SUPPLY CHAIN SECURITY
MAINTAINING INTEGRITY OF YOUR SUPPLY CHAIN

WORKSHOP

28 August 2017
Tony Zook
Why is this important?

AP  February 7, 2013, 4:06 PM

FDA warns about fake Avastin again

The FDA issued a warning on a popular cancer drug that turned out to be fake. The vials labeled "Avastin," contained a liquid that was worthless. But who would sell a fake to cancer patients? Chief investigative correspondent Armen Keteyian reports.

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WASHINGTON | The Food and Drug Administration is warning doctors about another counterfeit version of the cancer drug Avastin distributed in the U.S., the third case involving the best-selling Roche drug in the past year.

Why is this important?

Fake Avastin shipper tied to Canadadrugs.com

(CBS News) - Canadadrugs.com bills itself as the "largest and most trusted" online Canadian pharmacy. Based in an office building in Winnipeg, Manitoba, it says it
Why is this important?

Counterfeit Harvoni turns up in Switzerland, Israel

by Eric Palmer | Mar 8, 2016 8:49am

Given the high price of Gilead Sciences' ($GILD) hepatitis C cure Harvoni, it wasn't going to be long before it was targeted by counterfeiters. Now fakes have shown up in Switzerland and Israel.
Why is this important?

More fake Avastin found, this time in Cyprus

Five years after falsified versions of Roche’s cancer drug Avastin first hit the headlines, fake packs are still being discovered in the supply chain.

Cyprus’ Ministry of Health has revealed that three batches of fake Avastin – bearing the Altuzan tradename used in Turkey – have been identified on the northern (Turkish-speaking) side of the island. Avastin (bevacizumab) is used to treat a range of cancers, including colorectal, breast and lung cancer.

https://www.securingindustry.com/pharmaceuticals/more-fake-avastin-found-this-time-in-cyprus/s40/a5034/#.WW46fITyuUk
Gilead investigates counterfeit Harvoni in Japan

Gilead Sciences is analyzing the composition of fake pills sold in Japan under the Harvoni brand.
Why is this important?

Counterfeit drugs: 'People are dying every day'

By Matthew Wall
Technology of Business editor

27 September 2016 | Business
Why is this important?

Counterfeit medicines killing people and brands

Fake medicines are killers and can destroy a genuine brand unless manufacturers do more to protect themselves and the public.

By Jane Simms  – December 13, 2016
Pharmaceutical Crimes – 2016

- 3,147 incidents of counterfeiting, diversion, and theft
- 124 countries impacted
- 1,258 different drugs
- 1,106 counterfeit incidents
- 272 counterfeit incidents (25%) reached legitimate supply chain of licensed pharmaceutical wholesale distributors or pharmacies in 45 countries
- 945 LE seizures of illicit medicines (49%) were commercial scale (>1,000 dosage units)
- 1,258 arrests
Pharmaceutical Crimes – Historical Trends

Year | Incidents
--- | ---
2007 | 1759
2008 | 1834
2009 | 2003
2010 | 2054
2011 | 1986
2012 | 2018
2013 | 2193
2014 | 2177
2015 | 3002
2016 | 3147

Pharmaceutical Security Institute 2016 Situation Report
Counterfeit Medicines – 2016 Supply Chain Breaches

- Asia: 30%
- Latin America: 28%
- MEA: 18%
- Eurasia: 17%
- EU: 6%
- NA: 1%

Bar chart showing the number of breaches in different categories:
- Anti-Infective: 72
- CNS: 38
- Alimentary: 32
- Hormones: 29
- Cytostatics: 22
Product Integrity Operations

• Secure the Supply Chain
  – Provide Supply Chain Security capacity that maintains the security and integrity of materials and products
  – Deploy the use of anti-counterfeiting security features to prevent counterfeiting and tampering, and enable rapid authentication of questioned materials

• Investigations and Enforcement
  – Provide intelligence-driven proactive and reactive investigative capacity engaging high-risk/high-value targets
  – Provide robust forensic analysis capability to identify and characterize illicit products
  – Enable meaningful enforcement actions that mitigate identified/confirmed threats

• Raise public and stakeholder awareness
  – Create public awareness campaigns and other communication tools to effectively raise public awareness of threats to public safety associated with illicit pharmaceutical products
  – Advocate for policy and regulatory changes that further protect patient safety from these threats
Current Product Integrity Threats

- Rogue on-line drug sellers
- Direct-to-physician marketing and distribution
- Re-use of authentic packaging components
- Reverse Distribution compromise
- Humanitarian/Charitable/Discounted Pharmaceuticals fraud
- Cargo Theft
- Drugs of abuse/illicit value
- Drugs with limited access/availability
- Regulatory weaknesses
- Organized criminal networks
- Illegal generics of high value products
- Counterfeit biologics
Current Threats – Counterfeit Biologics

Biologics are at an increasing level of risk

- High value
- High visibility
- Limited market access
- Desired medical outcome
- Product may have no short-term detectable outcomes

Increasing penetration of legitimate supply chain

- These are often hospital or clinician administered products
- Cold chain issues with diversion

Quality release testing methods are not very specific

Forensic testing for biologics heavily reliant on packaging analysis

Seeing reuse of authentic packaging components

Biosimilars
What We Are Learning

• Recognize and appreciate the significance of the threat
• Don’t underestimate the capabilities and applied effort of the counterfeiter
  – Highly motivated
  – Will do anything to make money
  – Everything can be copied
  – There are no rules

• Matter of supply and demand
  – Can artificially create demand
  – Need to create awareness of the supply
  – Someone will buy it

• Threat is constantly evolving
  – What happened yesterday not necessarily what is going to happen tomorrow
  – But we can be constantly learning and applying what we’ve learned
What We Need To Be Doing

• Think like the bad guy
  – What do we know about their capabilities/limitations?
  – What are the vulnerabilities in our systems that can be exploited?
  – What is the next supply/demand issue that creates opportunity for counterfeiters?

• Develop effective threat detection capabilities
  – Identify triggers/indicators and monitor for them
  – Apply what we’ve learned to predict additional threats

• Develop effective threat mitigation capabilities
  – Product security features: development and application

• Develop effective enforcement strategies
  – Collaborative relationships with Law Enforcement Agencies to support criminal actions
  – Civil enforcements
  – Administrative enforcements

• Develop external relationships to support on-going learning and engagement
Pharmaceutical Supply Chain

Legitimate
- Manufacturer
  - Finished products
  - Distribution warehouse

Commercial Distribution
- Distributors
  - Hospitals Pharamcies
  - "Retail"

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Illegitimate
- Illegal Distributors
  - Illegal Retailers
  - Internet Sale

Genuine product flow

Fraudulent product flow

Stolen products
Misbranded/ Diverted products
Counterfeit products

Finished products
Distribution warehouse
Hospitals
Pharmacies
"Retail"
Patients
THANK YOU

Tony Zook
anthony.zook@merck.com
(215) 652-9394