Worldwide Landscape of Counterfeit Drugs

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Presented at the 35th Annual Eastern Medicaid Pharmacist Administrators Association (EMPAA)
October 24, 2011
Presentation Topics

- Vulnerability points of the Drug Distribution System
- Relationship of drug diversion and counterfeit medications
- Relationship between drug diversion, counterfeit drugs and importation
- Definitions and examples of overt covert and forensic package marking
- FDA recommendations for serialization and track and trace techniques
- New developments in the pursuit of serialization
- Strategies pharmacists can use to protect against counterfeit medications
Definition of Counterfeit Prescription Drugs

- Counterfeit medication is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.
- Counterfeiting can apply to both brand and generic products.
- Counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with insufficient quantities of active ingredient or with fake packaging.
The counterfeit drug problem is a worldwide problem!

Over 100 countries have reported a problem with counterfeit drugs in 2008.

And it is not just “life style” drugs, 19 out of top selling 25 drugs have been found to be counterfeited across the globe.
Fake drug criminals are well organized. They are driven by greed. Many of the people involved are criminals, felons; many have ties with organized crime, narcotic cartels, and terrorist groups.
Sources of Counterfeit Drugs

- Some counterfeit drugs (ie. Epogen, Procrit, Botox) have been made in the U.S.A. and have illegally entered our drug distribution system.
- Most fake drugs are made outside the U.S., smuggled into the U.S. and then illegally get into the drug distribution system.
- In addition, counterfeit drugs have entered directly into U.S. homes via the foreign and domestic internet pharmacy sites.
Extent of Counterfeit Drugs

- Over 109 countries reported counterfeit medications last year.

- World Health Organization (WHO) estimates that counterfeit drugs comprise 1% to 10% of the world market.

- For developed countries, WHO estimates are less than 1%. For developing countries (African, parts of Asia, and Latin America) counterfeit drugs comprise 30 - 40% of the market. WHO, IMPACT, November 15, 2006, Counterfeit drug update report.

- It has been estimated that fake drugs are $75 billion market.

- However, in June, 2010, the World Customs Organization has estimated it was $200 billion market and for 2007 it has increased 597%.

World Customs Organization, http://www.reuters.com/article/idUSTRE65961U20100610
Many Forms of Fake Drugs

- 32.1% of counterfeit drugs have no active ingredient
- 20.2% have incorrect quantities of active ingredients
- 21.4% have wrong active ingredients
- 15.6% have right active ingredient but fake packaging and
- 8.5% have high levels of impurities or contaminants

Source: World Health Organization
It is estimated about a third of the counterfeit medication found has no active ingredients. The remaining have the wrong active ingredient, too much or too little active ingredient.

Please note that the trend is to put active ingredients in the fake drug. As noted by Jeff Gren of the U.S. Commerce Department:

“What we’re seeing more and more is counterfeit that not only looks like the real product in tablet and packaging, also in real APIs, they have real excipients. Sometimes not the right amounts, sometimes the wrong API…But there is an attempt by counterfeiters to make these products with active ingredient. And what I find scary is, the reason they’re doing this is because they’re looking for repeat business.”

It requires a worldwide, coordinated response. No one country can bring this hideous crime under control. It requires both private and international governmental efforts. It requires added resources, defining the roles of each fighting component, technical expertise, and coordinated strategies working with law and regulatory agencies worldwide.
Countries Either Producing or Have Problems with Fake Drugs

- China
- India—it is estimated at 10 to 20%
- Brazil
- Mexico (10% to 12%)
- Pakistan
- Indonesia (25%)
- Russia can be up to 20% depending on republic
- Cambodia (13%)
- Columbia (5%)
- Belize
- Nigeria (70%)
- Southeast Asia Countries (10 to 40%)

Pharmaceutical Security Institute

- PSM is a major source for information on counterfeit drugs.

- The Pharmaceutical Security Institute is a not-for-profit, membership organization dedicated to:
  - Protecting the Public Health
  - Sharing Information on the Counterfeiting of Pharmaceuticals
  - Initiating Enforcement Actions through the Appropriate Authorities

- PSM was formed in 2002 by 14 Security Directors of pharmaceutical companies. It currently has 24 members from many different countries.

- Offices in Washington DC, Hong Kong and London.

- Website: http://www.psi-inc.org/index.cfm
Role of PSM

- Collects and consolidates information on drug counterfeiting, major drug thefts (greater than $100,000) anywhere in the drug distribution chain, and prescription drug diversion.

