

PAINWEEK[®]

Is that Medicine Real or Counterfeit?

Jay Joshi, MD

Disclosure

- Nothing to disclose

Learning Objectives

- Review the origin of counterfeit medications
- Describe various anticounterfeiting technologies
- Explain professional responsibility in reducing counterfeiting

World Health Organization

- A counterfeit 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 incorrect quantities of active ingredients or with fake packaging

Counterfeit Market



POSTED: 07/10/15, 9:41 AM EDT

UPDATED: 3 WEEKS, 1 DAY AGO

COMMENTS

An emotional Farid Fata admitted a “quest for power” that was “senseless and destructive” moments before being sentenced to 45 years in prison in a Medicare fraud case in which cancer patients received treatment that they either did not need or would not benefit from.



“This is a huge, horrific series of criminal acts that were committed” by Fata, 50, of Oakland Township, U.S.

District Judge Paul Borman said. “This is horrific. It’s unprecedented to think in terms of the amount of unnecessary medical treatments.”

Borman noted that the Rochester-based doctor provided 2,770 unnecessary chemotherapy treatments to 100 patients, according to a medical expert’s review of those patients’ medical files. Both sides agreed that more than 550 people were victims.

“It’s true that this is an unusually large in terms of the amount of fraud and also terribly significant with regard to not just the infusions and injections and tests but to the physical injuries suffered by the victims in receiving the treatments,” Borman said.

JULY 16, 2015, 7:21 PM

The University of Maryland's Baltimore Washington Medical Center is sending letters to about 250 spinal fusion patients who received hardware from a defunct California company accused of selling fake parts.

The Glen Burnie hospital is continuing to investigate whether any counterfeit parts were used in patients and sent the letters to "address any concerns." Officials said they've found no evidence yet its patients were affected.

A number of hospitals across the country, including Baltimore Washington Medical Center, have been sued by health insurers alleging the hospitals used the fake parts and overbilled for them. The suit also named one of the hospital's spinal surgeons, Dr. Randy Davis. Local law firms are also investigating and reaching out to patients.

“
Shadowy product makers are trying to worm their way into the supply chains.

”

- James Quiggle, spokesman for the Coalition Against Insurance Fraud



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The parts in question were distributed by a company called Spinal Solutions LLC, which was cited in 2012 by the U.S. Food and Drug Administration for quality control problems. The following year, the company recalled parts used in lower spine fusions, specifically saying that some had been distributed in Maryland.

In announcing the recall, the FDA said inadequacies in the parts "might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

One local lawyer questioned why the recall didn't prompt hospitals that used the hardware to investigate earlier and notify patients there was a possibility that counterfeit hardware had been implanted.

Lawsuit alleges fake spinal parts used by doctors and hospitals nationwide

Thousands of spinal surgery patients may have had knock-off screws, cages and rods implanted, a new lawsuit alleges

May 28, 2015 11:00PM ET

by [Karen Foshay](#) - [@karenfoshay](#)

LOS ANGELES – Fifteen surgeons and 17 hospitals nationwide along with more than a dozen other people, are accused of participating in a counterfeit spinal-hardware ring that resulted in patients receiving non-FDA approved implants, according to a civil complaint obtained by America Tonight.

The document, which was filed in February in California on behalf of dozens of insurance companies, was unsealed Thursday and details a massive alleged health care fraud scheme and conspiracy involving the use and billing of fake surgical hardware to hospitals and doctors across the country.

According to the filing, owners and operators of California-based Spinal Solutions, LLC, manufactured faked spinal implants and “insidiously co-mingled fake implantable hardware with genuine” parts. The fake parts were then implanted in patients at hospitals in California, Texas, Maryland, Wisconsin and Nevada, according to the complaint.

Production of the counterfeit rods and cages began in 2007 at a machine and tool shop in Temecula, California, according to the complaint. It’s alleged the defendants – doctors, hospitals and distributors – began a five-year relationship with Spinal Solutions to market the fake parts.

Convicted neurosurgeon accused in counterfeit implant scheme

By Cary Spivak

June 3, 2015

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Just six months after completing his federal prison sentence, onetime neurosurgeon [Cully White](#) is back in court — this time as a defendant in a newly unsealed California whistle-blower suit alleging a massive medical scheme involving kickbacks and counterfeit implants.

The suit, which also names Aurora St. Luke's Medical Center and Wheaton Franciscan Healthcare's St. Francis Hospital, charges that White, once one of the busiest spine surgeons in the Milwaukee area, took kickbacks in return for putting counterfeit parts in patients. The parts were manufactured by a California machine and tool shop and sold by Spinal Solutions LLC, a defunct California company that had been owned by Roger Williams, the suit charges.

"The counterfeit spinal hardware was delivered to defendant White in Wisconsin by defendant Williams' private aircraft, and flight logs confirm that these deliveries originated in California," alleges the suit, which names about a dozen hospitals and 16 doctors nationwide as defendants. "White then performed his end of the contract by implanting the counterfeit hardware into unsuspecting patients at St. Francis Hospital and Aurora St. Luke's Medical Center."

White "introduced the bogus products" to St. Francis and Aurora St. Luke's, where he once had privileges, the suit charges. The action charges all of the hospitals named as defendants with failing to properly vet their surgeons and the suppliers of implants.

