



Securing the Online Supply Chain



Parenteral Drug Association
Connecting People, Science and Regulation®

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

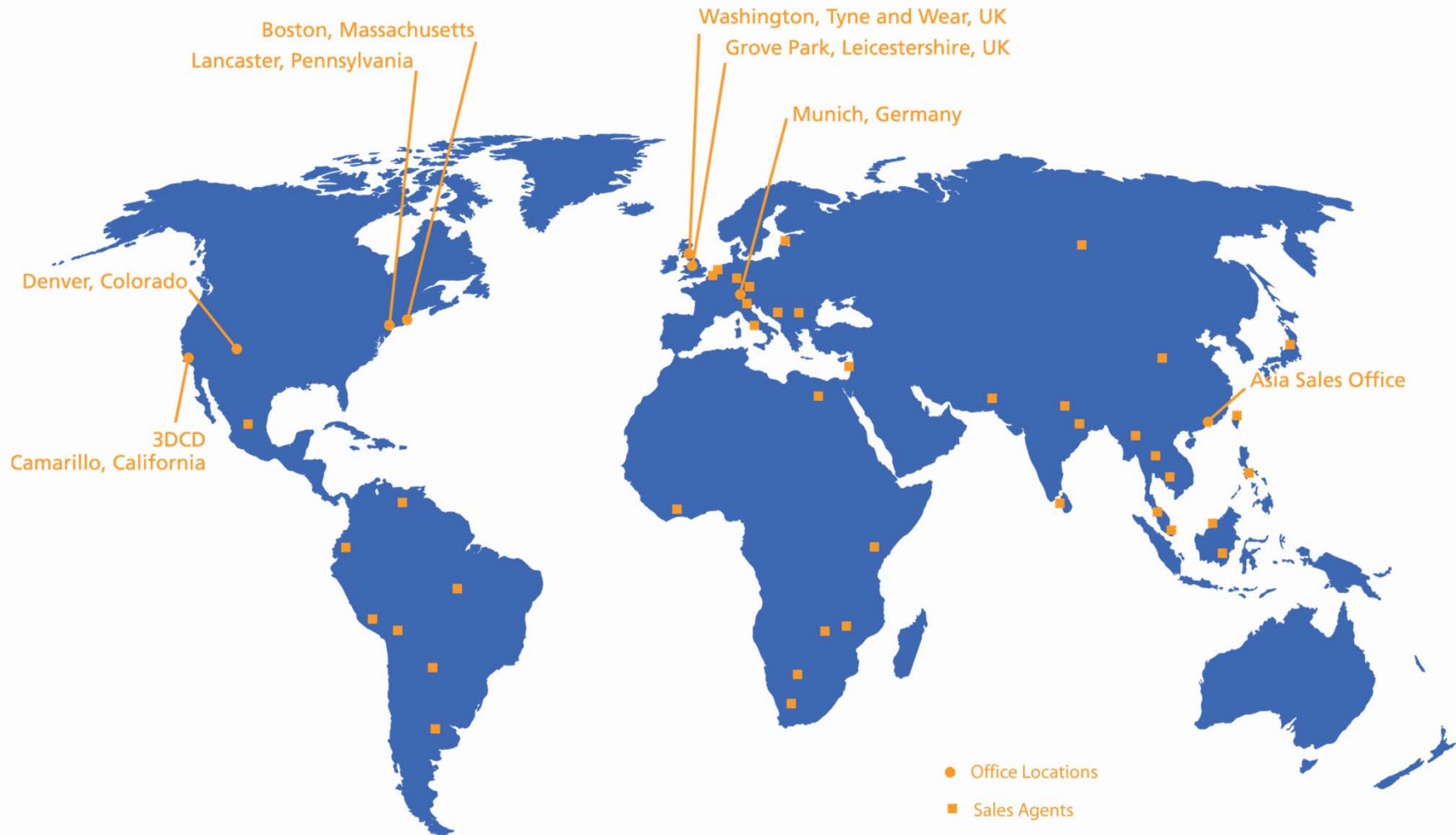


ONLINE BRAND PROTECTION

- 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

