

To: 'smays@amerisourcebergen.com'[smays@amerisourcebergen.com]  
Cc: Mapes, Michael R. [Michael.R.Mapes@usdoj.gov]  
From: Wright, Kyle J.  
Sent: Fri 8/12/2005 2:43:29 PM  
Subject: RE: Internet Pharmacy Presentation  
Attachment: INTERNET PHARMACY.ppt

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Steve

We too enjoyed the meeting with you and thought that it was very productive.

Per your request, I have attached the requested powerpoint presentation.

If you have any questions or need assistance, please feel free to contact me at any time.

Kyle J. Wright, Chief  
E-Commerce Operations Unit  
(703) 653-2103 - Office  
(703) 653-2066 - FAX

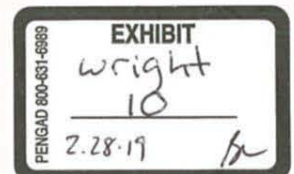
-----Original Message-----

From: smays@amerisourcebergen.com [mailto:smays@amerisourcebergen.com]  
Sent: Thursday, August 11, 2005 11:20 AM  
To: Wright, Kyle J.  
Cc: CZimmerman@amerisourcebergen.com  
Subject: Internet Pharmacy Presentation

Kyle,

I enjoyed meeting with you, Mike and Charles yesterday at DEA's headquarters. Would it be possible for me to get an electronic version of the PowerPoint presentation? The pictures would be especially helpful when training our sales people. ABC looks forward to working closely with DEA in its efforts to eliminate illegal Internet Pharmacy operations and to prevent the overall diversion of controlled substances from the legitimate supply chain. Please do not hesitate to contact me directly if you have any questions or concerns.

Steve Mays  
Director, Regulatory Affairs  
Corporate Security & Regulatory Affairs  
AmerisourceBergen Corporation  
610-727-7467 Phone  
610-727-3650 Fax



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PLAINTIFFS TRIAL  
EXHIBIT

**P-21756\_00001**

US-DEA-00003880

P-21756 \_ 00001

**DOCUMENT PRODUCED IN NATIVE FORMAT**

# INTERNET PHARMACY DATA

Meeting With  
AmerisourceBergen  
DEA Headquarters  
August 10, 2005



# Internet Pharmacies

- Domestic Based
  - Related to an existing pharmacy
    - Walk in patients with prescriptions
    - Some legitimate some not
  - Unrelated to brick and mortar pharmacy
    - No local patients or doctors
    - No walk-in business
- Foreign based



# ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor



# DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
  - Is the registration in the public interest?
    - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels



# Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
  - Mail order sales to doctor
  - Most sales were Morphine
  - Increase in quantities purchased
  - Business practices attracted customers who were violating the law
  - Drugs have inherent susceptibility to harmful and illegal use



# EZ RX, LLC

- 69 FR 63,178 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 300,000 dosage units in three months
    - Phentermine, Phendimetrazine, Ambien



# RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 19,300,000 dosage units of various controlled substances
    - Based on Internet Questionnaires
  - Not in the course of professional practice
  -



# Supreme Court Case

- United States v. Moore  
423 U.S. 122 (1975)
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed



# DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances



# VERIFIED INTERNET PHARMACY PRACTICE SITES (VIPPS)

- National Association of Boards of Pharmacy
  - Licensed, legitimate, Inspection
  - 14 VIPPS Approved Pharmacies as of 06-27-2005
  - [www.nabp.net/vipps/consumer/faq.asp](http://www.nabp.net/vipps/consumer/faq.asp)



# American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
  - valid patient-physician relationship, includes, but not limited to:
    - History and physical exam
    - Dialogue with patient
    - Follow up to assess outcome
    - Maintain medical record
    - Include electronic prescription in patient's medical record



# Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
  - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
  - Treatment based solely on an online questionnaire is not acceptable



# Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered



# Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion



# Suspicious Orders

- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision



# Example #1

- Retail pharmacy
  - Quantities of drugs
  - Range of drugs sold
  - % controlled and % non-controlled
  - Size of orders over time
  - Location of store
  - Internet prices



# Example #1





# Example #2

- Retail Pharmacy
  - Location of store
  - Only Hydrocodone and Alprazolam
  - Very large quantities
  - FedEx boxes for delivery
-



# INVESTIGATORS AT PHARMACY









# Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit



# AN INTERNET PHARMACY





# Popular Internet Drugs

- Hydrocodone
- Phentermine
- Alprazolam



# SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies



# SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds



# SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor



# SUMMARY

- DEA will:
  - Meet with other distributors involved in distributing to Internet pharmacies
  - Provide this information to your employees at your request
  - Meet with Industry groups or associations to discuss issue if requested



# Contact Information

Michael Mapes

Chief, E-Commerce Section

703-653-2048

Kyle Wright

Chief, E-Commerce Operations Unit

703-853-2103