Counterfeit Drugs
A tough pill to swallow

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Authentix
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Authentix Overview

Global Leader in Authentication
- Healthcare and Life Sciences
- Oil and Gas
- Consumer Goods (Spirits, Tobacco, Luxury goods)
- Excise Tax Recovery (National Governments)
- Military and Government Security Applications
- Fortune 500 customer base across 5 continents

Facilities (NASPO and ISO Certified)
- Global Headquarters - Dallas, TX
- European Headquarters - York, UK
- Business Development and Tech Apps - Mumbai & Delhi India
- Business Development and Tech Apps - Capetown, RSA

Staff
- Science and Engineering Skill Sets
- Industry Subject Matter Expertise
- Approx. 120 employees

*Providing security to over $50 billion worth of commercial healthcare products*
Brand Protection - Now a Strategic Issue

- Globalization of trade
- Availability of advanced technologies
- Global marketing reach via the Internet
- Highly profitable - low penalties
- Organized crime heavily involved
Trade in illegitimate goods represents estimated 5-7% of all worldwide trade.

Counterfeit Drug Problem
How Pervasive are Counterfeit Drugs?

Center for Medicine in the Public Interest estimates:\n• Worldwide counterfeit drug sales rising 13% annually
• Nearly 2x the pace of legitimate drugs
• Fake drugs are approaching a $75 billion industry

Law enforcement ability to detect and prosecute hindered by:\n• Shortage of financial resources
• Lack of coordination between countries
• Weak anti-counterfeiting laws in some regions

1. The Center for Medicine in the Public Interest is a non-partisan, non-profit educational charity (cmi.org)
2. Source – National Association of Board of Pharmacy (www.dangerouspill.com)
Counterfeit Medicines are Priority for FDA

Other Counterfeit Products
- FDA warns about counterfeit ExtenZe dietary supplements
- FDA Issues Warning on Counterfeit Surgical Mesh
- FDA Updates Its Nationwide Alert on Counterfeit One Touch Blood Glucose Test Strips

Consumer Information
- The Possible Dangers of Buying Medicines over the Internet
- Questions and Answers about Counterfeit Drugs
- Counterfeit Medicine: Educational Materials
- Technology Protecting the Drug Supply (RFID)
- FDA 101: Health Fraud Awareness
- Buying and Using Medicine Safely

Guidance Documents and Reports
- FDA Guidance on Standards Development for Prescription Drug Supply Chain Security
- FDA Draft Guidance for Industry on Anticounterfeiting (PDF - 79KB)
- FDA Counterfeit Drug Task Force Reports

Other Government Resources
- Centers for Disease Control: Counterfeit Drugs and Travel
- U.S. Customs and Border Protection: Restrictions on Prescription Drugs
- Federal Trade Commission: Buying Prescription Drugs Online
- Drug Enforcement Administration: Buying Prescription Drugs Online

Information in different file formats, see Instructions for Downloading

Counterfeit Medicine

Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. Counterfeit drugs are illegal and may be harmful to your health.

FDA takes all reports of suspect counterfeits seriously and, in order to combat counterfeit medicines, is working with other agencies and the private sector to help protect the nation’s drug supply from the threat of counterfeits.

News and Events
- Speech by Commissioner Hamburg on Counterfeit Medicine (PDF - 90KB)
- Unapproved emergency birth control medicine possibly in U.S. distribution may be ineffective and unsafe
- FDA Warns About Fraudulent Tamiflu
- FDA Warns Consumers about Counterfeit Alli
- Internet Pharmacy Sold Counterfeit Viagra, Misbranded Drugs
- Belgian Citizen Sentenced for Selling Counterfeit, Misbranded Drugs
- Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug
- Two Arrested for Illegally Trafficking Counterfeit Weight Loss Medication

More News and Events

Spotlight
- Reporting a Counterfeit Drug
- Criminal Investigations
- Speech by FDA Commissioner Hamburg on Counterfeit Medicine (PDF - 90KB)
- Counterfeit Alert Network

Do You Know?
- What can I do to help ensure I do not receive or take counterfeit medicine?
- What should I do if I believe I have received or taken counterfeit medicine?
- How to Protect Yourself

Contact Us
- Human Drug Information
  - (888) 463-6332
  - (301) 756-3400
druginfo@fda.hhs.gov
- Division of Drug Information (CDER)
- Office of Communications
Counterfeit drugs found in legitimate supply chains

1. Pfizer Counterfeit Pharmaceutical Brochure (www.pfizer.com)
Counterfeit Procrit

Information provided by PHRMA
Counterfeit Viagra found in California retail pharmacies during summer 2004

Information provided by PHRMA
Counterfeit Viagra

Teddy bears stuffed with counterfeit Viagra being shipped to a carpet cleaning business in Ohio.

