Tackling counterfeit pharmaceuticals & medicines – the SAVEmed project

Why is organized crime successful in circumventing governments and industry ?

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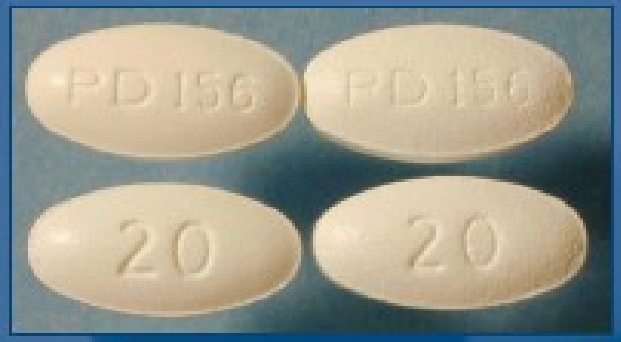
Can You Tell The Difference?



Visually, the only distinction between these Lipitor tablets is that the counterfeits (far left) are slightly thicker than the authentic medicine.

1: What is a counterfeit medicine?

A counterfeit medicine is one that has been deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. Counterfeit products include drugs with no active ingredient, drugs that are super potent, and drugs with dangerous impurities.*

*Source: Pharmaceutical Security Institute

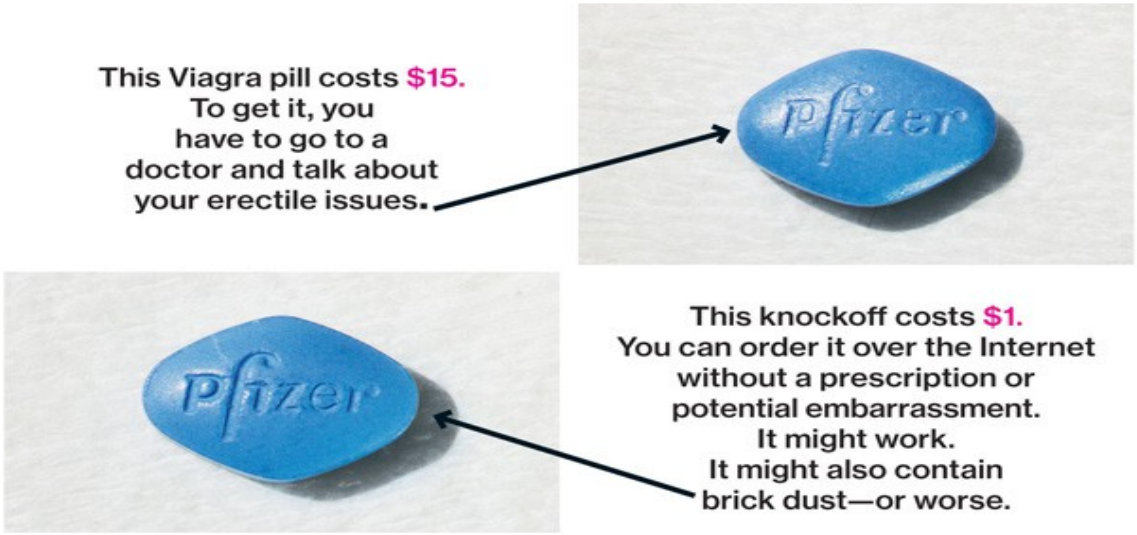
Pfizer Medicines That Have Been Counterfeited Include:

- Lipitor
- Viagra
- Norvasc
- Zoloft
- Celebrex
- Aricept
- Diflucan
- Dilantin
- Feldene
- Ponstan
- Vibramycin

When did Pfizer publish this ? And what has happened in the meantime ?

