Securing the Online Supply Chain

PDA New England Chapter: Supply Chain Integrity - Overt, Covert and Forensic Methods

May 9, 2012
Tara Steketee
OpSec Security, Inc
Overview

• Statistics
• Internet Supply Chain
• Internet Overview
• Avastin issue review
• Sample Ecosystem – how did the Avastin issue happen?
• How to manage Internet data
Integrated Brand Protection Solutions

PRODUCT AUTHENTICATION
Broadest portfolio of overt & covert authentication technologies

SECURE PRODUCT TRACKING
Securing the supply chain against fraud, over-production & diversion

ONLINE BRAND PROTECTION
• Internet monitoring & enforcement
• Anti-piracy
• Sentiment analysis
• E-channel management

OpSec is the only company in the industry to combine all services into one comprehensive security program.
Statistics

- 2011 Customs & Border Protection # of counterfeit pharmaceutical seizures: 1,239
- Domestic value of 2011 pharmaceutical seizures: $16.8 M
  - Almost a 200% increase from 2010
  - Value of pharmaceutical seizures from China increased by more than $4.3 M
- MSRP value of 2011 pharmaceutical seizures: $25 M
Internet Distribution & Sales Model: Why We Need Online Analysis

- Manufacturer
- Authorized Online Pharmacies
- Online Auctions/Classified Platforms
- Unauthorized Manufacturer
- Online B2B Trade Boards
- Wholesalers Buying Groups & Drop Shippers
- Retail Pharmacies
- Spam Network
- Doctor's Offices
- Distributors, Donations
- Illegal Online Pharmacies
- Distributors, Donations
eCommerce & Online Promotion: How Pharmaceuticals are Sold

Promotion & Intelligence

B2C Auctions

B2B Trading Platforms

Retail Websites

Search Engines
- Google
- Yahoo!
- Bing

Social Media
- Blog
- Facebook
- YouTube

Spamming

Independent Sites

Network Hubs

Marketing Affiliates
Internet Pharmacy Exposure: Sample Branded Products Analysis

While the numbers for parenteral drugs are not as high as they are for highly counterfeited lifestyle drugs, the quantity available via internet sources is alarming.
Avastin Counterfeit Incident:
2/14/12 – Sold to US Providers

19 Physicians Warned

Quality Specialty Products – Montana Healthcare Solutions named as counterfeit source

Product contained no API

Source: http://www.fda.gov/drugs/drugsafety/ucm291960.htm
A Murky Path

The convoluted route of the fake Avastin found in February raises questions about oversight of the fragmented global pharmaceutical trade.

1. Swiss company Hadicon AG orders Avastin from Egyptian company Sawa.

2. Sawa intermediary contacts Syrian businessman who finds fake Avastin in Turkey.

3. Through Turkish entity Kirbaç Medikal, the drug is shipped to Hadicon in Switzerland.

4. After passing through Danish reseller CareMed ApS, the fake Avastin reaches the U.K.'s River East Supplies Ltd.

Avastin / Altuzan Counterfeit Incident: 4/4/12 – Sold to US Providers

Richards Pharma, Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI) named as counterfeit source

120 units

Product contained no API

How does this happen?

Examples of Internet Ecosystem for Pharmaceutical Sales
You Tube – Sellers Targeting Providers, Much Like a Fax Blast…Lumigen
You Tube – Sellers Targeting Providers, Much Like a Fax Blast…Taxotere
Facebook Page: Seller of Injectables

About
Orthovisc
Description
At Mosaic Medical Supplies you can Buy Orthovisc online and also get information about Orthovisc, Orthovisc effects and Side effects.
Twitter Page: Seller of Injectables

Medica Depot
@medicadepot
http://www.medicadepot.com

Tweets

Medica Depot @medicadepot
Family presence does not impede pediatric trauma care
div.r/1XcYiK

Medica Depot @medicadepot
High court arguments did not shift public opinion on health reform
div.r/1XNdiJ

May 08 2012
Preventive cardiology training sorely lacking, study says

Cosmetic Products
Buy Botox 100IU
Dysport (Reloxin) 500IU
Xoomin
Juvederm Ultra 2
Juvederm Ultra 3
Juvederm Ultra 3 2x8ml

Most physicians being trained to specialize in cardiology are not practicing cardiology, according to a survey of 43 cardiology fellowship programs at the American College of Cardiology Foundation. The study found that only 24% of the respondents had any expertise in preventive cardiology, a field that focuses on managing acute rather than chronic conditions. Dr. Pack, a general cardiologist at Henry Ford Hospital in Detroit, said that preventive cardiology is vital because it is often performed after the disease is already established, and that many of the respondents had limited experience in this field.
Online Pharmacy – Targeting Patients

FILL A PRESCRIPTION

Combivent UDV (20 x 2.5ml) 0.5mg/2.5mg/2.5ml

Marketed as Combivent UDV in United Kingdom

Ipratropium Bromide/albuterol Sulfate
Manufactured by: Boehringer Ingelheim
This product is offered for sale by a UK Pharmacy Partner from United Kingdom

Tell a Friend about Combivent UDV (20 x 2.5ml) 0.5mg / 2.5mg / 2.5ml
Combivent UDV (20 x 2.5ml) 0.5mg/2.5mg/2.5ml

Ipratropium Sulfate warnings, side effects and general information

From $1.97 USD/ nebul
Online B2B Trading Platform – Targeting Bulk Importers, Physicians and Online Pharmacies

Send Video Files for Free Easily Send Video Files Up To 2GB. 30+ Million Users. Try It Free! YouSendIt.com/Send
Retail Supplies Wholesale Over 6000 items wholesale direct with free shipping daily execustomersdirect.com

providing BOTOX
Posting Date: May 01, 2012 GMT

Company: Pharmaceutical
Membership: Free Member since Mar 06, 2009
Country/Region: China
Address: No 26, kangshun road, daxin district, beijing, Beijing, China 102600
Contact: Mr. Jeff Tu
Phone: 86-138-1106-1141
Fax: 86-010-6923-4567
Mobile: 86-138-2100-5667
Tags: botox
Online Postings: More 6 Trade Leads, Product Catalog(s)
Pharmacy Dropship India
E-Selling Simplified. You sell, We ship!