Information provided by PHRMA
Counterfeit Ponstan (Columbia)

Ponstan is an anti-inflammatory.

This powder consisted of boric acid, floor wax and yellow leaded highway paint.

*Information provided by PHRMA*
Counterfeit Operations

This shows the conditions in which the counterfeit Panadol example was found to be made.

Many counterfeiting operations around the world make their products under similar conditions.

Information provided by PHRMA
Counterfeit Ethicon Prolene Mesh (wound repair)
Counterfeit Ortho Evra (Contraceptive patches)

Authentic

Fake - no active ingredient
Counterfeit OneTouch® Test Strip Alert

LifeScan, Inc. has discovered incidents of counterfeit OneTouch® Test Strips in various countries around the world. Counterfeit product is fake product not made by LifeScan. Use of these counterfeit test strips could result in inaccurate test results that may lead to improper treatment.

If you determine you have counterfeit test strips, you should immediately discontinue their use and replace them. You should also contact your physician to assess potential treatment implications and report your discovery immediately to LifeScan.

For detailed information regarding known counterfeit test strips in a specific country, select the appropriate country link. We recommend you periodically visit this Web page or bookmark www.GenuineOneTouch.com for important Counterfeit Product Alerts or future updates.

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<tr>
<th>Country/Region</th>
<th>Details</th>
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<tr>
<td>China</td>
<td>警告 OneTouch® tester型血糖試紙、请注意辨别真伪 -- 2007.8.28</td>
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<td>Hells (Greece)</td>
<td>Εντοπισμός αλλεπαραγωγής στην Ελλάδα - Δεκέμβριος 18, 2006</td>
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<td>Saudi Arabia</td>
<td>Counterfeit OneTouch® Basic®/Profile® Test Strips Discovered in Saudi Arabia and Dubai -- May 15, 2007</td>
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<td>Turkey</td>
<td>Türkiye' de Tespit Edilen Sahaya OneTouch® Ultra® ve OneTouch® Basic®/Profile® Test Strips -- Mar, 2007</td>
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<td>Counterfeit OneTouch® Ultra® and OneTouch® Basic®/Profile® Test Strips Discovered in Turkey -- March, 2007</td>
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<td>United Arab Emirates</td>
<td>Counterfeit OneTouch® Basic®/Profile® Test Strips Discovered in Saudi Arabia and Dubai -- May 15, 2007</td>
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<td>United States</td>
<td>Counterfeit OneTouch® Test Strips (for OneTouch® Basic®/Profile®) Discovered in U.S. -- UPDATED December 18, 2006</td>
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Counterfeiters have no concern for the patient

News & Events
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FDA NEWS RELEASE
For Immediate Release: Jan. 7, 2011
Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA warns public of continued extortion scam by FDA impersonators

The U.S. Food and Drug Administration is warning the public about criminals posing as FDA special agents and other law enforcement personnel as part of a continued international extortion scam.

The criminals call the victims -- who in most cases previously purchased drugs over the Internet or via "telepharmacies" -- and identify themselves as FDA special agents or other law enforcement officials. The criminals inform the victims that purchasing drugs over the Internet or the telephone is illegal, and that law enforcement action will be pursued unless a fine or fee ranging from $100 to $250,000 is paid. Victims often also have fraudulent transactions placed against their credit cards.
Another type of Counterfeit
Counterfeiters making product improvements!

Viagra as low as £1.28
Generic Viagra, containing Sildenafil Citrate, enables many men with erectile dysfunction to achieve or sustain an erect penis for sexual activity. Since becoming available Viagra has been the prime treatment for erectile dysfunction.

Clialis as low as £1.21
Clialis is a highly effective orally administered drug for treating erectile dysfunction, more commonly known as impotence. Recommended for use as needed, Clialis can also be used as a daily medication.

Clialis + Viagra Powerpack special price
Clialis + Viagra Powerpack is a powerful combination of drugs used for treating erectile dysfunction, more commonly known as impotence. Since becoming available, both Clialis and Viagra have been the prime treatment for erectile dysfunction. Effective and quick-acting, Clialis and Viagra provide restored and enhanced ability for sexual intercourse.

Viagra Super Active+ as low as £1.93
Viagra Super Active represents the fourth generation of phosphodiesterase inhibitors. This new formulation of a world-known medication provides even more powerful penis blood circulation, increased stamina and sensitivity to stimulation.