- Drug diversion is when a legitimate drug product is illegally diverted and sold in another country. Or, it may be legitimated drug products purchased by a government agency for use in a state hospital but are illegally diverted to another market.
The PSI Counterfeiting Incident System (CIS) is used to record incidents of counterfeiting, theft and illegal diversion of pharmaceutical products worldwide. CIS incidents come from a variety of sources, including open media reports, PSI member company submissions, and public-private sector partnerships.
Drug Diversion

- Drug diversion is when the authentic or legitimate drug product gets out of the legal drug distribution system. The product is sold illegally.

- The product can be diverted to other legal distributors, other illegal diverters and ultimately to consumers.

- The product could be diverted between countries (donated drug in one country sold to another).

- Drug diversion is commonly referred to as the “gray market.”
Number of incidents includes counterfeit, illegally diverted or stolen drugs.


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- The 2,003 incidents involved 808 different pharmaceuticals.
- Most frequent therapeutic categories were:
  - Genito-urinary
  - Anti-infectives
  - Cardiovascular
  - Central Nervous System
- The vast majority of counterfeit products involved both fake product with fake packaging.
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A steamroller destroys fake medicine in Suqian, in East China's Jiangsu province.
Source: Rediff Business “China Selling Fake ‘Made in India’ Drugs,” June 18, 2009

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9 tons of fake medicine seized in East Africa

Authorities have seized 9,072 kilograms (20,000 pounds) of counterfeit medicine and arrested 80 people suspected of illegal trafficking in six East African nations, Interpol said Thursday. The confiscated loot included anti-malaria drugs, vaccines and antibiotics. There was also a significant quantity of government medicines diverted to illegal resale markets.

Women sells smuggled, counterfeit medicine in June 2007 at a market in Abidjan, Ivory Coast.

CNN World News, CNN.com, August 26, 2010
Counterfeit Drugs Reported by Dosage Form

- Tablets & Capsules: 87%
- Injectibles: 10%
- Other: 3%

## Top Ten Countries Reporting Drug Counterfeiting Incidents in 2007

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Counterfeiting Incidents</th>
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<tbody>
<tr>
<td>China</td>
<td>395</td>
</tr>
<tr>
<td>India</td>
<td>130</td>
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<tr>
<td>Peru</td>
<td>107</td>
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<td>Russia</td>
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<td>South Korea</td>
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<td>United States</td>
<td>63</td>
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<tr>
<td>Brazil</td>
<td>60</td>
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<tr>
<td>Colombia</td>
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</table>

Fake drug manufacturer in Columbia

Fake drug manufacturer in China

Storage of fake drugs in Mombassa

Source: American Chemical Society, *Central Science*

http://cenblog.org/2010/01/fake-medicine/  Jan 2010
A wide variety of counterfeit drugs have been found in the U.S. and represent many therapeutic categories. Here's a partial listing.
Trend in Number of FDA Counterfeiter Drug Cases 1997-2010


- www.fda.gov/oc/speeches/2006/rfid0301.html
- Partnership for Safe Medicines, “US Fake Medicines Increase Year over Year”
It is important to realize that in many cases, prescription drug diversion, counterfeit drugs and drug importation are linked together. Diverters get greedy and realize that profits can increase by distributing fake products.
Drug Sources for Gray Market Diverters

- Counterfeit Drugs
- Special priced drugs from closed pharmacies, hospitals, physician offices
- "Buy-Back" drugs from street buyers - Medicaid and Medicare Patients
- Repackaged Foreign Drugs
- Legitimate Drugs
- Stolen Drugs
- Drugs intended for export to charitable foreign missions

"Gray Market" Drug Distributors

Drug Sources for Diversion or the Gray Market
Increase in Cargo Thefts

Warehouse and cargo thefts have increased dramatically. The top five thefts 2009-2010 are:

- Eli Lilly Warehouse-$76M
- Eli Lilly Truck-$37M
- Teva Truck $11.8M
- Novo Nordisk Truck $11M
- Astellas Truck $10M

Pharmaceutical cargo theft represents 16.5% of all cargo thefts, but ranks the highest on the average dollar amount per theft--$1.5M.

Just in September, 2010 there were three major cargo thefts: Daytona, Florida, Dandridge, Tennessee, and Chicago, Illinois.