- When did Pfizer publish this ? 2005 !!
- And what has happened in the meantime ? Not much one is forced to say, except that organized crime was even more successful in the last 10 years.
- What did companies do during this period? Business week article provides a hint:

http://www.businessweek.com/articles/2013-01-17/inside-pfizers-fight-against-counterfeit-drugs#p1



Intro to the article

- Apparently, big pharma has hired whole armies of former law enforcement people in an attempt to COMBAT the problem; from the article:

- Donnelly, 56, is director of Pfizer's global security team in the Americas. A pharmacist by training with a Ph.D. in pharmacology and toxicology, Donnelly is also a detective. For 21 years before joining Pfizer, he worked as a special agent for the FBI.

- Among counterfeiters, Viagra is prize. It's the king of the erectile dysfunction market, racking up $1.04 billion in U.S. sales in 2011, according to IMS Health. It's been fighting off counterfeiters almost since its introduction in 1998, which happened to coincide with the rise of the INTERNET.

- Pfizer's squad, says Donnelly, benefits consumers and protects the Viagra brand.

- One of the criminal distributors was caught and sentenced to 10 months and a fine of 5100 Dollars

- Two months after the sentencing, the distribution website hardtofindrx.com is going strong, although it has yet to respond to a request for comment. A recent look revealed offers for Viagra Herbal, Viagra Oral Jelly, Viagra Professional (generic), Viagra strips, Viagra Super Active, and Red Cialis Viagra. The site sells dozens of other medications ranging from "morning after pill" to "Slimmer X" to "Boob builder." Satisfaction is guaranteed.

The New York Times | http://nyti.ms/1fnB61R

ASIA PACIFIC

Medicines Made in India Set Off Safety Worries

By GARDINER HARRIS FEB. 14, 2014

NEW DELHI — India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators for safety lapses, falsified drug test results and selling fake medicines.

Dr. Margaret A. Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms."

India's pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for American consumers.

From the same article: ……

counterparts in the West. But others suffer from serious quality control problems. The World Health Organization estimated that one in five drugs made in India are fakes. A 2010 survey of New Delhi pharmacies found that 12 percent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of ..... infant deaths.

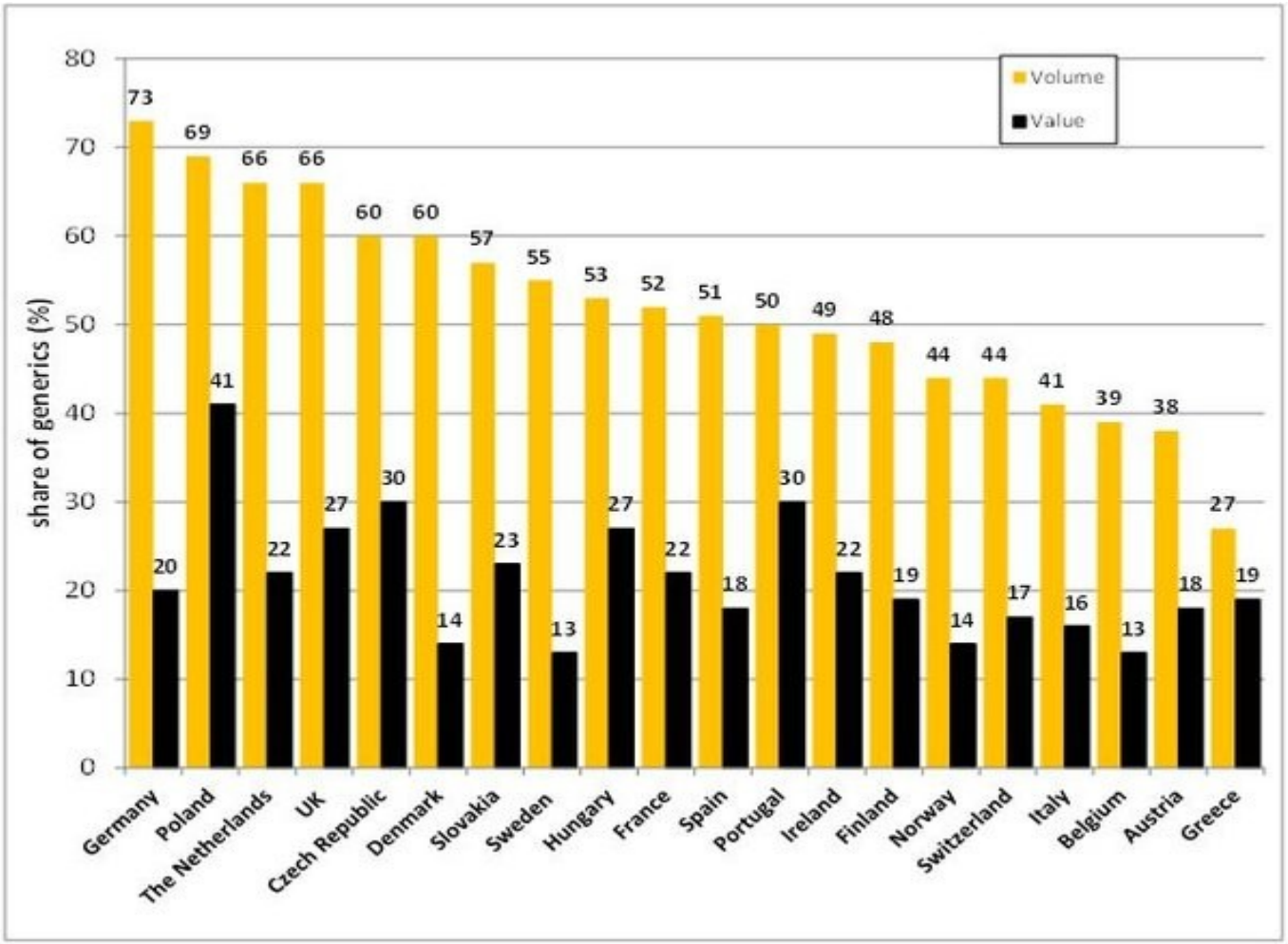
Another case, another “related problem”