The suit was filed by about 50 insurance companies, including three in Wisconsin, and makes similar allegations against doctors and hospitals nationwide. The suit says they were involved in "a massive health care fraud scheme and conspiracy" that involved charging patients and their insurance companies full price for counterfeit implants.

Who Provides “Pain Management”

- Physician specialties involved with pain treatment include:
 - Anesthesiology
 - Emergency medicine
 - General surgery
 - Interventional pain management/anesthesiology
 - Oncology
 - Neurology
 - Neurosurgery
 - Orthopedics
 - Physiatry
 - Psychiatry
 - Primary care/internal medicine/hospitalists
 - Radiology
 - Rheumatology
 - Trauma surgery

Other Providers

- In addition to physicians, pain management services can be provided by:
 - Chiropractors
 - CRNAs
 - Nurse practitioners
 - Physical assistants
 - Physical therapists
 - Massage therapists
 - Acupuncturists
 - Holistic/homeopathic “doctors”
 - DME providers
 - Hospice and home health providers

Case Study

- A 55-year-old man came into the office for his monthly prescription. He has been on a fixed dose of gabapentin and his pain has been relatively well controlled. However, last month, his pain was much higher and he was having side effect from his medication. Which of the following is true?
 - a) Random coincidence
 - b) He is allergic to gabapentin
 - c) He was given a different manufacturer of gabapentin
 - d) He is a drug seeker

Counterfeit Market



An example of a makeshift factory in China penetrating our USA supply chain

“Counterfeit”

- A counterfeit is:
 - An unauthorized copy;
 - Not conforming to the original manufacturer’s design, model, and/or performance standards;
 - Not produced by the stated manufacturer or produced by unauthorized contractors;
 - An off-specification, defective, or used product sold as “new” or working; or
 - Has incorrect or false markings and/or documentation

The Market

- Up to 7% of all goods traded on the global market are counterfeit
- >\$1 trillion lost each year to counterfeiting and diversion
- Approximately \$3 billion is estimated to be spent in 2014 on brand protection solutions
- Anticounterfeiting packaging market is >\$40 billion

Industry Stats (2012)

- Auto parts – \$3.8B counterfeit parts in US, \$12B globally
- Electrical parts – \$15B, 2nd largest counterfeit market
- Personal care products – >\$4B US counterfeit market
- Pharmaceutical – >\$430B worldwide counterfeit sales
- Med device – >8% of the med devices in circulation are counterfeit
- Aerospace & defense – >520,000 counterfeit parts US
- Wines & spirits – 5% of wine sold on the secondary market is counterfeit

Causes of Counterfeiting

- There is a lot of money to be made
- Lifestyle medicines are wanted
- Equipment is widely available
- Distribution is now easy, eg, Internet and postal delivery
- Patients are self-prescribing
- Weak legislation and enforcement
- Organized crime has moved in

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

Types of Medicinal Product Affected by Counterfeiting

- High volume (high level of prescribing)
- High price
- Known brand
- “Lifestyle”/nonreimbursed
- Blockbusters
- Parenteral (in developing world)
- All generics
- Off-label use drugs
- Drugs in short supply

No Active Ingredients

■ 1995

— Niger – Fake meningitis vaccine led to 3,000 deaths

■ 1998

— Uganda – 60% of all malaria deaths attributed to fake quinine sulphate

■ 2000

— Cambodia – 30 people died after taking fake malaria drugs being sold as mefloquine or artesunate

Toxic Ingredients

- 1990

- Nigeria – 109 children die after taking a fake preparation containing diethylene glycol

- 1992

- Bangladesh – paracetamol preparation containing diethylene glycol believed to have killed hundreds of children

- 1995

- Haiti – 30 children die after taking medicines containing diethylene glycol

- 1998

- India – 30 infant deaths (diethylene glycol)

- 2006

- China – 11 people died from an antibiotic that was not properly sterilized

Counterfeit Medicines: A Special Case

- For most counterfeit products, the costs to consumers are indirect – ie, product development
- 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

Pharmaceutical Counterfeiting

- There is no such thing as a “good quality” counterfeit drug
- Developing countries are affected the worst 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: ie, generics are more extensively counterfeited – especially in poor regions

Former SFDA chief executed for corruption

(Agencies/chinadaily.com.cn)

Updated: 2007-07-10 12:51

China's former drug and food safety watchdog chief was executed on Tuesday after being found guilty of corruption and dereliction of duty, Xinhua news agency said.