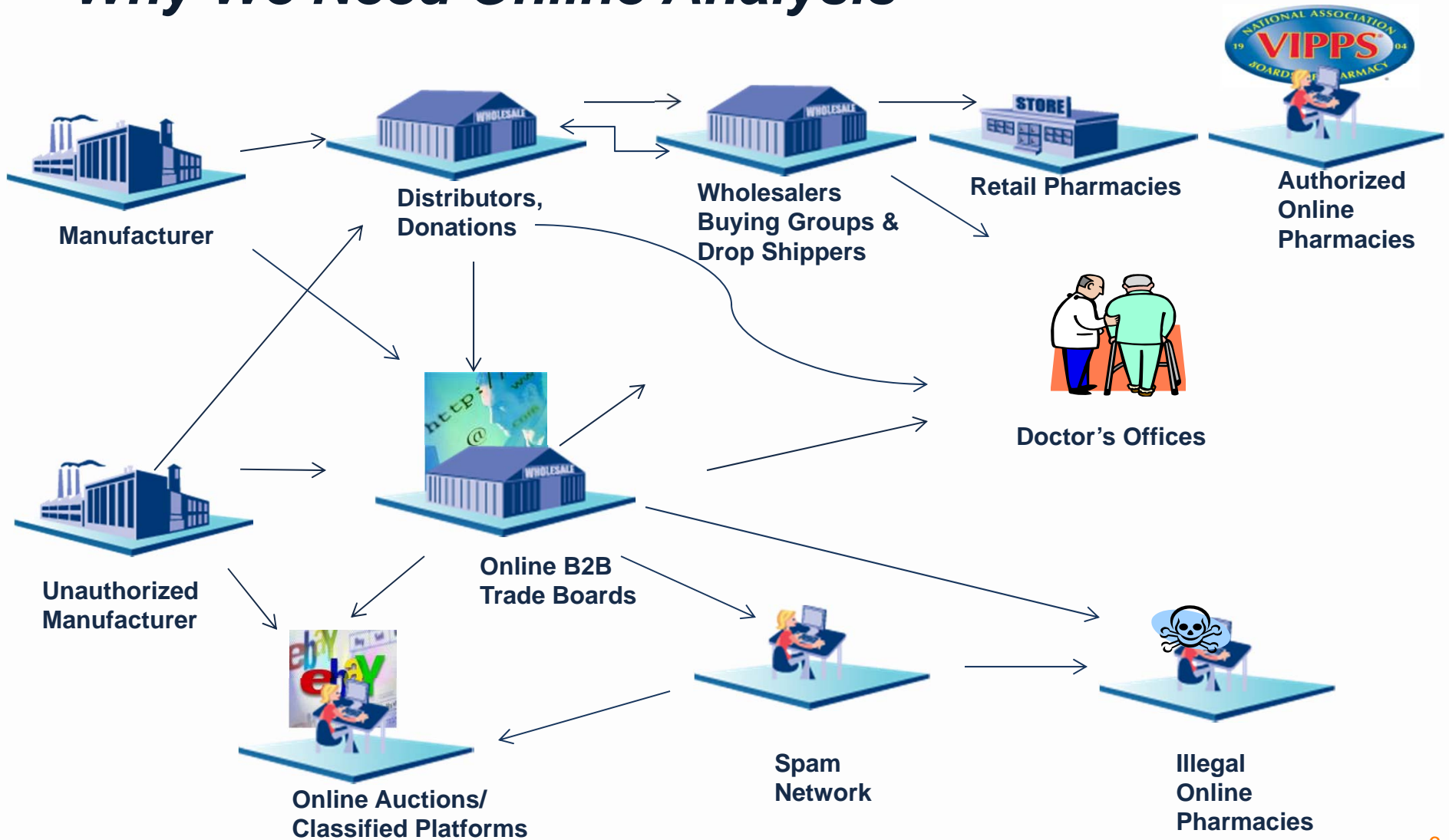
Global Sales & Distribution



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

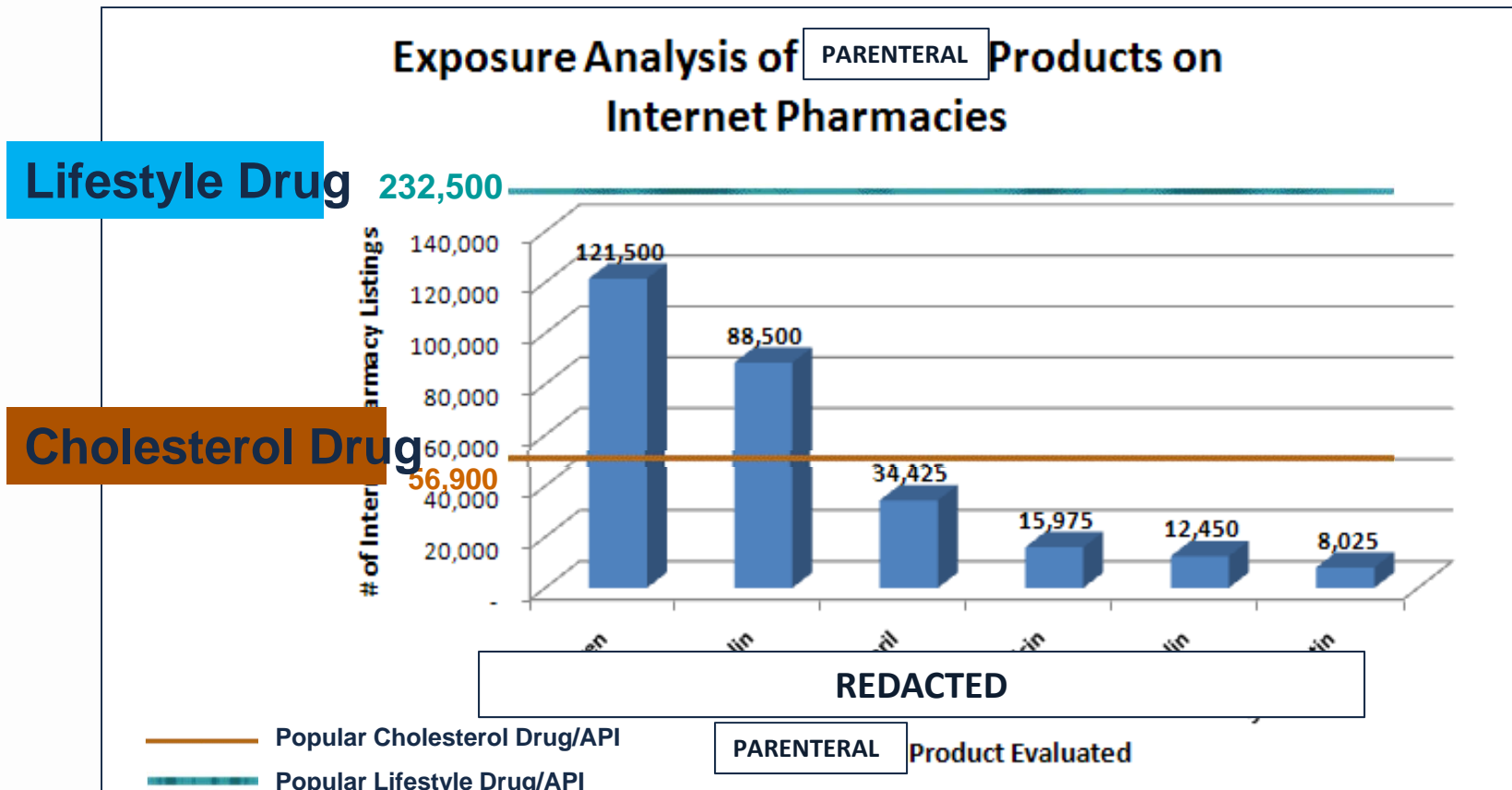
Internet Distribution & Sales Model: Why We Need Online Analysis



eCommerce & Online Promotion: How Pharmaceuticals are Sold



Internet Pharmacy Exposure: Sample Branded Products Analysis



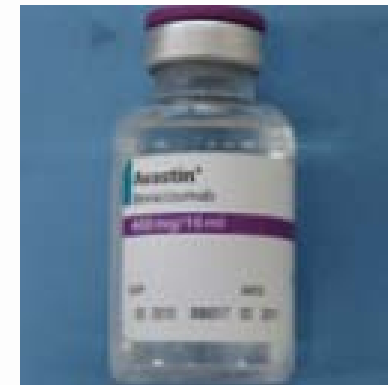
While the numbers for parenteral drugs are not as high as they are for highly counterfeited lifestyle drugs, the quantity available via internet sources is alarming



