PHARMACEUTICAL PRODUCT DIVERSION:
BEYOND THE PDMA

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What is Diversion/Gray Marketing?

- An unlawful channeling of regulated pharmaceutical/medical device products from a legal source to an unauthorized marketplace or “channel”
  - Abuse of distribution system
  - Occurs when products intended for specific market are “diverted”, i.e., sold to alternative, unauthorized markets in violation of the parties’ stated intent
  - Price typically drives market – aka Arbitrage
What Does Diversion Do?

- Single biggest factor contributing to counterfeit drugs in the supply chain – see FDA Counterfeit Drug Task Force Report 2/9/06

- “Corrupt” distributors in the supply chain are responsible for supplying counterfeit drugs to retail pharmacies – Roberts Brice, Ann – Life Science Leader – March 2009 – Quoting Katherine Eban, author of “Dangerous Doses”

What are the Significant Threats Presented by Diversion?

- Theft
- Product Tampering
- Intellectual Property Rights Violations
  - Trademarks
  - Copyrights
  - Patents
- Counterfeiting
- Internet Prescription Abuse
PDMA Enforcement Challenges in Pharma

- Ignorance of opportunities
- Judicial resources
- Lack of clear sanctions
- Lack of consistent messaging & education
Source of Diverted Drugs

- Stolen goods
- International diversion
- "Own Use" fraud
- Internal conspiracies
- Samples
- Doctor shopping and pill mills
- Repackaging
- Breach of contract
- Sales quotas
Potential Pathways to Diversion

- Group purchasing organizations
- Health maintenance organizations (HMOs)
- Pharmacy benefits managers (PBMs)
- Chargeback/rebate agreements
- Durable Medical Equipment (DME) suppliers
- Retail and Closed Door Pharmacies
Diversion – How Does it Happen?

- **FRAUD:** Purchaser poses as institution or non-retail customer (legitimate or shell companies)
  - Manufacturer substantially discounts products and sells to purchaser – “contract price”
  - Purchaser resells discounted products into retail channels or other distribution channels at a profit
Diversion – How Does it Happen?

- Abuse of contract terms and conditions
  - Chargebacks
  - Rebates
  - Volume commitment agreements
  - “Own use” violations
Chargeback Abuse

- Pharma negotiates price with Wholesaler
- Pharma negotiates a lower contract price with a GPO or other buyer who buys from Wholesaler
- Chargeback – is difference between what Pharma charged Wholesaler and contract price offered to GPO/buyer
- Wholesaler may purchase product from diverter at a discount
- ABUSE – Wholesaler submits Chargeback for (a) diverted products or (b) counterfeit products
Rebates

- Medicaid – drug coverage involves rebates and participation in other related programs

- Abuse: Rebates claimed for 340B drugs purchased for non-340B patients

- Submission of false claims to substantiate rebate
Volume Commitment Agreements

- Purchaser commits to volume that is designed to include products that will be resold
- Sales Reps “overlook” volume issues
Own Use

- Purchaser commits to buying products for “own use”
- Typically Institutional purchasers, i.e.,
  - Hospitals
  - Nursing Homes
  - Prisons
  - Assisted Living Facilities
Secondary Channels Create Pathways for Counterfeiting

- Legitimate Channels infiltrated by diverters
- Diverters buy “any” product on sale
- Result: Altered, re-labeled, expired, counterfeit, defective product finds its way into retail channels
Pharmaceutical Manufacturers

Primary Wholesalers

Secondary Wholesalers/Repackagers

Importers

Exporters

Foreign Countries

Pharmacies

Destruction Sites

Discounted Groups

Expired/Short-dated

Stolen/U-Boat/Donations

Counterfeiters

Diverters

Internet Pharmacies/TBB

Green = Legitimate
Yellow = Stolen/Diverted/Counterfeit
Red = Counterfeit

All Consumers

Repackagers

Primary Wholesalers

Pharmacies
Diversion Overseas

• Product for Overseas distribution is resold outside intended channel

• Divers buy “any” product on sale

• Result: Altered, re-labeled, expired, counterfeit, defective product finds its way into retail channels

• “U-Boats” - Product can find its way back into US
Tracing a Trade Route

The authorities say that drugs sold by a Canadian online pharmacy, RxNorth, did not originate in Canada, but were made in China and shipped to the United States along a complex intercontinental trade route.