Levitra as low as £1.73
Levitra is a new FDA-approved oral prescription medication for the treatment of erectile dysfunction (ED) in men.

Sora as low as £0.73
Sora is a skeletal muscle relaxant that relaxes muscles and relieves pain and discomfort caused by strains, sprains, spasms or other muscle injuries. It works by blocking pain messages sent to the brain.

Viagra Super Force as low as £3.44
Viagra Super Force is a new combination product containing well-known sildenafil (the active ingredient in Viagra) and recently developed dapoxetine, the first oral medication to be approved for the treatment of premature ejaculation. The efficacy of both components as well as their combination has been proven in placebo-controlled clinical studies.

Clialis Super Active+ as low as £2.30
Clialis Super Active has answered our high expectations in its ability to treat and cure the widespread disease of erectile dysfunction by super-active formulation that gives the pill the shortest activation time and the most prolonged time of action. The drug provides a long-lasting erection, restoring and enhancing sexual activity in men.

Clialis Soft Tabs as low as £1.73
Just like regular Clialis but specially formulated, these pills are soft and dissolvable under the tongue. The effect of this is more direct absorption into the bloodstream, rather than through the stomach. Result - a powerful, lasting effect of being able to achieve and maintain an erection up to 36 hours.

Clialis Professional as low as £3.20
Clialis Professional is an orally administered drug used to treat male erectile dysfunction (impotence). It quickly helps to achieve and maintain proper erection in case of erectile dysfunction in men and restore sexual activity.

Viagra Soft Tabs as low as £1.39
Viagra Soft Tabs are mint flavored soft tablets for the treatment of male erectile dysfunction. They are equivalent to regular Viagra, however due to their soft formulation, they are absorbed directly into the bloodstream.
Programs Available to Combat Counterfeits
Strategic Approach to Product Security

Package design features (microtext, die cuts, etc.)

Optically variable features

Marker in Visible Inks on Packaging or Product

Invisible printing
- on the carton
- on the blister pack foil

Unique Serialized code for item-level tracking

Marker in drug substance, tablet coating or in/on capsule

Marker in Closures
- Carton card
- Blister foil lacquer

Strategic Approach to Product Security
<table>
<thead>
<tr>
<th>Depth of Security</th>
<th>Technologies</th>
<th>Inspection Levels</th>
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</table>
| Overt             | Color Shifting Ink  
                   | Holograms & Micro lens arrays  
                   | Thermochromic Inks | Field Visual |
| Covert            | Pen revealable marker | Field Disposable |
| Covert            | Laser Authentication | Field Instrument |
| Covert            | Spectral Fingerprint A | Field Instrument |
| Forensic          | Spectral Fingerprint B | Laboratory Analysis |
| Forensic          | Molecular Markers  
                   | - stable isotope  
                   | - binding pair | Laboratory Analysis |
| Traceability/  
    Serialization | Overt/Covert Item-level Serialization | 2-D Scans at Change of Custody Points |
Human Hand

Skin

White blood cell

DNA

Proteins

Atoms

Quantum Photonic

Molecular Recognition

Stable Isotope
Protecting the Product and Package

**Overt Package Authentication Features**

Optically Variable Inks (OVI), Polarizing Optically Variable Ink, Thermochromic Inks and Holographic features

**In-Product Dosage Authentication**

- Markers are simple organic GRAS compounds used at trace levels (ppm to ppb)
- Field detection is based on immuno-assay and offers extremely high sensitivity, specificity, and accuracy

**Tamper Evident Labels & Closure Seals**

Covert/Thermal transfer printed variable data, transparent holographic or colorshift features with leave behind void pattern or die cuts

**Through the Cap Authentication**

Protecting Injectable Products
Reader authenticates presence of security print on the aluminum crimp beneath the plastic flip top
Serialization/Authentication

- Mass serialization is coming…
- As digital verification becomes more routine, more exceptions will be flagged in the supply chain (quarantined, set aside, etc.)
- How will the exceptions be investigated and dispositioned?
  - rapid
  - fieldable
  - definitive

Importance of physical authentication will increase as digital verification becomes routine
Comprehensive Authentication Traceability System (CATS)

CATS is a fully integrated beginning-to-end product oversight system for asset protection and risk management that provides:

- complete visibility into upstream & downstream supply chains,
- links all transactions during product life cycle in near real time
- helps maintain supply chain integrity,
- manages risk for brand owners

by combining item-level serialization, authentication, and traceability in a single offering.