Avastin Counterfeit Incident: 2/14/12 – Sold to US Providers

19 Physicians Warned

Quality Specialty Products –
Montana Healthcare
Solutions named as
counterfeit source



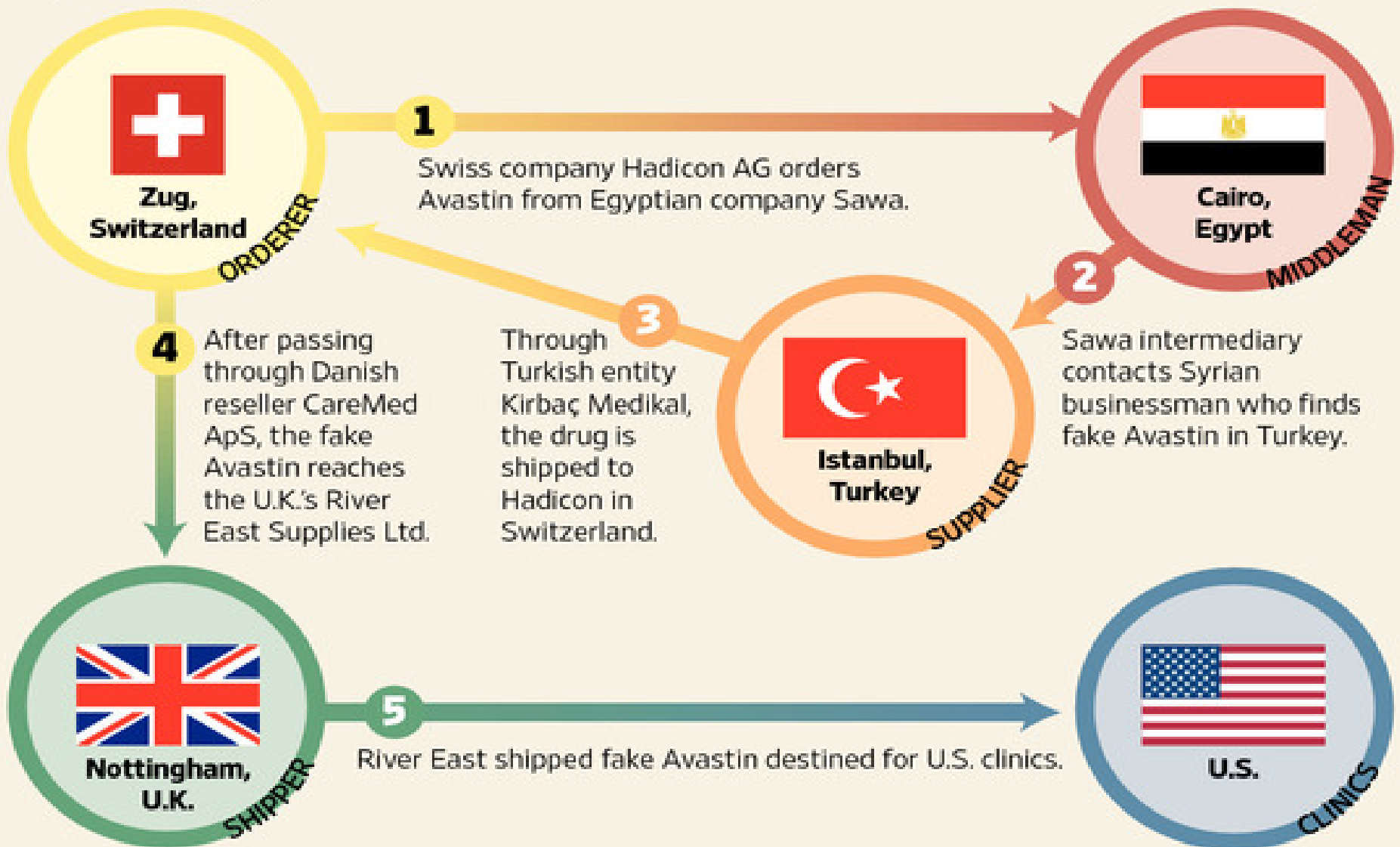
Product contained no API

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.



Source: WSJ reporting

The Wall Street Journal

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

120 units

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



Product contained no API

Source: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm>



How does this happen?