1. Drugs from an unknown manufacturer on the Chinese mainland were trucked to Hong Kong.
2. From Hong Kong, the drugs were shipped to a free trade zone in the emirate of Sharjah.
3. From the United Arab Emirates, the drugs were flown to London Heathrow Airport.
4. The drugs were shipped to the Bahamas, where pharmacists filled the individual orders.
5. The packaged drugs were sent back to Britain, then mailed to buyers in the United States.

Sources: Drug company investigators and British law-enforcement officials

Image Courtesy of CTV/The New York Times
Diversion From Within

- **Intentional**
  Sales quotas can lead to intentional sales to diverters

- **Unintentional**
  Sales Reps can unwittingly provide diversion opportunities
  - Failure to do due diligence on the front end
  - Failure to confirm legitimacy of company
  - Failure to monitor spikes in orders
  - Failure to maintain updated info on purchaser
Combating Diversion

- Prevention
- Detection
- Deterrence
Prevention – Establish SOPs for New Accounts

- Train “detail – oriented” employees
  Fully informed of company compliance procedures

- Back-up training in absence of responsible personnel

- SOPs – written, maintained and available
Prevention – Be Proactive

• Due Diligence
  o Know the customer
  o Obtain background info
  o Review background info
  o Verify background info
  o Independently investigate
  o Maintain a database to cross-check information supplied
Prevention – Applications and Background Checks

• Credit application and background questionnaire should include:
  o Nature of business
  o Customer base
  o Average product needs (per month/year)
  o Patient population (monthly/annually)
  o Copies of applicable state/federal licenses and registration
  o Presence of retail/internet pharmacies
Prevention – Background Checks

- Check FDA MedWatch & counterfeit site: [www.fda.gov](http://www.fda.gov)

- Wholesaler oversight – Verified Accredited Wholesalers Distributor (VAWD)? See National Association Boards of pharmacy list: [http://www.nabp.net/indexvawdlist.asp](http://www.nabp.net/indexvawdlist.asp)
Prevention

- **Verify information provided by prospective customer**
  Complete, accurate and current?

- **Investigate**
  Visit premises and call references

- **Protection “plus”: reviewer signs and dates customer info**

- **Contract Terms**
Prevention

• Contract terms – incorporate “own use” certification with reps and warranties (Abbott Labs. v. Portland Retail Druggists, 425 U.S. 1 1976)
  o Incorporate “Own use” certification with reps and warranties
  o Right to audit – anytime
  o Liquidated damages
  o Right to injunctive relief
  o Admission as to harm caused by resale outside authorized channels
Implement Detection System

• With system design in place
  o ID product with classes of trade i.e., hospital, nursing home, prison
  o Establish thresholds (lower for new accounts)
  o Monitor purchasing trends: anomalies and volume increases require further inquiry suspension/shutdown
  o Periodic reviews and inspections
Deterrence

- **Civil legal action**
  - Recover economic losses
  - Recover product – ex parte seizures
  - Injunctive relief
  - Seek an accounting
  - Recover punitive damages
  - Close the diverter down
Legal Theories against Diverters

- Fraud/misrepresentation
- Breach of contract
- Breach of implied duty of good faith and fair dealing
- Civil RICO (mail and wire fraud)
- Unjust enrichment
- Lanham Act – 15 U.S.C § 1501
  - Injunction
  - Trademark confusion
Deterrence through Resolution of Lawsuits against Diversers

- Monetary terms

- Diverter agrees to refrain from doing business with company

- Diverter reps and warrants that no other affiliated/related company is doing business with company

- Diverter identifies source of products
Diversion and Now Counterfeiting

- 40% of all finished medicines are sourced overseas
- 80% of all APIs sourced overseas

And That’s the Authentic Stuff!!!