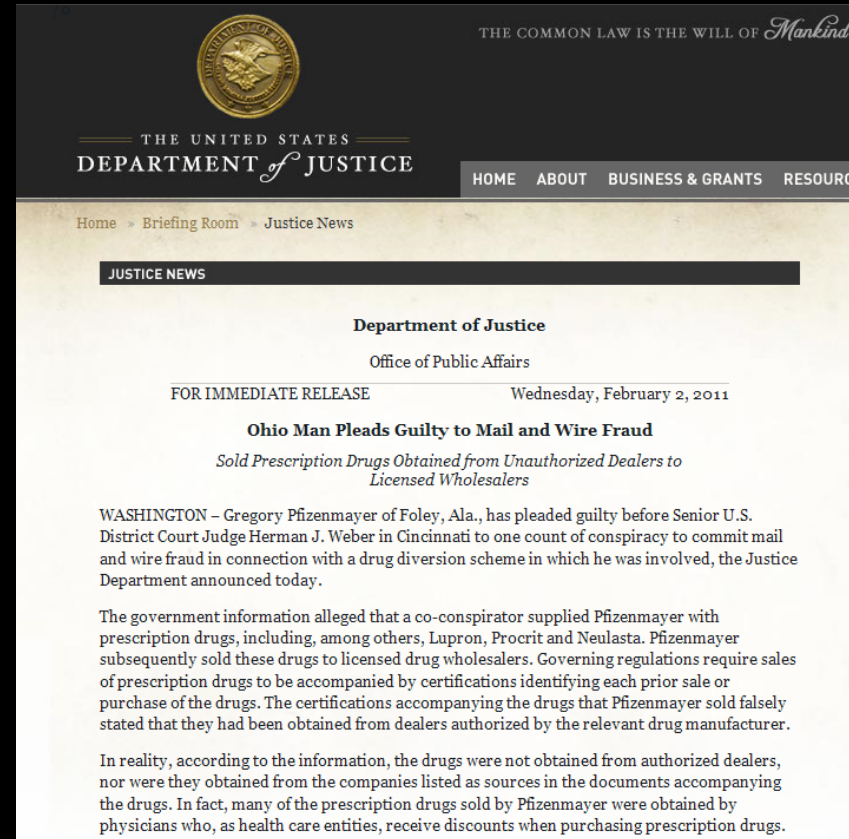
Zheng Xiaoyu (centre), head of China's State Food and Drug Administration from 1998 to 2005, reacts to his death sentence at the Supreme People's Court in Beijing.

 [Click for more news photos...](#)

The Supreme People's Court approved the death sentence against Zheng Xiaoyu, 62, who was convicted of taking bribes worth some 6.5 million yuan (\$850,000) from eight companies.

Diverted Drugs

- The sale of drugs outside of the distribution channels for which they were originally intended
- Can originate domestically or internationally
- Counterfeiting is usually associated with a diversion scheme



Reselling of Rx drugs obtained by doctors

Doctor to pay \$2M, pleads guilty to dispensing foreign cancer drugs

April 2, 2015 | By Eric Palmer

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Reprint

The FDA has rolled up yet another doctor in its campaign to punish practitioners who knowingly bought unapproved foreign drugs on the cheap, taking the risk of giving patients ineffective or even counterfeit medications, which some of them ended up doing.

Robert L. Carter, 74, an oncologist who ran a clinic in Joplin, MO, pleaded guilty this week to buying and selling misbranded prescription drugs. Carter also paid about \$972,000 in restitution today to Medicare, Tri-Care, Medicaid programs, which he charged for the drugs, and has agreed to forfeit \$1.2 million. He also faces up to a year in federal prison and a fine of up to \$100,000.

According to the FDA, for a couple of years beginning in 2010 Carter bought prescription cancer drugs from Quality Specialty Products (QSP) in Winnipeg, Manitoba, Canada, drugs that QSP obtained from foreign sources and so were not approved for use in the U.S. Some of the drugs included mixing instructions in languages other than English.

QSP is one of the companies that has been at the heart of a shipments of foreign-made drugs being used in the U.S. The FDA in 2012 warned 350 physician practices that foreign versions of Botox they had bought from QSP might be counterfeit. QSP is a company tied to Kris Thorkelson, the owner of the internet pharmacy operation CanadaDrugs.com. Companies he controlled were also tied to a shipments of Altuzan, which is the the brand name for the version of Roche's (SRHHBY) cancer drug Avastin made in Turkey. Tests of those drugs found that they contained no active ingredients.



Doc goes to jail for lying about foreign-sourced Botox

FDA cracks down on physicians buying foreign drugs on the cheap

February 27, 2014 | By Eric Palmer

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Reprint

One tactic of U.S. authorities in fighting the onslaught of illegally imported and sometimes counterfeit drugs is to prosecute doctors who bought them knowing they came from outside the legitimate supply chain. A Missouri doctor whose practice, The Youthful Body, bought a foreign version of Allergan's (\$AGN) Botox to get a deal is now going to jail for just that.

The 41-year-old Dr. Erick Falconer was sentenced to 5 months in prison and 5 months of home confinement for lying to federal agents about his purchases of Botox that arrived in packages with labels in a foreign language. According to the FDA, Falconer made 50 purchases of the drug after getting a faxed ad with an 800 telephone number and a Gmail account for contacting the seller. The Botox was offered at a steep discount, selling for \$354.99 a vial, compared to the \$525 it usually costs. When agents questioned Falconer in February 2013, he told them he had made only three purchases of the foreign-made drugs.

The FDA and other federal authorities have stepped up efforts since counterfeits of Roche's (\$RHHBY) Avastin were first uncovered in the U.S. in 2012, but fakes continue to be found slipping into the drug supply. Two men from Turkey were indicted last month on charges related to that case. In December, the co-owner of Arlington, VA-based Gallant Pharma International pleaded guilty to a host of charges related to buying and selling misbranded and unapproved drugs to doctors in the U.S., including a foreign version of Botox.