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Drug Diversion Schemes
Involving Consumers

- Consumers have sold their medications back either to pharmacies, to secondary wholesalers or to an diverting agent who will divert the pharmaceutical product. Networks of Medicaid patients have been discovered selling medications. One Florida patient was making $5,000 a month selling Medicaid drugs he obtained.

- Physicians have also been implicated in such fraud schemes and networks.

- Products are diverted to the “gray” or to the “black” market.

- Sometimes consumers trade the products for other contraband.
Other Diversion Schemes

- Returned drugs back to wholesalers, especially expired or damaged drugs from hospitals, community pharmacies back to wholesalers have been known to have been diverted and relabeled.

- Drugs for long-term care facilities which have been discontinued or the patient has expired have been known to be diverted to community pharmacies and wholesalers.
Example of One Trade Route for Counterfeit Drugs

Tracing a Trade Route
The authorities say that drugs sold by a Canadian online pharmacy, RxNorth, did not originate in Canada, but were made in China and shipped to the United States along a complex intercontinental trade route.

1. Drugs from an unknown manufacturer on the Chinese mainland were trucked to Hong Kong.
2. From Hong Kong, the drugs were shipped to a free trade zone in the emirate of Sharjah.
3. From the United Arab Emirates, the drugs were flown to London Heathrow Airport.
4. The drugs were shipped to the Bahamas, where pharmacists filled the individual orders.
5. The packaged drugs were sent back to Britain, then mailed to buyers in the United States.

Sources: Drug company investigators and British law-enforcement officials

Facilitation of Counterfeit Drug Products

- Price differentials create drug diversion within and between distribution channels.
- Weak regulatory control and enforcement.
- Scarcity and/or erratic supply of medications.
- Extended and unregulated markets and distribution channels in both developed and under-developed countries.
- Lack of effective intellectual property protection.
Many countries do not have the people nor the legal processes which companies can use for remedial action against counterfeiters.

Weak penalties for convicted counterfeiters.
Drug diversion and the gray market opportunities within the U.S. provide the conduit for the entry of fake drugs into the drug distribution system.

Criminals, felons, narcotic cartels and terrorist organizations have been involved with fake pharmaceutical production and distribution.

Health care practitioners, including pharmacists and physicians have been involved in drug diversion schemes and counterfeiting.

Thefts from manufacturers, shippers, wholesalers, pharmacies, hospitals and clinical sites have been used to obtain drugs for diversion.
Sources of Counterfeit Products

- Counterfeiters can be small “garage operations” to large international firms including consortia operations.
- Counterfeiters have also been identified in counterfeiting a variety of products: perfumes, cosmetics, alcohol and tobacco.
- Wide spread corruption including bribery, threats to politicians, law officials, regulators and health care practitioners.
The Counterfeiter
The story of how one of pharma’s biggest enemies was nabbed in Houston, Texas

By Brendan Borrell

...Now, he thought he finally had an entrée to the US market. His contact, going under the name “Mr. Ed,” was a bald, middle-aged man with a sketchy background in the clothing business. Ed ran a company based in Houston, Texas called Tri State Distributors. Back in March, Xu and his wife, Jennifer, met Ed at the Starbucks in the Bangkok airport. Xu promised he could deliver orders of 100,000 pills if Ed gave him time to prepare. One month after that meeting, Xu shipped $5720 worth of drug samples, including 130 boxes of Zyprexa, the Eli Lilly drug for bipolar disorder, to Tri State’s headquarters in a bleak office park a short drive from George Bush Intercontinental Airport.

Source: The Scientist, Vol 24, Issue 2, Page 26, February 2010
Xu's fake 10-mg Aricept tablets (left) alongside authentic tablets (right). In addition to containing a substandard formulation, the fake tablets were slightly wider than normal, darker yellow in color, and had a dull film coat.

...some 40 distributors had handled Xu’s products, and 70,000 packages were recalled, although at least 30,000 made it into the hands of patients.

In the end, Xu was convicted, and given the maximum sentence of 6 years in prison. In January, he was shipped out to Big Spring, Texas where he is waiting for an appeal and serving out his sentence. He was also ordered to pay $1.3 million restitution to Pfizer and Eli Lilly.
How do diverted or counterfeit products enter our drug distribution system?

