



CLAIMANT'S REQUEST FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF

Supplemental Response to Request No. 9



**Drug Enforcement Administration's
Office of Diversion Control**

13th Pharmaceutical Industry Conference

Houston, Texas
September 11 - 12, 2007

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Friday, September 07, 2007

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U.S. Department of Justice - Drug Enforcement Administration
Office of Diversion Control

13th Pharmaceutical Industry Conference

Houston, Texas
September 11 - 12, 2007

Power Point Slide Presentations:

- Thomas McLaughlin - Pharmaceutical Drug Theft
- Michael Mapes - Suspicious Orders
- Susan Carr - Ongoing Quota Issues
- Susan Baker - Overview of DEA Form 106
- Mark Caverly - Regulatory Update
- Mark Caverly - Combat Methamphetamine Epidemic Act (CMEA)
- John Bossert - CSOS, ARCOS, and Registration Update
- Mary Johnson-Rochec - CSOS, ARCOS and Registration Update

Tuesday, September 11, 2007

- Welcoming Remarks
- Introduction and Conference Objectives
- Drug Theft / In-Transit Loss Panel
- Methadone Mortality
- Suspicious Orders
- Recent Drug Scheduling Actions / Drug Reviews
- Ongoing Quota Issues
- Overview of DEA Form 106
- Regulatory Update

Wednesday, September 12, 2007

- Internet Investigations
- Combat Methamphetamine Epidemic Act (CMEA)
- Dangers of Methamphetamine
- Chemical Drug Trends
- Promethazine with Codeine Abuse
- CSOS, ARCOS, and Registration Update

BREAK-OUT SESSIONS

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- Field Issues
- Policy and Methadone Mortality
- CSOS, ARCOS, and Registration
- Regulatory and Drug and Chemical Evaluation
- CMEA

Tuesday, September 11, 2007

Welcoming Remarks

Associate Special Agent-in-Charge, Joseph Arabit of the Houston Field Division opened the 13th Pharmaceutical Industry Conference. The conference was held September 11-12, 2007 at the JW Marriott in Houston, TX. Approximately 140 pharmaceutical industry representatives participated in the meeting. Associate SAC Arabit briefed the attendees on his background and career with the Drug Enforcement Administration (DEA) and discussed local trafficking issues experienced in the DEA Houston Field Division. He then introduced Judett Black, Diversion Program Manager, DEA Houston Field Division, to present opening remarks and welcome the attendees to Houston.

Denise Curry, Deputy Director, Office of Diversion Control, greeted the conference participants on behalf of DEA's Office of Diversion Control and Deputy Assistant Administrator Joseph T. Rannazzisi. Deputy Director Curry stated that the purpose of the conference was to strengthen ties and facilitate communication and cooperation between DEA and the pharmaceutical industry. Deputy Director Curry emphasized the primary mission of the Office of Diversion Control to ensure an adequate supply of controlled substances for legitimate needs while preventing diversion into the illicit market. She gave a brief overview of recent organizational changes at DEA and a synopsis of current issues involving the abuse of prescription drugs.

Introduction and Conference Objectives

Mark Caverly, Chief, DEA Liaison and Policy Section, provided an overview of the conference agenda, listed conference goals, and introduced the first presentation.

Drug Theft / In-Transit Loss Panel

Participants on this panel included Thomas McLaughlin (DEA Staff Coordinator), Kevin Nicholson (National Association of Chain Drug Stores), Ryan Toole (FBI Supervisory Special Agent), and Tammy Robertson (White Glove Services, FedEx Custom Critical). Discussion focused on current issues relevant to theft and in-transit loss of controlled pharmaceuticals. Each participant gave an overview of the problem and the methods used to stop diversion and theft. -Presentation Slides Attached

Methadone Mortality Discussion

Denise Curry, Deputy Director, began the presentation by stating that there is a public health crisis related to methadone overdose deaths. She gave statistics and a general overview of DEA's concern. Gretchen Feussner, Pharmacologist, DEA Drug and Chemical Evaluation Section, discussed the fact that methadone-related deaths continue to escalate. She provided current data suggesting that medication from pain management is likely the source of methadone for illicit use. However, she also pointed out that DEA cannot discount diversion from Narcotic Treatment Programs. She noted that several of the top prescribers of methadone are practitioners who do not specialize in pain management and more than one-half of all 40mg diskettes of methadone are distributed to pharmacies despite the fact that this formulation has not been approved by the Food and Drug Administration (FDA) for pain management. She stated that a single 40mg diskette can be lethal in an opioid naive person. Statistics from 1999-2004 from the CDC reported an 11-fold increase in deaths among individuals age 15-24. According to results from the Substance Abuse and Mental Health Services Administration (SAMHSA), Methadone Mortality Assessment Group, methadone use must be carefully monitored in both pain management and narcotic treatment. Among other recommendations, studies regarding cardiotoxic effects in patients and better reporting of adverse events were advised.