Source: Food and Drug Administration
Total Number of Incidents by Year

CY 2002 – CY 2009

## Top Ten Ranked Counterfeit Products Seized/Discovered - CY 2009

<table>
<thead>
<tr>
<th>Country</th>
<th>Seizure/Discovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. China</td>
<td>273</td>
</tr>
<tr>
<td>2. Peru</td>
<td>141</td>
</tr>
<tr>
<td>3. Brazil</td>
<td>129</td>
</tr>
<tr>
<td>4. United States</td>
<td>100</td>
</tr>
<tr>
<td>5. Germany</td>
<td>77</td>
</tr>
<tr>
<td>6. United Kingdom</td>
<td>71</td>
</tr>
<tr>
<td>7. Japan</td>
<td>64</td>
</tr>
<tr>
<td>8. South Korea</td>
<td>59</td>
</tr>
<tr>
<td>9. Israel</td>
<td>52</td>
</tr>
<tr>
<td>10. India</td>
<td>49</td>
</tr>
</tbody>
</table>

*Source: Pharmaceutical Security Institute – 2009 Situation Report*
Top Five Ranked Counterfeit Products Origin – CY 2009

<table>
<thead>
<tr>
<th>Country</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. China*</td>
<td>192</td>
</tr>
<tr>
<td>2. India</td>
<td>106</td>
</tr>
<tr>
<td>3. Paraguay</td>
<td>49</td>
</tr>
<tr>
<td>4. Syria</td>
<td>8</td>
</tr>
<tr>
<td>5. Thailand</td>
<td>8</td>
</tr>
</tbody>
</table>

*31% in legitimate commerce

The Wall Street Journal online – February 14, 2008 reported that

“A Chinese facility that hasn’t been inspected by the U.S. Food and Drug Administration made the active ingredient in much of the widely used .... [product] that is under investigation after reports of hundreds of allergic reactions and four deaths among the drug’s users, the agency said yesterday”
Fake Versions – Examples

- Counterfeit version 3x the daily dose of the prescription drug
- Counterfeit version was purchased on eBay and other websites
Fake Version

- Counterfeit products look similar to authentic product

- Differences reported by FDA and Manufacturers:
  - Authentic Version
    - Outer package contains “Lot” code
    - Expiration date includes month and the year, such as a “5/12”
    - Foil seals read: “sealed for your protection” in white ink
    - Content of capsule has a defined pellet shape
  - Counterfeit Version
    - Outer package missing “Lot” code
    - Expiration date includes the month, day, and year
    - Foil seal is plain and doesn’t contain any printing
    - Capsule size is slightly larger and the content inside the capsule is different
Why this Works

- U.S. and state regulation of pharmaceutical supply chain is weak
- Manufacturers do not control their own distribution system
- Wholesalers deal in gray market
- Criminals are sophisticated and deal in large quantities of product
And What About the Internet?

- 2009: 23,232 billion sites indexed by Netcraft™
- “Only” 700 million active
- > 100 B2B/B2C trade boards
- > 1,400 internet pharmacy sites/daily
What to Know About the Internet

- 50% men using Internet to purchase ED medicine
- 90% medicines on Internet believed to be counterfeit
- 68% suspected ingredients were counterfeit

Source: Pfizer/TNS European Study, 2008
Websites Selling Prescription Drugs

• Approved Internet pharmacies on the NABP website are accredited by the VIPPS (Verified Internet Pharmacy Practice Sites)

• VIPPS-accredited Internet pharmacies successfully complete NABP’s rigorous 19-point criteria evaluation and on-site inspection

• NABP website: www.nabp.net
NAPB’s New e-Advertiser Approval Program

- e-Advertiser Approval Program now required by Google, Microsoft, and Yahoo!
- Launched in April 2010, NAPB rolled out first approvals in July 2010
- Approved entities clear comprehensive standards review designed to ensure advertisers offer reliable and trustworthy resources for patients seeking to purchase medications safely online
The Challenges of the Internet