A variety of methods and drug diversion schemes are employed!
Pharmaceutical Manufacturer

Counterfeiters

Stolen Products Could be compromised

Foreign Country

Repackagers

Parallel Trade

Importers

Relabeled Foreign Drugs

Relabeled Foreign Drugs

Big Three Wholesalers

Big Three Wholesalers

Secondary Wholesaler

Some proclaim this does not happen.

Gray Market Distributors

Diverters

Diverters

Relabeled Foreign Drugs

Sell Rx Drugs

Pharmacies

Pharmacies

Consumers

Consumers

Online Purchase

Foreign Web Site Pharmacies

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Pharmacies

Foreign Web Site Pharmacies

Pharmacies

Consumers

Consumers

Authentic Drug

Counterfeit Drug

Unknown-- Questionable
Possible Risk Areas for the Introduction of Counterfeit Drugs

Suppliers
- Supply of raw materials, excipients, Active pharmaceutical ingredients (API) packaging

Manufacturer
- Drug (API) Formulation Dosage form production

Warehousing & Distribution
- Wholesale with Multi-Level Secondary Wholesalers

Consumer Drug Acquisition Sites
- Pharmacies
- Retail
- Hospital
- Internet sites
- Long-term care
- Physician clinics
- Hospice sites
- Retail outlets for OTCs

Drug counterfeits
- Product Diversion
- Theft/Diversion
- Fraudulent Labeling
- Label Switching
- Illegal Repackaging
- Cutting legitimate product with counterfeits

Substitution (counterfeit), Contamination, Alduterated Disguise, Deceptive Labeling

Consumer
- Sells drug to “gray” market

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Foreign Internet Pharmacies as a Source of Counterfeit Products
One major source of counterfeit and substandard medications is from rogue and foreign web sites. With more and more people using home computers to purchase pharmaceuticals from a foreign vendor, the risk of receiving a counterfeit or substandard drug is very high.

NABP Issues Rogue Online Drug Outlet Public Health Alert

August 04, 2011 03:53 PM | Topics: Internet Pharmacy

New Report Shows 85% of Fake Online Drug Outlets Don’t Require Valid Prescription, Fuel Prescription Drug Abuse

NABP has issued a public health alert to warn Americans about the serious dangers associated with medicines purchased through fake online pharmacies. NABP’s report on Internet drug outlets found that 96% of 8,000 rogue Web sites analyzed continue to operate out of compliance with United States pharmacy laws, fuel prescription drug abuse and misuse, and provide an outlet for counterfeit medicines to enter the US drug supply – all of which significantly endanger the health and safety of Americans. More information about this alert is available in an NABP news release. The NABP “Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2011” (PDF) may be downloaded from the NABP Web site.

FDA has determined that imported products may

- Contain no active ingredient, too little or too much active ingredient
- Be expired or have a false expiration date
- Be contaminated
- Have been stored at the wrong temperature or under unsafe conditions
- Be a fake, counterfeit product
- Be fraudulently or inadequately labeled
- Be product which was withdrawn from the U.S. market
- Be animal drugs not approved for human use
- Be inappropriately packaged.
The following is a copy of a “flyer” I received from a pharmacy web site located in Mississauga, Ontario, Canada. The brochure is from Globalpharmacycanada.com

Looks like a legitimate pharmacy, however, the pharmacy is NOT licensed in Ontario. It is basically a mailing address. They send prescription information to a pharmacy in India for filling. The brochures states “send us or fax a copy of the original prescription or you can send a copy/picture of the pill bottle label or send us your detailed pharmacy receipt/invoice.”
The following are “generic medications” available. The drugs are listed by brand name. Out of the 86 products listed, 55 products are under patent protection. Some examples include:

- Actos®
- Altace®
- Avodart®
- Aricept®
- Cialis®
- Crestor®
- Cymbalta®
- Diovan®
- Levitra®
- Lipitor®
- Lotrel®
- Tricor®
- Viagra®
- Vyroin®
- Zetia®
OTTAWA - Health Canada is informing Canadians about the potential dangers of buying prescription drugs online from www.globalpharmacycanada.com. The company responsible for the website recently removed Canadian access to it, but Canadians may have purchased from this website in the past.

Products sold at www.globalpharmacycanada.com have not been authorized for sale by Health Canada and Global Pharmacy Canada is not a licensed pharmacy in Canada. Canadians who have used any products purchased at www.globalpharmacycanada.com, or are concerned about their health, should consult with their healthcare practitioner.
Extent of Drug Importation

- At a U.S. House Congressional open hearing (June 24, 2003), Rep. Greenwood reported that 30,000 drug packages arrive each day at the Miami international mail facility.