Ranbaxy ordered to pay 500 milion Dollars in fines in mid-May 2013; as a result of manufacturing standards (GMP) not being maintained at an Indian manufacturing plant; **triggering a loss in Ranbaxy's share prize of 44% in roughly 3 months**

- People are now asking the question of whether it is sufficient for the US when manufacturers like Ranbaxy return to full GMP compliance; given the fact that WHO statistics seem to confirm an overall counterfeit rate of 20 % in the Indian pharmaceuticals market; and Indian generics manufacturers hold 40 % of the US market

- Conclusion: No matter how well GMP is policed in India, 8 % of the US generics market will likely remain to be counterfeit product! Is this acceptable??

What has this got to do with Europe? Generics market share 2014



What has this got to do with Europe?

The Institute of Research Against Counterfeit Medicines (IRACM) reports in late 2013

Summer 2013 - 500 Million packages of pharmaceuticals seized in Switzerland sent from China to Africa

October 2013 - 1 million of fake Xanax packs seized at Zurich/Kloten Airport

Low penal risk for this kind of criminal wrongdoing (as we saw in the Pfizer case); the criminal business is dramatically increasing and might, in the future, engage different forms of international organized crime, including terror organizations

Are there any solutions at all ?

Serialization as a government mandated approach

- United States: The Drug Supply Chain Security Act (DSCSA) mandates that manufacturers begin serializing all drug products at the saleable unit and case level for the U.S. market starting in Nov. 2017, with repackager deadlines beginning in 2018.

- European Union: Manufacturers serving the EU are preparing to meet serialization requirements (the EU Falsified Medizines Directive) at the package level which are now expected to phase in from early 2018, requirements that include supporting both global and national identifiers and following strict uniqueness regulations.

- China: Drug products on the Essential Drugs Lists (2009, 2012) already need to be serialized in China following unique China requirements for serial number acquisition, serial number and product data formatting, and barcode labeling. All drug products will need to be serialized, both domestically manufactured and imported medicines, by December 31, 2015.