Internet – Illegitimate Drug Sellers

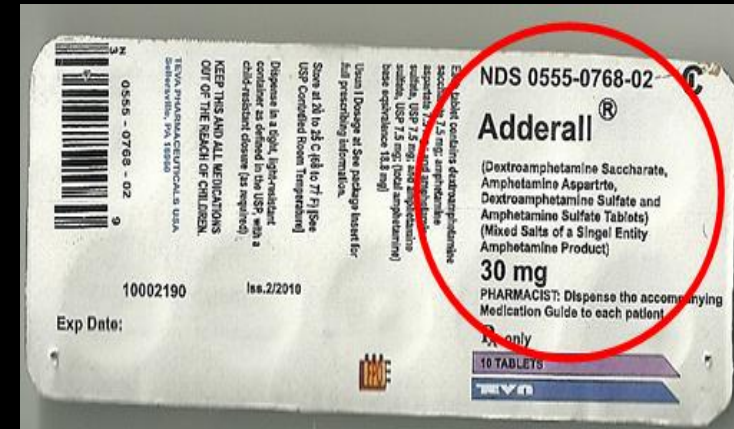
- Problems with current “buying online” practices
 - High volume
 - Vast scope
 - Unknown origin
- Drug quality concerns
 - Lack of “sameness”
 - Counterfeits or not FDA-approved
 - Potentially confusing names
- Websites
 - Misleading (fake online pharmacies, counterfeit products, false health claims)
- How patients can buy drugs online safely (www.fda.gov/buyonline)

Recent Counterfeit Drugs

- Counterfeit Adderall
- Counterfeit Avastin
- Counterfeit Altuzan



Counterfeit



Counterfeit

Drugs

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Home > Drugs > Drug Safety and Availability > Postmarket Drug Safety Information for Patients and Providers

Drug Safety and Availability
Postmarket Drug Safety Information for Patients and Providers
Index to Drug-Specific Information
Approved Risk Evaluation and Mitigation Strategies (REMS)
Postmarketing Safety Evaluation of New Molecular Entities: Final Report

UPDATED Public Health Alert: Counterfeit Alli containing sibutramine

1/23/2010

The U.S. Food and Drug Administration (FDA) is updating its warning to the public about a counterfeit version of Alli 60 mg capsules (120 count refill pack) being sold over the internet, particularly at online auction sites. FDA advises people who believe that they have a counterfeit product not to use the drug.

Alli is an FDA-approved over-the-counter weight loss drug that contains orlistat as its active ingredient. The counterfeit version of Alli does not contain orlistat; rather, it is made with varying amounts of sibutramine, a stimulant drug.

Although sibutramine is the active ingredient in another FDA-approved prescription weight loss drug, it is only to be used in specific doses and under the supervision of a physician. The counterfeit product is illegal and unsafe.



Authentic alli Sample

Counterfeit alli Sample



Authentic alli Sample

Counterfeit alli Sample



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

A to Z

Devices Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Radi

and Availability

Counterfeit Version of Avastin in U.S. Distribution

Statement Issued: Feb. 14, 2012

FDA sends letters to 19 medical practices about counterfeit product and other unapproved cancer medicines

The U.S. Food and Drug Administration (FDA) is warning health care professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the United States. Avastin is an injectable medicine used to treat cancer and is administered to patients in clinics, hospitals, and doctors' offices. The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy.

In a related action, FDA has issued letters to 19 medical practices in the United States that purchased unapproved cancer medicines that may include the counterfeit Avastin. The counterfeit version is labeled as Avastin, manufactured by Roche. Roche is the company that manufactures Avastin approved for marketing outside of the United States.

Roche conducted laboratory tests that confirmed the counterfeit version of Avastin. Packages or vials may be counterfeit if they:

- are labeled with Roche as the manufacturer
- display batch numbers that start with B6010, B6011 or B86017

The only FDA-approved version of Avastin for use in the United States is marketed by Genentech (a member company of Roche). The FDA-approved version does not include the Roche logo on the packaging or vials. In addition, Genentech's FDA-approved version of Avastin vials and packaging have a 6-digit numeric batch number and expiration dates in a 3-letter month and 4-digit year format (e.g., JAN 2014). Genentech's Avastin products are safe and effective for their intended uses.

The 19 medical practices in the United States purchased unapproved cancer medicines and, potentially, the counterfeit Avastin, from Quality Specialty Products (QSP), a foreign supplier that may also be known as Montana Health Care Solutions. Volunteer Distribution in Gainesboro, Tennessee is a distributor of QSP's products. FDA has requested that the medical practices stop using any remaining products from these suppliers. FDA cannot ensure the safety or efficacy of any of these unapproved products.