- Over 10,000 parcels arrive daily at the Carson City mail facility here in California.

- 40,000 parcels arrive daily at the JFK airport.

Each package contained chewable sildenafil (Viagra).
Many parcels contain more than one drug.
It is unknown the quantity of prescription drugs being imported annually. Estimates run as low as 2 million packages to 20 million per year. Officials at one facility reported 3,300 packages containing prescription drugs in one week, whereas another facility was receiving 4,300 drug packages a day. The average package has approximately 2.5 prescription drugs. (Source: GAO Report-05-372 Prescription Drugs, September 2005)
Teddy bears stuffed with counterfeit Viagra being shipped to a carpet cleaning business in Ohio.
What is troubling is that the vast majority of the pharmaceutical products coming into the U.S. from foreign pharmacies are NOT FDA approved. Many are substandard products and mislabeled. Some are drug counterfeits.

Threat of Counterfeit Pharmaceuticals

CAUTION: MEDICINE MAY BE FAKE

WARNING: MAY BE EXPIRED, WATERED DOWNED OR MISLabeled

DIRECTIONS: TAKE WITH HEALTHY DOSE OF SKEPTISM
Often times the counterfeit product is mixed with legitimate products to confuse investigators. The counterfeit Lipitor found in the U.S. was mixed with authentic product.

- Makes it difficult to determine the extent of counterfeiting.
Lipitor® (atorvastatin calcium)

Which one is the counterfeit Lipitor®?

Source: Pfizer Inc.
Lipitor® (atorvastatin calcium)
Which one is the counterfeit Lipitor®?

FAKE

AUTHENTIC

Source: Pfizer Inc.
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Celebrex® (celecoxib)

Which one is the fake Celebrex®?

Source: Pfizer Inc.
Celebrex® (celecoxib)

Which one is the fake?

COUNTERFEIT

AUTHENTIC

Source: Pfizer Inc.

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Ponstan is an anti-inflammatory product. This counterfeit was found in Columbia. First is the yellow powder; it consists of boric acid, floor wax, yellow highway paint. Pressed into tablets and placed in foil packs with labeling.

Source: Pharmaceutical Manufacturer Research Association

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Viagra® (sildenafil)
Which one is the fake drug?
Authentic Ortho Evra Contraceptive Patch and packaging

Counterfeit Patch—no active ingredient
Counterfeit Alli

On January 18, 2010, FDA warned consumers about a counterfeit and potentially harmful counterfeit version of Alli 60mg capsules. Alli is a weight loss product made by GlaxoSmithKline. The fake product had the wrong active ingredient, it contained sibutramine. The authentic product has orlistat. Sibutramine can have dangerous interactions with other medications.
FDA states that there is no “silver bullet” to counter counterfeit drugs. The “best strategy is to use multiple, periodically changing authentication measures on a product specific basis accounting for the risk of the product being counterfeited.”

Source: *FDA Combating Counterfeit Drugs Report*, February 2004
Authenticity Technology

- FDA is recommending at least two types of anti-counterfeiting technologies into the packaging and labeling. At least one method must be a covert method—not made public and requiring special scanners.
- Taggant, a chemical marker within the product is also recommended.
Authentication Techniques

- **Overt Package Markings**
  - Can be seen with a human eye.
  - Polychromatic, color shifting security inks. Can be seen by the eye, open to the public.
  - Other overt methods are holograms, raised printing. They can be difficult for counterfeiters to copy.

Holograms are now being used in combinations with other covert and forensic methods.
Example of Overt Marking: Color Shifting Ink

New genuine Viagra packaging with color-shift logo
The holograms for authentic Guilin, artesunate blister package is top left. The other three are holograms from fake products. The last hologram lower right corner was very close to the authentic.

Sometimes overt methods are combined with seals and tamper proof container tops that can also change colors or produce tamper-apparent patterns if broken.
Authentication Methods

- Covert Markers
  - Cannot be seen with the eye, usually requires a special instrument or scanner. Examples include micro wires, magnetic threads, invisible inks, hidden computer chips, “Nano-encryption.
  - For obvious reasons, secrets are not usually available to pharmacists.
Example of a “Revealable” Covert Ink

Chemically reactive markers within the ink are revealed using appropriate developing reagents. Fixed or variable information can be applied using conventional printing equipment.

