unregulated and Counterfeit Drugs



Counterfeit Medicines: A Special Case

- For most counterfeit products, the costs to consumers are indirect – I.e., product development
- Not so for medicines – costs are direct and serious – death, disability, resistance to legitimate drugs
- There is a need for far greater awareness of the hazards to health and a far greater political commitment to international cooperation
- Pharmaceutical companies: not only concerned about loss of revenue but also about the damage to patients' and physicians' confidence in legitimate products if ineffective or dangerous copies are in circulation

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Why are Medicines a Target?

Medicines represent one of the most regulated sectors of industrial activity. Why do they attract counterfeiters?

- They are a relation to their bulk and a fake can be made relatively cheaply
- Many countries, especially in the developing world are without adequate regulation and enforcement
- Even in the industrialized countries, the risk of prosecution and penalties for counterfeiting are inadequate
- The way in which medicines reach the consumer is also different from other goods: the end-user has little knowledge of the product – a 'credence' good

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FDA Concerns About Drug Safety (September 2003)

- Of 1,153 imported drug products examined, the overwhelming majority, 1,019 (88%)…contained unapproved drugs. Many of these imported drugs could pose clear safety problems.
- From many countries. For example,15.8% (161) entered the U.S. from Canada; 14.3% (146) from India; 13.8% (141) from Thailand; and 8.0% (82) from the Philippines. The remaining entries came from other countries.
- Drugs: 1) different from those approved by FDA; 2) requiring careful dosing; 3) with inadequate labeling; 4) inappro-priately packaged; 4) with dangerous interactions; 6) that carry risks requiring initial screening and/or periodic patient monitoring; 7) controlled substances; 8) only for animals

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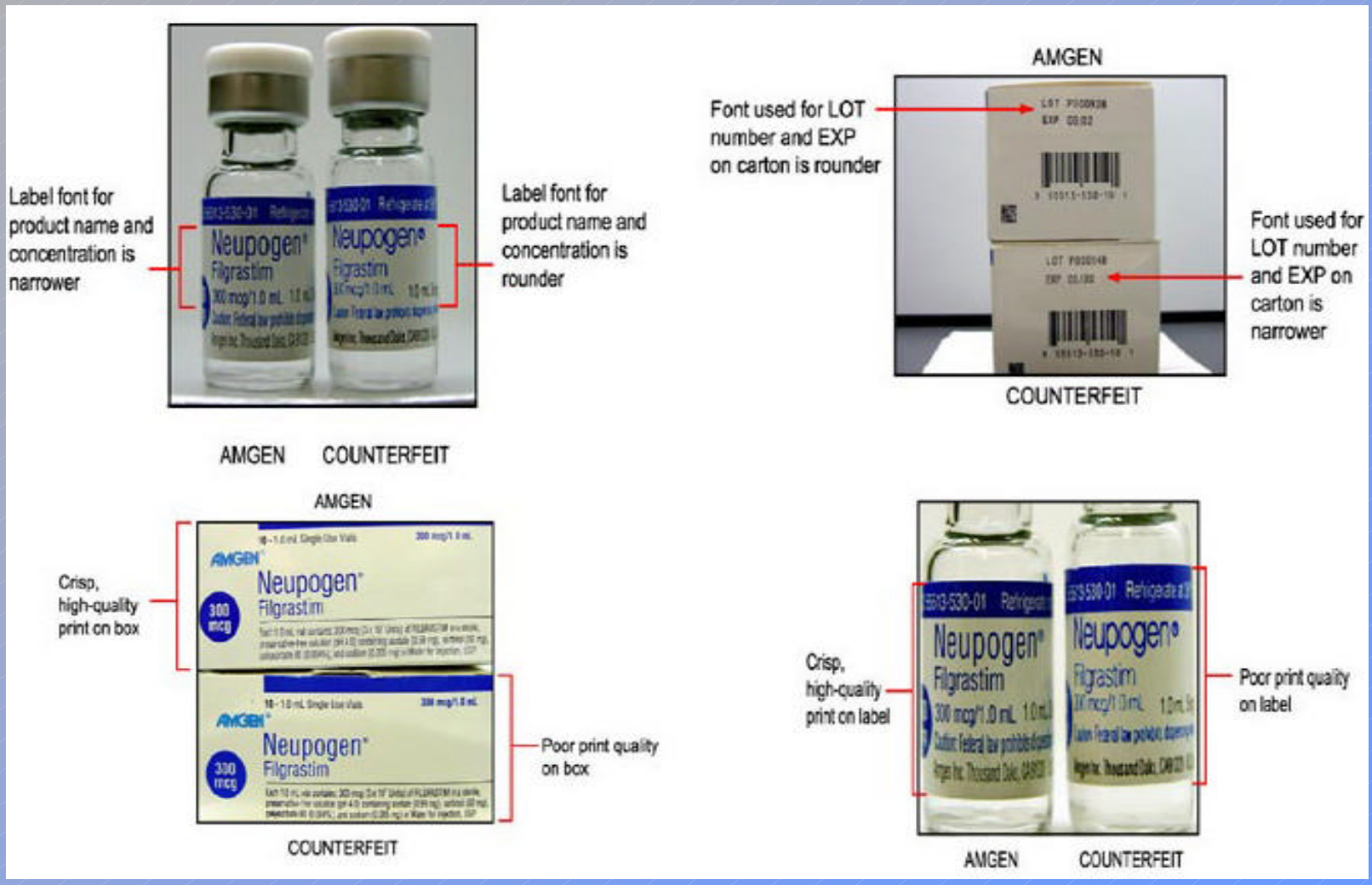
FDA Backgrounder: New FDA Initiative to Combat Counterfeit Drugs -- Attachment