- [Letters to Doctors About Purchasing Unapproved Injectable Cancer Medications](#)

Based on information to date, FDA has determined that none of the unapproved cancer medicines received by these medical practices from Volunteer Distribution are in shortage in the United States. FDA-approved



Counterfeit Altuzan

- Altuzan[®] 400mg/16mL vial with lot number B6021
- Vial contains no active ingredient
- Writing is in English



- At least 10 people have died as a result of the counterfeit Norco outbreak in March 2016 in the Sacramento area
- Over 50 overdoses were linked directly to the counterfeit Norco
- Additional counterfeit hydrocodone and oxycodone outbreaks have occurred in California in 2016



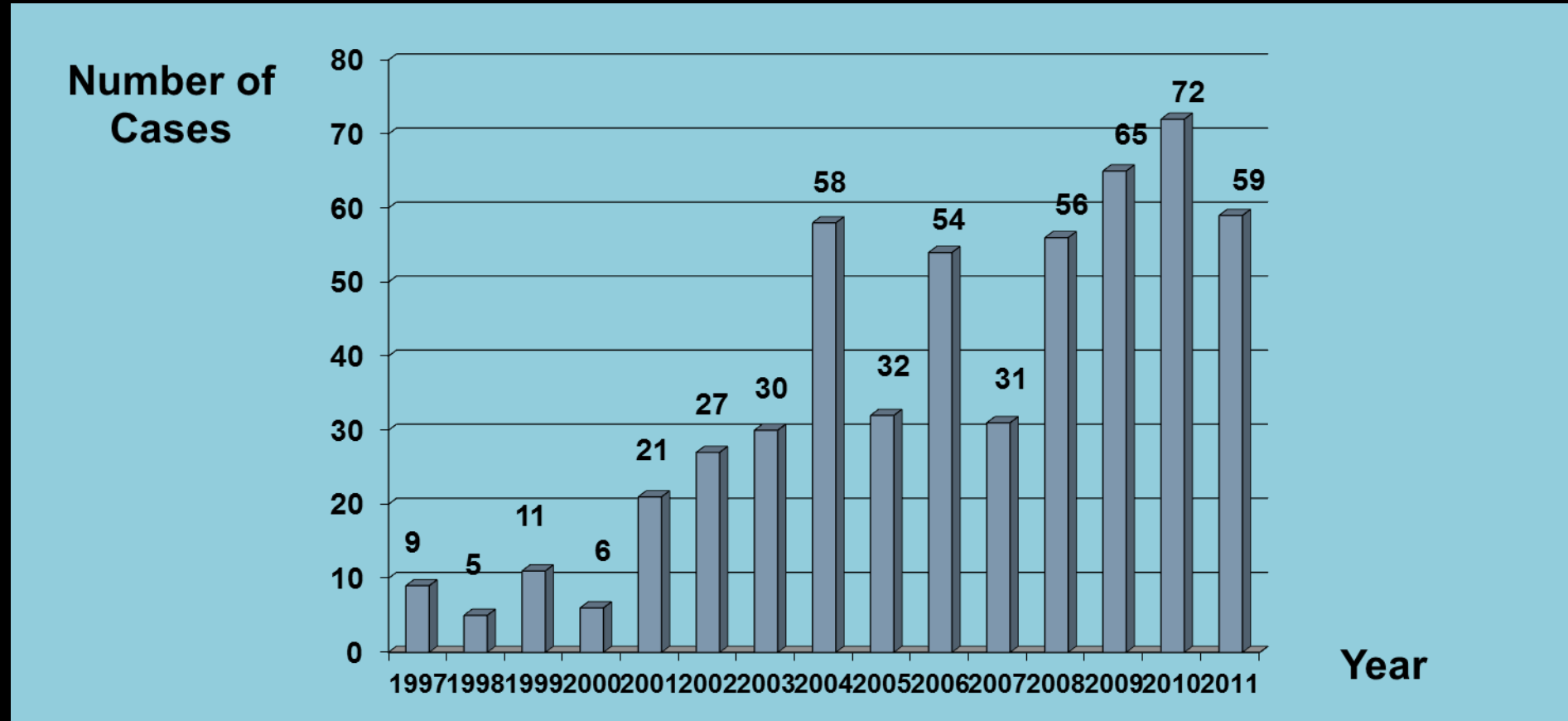
Whose Problem Is It?

- Police
- Regional drug squad
- Customs
- Trading standards office
- Regulatory Agency (MHRA)
- Pharmaceutical company
- Pharmacy organisations
- Pharmacists

Case Study

- A 45-year-old woman came into the office for an early refill. She has been on a fixed dose of oxycodone but states that she was shorted this month. Which of the following may be true?
 - a) She took more oxycodone and isn't telling
 - b) The pharmacy shorted her pills
 - c) She diverted pills
 - d) She is a drug seeker
 - e) All of the above

Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year



Spurious/Falsely-labelled/ Falsified/Counterfeit (SFFC) medicines

SFFC medicine	Country/Year	Report
1. Avastin (for cancer treatment)	United States of America, 2012	Affected 19 medical practices in the USA. The drug lacked active ingredient ¹
2. Viagra and Cialis (for erectile dysfunction)	United Kingdom, 2012	Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer ²
3. Truvada and Viread (for HIV/AIDS)	United Kingdom, 2011	Seized before reaching patients. Diverted authentic product in falsified packaging ³
4. Zidolam-N (for HIV/AIDS)	Kenya, 2011	Nearly 3,000 patients affected by falsified batch of their antiretroviral therapy ⁴
5. Alli (weight-loss medicines)	United States of America, 2010	Smuggled into the USA. Contained undeclared active ingredients with possible serious health risks to the consumer ⁵
6. Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained 6 times the normal dose of glibenclamide. Two people died, nine people were hospitalized ⁶
7. Metakelfin (antimalarial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies. The drug lacked sufficient active ingredient ⁷

1. FDA. www.fda.gov/Drugs/DrugSafety/ucm291960.htm. 2012.

2. Science Direct. www.sciencedirect.com/science/article/pii/S0007681312001590. 2012.

3. Safe Medicines. www.safemedicines.org/2011/12/counterfeit-hiv-medication-discovered-in-uk-supply-chain-391.html. 2012.

