The Supply Chain of Controlled Substances

- Wholesale Drug Diversion
- The Problem and DEA’s New Strategy

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Outline

• Recent trends in medical use distribution of prescription opioids
• Relationship between increases in medical use of prescription opioids and abuse-related morbidity and mortality
• DEA Responds to prescription drug abuse “epidemic” with Distributor Initiative Program
• DEA cases against wholesale drug distributors 2006-2013
• Anatomy of DEA Regulatory Investigation (vs. Distributor)
• Future Warning Signs for the Industry
• Conclusions
Distribution of Prescription Opioids for Medical Use

Distribution of Prescription Opioids for Medical Use

HYDROCODONE GRAMS/100K POPULATION

Distribution of Prescription Opioids for Medical Use

METHADONE GRAMS/100K POPULATION

Distribution of Prescription Opioids for Medical Use

Distribution of Prescription Opioids for Medical Use

HYDROMORPHONE GRAMS/100K POPULATION

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>370.14</td>
<td>423.25</td>
<td>482.3</td>
<td>506.9</td>
<td>569.08</td>
</tr>
</tbody>
</table>

Distribution of Prescription Opioids for Medical Use

Distribution of Prescription Opioids for Medical Use

BUPRENORPHINE GRAMS/100K POPULATION

Distribution of Prescription Opioids for Medical Use

**Fentanyl Base Grams/100K Population**

Distribution of Prescription Opioids for Medical Use

<table>
<thead>
<tr>
<th>DRUG</th>
<th>2007 GM/100K</th>
<th>2011 GM/100K</th>
<th>DELTA (Δ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXYCODONE</td>
<td>15,782.44</td>
<td>22,885.44</td>
<td>+45%</td>
</tr>
<tr>
<td>HYDROCODONE</td>
<td>12,084.18</td>
<td>15,263.64</td>
<td>+26.3%</td>
</tr>
<tr>
<td>METHADONE</td>
<td>5,351.96</td>
<td>5,512.09</td>
<td>+3%</td>
</tr>
<tr>
<td>MORPHINE</td>
<td>6,851.54</td>
<td>8,513.22</td>
<td>+24.3%</td>
</tr>
<tr>
<td>HYDROMORPHONE</td>
<td>370.14</td>
<td>569.08</td>
<td>+53.7</td>
</tr>
<tr>
<td>CODEINE</td>
<td>6,517.20</td>
<td>6,054.13</td>
<td>-10.8%</td>
</tr>
<tr>
<td>BUPRENORPHINE</td>
<td>183.09</td>
<td>615.18</td>
<td>+236%</td>
</tr>
<tr>
<td>FENTANYL BASE</td>
<td>167.32</td>
<td>180.67</td>
<td>+8%</td>
</tr>
</tbody>
</table>

The Centers for Disease Control and Prevention reports that 38,329 people in the U.S. died from a drug overdose in 2010. Nearly 60 percent of these overdose deaths (22,134) involved prescription drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about 3 of every 4 prescription drug overdose deaths (16,651), confirming the dominant role opioid analgesics play in prescription drug abuse and mortality.¹

Medical Distribution of Oxycodone in U.S. in Gms/100K Population, Compared with Hospital Emergency Department Admissions for Misuse/Abuse of Oxycodone, 2004-2011

$r = 0.9796 \quad p > 0.001$

Medical Distribution of Hydrocodone in U.S. in Gms/100K Population, Compared with Hospital Emergency Department Admissions for Misuse/Abuse of Hydrocodone, 2004-2011

$r = 0.9123 \ p > 0.001$

DEA Responds With *Distributor Initiative Program* Aimed at Supply Chain Drug Diverters

• In 2005, DEA initiated a special operation (*Distributor Initiative Program*) to enforce provisions of the Controlled Substances Act requiring registrants authorized to distribute controlled substances to prevent diversion by designing and operating a system to identify *suspicious orders* and report them to DEA.¹

• The law defines *suspicious orders* as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²


² Title 21, United States Code, Sect. 823(b); Title 21, Code of Federal Regulations, Sect. 1301(b).
Automation of Reports and Consolidated Orders System (ARCOS) – DEA’s Secret Weapon Against Diversion

• Mandated by law, ARCOS is a DEA database that monitors controlled substances from their point of manufacture through wholesale distribution channels to point of sale or distribution at the dispensing/retail pharmacy level.

• ARCOS tracks transactions for: Schedule I and Schedule II drugs (manufacturers/distributors); Schedule III narcotics, and gamma-hydroxybutyric acid (GHB) (manufacturers/distributors); and selected Schedule III and Schedule IV psychotropic drugs (manufacturers only).

• DEA analysts review ARCOS data for signals of diversion (e.g., distributors who fill suspicious orders and do not report them to the nearest DEA field office, as required by law). ARCOS information is used by DEA to enforce civil and criminal provisions of the law.¹

¹ Drug Enforcement Administration, ARCOS Background (www.deadiversion.usdoj.gov)
DEA’s *Distributor Initiative Program* pays dividends...