FDA Interim Conclusion: Actions

"As a result of the current blitz, we are re-evaluating the enforcement strategies and objectives we use to target the entry of unapproved and/or counterfeit drug products through international mail facilities."

FDA News 29 September 2003

What is Special About Pharmaceutical Counterfeiting?

- There is no such thing as a "good quality" counterfeit drug
- Developing countries are the worst affected because regulatory structure is weaker; useful generics counterfeited
- Prices vary widely globally, thus counterfeit medical products are often widely (parallel) traded
- Counterfeiting is not just a "brand" issue: i.e., generics are more extensively counterfeited – especially in poor regions

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Factors Behind Counterfeiting

1. Large numbers of producers of poor quality medicines
2. Freer trade – relaxed border controls
3. Long distribution chains; parallel trade; trading of pharmaceuticals by brokers as commodities
4. Economic motive – poverty, and looking for "bargain" products
5. Lax enforcement – low prioritization to counterfeits
6. Loose distribution systems outside pharmacies
7. New element -- the Internet
8. Weak intellectual property protection
9. Not recognized as an international threat

Pharmaceutical Security Institute (PSI)

- Aim is to combat counterfeiting and illegal diversion which result in danger to the patient and damage the image of the Industry as a whole and as individual companies
- Mission:
  - To act as an intelligence center for member companies
  - To establish world-wide investigative programs
  - To work closely with Interpol and WCO
  - To establish and maintain a database of information obtained in collective inquiries into counterfeiting
  - To provide information on illegal activities to governments and international agencies
- Private and limited ability to reach some countries

Why No Collective Global Action???

1. Problem is not recognized as more than a “commercial issue”: association with “branded” products
2. Ignorance about the scope of the problem and its extent in sector of generic products
3. Confusion of counterfeiting issue with patent issues
4. Confusion of counterfeiting with issue in jeans and watches
5. Priority in global monitoring and control by police authorities given over to illegal drugs
6. Refusal of regulatory agencies to admit problem
7. WHO’s disease focus; traditionally, low priority given to quality

What Needs To Be Done?

- Consumer: greater awareness of risks
- Government:
  - Elevate priority and raise penalties
  - Interagency coordination (police, customs, regulatory, postal)
- Industry: pursue counterfeiters with laws in place; use technology to foil counterfeiting; lobby new laws
- Wholesalers: higher standards of association
- Pharmacists: know supply chain
- *Everyone: Work to improve access to quality medicines*

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