4. Médecins Sans Frontières . www.msf.org/article/falsified-medicines-enter-supply-chain-kenya. 2011.

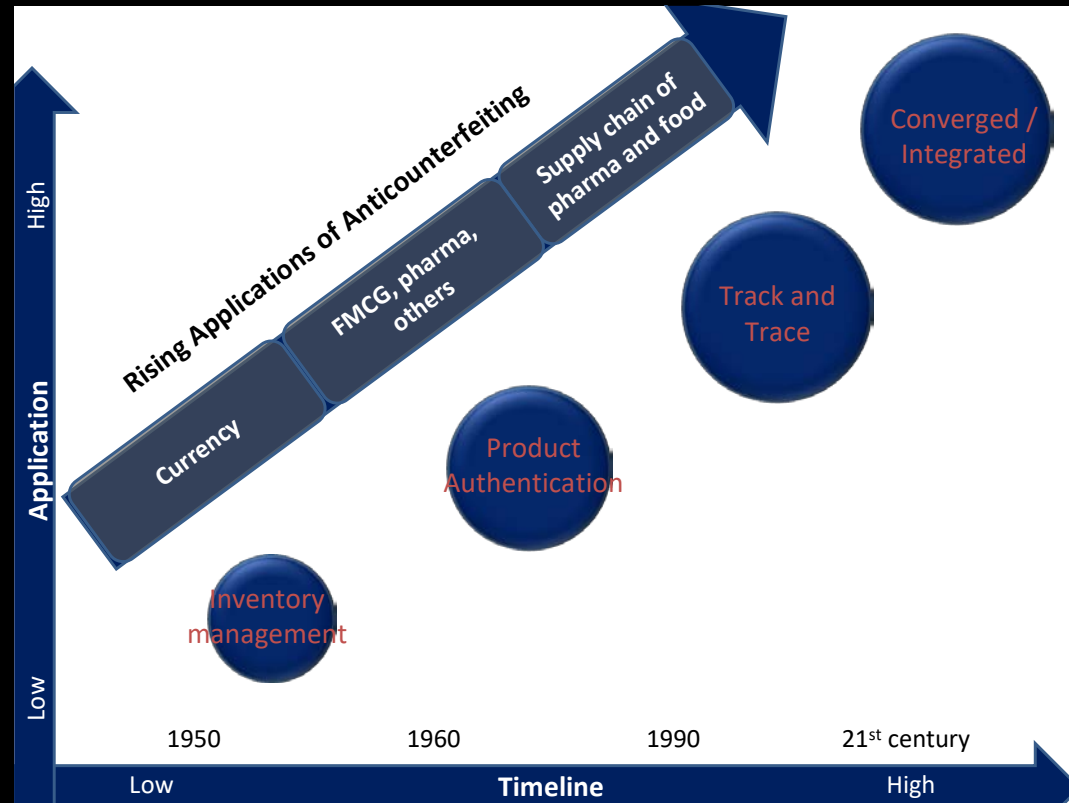
5. FDA. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm197857.htm. 2010.