About us

Pharmacy dropship india is a legal FDA approved Online Pharmaceutical Dropshipping company. Pharmacy dropship india is a professional pharmacy dropshipper based in India. We are in this business for the last 9 years. We are a legally registered company. We dropship generics and branded medicines all over USA, Europe and other countries. We undertake contract dropshipping of medicines to online pharmacies in USA and online pharmacies in Europe. We have our own distribution networks in India. We are not sourcing agents like all other pharmacy dropshipping companies. We have our own team of dedicated professionals who are involved in order processing, packaging and shipping the orders. We supply more than 1000 generics and branded medicines. Generics supplied by us is manufactured in WHO GMP certified manufacturing facilities in India.

We sell generics of Viagra, Cialis and Levitra. We are offering a wide range of drugs for Erectile Dysfunction. Pharmacy dropship india is a FDA approved pharmaceutical company. We offer high quality medicines at most affordable prices. We offer better price and better service than other pharmacy dropshipping companies. We supply all types of generics available here in India. We undertake all types of bulk and small pharmaceutical dropshipping assignments. This company is managed by young and energetic professionals who believe in themselves. Kindly contact our Customer Support Managers for any specific requirement of pharmaceuticals.

Benefits working with Pharmacy dropship india:

- We offer 24x7 online Support
- 24x7 Telephone Support
- Client data stored in safe and secure offshore servers
- Discreet Packaging
- Discreet Shipping
- We have a permanent establishment and a registered pharmaceutical company in India
- Generics supplied by us are manufactured in WHO GMP certified manufacturing facilities.
- Our company is registered with EMS (India), Indian Foreign Post
- Our company is registered with the DGFT (DEPARTMENT OF FOREIGN TRADE)
- Pharmacy dropship india is registered with the customs
- Pharmacy dropship india has a valid Pharmaceutical Licenses for Exporting Pharmaceuticals.
- Customized manufacturing options for bulk pharmacy clients.
- Most advanced order processing systems
Signals – Where will they be obtained?

- Patient & Doctor Complaints
- Online Pharmacies & B2B Trade Boards
- Forums & Blogs
- Spam Emails/Faxes
- Internet Search
- Media Reports

Review data feeds for incoming signals
Criteria for Prioritization: Risk Analysis

Criteria Overview

Sample Prioritization Criteria:

- Site Location (based on site registrant contact details and/or server location)
  - Site is based in high risk regions
  - Purported location is different than actual location
- Pricing is above or below threshold
- Linkage to a known network of confirmed or suspicious sites according to network analysis and/or additional research
- Suspicious payment processing (site will only accept Western Union payments made to individual in a high risk region)
- Not an Authorized Distributor
- Sells product without an Rx

Follow-up:

- Send Warning letter...
- Conduct Online Investigation into Unauthorized Distributors – follow-up with additional enforcement
Sample Methodology for Processing Incoming Signals

- Patient Safety
  - Tampered/Expired
  - Diversion/Theft
  - Counterfeit

- IP Protection
  - Patent Infringements
  - Trademark/Copyright Infringements

Follow-up on signals based on best practices workflow.
Information should be stored, managed and enforced upon based on best practices for regulatory adherence and corporate business goals.

- Online Monitoring
- Network Analysis
- Case Building
- Test Buys

- Civil Litigation
- Restitution
- Criminal Litigation
- Online Enforcement

- Online Enforcement
- Civil Litigation
- Restitution
Engage Key Stakeholders

Recommendations:
• Information management & enforcement workflow executed by outside consulting firm
  • Include key internal & external stakeholders
  • Ensure that best practices and regulatory requirements are met
Case Study: Pharmaceutical Criminal Case

Problem
- Single website identified selling potentially counterfeit pharmaceuticals

Solution
- **Linked numerous sites worldwide** connected to a single hub
- Test purchases **confirmed counterfeit** and site linkage through order fulfillment
- Client & LE used Internet data as supporting evidence

Outcome
- **5 arrests made**
- Client initiated **PR campaign to send a strong message**
# Internet Enforcement

## A Multi-pronged Approach is Key

### Make it more difficult for counterfeiters to get their products to market:

<table>
<thead>
<tr>
<th>Make it difficult</th>
<th>Countermeasures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce availability of counterfeit/diverted product:</td>
<td></td>
</tr>
<tr>
<td>Quickly terminate listings/postings on B2C and B2B platforms with Right’s Owners policies</td>
<td>Establish &amp; maintain relationships with platforms to influence policies, outcomes</td>
</tr>
</tbody>
</table>

### Get to the source – the large-scale players:

<table>
<thead>
<tr>
<th>Source</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigate targeted sellers on B2B exchanges &amp; across all online platforms</td>
<td>Focus on regions where you can take action</td>
</tr>
<tr>
<td></td>
<td>Identify ‘hubs’ or sites with high traffic &amp; product/sales</td>
</tr>
</tbody>
</table>

### Reduce availability of counterfeit/diverted product:

<table>
<thead>
<tr>
<th>Action</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect Patients</td>
<td>Improve Brand Equity</td>
</tr>
<tr>
<td></td>
<td>Create tangible ROI</td>
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</tbody>
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Questions?
Thank you

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