CATS is SAP & EPC Global certified & has the ability to be deployed and implemented quickly and incrementally.
CATS Program Overview

Data Store
Data transfer at each transaction point in supply chain

Manufacturing
Create Unique Product IDs
Apply IDs to individual items
Apply Authentication features
Aggregate data
Verify & validate data
QA & process control
Data exchange with ERP

Warehousing
Shipping & Receiving
Data exchange with Data Store
Verify & validate data
Manage returns & recalls

Distribution
Shipping & Receiving
Reaggregate data, if items are re-packaged
Manage returns & recalls
Data exchange with Data Store
Verify authentication features in printing ink

Retail Inspection
Sampling & Field monitoring
Verify authentication features in printing ink
Data Exchange with Data Store

Consumer
Verification through SMS/Text

Field inspectors authenticate product via handheld device
Consumers validate product via smartphone

Products re-packaged and data re-aggregated

Unique Product ID applied
Guidance for Industry
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
July 2009
CMC
Examples of various government initiatives

• US pursuing e-pedigree system with unit level ID
• Europe pursuing “bookend” system with unit level ID
• Turkey pursuing system with Gov’t database and unit level ID
• Malaysia has implemented Meditag system
• Healthcare reimbursement fraud
  – Italy - Bollini, France - EAN13, Portugal - Code 39, Belgium EAN128
• Other regions developing other systems (e.g. Brasil, Korea …. )
What can consumer do to avoid counterfeit medicines?

- Purchase prescription medicines from reputable pharmacy
- For on-line purchases only use sites certified by NABP\(^1\)
- Don’t buy from on-line pharmacies that are unlicensed
- Don’t buy from sources that offer to write prescription or sell without prescription
- If price of medicine seems too good to be true… be suspicious

1. NABP – National Association of Boards of Pharmacy ([www.nabp.net](http://www.nabp.net)). Only use sites listed as ‘Verified Internet Pharmacy Practice Sites (VIPPS) program’
What can consumer do to detect counterfeit medicines?

• It is often difficult to detect fakes because technology to copy products is widely available

• Buy from known sources and be vigilant
  – different reaction after taking drug
  – different taste
  – different odor
  – different color
  – different texture

Identifying a Counterfeit

The counterfeit tablet (far left) had a pinkish tinge and a rougher surface texture than the authentic. The debossing was poorly rendered, particularly “Pfizer,” and in a narrower font. The counterfeit contained little, or none, of Norvasc’s active pharmaceutical ingredient.
Case Studies
Product Protection Program Case Study

• Issues
  – Counterfeit copies of a major pharmaceutical brand were discovered in the US market.
  – No security measures in place
  – Patient welfare and the manufacturer's reputation were under threat
  – $1 billion of authentic product in the distribution pipeline could not be sold

• Solution
  – Product was repackaged to include authentication features that could be identified by patients and inspectors, both in the field & laboratory.
  These included:
    – Overt, Covert, Forensic
    – The solution applied to packaging, labels and other components
  – Solution developed & approved by the client and FDA within 3 weeks

• Outcome
  – Secure means of distinguishing authentic from counterfeit
  – Confidence restored in the brand amongst physicians, pharmacists and patients
  – Mitigation of lawsuit risk
  – $1 billion of product frozen within supply chain was released for sale
  – Full product recall was averted.
Tamper Evident Security Label Case Study

• **Issues**
  – Multiple products requiring authentication in high risk territory
  – Significant amount of unauthorized distribution
  – Compatibility with other corporate security programs
  – High corruption levels in region

• **Solution**
  – Late stage customization to add security in region post production
  – Tamper evident security labels with covert and forensic features
  – Labels supplied to high risk territory to Authentix secure print facility
  – Labels printed with region specific information to meet local regulations

• **Outcome**
  – Secure means of ensuring product authenticity in high risk region
  – Compliance with regional regulations
  – Supply chain control maintained through successful raids and seizures
  – Now expanding into other product categories
API Marking – Case Study

• Issues
  – Active ingredient sold for formulation into tablets and capsules
  – Formulators and distributors violating supply agreements and patents by using API from unauthorized sources

• Solution
  – Use proprietary trace marker in API
    • Marker - Inactive Ingredient, FDA GRAS status
    • Regulatory - Short term stability data generated
    • Rational sampling program instituted
    • Routine monitoring program in place

• Outcome
  – All formulated product using original API contains mark and can be authenticated
  – Brand owner is able to monitor and control the manufacturing and distribution chain
  – Infringers identified, confronted, and successfully prosecuted
Summary

• Counterfeit drugs are a significant and growing threat
• Internet provides an uncontrolled outlet for fake drugs
• Any drug could be a target
• Manufacturers are taking steps to confront the threat
• Governments are working to address the threat
• Consumers need to be aware and vigilant