Examples of Internet Ecosystem for
Pharmaceutical Sales



You Tube – Sellers Targeting Providers, Much Like a Fax Blast...Lumigen



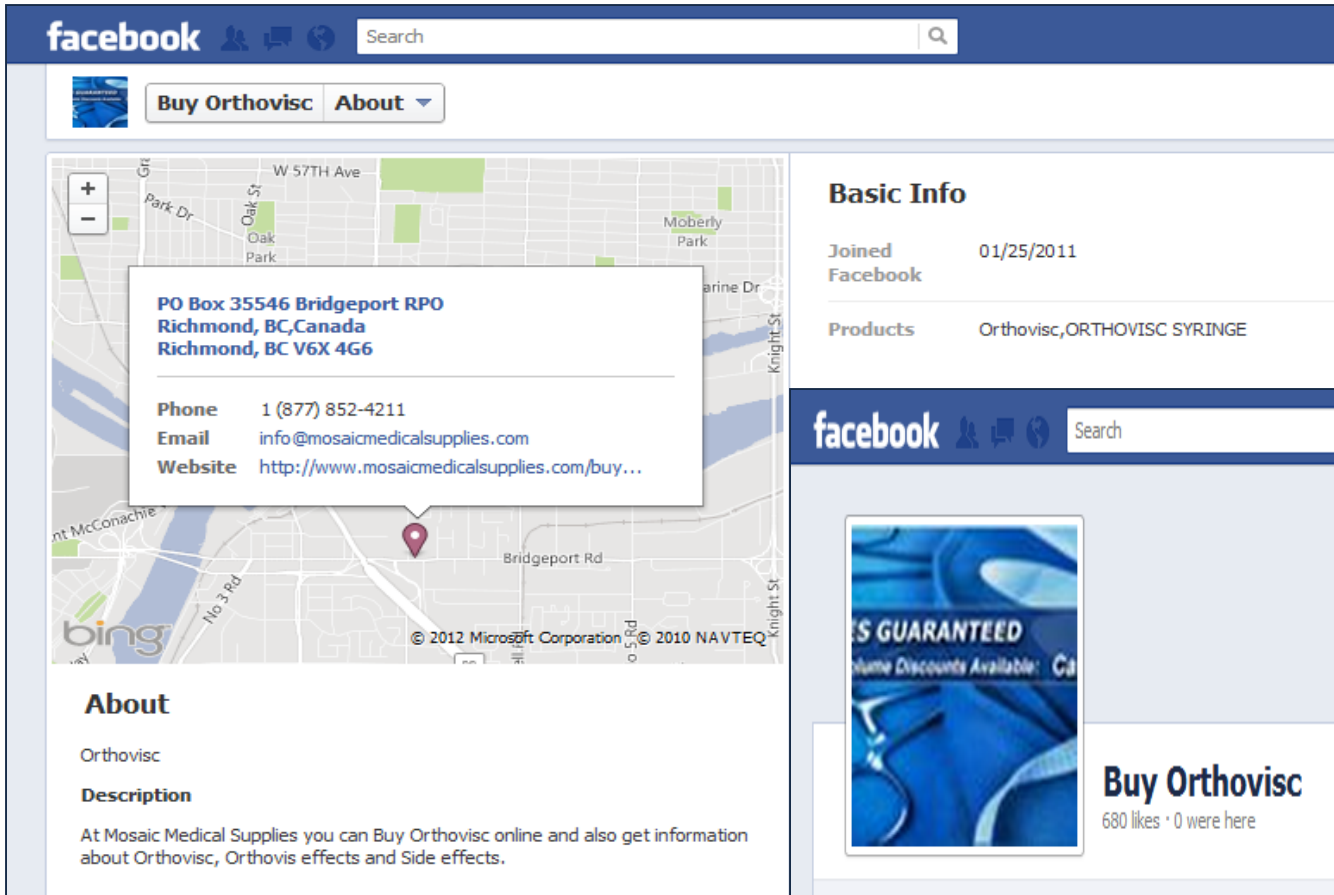
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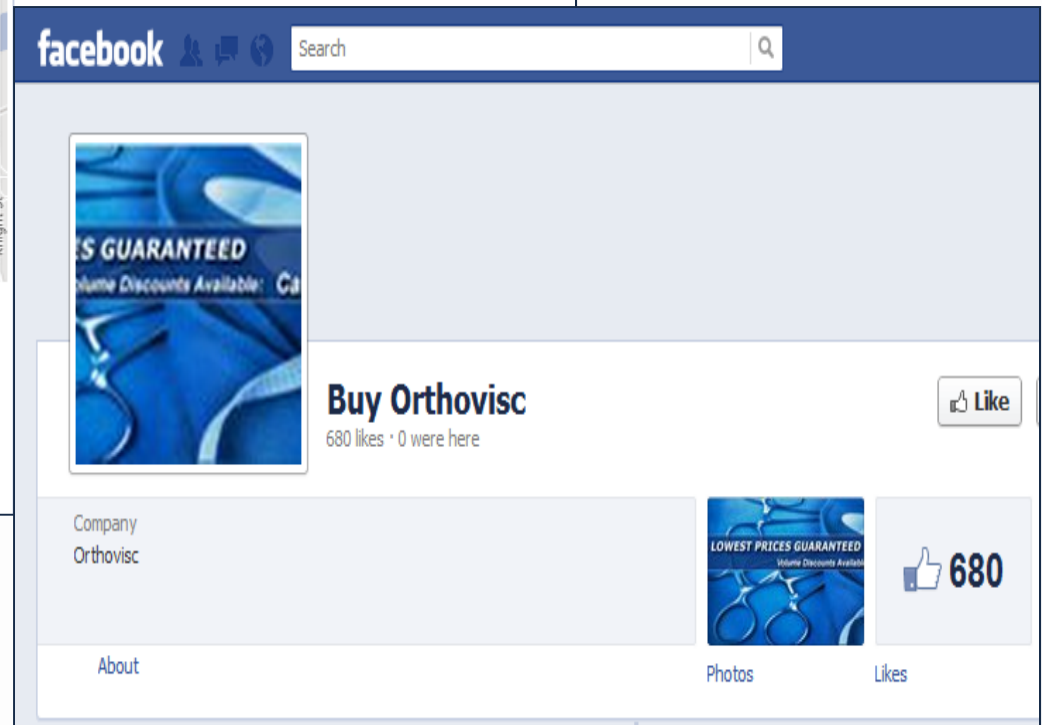
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Preventive cardiology training sorely lacking, study says
2012 May 04 16:16
Most physicians being trained to specialize in cardiology are not getting enough training in preventive cardiology, according to a survey of 43 cardiology fellowship programs met American College of Cardiology Foundation guideline training dedicated to preventive cardiology. Another 24% had no focus on preventive cardiology, says the American Journal of Cardiology. Dr. Quinn Pack, MD, lead study author and a preventive cardiologist at Henry Ford Hospital, said the study shows a lack of competing demands for the education time of cardiology fellows by respondents included limited time, a lack of a developed curriculum, and a focus on acute care. Teaching preventive cardiology is vital, because many of the leading causes of preventable death, but cardiology fellows never set foot in a preventive medicine during their internal medicine training, but card