Source: Authentix Corporation.

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Authentication Techniques

- Forensic Markers
  - Forensic markers are covert markers.
  - Require special analysis of the product.
  - A special taggant marker (chemical marker) can be added to the product by the manufacturer. This marker can be easily detected.
  - FDA has an approved list of taggants.
  - Taggants can also be added to the packaging, labeling and tablet coatings.
Example of Forensic Marker: Nano-encryption

Nano-encryption can contain unlimited information supporting authentication and tracing from plant to patient.

Source: NANO GUARDIAN™
Other Techniques

- **Unit of Use Packaging**
  - Needs further investigation-Europe is using unit-use-packaging, but still has problems with fake medications.
  - Provides for overt and covert codes on each package. But this is only one layer in fighting drug counterfeits.
  - Can provide tamper evident packaging
    - Use of seals, magnetic readable tapes and seals
Product Serialization

The foundation of a high quality, reliable system is that each product have a unique serial number. That is, each bottle, package, or container of medication has a unique “license plate” number. Product serialization is the foundation of “track and trace” and authentication systems. It can be used with either bar codes or Radio Frequency Identification Systems (RFID).

Note: Lot numbers are not serialized numbers.
In March of 2007, the Obama Administration’s Inter-agency Working Group on counterfeit pharmaceuticals made many recommendations. One was that Congress adopt a track-and-trace system for pharmaceuticals and related products.
FDA Proposed Guidance
Securing the Drug Supply Chain

- The numbering system is a standardized, numerical identifier (SNI) using a serialized national Drug Code (sNDC).
- SNDC is composed of the NDC combined with a 8-digit serial number generated by the manufacturer or repackager for EACH individual package. No compliance date was set.
Proposed FDA Serialized NDC Number

NDC (national drug code)  
5555  666  77  
Serial Number  
+ 11111111

This is a unique “license plate” number for each package. Manufacturers can include a lot number or an expiration date in the code, however, the SNI must be present.

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FDA does not specify a particular means on incorporating SNIs onto the package. They want the system to be compatible and flexible for encoding into a variety of machine readable forms—s-dimension bar codes, RFID. FDA expects the SNI to be human readable and machine readable.

NOTE: the SNI is compatible with global standards (GS1).
Countries Leading the Way

- Europeans are ahead of U.S. in putting implementing serialization and labeling packaging. However, each country has a different coding process.
- Turkey has lead the way.
- German and France have passed legislation. France is requiring 2-D bar codes by 2011.
- Brazil has been aggressive with passage of serialization laws in 2009 requiring serialization by 2012.
- In the U.S., California is the only state that has track and trace deadline of 2015 with serialization on every package.
I-D Bar Codes

- I-D (One-Dimensional) Bar Codes are commonly used. They normally hold 14 digits of information, thus are very limited in their information capabilities. I-D is NOT a good option for sNDC.

- I-D codes are very popular. They are CHEAP to provide, less than a penny to produce.
2-D Bar Codes can contain hundreds of characters of information. They can include the serialized number, NDC code, lot number, and expiration date. Serialized numbers can be long so that they can differentiate multiple packages of the same product.

Bar codes must be scanned into a database.
Limitations Bar Codes

- The major limitation is that each item needs to be scanned. A “line of sight” is required. This requires added personnel time and work in the pharmacy and throughout the distribution system.
- In other words, bar coding has high end-user costs.
- Another limitation is that bar codes can be copied and placed on other containers thus counterfeiting is not detected not deterred.
- They can get dirty, marked on, torn or have moisture damage which may cause readability problems.
Radio Frequency Identification

- RFID uses a small computer chip embedded in the packaging
  - The chip sends identification code chips to a central data base so drugs can be “tracked and traced” throughout the distribution system. In other words, you can follow the “drug pedigree.”
  - PLEASE NOTE: This also can be done by bar codes.
Examples of Radio Frequency Radio Tags
RFID Tags

Some firms are embedding the chip within the container.
Electronic Track and Trace

- More effective than today’s paper pedigree system.
- One advantage of RFID over bar code screening is that no line-of-sight is needed. The distance to read a RFID depends on the strength of the signal and transponders.
- In theory, you can have a full box of different drugs come into the pharmacy from the wholesaler and your system will be able to read all the RFID tags upon arrival. You can check authenticity at that point.
How the RFID System works.

Basically, the RFID reader sends out a signal asking “who are you?”

