

Breakout Group 3:

Agency Roles

- DEA is the lead Federal Agency in countering diversion
- FDA/CDER mission is to promote and protect the public health by ensuring that safe and effective drugs are available to U.S. citizens
- FDA responsibilities fall under the FDCA (Food, Drug and Cosmetics Act) and the CSA (Controlled Substances Act)

RiskMAPs and the Supply Chain

- Issues such as supply chain integrity from manufacturer to pharmacy are the responsibility of the DEA
- The patient is the sole legitimate recipient of the controlled drug who is not a DEA registrant
 - FDA's RiskMAP's includes information for patients and family members on the safe use of the controlled drug and patient surveillance and monitoring.
- Prospective measures to assess the success and impact of the RiskMAP are needed.

Background

- The environment changed
- 2004-2005 - DEA realized it needed to quickly respond to the rapid increase of diversion involving rogue Internet pharmacies
- DEA conducted investigations of pharmacies – Time consuming/Resource draining.
- Looked at the supply chain – Distributor to Pharmacy



Rogue Cyber vs. Brick & Mortar Sales

- The average independent pharmacy in the U.S. fills **181** prescriptions per day
 - **11%** are for controlled substances (**20** prescriptions per day)*
- One rogue internet pharmacy filled an average of **450** 'cyber-prescriptions' per day
 - Approximately **95%** were for controlled substances (**425** prescriptions per day)

*SOURCE: 2003 NCPA-Pfizer Digest
New York, New York - June 26, 2003

DEA Supply Chain Actions

- Aug 10, 2005 – Aug 23, 2007 - DEA met with 24 distributors to remind them of their regulatory obligations:
 - The process of due diligence to establish customer accounts (Know your customer)
 - Design and operate a system to disclose suspicious orders to the registrant
 - Suspicious orders versus excessive purchases (reporting before the order is filled instead of after its shipped).
 - Reporting to DEA
- July 31, 2007 - Letter sent to all pharmacy registrants discussing that the illegal sale of controlled substances via the Internet poses a serious threat to the public health and safety.
- December 20, 2007 - Letter sent to all manufacturers and distributors discussing the requirement for the registrant to report suspicious orders.

Suspicious Orders

Title 21 CFR 1301.74(b)

Requires registrant to design & operate a system to disclose suspicious orders of controlled substances to the DEA

The requirement is to report suspicious orders, not suspicious sales after the fact.

Suspicious Orders

- Suspicious orders include:
 1. Unusual size
 2. Deviations from a normal pattern
 3. Unusual frequency
- Each controlled substance distributor must define their own parameters for a suspicious order.
- Suspicious order monitoring programs must evolve with the demands of fighting the constantly changing illicit drug market.

Suspicious Orders

The responsibility for making the decision to ship rests with the supplier.

Registrants who routinely report suspicious orders yet fill these orders, with reason to believe they are destined for the illicit market, are failing to maintain effective controls against diversion.

Closing remarks

- DEA cannot establish finite guidelines for industry.
- DEA cannot tell a distributor whether to ship or not.
- Industry knows their customers and is in a better position to evaluate to whom they are selling controlled substances.
- Communication between distributors and pharmacies is critical.
- All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.
- DEA is mandated to protect the public's safety. Industry shares in that responsibility.

Supply Chain Issues

- Supply chain security is relevant to many public health and safety issues affecting many drugs including opioids
- For example WHO estimates that 25% of world's drug supply is counterfeit
- Supply chain control is the responsibility of the DEA registrant in possession of the drug
- These registrants are subject to pedigree laws and many other requirements to ensure integrity of supply chain
- State licensing requirements are of variable quality and are variably enforced
- Presently pedigrees and other requirements are not standardized, which does not sufficiently allow for understanding of supply chain losses
- Consequences include potential exposure to bad medicine via gray market, as well as diversion into black market

- Standardized approaches including RFID could be used to generate better data and better security of supply chain; however there are numerous obstacles
- Distributors also examining whether developing supply chain security standards would be (1) feasible and (2) useful

Pharmacy Security

- Purdue has conducted and is in process of publishing a study on pharmacy theft resulting in suggested security measures
- Purdue and DEA are considering mass dissemination to US pharmacies

Data

- Improvements in Form 106 data would help understand supply chain security

Supply Chain Summary

- Description of supply chain
 - Actors, regs
 - Purposes: decrease counterfeiting, diversion, black/gray markets
- Weaknesses in system, potential public health and other consequences
 - Insufficient standardization/enforcement
 - Inadequate data; inadequate reporting
 - Bad drugs, diverted/abused drugs
- Suggestions for improvement
 - Improve 106 form data, online version; integration of state loss reports
 - Promote adoption of RFID technology; FDA notice; legislation
 - Discussion of security standards among distributors
 - Pharmacy security standards
 - Better state enforcement of regs
 - More uniformity of supply chain standards
 - Develop mechanisms to improve enforcement of standards