<table>
<thead>
<tr>
<th>Distributor</th>
<th>Date</th>
<th>Drug</th>
<th>Amount</th>
<th>Disposition</th>
<th>DEA Registration(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal Health</td>
<td>2007</td>
<td>Hydrocodone</td>
<td>&gt;8m d.u.</td>
<td>$34m Fine/MOA</td>
<td>3 Restored</td>
</tr>
<tr>
<td>AmerisourceBergen</td>
<td>2007</td>
<td>Hydrocodone</td>
<td>3.8m d.u.</td>
<td>MOA</td>
<td>1 Restored</td>
</tr>
<tr>
<td>McKesson</td>
<td>2008</td>
<td>Hydrocodone</td>
<td>~3m d.u.</td>
<td>$13.25m Fine/MOA</td>
<td>6 Restored</td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>2012</td>
<td>Oxycodone</td>
<td>&gt;3m d.u.</td>
<td>2-Yr Reg. Suspension</td>
<td>1 Suspended</td>
</tr>
<tr>
<td>Southwood Pharm.</td>
<td>2006</td>
<td>Hydrocodone</td>
<td>8.7m d.u.</td>
<td>MOA</td>
<td>1 Restored</td>
</tr>
<tr>
<td>Masters Pharm.</td>
<td>2009</td>
<td>Hydrocodone</td>
<td>&gt;4m d.u.</td>
<td>$0.5m Fine</td>
<td>1 Restored</td>
</tr>
<tr>
<td>Sunrise Wholesale</td>
<td>2010</td>
<td>Oxycodone</td>
<td>n/a</td>
<td>n/a</td>
<td>Surrendered</td>
</tr>
<tr>
<td>Harvard Med. Grp.</td>
<td>2010</td>
<td>Oxycodone</td>
<td>&gt;13m d.u.</td>
<td>$8m Fine/MOA</td>
<td>1 Restored</td>
</tr>
<tr>
<td>KeySource Med.</td>
<td>2010</td>
<td>Oxycodone</td>
<td>~48m d.u.</td>
<td>$0.32m Fine/MOA</td>
<td>1 Restored</td>
</tr>
<tr>
<td>Omnicare</td>
<td>2012</td>
<td>Various CS</td>
<td>Unk.</td>
<td>$50m Fine</td>
<td>Unaffected</td>
</tr>
<tr>
<td>CVS</td>
<td>2012</td>
<td>Various CS</td>
<td>Unk.</td>
<td>$11m Fine</td>
<td>Unaffected</td>
</tr>
<tr>
<td>Walgreens</td>
<td>2013</td>
<td>Various CS</td>
<td>Unk.</td>
<td>$80m Fine/MOA</td>
<td>7 Susp. 12-16 Mos.</td>
</tr>
<tr>
<td>UPS</td>
<td>2013</td>
<td>Various CS</td>
<td>Unk.</td>
<td>$40m Fine</td>
<td>Unaffected</td>
</tr>
</tbody>
</table>

Warning Signs for Distributor-Registrants

1. A review of court documents for several major cases reveals cavalier approach by industry to legal requirements for preventing drug diversion by identifying and reporting suspicious orders.

2. Fines and individual suspensions may not have the intended effect of deterring repeat violations (e.g., Cardinal Health 2007 & 2012).

3. In opposing Cardinal Health’s motion for a preliminary injunction to halt DEA’s ISO on the grounds of economic hardship, DEA advised the court: “The most that will occur is that Plaintiff [i.e., Cardinal Health] may have to re-route controlled substances through Plaintiff’s other distribution facilities.”

4. Cardinal Health, like many other wholesale distributors of controlled substances, has multiple distribution facilities throughout the U.S., each with a separate DEA registration to distribute controlled substances.

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Warning Signs for Distributor-Registrants

5. Critics of “checkbook justice” claim that large corporations may not be deterred from committing regulatory infractions by the threat of fines.¹

6. Fines, they claim, may be spread across the company’s numerous profit centers so that the overall bottom line effect is minimal.

7. Or, the financial impact of a fine may simply be passed along to the consumer in the cost of the company’s goods and services.

8. Policy experts recommend, if warranted, that regulatory agencies consider using criminal provisions to ensure compliance.

9. A key penalty statute used in DEA’s *Distributor Initiative Program* has both civil and criminal provisions, the difference being that a criminal charge requires a showing of “knowledge” on the part of the person(s) whose action has allegedly violated the law.²

² See 21 USC 842(c).
10. A review of court filings in several DEA distributor cases revealed documentation and evidence of “knowledge” on the part of company officials who allegedly and knowingly failed to prevent drug diversion by intentionally not reporting identified suspicious orders to the nearest DEA office and, instead, filled them.

11. In one case, according to evidence obtained by DEA pursuant to an administrative inspection warrant and presented in court, company officials identified numerous suspicious orders and filled them despite written recommendations by company investigators to their superiors that the orders were suspicious and needed to be reported to DEA.

12. How long the government will continue to handle these cases as civil law infractions is unknown.

13. Much will depend on whether the current prescription drug abuse epidemic continues to increase or is reduced or otherwise affected positively by the DEA’s strategy as it is now being pursued.
Conclusions

1. The nation’s problem of prescription drug abuse is serious and increasing at alarming proportions.

2. Wholesale drug distributors, registered by DEA to sell controlled substances, are required by law to prevent drug diversion by designing/implementing a program to identify suspicious orders so that they can be referred to the nearest DEA office.

3. Distributors may have inherent conflict of interest between complying with the law and pursuing the business of selling drugs.

4. DEA’s Distributor Initiative Program will continue to focus on excessive (i.e., unlawful) sales of controlled substances.

5. Because system is “closed,” whenever DEA enters a supply chain case at the distributor level, it often leads to investigations of customers (e.g., pharmacies, pill mills, etc.) of the distributor, as well as investigations of the prescribers and dispensers of controlled substances affiliated in some way with the customers.

6. If the current DEA strategy does not accomplish its goal of reducing prescription drug abuse, we may expect the agency to begin pursuing criminal law violations against some distributors.
Thank You!

John J. Coleman, PhD