The radio waves from the reader carry minute amounts of electrical power which give power to the tag. The RFID tag (passive tag) responds and says, “I am product ABC from XYZ company.”

These “passive tags” act as small computers (printed circuits) and do not require a battery.

PC receives message from reader and links to a database.
Testing or Using RFID

Many companies are moving toward RFID
- Pfizer
- Johnson and Johnson
- Purdue
- Walmart
- Department of Defense
- Many others

Firms that have tested RFID
- Albertsons
- Walmart
- Walgreens
- CVS
- Rite Aid
- Cardinal Health
- McKesson
- J&J
- Proctor Gamble
- Pfizer
Effective Patient Strategies

- Know your Pharmacy! Deal only with trustworthy reputable pharmacies.
- Be careful of the “Good Deal.” If it appears to be too good to be true, you may have a problem. Be very careful, especially if it is from a new source. Due diligence is needed to check on suppliers.
- Be careful of fax and email deals you receive daily.
Effective Patient Strategies

If you are buying from an online pharmacy, look for the VIPPS designation seal on the site. VIPPS stand for Verified Internet Pharmacy Provider Site. The National Association of Boards of Pharmacy issues the accreditation seal. There are currently 29 approved VIPPS sites in the U.S.
Identifying Suspect Advertising
Sales Offers

- The ad offers a generic form of the product when there is no generic product approved by the FDA. — In other words, they offer a generic drug when no generic product should be on the market.
- The ad has misspellings of ingredients or misspells the brand name. This usually indicate foreign language spelling.
- The firm does NOT have a dedicated “land line” telephone line or number.
Identifying Suspect Advertising Sales Offers

- The ad does not list an address.
- The ad states that they are located outside the U.S. or list a foreign phone number.
- Promises product availability, especially in times when there is product shortage.
- The vendor does not hold a state pharmacy license. All pharmacies which supply drugs to Texas residents must have a license with the Texas State Board of Pharmacy.
- Verification Web site: http://www.tsbp.state.tx.us/dbsearch/phy_search.asp
Identifying Suspect Drug Packages

- A single drug product has multiple lot numbers.
- Packages look worn, torn, faded—just do not look like new products.
- Labels are faded especially near the expiration date.
- Product packaging is missing overt marking such as a color shifting markings, raised printing or holograms.
Identifying Suspect Products

- Tablet or capsule colors and size are different when compared to authentic products.
- The product has a different taste or feel.
- Product comes in a different dosage form or different strength than approved by FDA.
- You notice a difference or lack of effect of the drug.
Identifying Suspect Labels

- Trade marks look different—colors or size are not the same.
- Labels or package inserts have misspellings.
- Font size and color do not match existing products.
- Labels are not written in English.
- Can see extra glue or tacky residue around the label.
- Label states “not for resale,” “sample” or “for physician use only.”
Effective Strategies

- Look for signs of a removed label.
  - Look for a tacky adhesive residue on or near the label. When labels are removed and replaced with a counterfeit label there may be an adhesive residue on the bottle.
  - Look for a discolored label. The solvent used to remove existing print may discolor the label.
Effective Pharmacist Strategies

- Listen to patients—most drug counterfeits are caught by patients
  - Listen for complaints or differences in taste, feel or adverse effects associated with the drug product (i.e. pain at injection site, difference in taste).
  - Listen to see if the patient is progressing well or has the patient’s progress declined.
- Look for changes in lab/test values, a worsening in the patient may be due to an ineffective, fake medication.
The Partnership for Safe Medicines (PSM) is a nonprofit organization dedicated to combating counterfeit drugs. It consists of over 50 consumer groups/associations. The website is: Safemedicines.org

PSM has a variety of documents on how to protect yourself from counterfeit drugs.

http://www.safemedicines.org/resources/PSM-Consumer-Resources.pdf
U.S. has one of the safest drug distribution systems in the world.

Maintaining drug integrity is a worldwide problem. It requires that we all work together.

Maintaining drug integrity is a worldwide problem. The U.S. is a target for counterfeiters and substandard drug producers because the demand for CHEAP drugs will not go away.
Remember: Fake drugs are not the same as fake handbags and DVDs. Fake handbags and DVDs don’t kill people, fake drugs can kill people.
It is my honor to be with you today. Thanks so much for the invite.

As my dad would say.

“I haven’t had this much fun with my boots on in a long time.”

Thanks

Marv Shepherd