6. WHO. www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/WM-1_2Dec.pdf. 2010-2012.

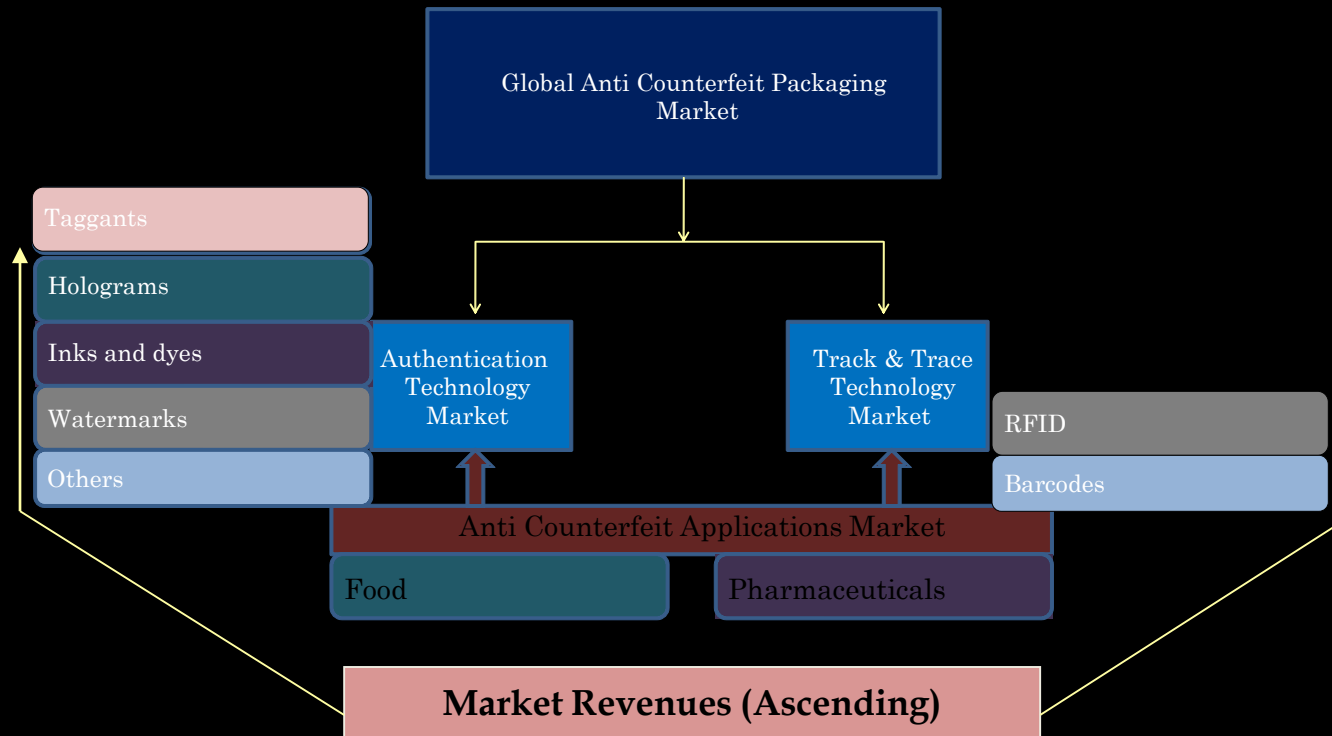
7. International Pharmaceutical Federation. www.fip.org/menu_counterfeitmedicines_policy. 2014.