- 5,231 internet drug outlets have been assessed since May 2008*

- 96% non-compliant
  - >75% invalid prescriptions
  - > half (2,762) accept brief online questionnaire
  - 25% physical address outside of U.S.
  - 2,436 have no physical address
  - 2,216 offer foreign/unapproved drugs
  - 20% are unsecure

- Most operators have no knowledge of patient safety

Source: NABP
Sample Internet Purchase

- Internet site reportedly located in Canada
- The site is registered in China
- Package arrived with Dallas postmark and a Miami return address
- The credit card was billed to St. Kitts

So how should we feel about the authenticity, safety and efficacy of your prescription drugs?

*Giuliani Partners: Examination and Assessment of Prescription Drugs From Foreign Sources to the United States*
KnujOn & Legit Script Reports

- 89% online pharmacy ads from rogue pharmacies
- Most sites did not require prescriptions
- Most sites re-directed users
- Majority of products counterfeit
- Some sites linked to international organized crime
Dear Dick Wilson,

You have received a quotation from G.L TRADERS, in response to your buy offer (Looking for Diltiazem (Quantity: 25)) posted on TradeKey.com.

**From:** G.L TRADERS | Silverkey Member (TrustPoints 10)

(This company is a Silverkey member of TradeKey.com)

**Subject:** all kind of medicine

**Country:** Pakistan

**Date:** 4/3/2009 14:49:37

**Message:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Unit</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sustanon 250mg</td>
<td>1mg</td>
<td>1 (inj)</td>
</tr>
<tr>
<td>Testosterone Enanthate 230mg</td>
<td>250mg*10 (inj)</td>
<td></td>
</tr>
<tr>
<td>Deca-Durabolin 100mg</td>
<td>100mg *1 (inj)</td>
<td></td>
</tr>
<tr>
<td>Testosterone Dipropionate 100mg</td>
<td>100mg *5 (inj)</td>
<td></td>
</tr>
<tr>
<td>Winstrol 1mg</td>
<td>3ml * 3 (inj)</td>
<td></td>
</tr>
<tr>
<td>Testosterone Propionate 100mg</td>
<td>100mg * 10 (inj)</td>
<td></td>
</tr>
<tr>
<td>Prohijin I U 1500mg</td>
<td>1500 * 5 (inj)</td>
<td></td>
</tr>
<tr>
<td>Prohijin I U 5000mg</td>
<td>5000 * 5 (inj)</td>
<td></td>
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<tr>
<td>Estanorone</td>
<td>1ml * 1 (inj)</td>
<td></td>
</tr>
<tr>
<td>Normapon 120mg</td>
<td>120mg * 1 (inj)</td>
<td></td>
</tr>
<tr>
<td>Proviron Mesterolone</td>
<td>25mg * 20 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Primobolone inj 100mg</td>
<td>100mg * 5 (inj)</td>
<td></td>
</tr>
<tr>
<td>Clomifene citrate tablet</td>
<td>5mg * 50 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Ketofit</td>
<td>1mg * 30 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Levoce / Laurumycin 40mg</td>
<td>40mg * 50 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Estanorone prolongatum</td>
<td>1ml * 1 (inj)</td>
<td></td>
</tr>
<tr>
<td>Proscar / Finasteride</td>
<td>5mg * 30 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Cytomel 25mg</td>
<td>25mg * 30 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Avisanol 1mg</td>
<td>30 (Tablet)</td>
<td></td>
</tr>
<tr>
<td>Androlic / Testosterone undecanoate</td>
<td>40mg (tab) * 40mg *50 (bottail)</td>
<td></td>
</tr>
<tr>
<td>Thyroxin / Levothyroxin sodium 100mg</td>
<td>100mg * 100 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Anabol (pink) 5mg</td>
<td>5mg * 10000 (bottail)</td>
<td></td>
</tr>
<tr>
<td>Stanozol (Winstrol) 5mg</td>
<td>200 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Stanbol 10mg</td>
<td>10mg * 1000 (tablet)</td>
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</tr>
<tr>
<td>Anavar / Oxandrolone 10mg</td>
<td>30 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Anavar / Oxandrolone 5mg</td>
<td>30 (tablet)</td>
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<tr>
<td>Cledbutol / Clenbuterol hydrochloride</td>
<td>20mg * 200 (tablet)</td>
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<tr>
<td>Cytomel T3 LA Pharma 100mcg</td>
<td>100mcg * 100 (tablet)</td>
<td></td>
</tr>
<tr>
<td>British dispensary (yellow) 10mg</td>
<td>10mg * 300 (tablet)</td>
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<tr>
<td>Danabol 10mg</td>
<td>10mg * 500 (tablet)</td>
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<tr>
<td>Anidolic / Anadrolcholine 50mg</td>
<td>50mg * 100 (tablet)</td>
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<tr>
<td>Azolol 5mg</td>
<td>5mg * 100 (tablet)</td>
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<tr>
<td>Phenetermine 37.5mg</td>
<td>37.5mg * 500 (tablet)</td>
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<tr>
<td>Reducil 15mg</td>
<td>15mg*28 (caps)</td>
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<tr>
<td>Xanicol 120mg</td>
<td>20mg*28 (caps)</td>
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<tr>
<td>Ephedrine HCL 30mg</td>
<td>30mg * 1000 (tablet)</td>
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<tr>
<td>Gerovital H3 / Procaine HCL / Carbopenteleg 10ml</td>
<td>10ml*10 (inj)</td>
<td></td>
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<tr>
<td>Diazepam 10mg</td>
<td>10mg * 100 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Temazepam (pab) 20mg</td>
<td>20mg*500 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Xanam / Alprazolam 1mg</td>
<td>500 (tablet)</td>
<td></td>
</tr>
<tr>
<td>Resolam / Benzodiazepem 30mg</td>
<td>30mg * 20 (caps)</td>
<td></td>
</tr>
<tr>
<td>Nitrazepam/mogdom/apodium</td>
<td>5mg 5mg*30 (tablet)</td>
<td></td>
</tr>
</tbody>
</table>