- Brazil: RDC 54 regulations establish very complex new serialization requirements for all registered drug products which phase in starting in Dec. 2015. Manufacturers will need to apply unique Brazilian IUM identifiers into 2D DataMatrix barcodes for each saleable unit, serialize each transport container (case) and ensure aggregation relationships.

Serialization in the US and Europe

- From late 2017/early 18 new serialization standards will become effective in both territories
- Is it going to help?
- We fear not
- And why not ?
- Because as usual, governments and big industry have driven these standards towards the lowest common denominator; I am calling it the stakeholder trapdoor
- **As a result none of the new standards is going to directly require marking of product; instead only primary or secondary packaging gets marked!**
- We are still dreaming of a better world requiring the marking of packages or blisters (when most pharma products in the US and the developing world are not even packaged in blisters)

SaveMed – tackling counterfeit pharmaceuticals & medicines

nano4U 's catalogue of custom anti-counterfeiting solutions

Tackling counterfeit pharmaceuticals & medicines in general

nano4U **catalogue of custom anti-counterfeiting solutions**

- **Only marking the products themselves (tablets, syringes, vials, medical devices etc.) AND linking this information with coded packaging will prevent organized crime in this area from further growing exponentially**

- **Having said that, production mechanisms in industry and approval processes need to be affected as little as possible – no changes in pharmaceutical recipes, no changes in high-speed embossing of tablets etc.; keep the cost for manufacturers as low as possible while making it almost impossible for organized crime to continue**

Datamatrix codes for self-verification between product and packaging.

- Datamatrix codes have been laser structured onto the steel tooling used for tablet stamping. The codes are structured at different surface levels.

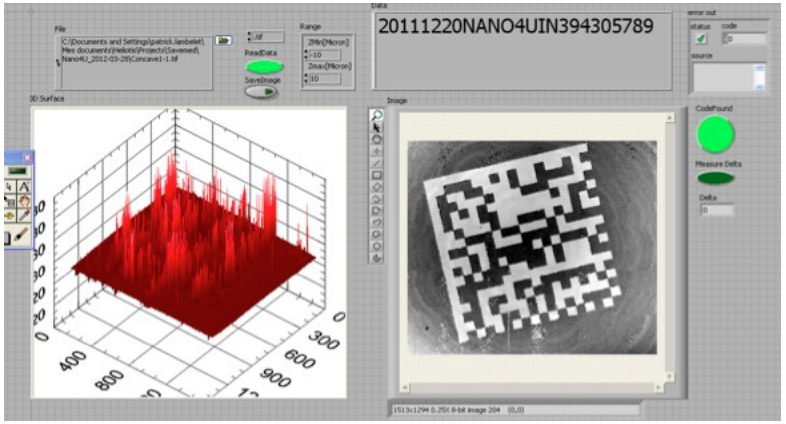
- The codes contain enough data for track & trace plus cryptographic signature to check for genuine product.

- The codes have been successfully embossed onto tablets using a normal industrial tableting press.

Datamatrix codes for self-verification between product and packaging. – continued.

- Embossed codes on the tablets can be scanned and read using appropriate «reading» system

- The scanner uses a special type of industrially proven tomography to read through clear blister packs or slightly porous materials to detect each interface at a microscopic level.
- Algorithms for scanning & decoding have been proven.
- Measurement on coated tablets and through coatings has been achieved, hiding the code completely in the surface of, or beneath the coating of, the tablet.