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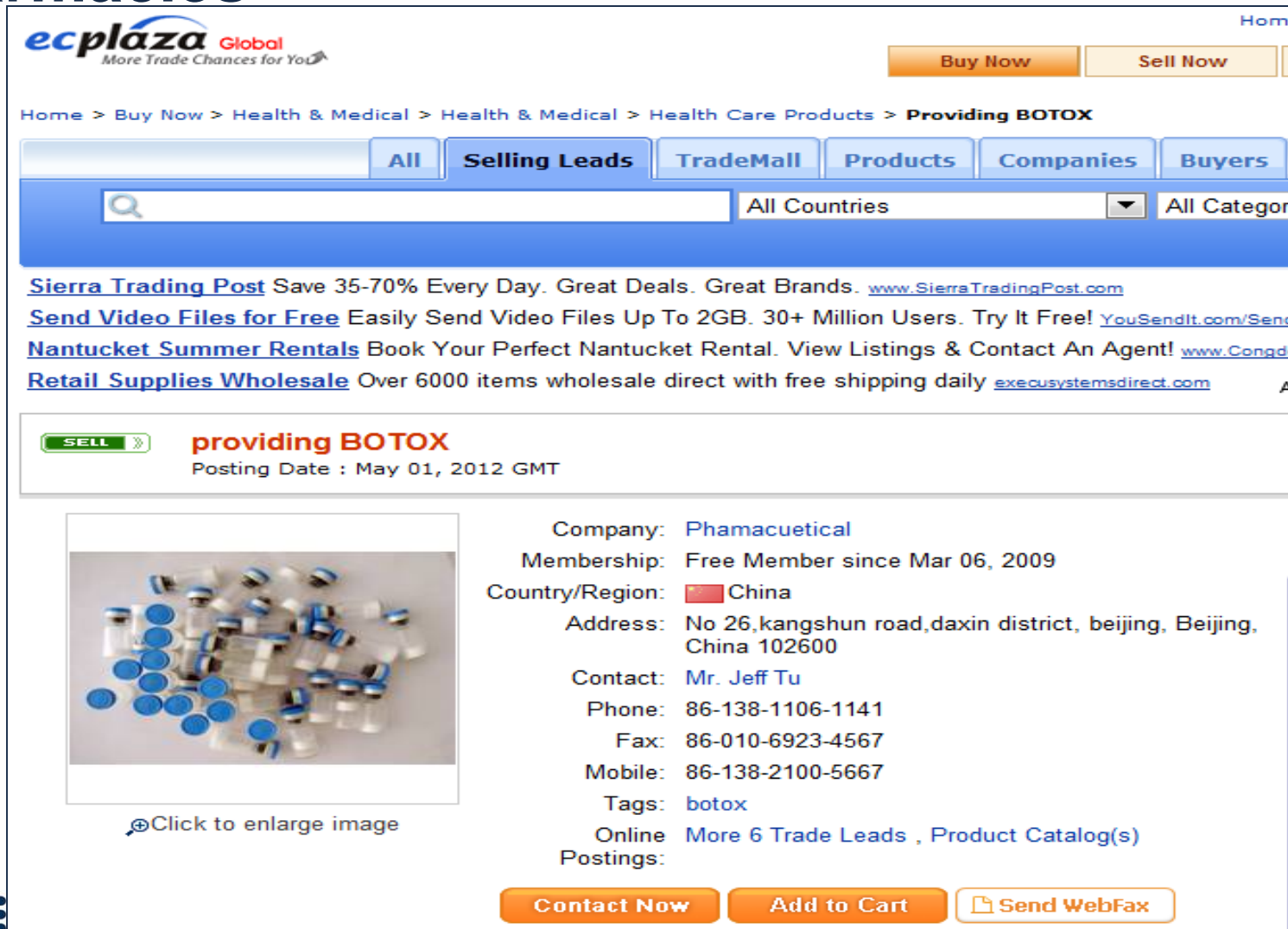
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Signals – Where will they be obtained?