http://mail.google.com/mail/?ui=2&ik=b317b1a3ac&view=pt&search=inbox&th=1206e7f... 4/20/2009
Internet – Superhighway to Trouble

- 95.6% of online pharmacies researched are operating illegally
- 94% of websites do not have a named, verifiable pharmacist
- Over 90% of websites supply prescription-only medicines without a prescription
- 86% of online “pharmacy approval” stamps are fake

Source: The European Alliance for Access to Safe Medicines, June 5, 2008
Brand Protection

• How can we protect our brand?
  o People
  o Technology Solutions
  o Processes/Procedures
  o Monitoring & Evaluation
How Can We Protect the Brand?

- **People (It’s ALL about relationships!)**
  - CEO
  - Cross-Divisional Teams
  - 3rd Parties
  - Law Enforcement

BREAK DOWN THE SILOS!

ALIGN ACROSS BUSINESS UNITS
How Can We Protect the Brand?

- Processes

1. Conduct a Risk Assessment
2. Assess and Quantify the Threats
3. Develop and Implement Responses
4. Monitor Results
5. Refine Strategy
Protecting the Brand

• **Intelligence Collection**
  - Internal
  - External
  - Market Surveys

• **Education**
  - Internal
  - Consumers
  - Business Partners
  - Law Enforcement
  - Government

• **Interdiction**

• **Ongoing Review and Improvement**
How To Protect the Brand?

- Procedures and Agreements
- Due Diligence
- Manage production waste and damaged or unusable inventory
- Vigorously pursue remedies
- Outreach to law enforcement and regulatory officials
- Consistently monitor brand integrity
THE END
The Power of Sharing 2010

The 2010 PDMA Sharing Conference
Hilton San Diego Bayfront • Oct. 3 - 6, 2010