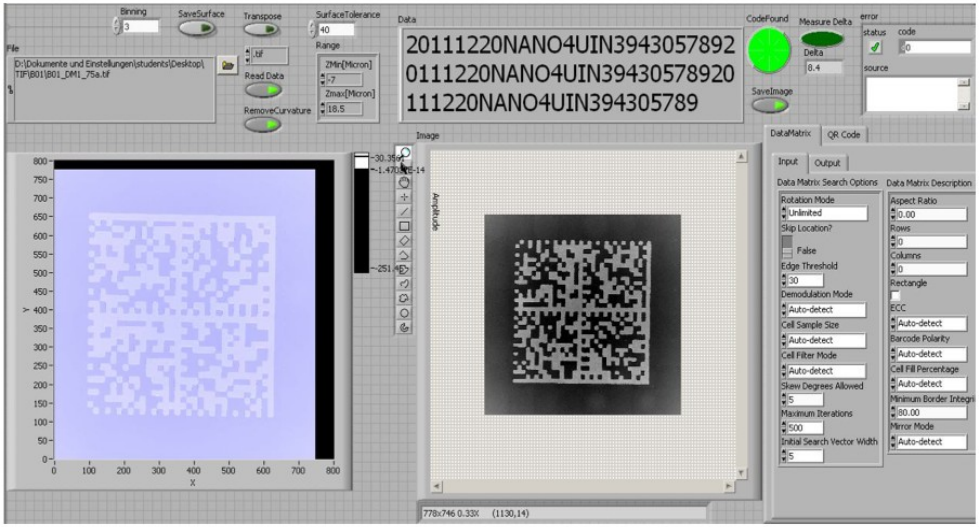
Device for product/package verification.

Rapid optical scan of structured surface (eg. Datamatrix.)

Point cloud of height data.

Adaption of data file using specific algorithms.

Decoding using standard Datamatrix or QR Code program.



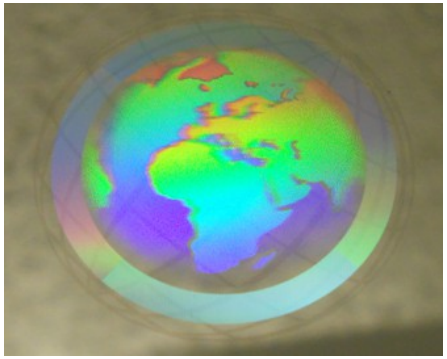
Device for product/package verification

- *We are now also providing in the field or end-user authentication solutions that work with SMART phone apps*
- *Some on product coding in the tabletting arena can also use random product characteristics instead of nanoscale markings (ongoing EUREKA research project)*
- *Product markings and/or random coding can also be used to create a link with coded packaging (GTIN etc.)*
- nano4U *anti-counterfeiting solutions also use state-of-the art cryptography, thereby preventing the need to store, safeguard, and access huge amounts of identification data*
- *In-the-field authentication thereby becomes possible without external database access*

Holograms including covert features.

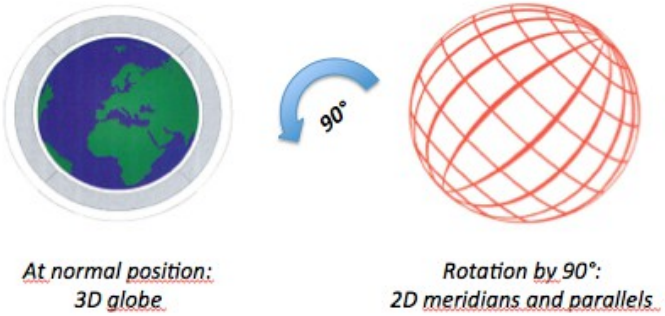
- We also offer the application of holographic gratings to flat or curved hardened steel surfaces such as those used in injection moulds and embossing tools.

- The new process can be used to apply simple and complex grating structures, Moiré structures, or random fingerprint structures directly onto steel tooling.



Moulded hologram security features

- Level 1: Holographic logo or pattern that diffracts the light to different colours at different angles (see plastic cap picture on previous slide).
- Level 2: Complex hologram that changes appearance when viewed from different angles. Example: Globe hologram (see below).
- Level 3: Hidden detail (only visible when inspected at a specific point or using a specific method). Examples include microtext, reflected diffractive patterns.