Patient & Doctor Complaints



Online Pharmacies & B2B Trade Boards



Forums & Blogs



Spam Emails/Faxes



Internet Search



Media Reports



Criteria for Prioritization: Risk Analysis

Criteria Overview

Region	Package	Price	Dosage Form & Ingredients		Description			Links to Fraudster Network	
Americas, Asia, Caribbean, n.n. = 4 Eastern Europe = 2 Other Countries = 0	Correct = 0 Wrong or missing = 2	outside range = 2 within range = 0	Dosage form correct = 0 Dosage form wrong = 4	Ingr. correct = 0 Ingr. wrong = 4	Correct = 0 Suspicious = 4	Prescr. needed = 0 not needed = 2	"Customs" mentioned = 4 not mentioned = 0	No links = 0 links likely = 2 links proven = 4	Known Fraudster 8
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2	0	n/a	0	0	4	2	4	4	0
2	0	n/a	0	0	4	2	4	4	0
4	0	n/a	0	0	4	2	4	2	0
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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

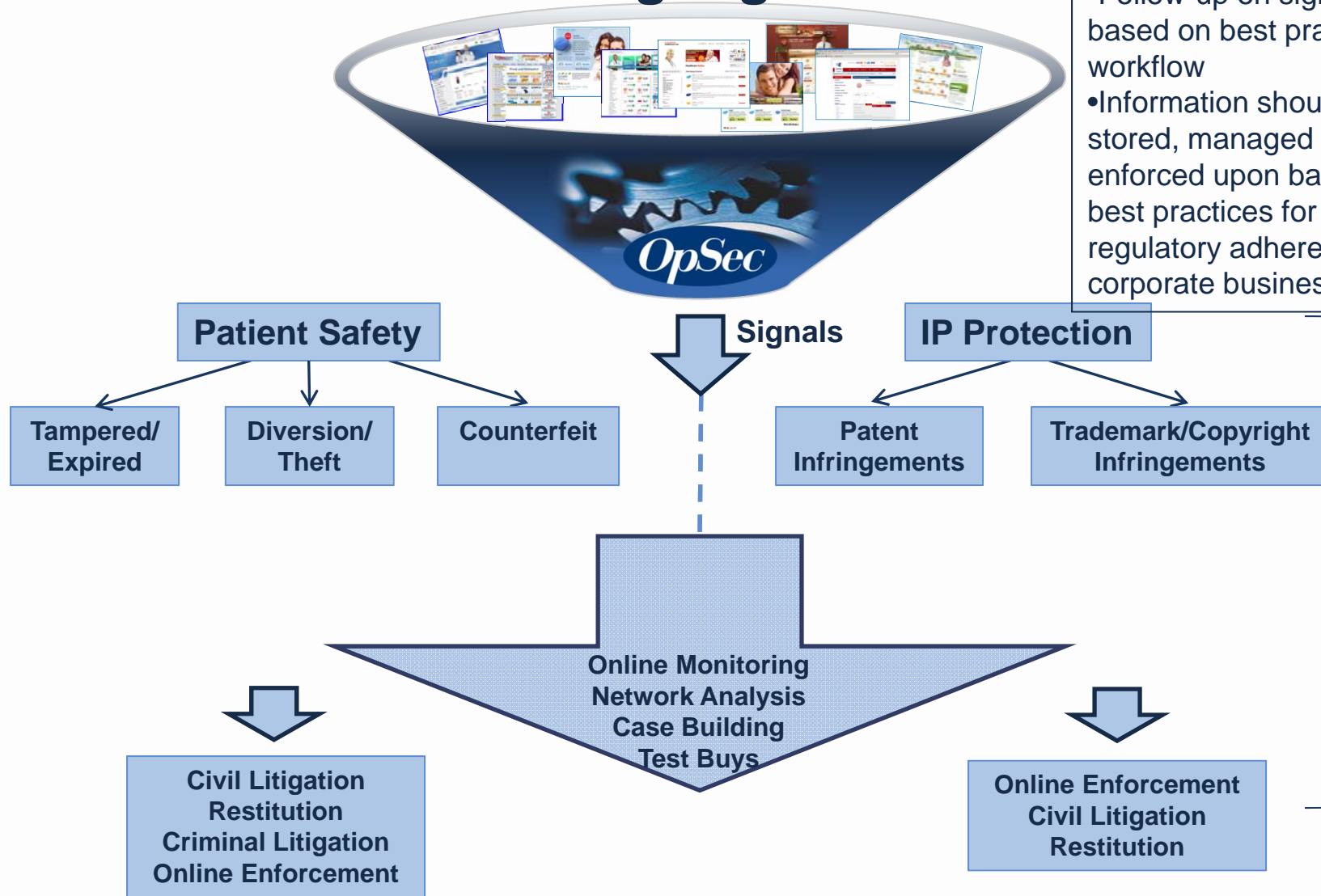
Follow-up:

- Send Warning letter...
- Conduct Online Investigation into Unauthorized Distributors – follow-up with additional enforcement



Sample Methodology for Processing Incoming Signals

- 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



Engage Key Stakeholders

Internal Stakeholders

External 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:

Quickly terminate listings/postings on B2C and B2B platforms with Right's Owners policies

Establish & maintain relationships with platforms to influence policies, outcomes

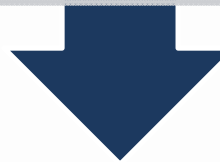


Get to the source – the large-scale players:

Investigate targeted sellers on B2B exchanges & across all online platforms

Focus on regions where you can take action

Identify 'hubs' or sites with high traffic & product/sales



Reduce availability of counterfeit/diverted product:

Protect Patients

Improve Brand Equity

Create tangible ROI



Questions?



Thank you

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