Suspicious Orders

Michael Mapes, Chief, DEA, Regulatory Section, and Chris Zimmerman, Vice President, Corporate Security and Regulatory Affairs, AmerisourceBergen updated the attendees on when suspicious order reports should be submitted to authorities. Mr. Zimmerman noted Title 21 Code of Federal Regulations (21 CFR) §1301.71(a) which states, "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." Methods to implement effective controls in the pharmaceutical industry directly mirror regulations in 21 CFR §1301.74. Other security controls include making a good faith inquiry; report suspicious orders; report significant losses. He also quoted 21 CFR § 1301.74(b), "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Diversion Office of the Administration in his area of suspicious orders when discovered by the registrant."

Mr. Zimmerman stressed the importance of knowing your customer, and providing due diligence investigations on all new retail and wholesale accounts, with the exception of retail chain pharmacies. Included in the new account setup process is a new account questionnaire. In addition, on-site visits are conducted which include the taking of

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photographs inside and outside the premises. Mr. Mapes stated that 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. -Presentation Slides Attached

Recent Drug Scheduling Actions/Drug Reviews

Christine Sammarud, Ph.D., Chief, Drug and Chemical Evaluation Section, provided an update on current scheduling actions. On July 2, 2007, DEA published a Final Rule regarding changes in the regulation of Iodine Crystals and Chemical Mixtures containing over 2.2 % Iodine and moved Iodine from List II to List I. For more information on drugs of concern, see the Drugs of Concern Website at www.deadiversion.usdoj.gov/drugs_concern/index.html

Examples of Drugs of Concern

- Carisoprodol
- Dextromethorphan
- Fentanyl
- Hydrocodone
- Methylphenidate
- Salvia divinorum
- Tramadol
- Clenbuterol (New)
- Human Growth Hormone (New)

Ongoing Quota issues

Susan Carr, Deputy Chief, Drug and Chemical Evaluation Section, explained the purpose for quotas which include: Provide for legitimate need of controlled substances; restrict the manufacture and procurement to those manufacturers registered by DEA; limit the quantity of drugs in schedules I and II which may be manufactured or produced; provide adequate inventories for manufacture. As defined in 21 CFR, there are 3 types of quotas: 1) Aggregate Production Quotas 21 CFR §1303.11 and 1303.13; 2) Individual Manufacturing Quotas 21 CFR §1303.21 through 1303.26; and 3) Procurement Quotas 21 CFR §1303.12. Descriptions of the quotas as well as the procedures for establishing and applying for the quotas can be found in the cited sections of the CFR. Ms. Carr provided an overview of quota tips and quota myths and briefly discussed the Combat Methamphetamine Epidemic Act (CMEA). -Presentation Slides Attached

Overview of DEA Form 106

Susan Baker, Unit Chief, DEA Regulatory Section, covered use of the DEA Form 106, and discussed what constitutes a significant loss, which included:

- The actual quantity of controlled substance lost in relation to the type of business.
- The specific controlled substances lost.
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances.
- A pattern of losses over a specific time period.
- Whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
- Whether the specific controlled substances are likely candidates for diversion.
- Local trends and other indicators of the diversion potential of the missing controlled substances.

Ms. Baker also went over the procedure for properly completing a DEA Form 106, with examples for the audience. - Presentation Slides Attached

Regulatory Update

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Mark Caverly, Chief, DEA Liaison and Policy Section, gave an update on DEA chemical regulations and noted the implementation of the Combat Methamphetamine Epidemic Act (which he covered on day two). He discussed the published CMEA rules finalized within DEA and those that remain pending. Mr. Caverly reviewed the multiple schedule 2 prescription Rule that will allow practitioners to issue multiple schedule II prescriptions on the same day with instructions stating the prescriptions are to be filled consecutively at set intervals. The proposed Rule will provide greater control to physicians for prescribing schedule II controlled substances. Mr. Caverly addressed CMEA rules pertaining to retail sales, the spot market, quotas, and briefly talked about the Controlled Substances Export Reform Act of 2005, which would authorize export of controlled substances from the United States to another country for subsequent export to one or more other countries, to include schedules I, II, and narcotic controlled substances in schedules III and IV. He also provided information on the following regulatory issues:

- *A proposed Rule which proposes a new format for the Official Order Form, DEA 222.*
- *Amended registration regulations to clarify requirement that when an individual practitioner practices in more than one state, a separate DEA registration for each state (21 CFR§ 1301.12) is required. The Final Rule was published December 1, 2006, and became effective January 2, 2007.*
- *A Rule to move Iodine from a List II chemical to a List I chemical: The Final Rule was published on July 2, 2007, and became effective August 10, 2007.*
- *Pending Regulations/Policies (see slides) -Presentation Slides Attached*

Wednesday, September 12, 2007

Internet Investigations

Matthew Murphy, Chief, DEA Pharmaceutical Investigations Section, addressed DEA's current Internet actions and initiatives. Since the early 2000's, the Internet has become a major source of prescription drug diversion. With the advent of diversion via the internet, it is even more vital to maintain a working partnership between DEA and the pharmaceutical industry. Due to the sensitive nature of his presentation, slides are not attached.