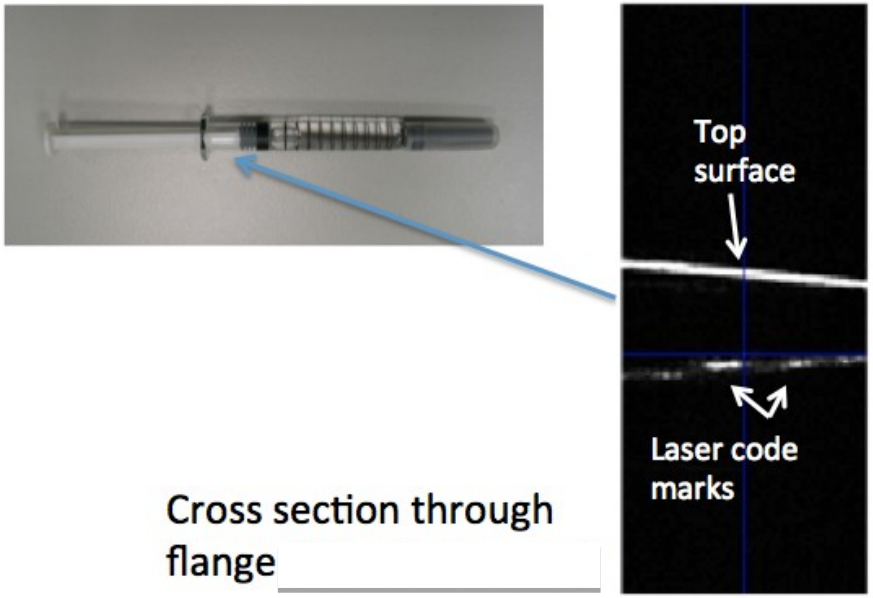


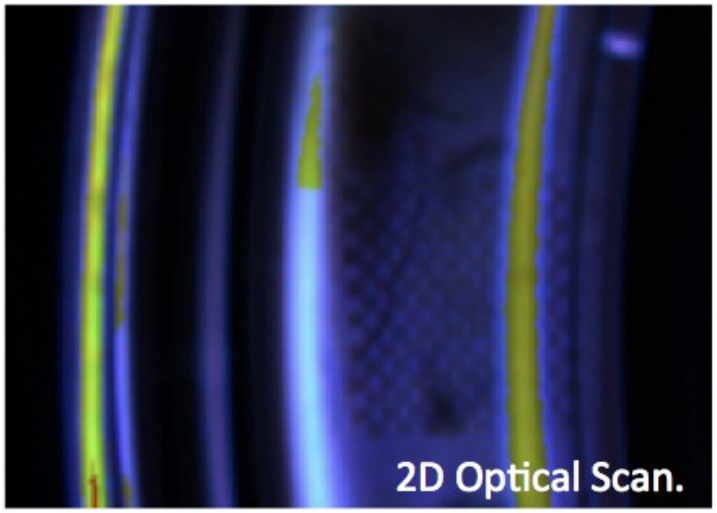
Holograms including covert features

- High-contrast holograms have been injection moulded onto plastic packaging directly from injection moulds with no secondary process.
- Using inserts from the special steel structuring process, holograms have been directly embossed onto blister packs in a standard packaging line.
- Holograms have also been embossed onto medical pouches as part of a standard film converting line.
- Optical gratings have been produced to locally couple light into a plastic material and reveal a hologram that was previously not obvious.

NANO 4 U anti-counterfeiting products in the area of glass vials & syringes.

- Code laser-written inside glass and decoded using high speed optical scan.
- Rapid optical scan allows coding at more than one level within the glass.
- Code is impossible to read using a normal microscope and can include hidden information levels.





NANO 4 U's current activities in the field

- Collaboration with a blister machine supplier in the pharmaceutical market
- Various discussions with pharma manufacturers about implementation of NANO 4 U products into their serialization solutions (custom application development)
- Upscaling of glass-marking system in packaging lines for liquid pharmaceuticals
- Early stage development projects in the luxury goods markets (drinks, perfume, sunglasses, jewelry, high-level brand protection)

Please do not hesitate to contact us for any contribution to your ongoing discussions!

THANK YOU