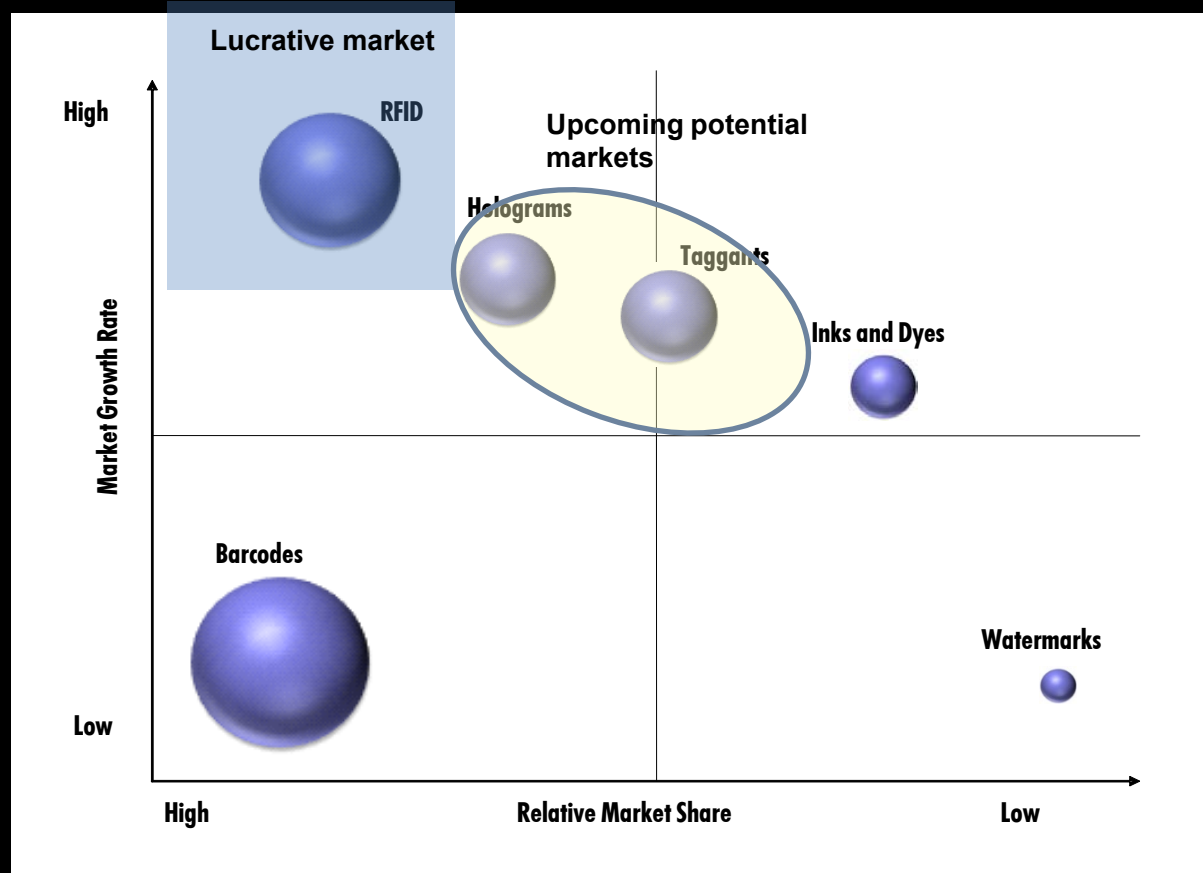
Anticounterfeiting Technologies

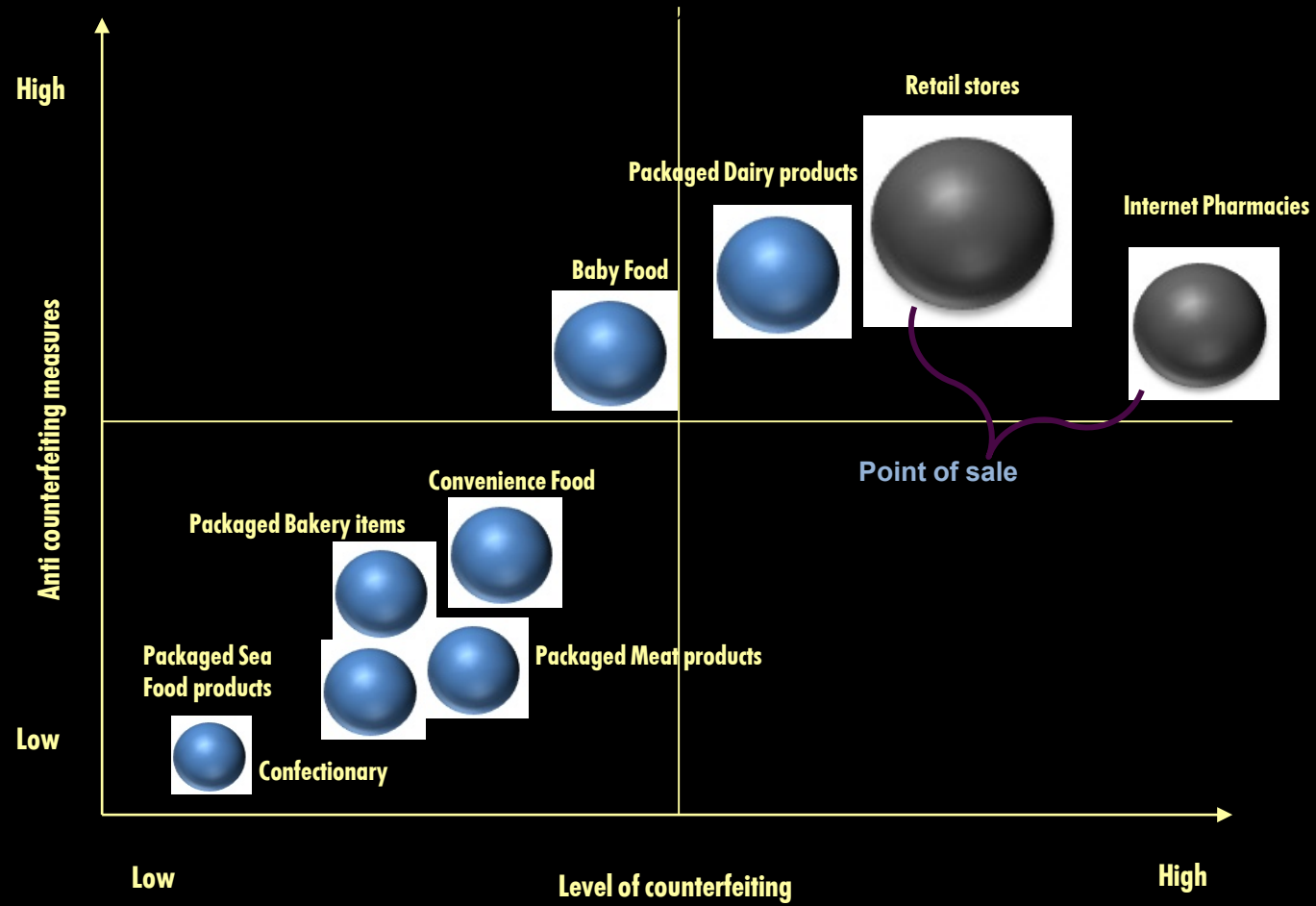
- Technologies include
 - Antibody pairs/DNA
 - Bar codes
 - Holograms
 - Invisible and security inks or phosphors
 - Magnetic resonance signatures
 - Microprinting
 - RFID (radio frequency identification)
 - Taggants
- There are various competitors using the above technologies with limited success
- None of the technologies above successfully address all five authentication principles
- No single player has achieved a dominant position or significant market share











Solution Principles

- The five principles of an authentication solution are:
 - Security strength
 - Ease of implementation
 - Authentication speed and simplicity
 - Supply chain accountability
 - Total cost of ownership with or without any solution

What Can You Do

- Ask companies what technologies and protocols they have implemented to fight counterfeiting
- Ask companies how you can be sure, without a doubt, that the product or medicine you are buying/prescribing is authentic
- If they have not implemented anticounterfeiting and authentication technologies, ask them why?
- Demand that companies take ownership and accountability for their obligation to deliver products that are genuine

COUNTERFEIT DRUGS KILL!



Counterfeits have harmful effects on patients' health and can kill

Counterfeits frustrate efforts to deal with high burdens of disease

Counterfeits undermine health care systems

Increased international collaboration is essential to defeat counterfeiting

Combating counterfeiters requires acting at the same time on legislation, regulations, enforcement, technology and communication strategies



Updated May 2008