Combat Methamphetamine Epidemic Act of 2005 (CMEA)

Mark Caverly, Chief, DEA Liaison and Policy Section, presented an overview of the CMEA with a brief summary of the new law and the purpose for implementation. He discussed the new category of chemicals called Scheduled Listed Chemical Products, (SLCP) which include retail preparations containing pseudoephedrine, ephedrine and phenylpropanolamine. Mr. Caverly explained the requirements for regulated sellers and described the online system available for sellers to self-certify. He talked about the DEA developed database containing self-certification records which are available to state and local law enforcement agencies and provided discussion of information required to be entered into a logbook. He discussed privacy requirements, as well as, the purchase and sales limits for (SLCP's). - Presentation Slides Attached

Dangers of Methamphetamine

Phillips Levine, Agent, Staff Coordinator, DEA Dangerous Drugs and Chemicals Section, presented video clips and slides depicting the history, dangers, abuse patterns, and trends related to methamphetamine use and illegal production. The abuse of methamphetamine is a worldwide problem, however, the majority of abuse is concentrated in North America and Asia. Ms. Levine discussed the different types of methamphetamine (crystal, powder, etc.) and the reasons for its abuse. She provided examples of the common household products used to manufacture methamphetamine with the most common ingredient being over-the-counter drugs containing pseudoephedrine. She stated that there are less small toxic labs being seized since the implementation of the CMEA by congress, and that the majority of methamphetamine is now being produced in supertabs in foreign countries. Due to the sensitive nature of this presentation, slides are not attached.

Chemical Drug Trends

Phillips Levine, Agent, Staff Coordinator, DEA Dangerous Drugs and Chemicals Section, gave a historical account of current and past abuse patterns and drug trends. Her focus was on the following topics:

- *Ongoing Efforts with Mexico (why it's important to you in Industry)*
- *Global Amphetamine & Methamphetamine Update*
- *Current Trends in Amphetamine and Methamphetamine Precursor Diversion*
- *Ephedra / E & PSE Derivatives*
- *MDMA and Other Synthetic Drugs*

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Due to the sensitive nature of this presentation, slides are not attached.

Promethazine with Codeine Abuse

Dawn Mathis, Agent, DEA Special Support Group, Houston Field Division and Susan Richards, Diversion Investigator, Houston Field Division, presented case studies and video regarding the Houston area problem with abuse of promethazine with codeine cough syrup and its ties to the rap/hip-hop culture. This presentation alerted the pharmaceutical industry to patterns and trends in the diversion of legitimate pharmaceutical products into the illegal market. Due to the sensitive nature of this presentation, slides are not attached.

CSOS, ARCOS, and Registration Update

Mary Johnson-Rochee, Deputy Chief, DEA Registration and Program Support Section, and John Bossert, Chief, DEA Diversion Technology Section, presented an update on the Controlled Substance Ordering System (CSOS). This system is an optional online ordering system for controlled substances and does not have a separate registration fee for utilizing the system. Use of CSOS by industry was encouraged. Discussion of current registration information was also provided and a detailed explanation of how to use CSOS was outlined, to include:

- Suppliers and purchasers of controlled substances apply for a digital certificate through the CSOS program*
- A personal digital identity, called a digital certificate, is issued to each approved CSOS applicant*
- The digital certificate is downloaded and installed on the CSOS user's computer*
- Ordering software is installed onto the applicant's computer*
- The CSOS user is now set up to conduct electronic orders of controlled substances using the digital certificate as an electronic form of authentication with other authorized users*

Benefits of using the CSOS system were provided as well as updates on registration data. Further information can be found on the slides. -Presentation Slides Attached

Break-Out Sessions

After the conclusion of the conference, five Break-Out Sessions were held:

- Field Issues*
- Policy and Methadone Mortality*
- CSOS, ARCOS, and Registration*
- Regulatory and Drug and Chemical Evaluation*
- CMEA*

These sessions afforded attendees an opportunity to directly interact with DEA staff, ask questions, and discuss any concerns they had. Comments received from attendees suggest that these sessions were very well received and appreciated.

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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.

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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.

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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.

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SAMHSA 2005 National Survey on Drug Use

6.4 million persons aged twelve and older admitted to using prescription drugs for non-medical reasons

- 4.7 million used narcotic pain relievers
- 1.8 million used tranquilizers
- 1.1 million used stimulants
- 272,000 used sedatives

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SAMSHA

2005 National Survey on Drug Use

The illicit drug categories with the largest number of recent initiates:

1. Non-medical use of pain relievers
2. Marijuana
3. Non-medical use of tranquilizers
4. Inhalants
5. Cocaine

FURTHER INFORMATION

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