RECENT DEA ENFORCEMENT TRENDS

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Health Law Committee
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Federal Regulation of Controlled Substances

- The federal Controlled Substances Act vests authority for the regulation of controlled substances rests with the Drug Enforcement Administration (DEA).
- States also regulate controlled substances – no preemption.
- DEA is primarily a law enforcement agency; its mission is to eliminate illicit controlled substances like heroin and LSD, but its role is more complex as a regulatory agency overseeing legitimate medicines and companies.
- The Office of Diversion Control, with oversight of 1.4 million registrants, is the regulatory branch within DEA that carries out this function.
Understanding DEA’s Regulation of Controlled Substances

- Closed Chain of Distribution
- Accountability of Drug Supply
- Does not establish standards for medical care but there are grey areas:
  - Quotas
  - Pharmacist Corresponding Responsibility
  - Suspicious Order Monitoring

DEA Investigations

- Notice of Inspection
- Administrative Subpoena
- Administrative Inspection Warrant
- Data Sources:
  - Review of data supplied by company
  - Reports and reporting errors
  - Leads from other investigations
  - Leads from suppliers
  - Disgruntled employees
DEA Investigative Tools

- ARCOS data
- Increased Tactical Diversion Squads (from 5 to over 50)
- Scrutiny of pharmacy applications
- State Prescription Drug Monitoring Programs
- Analysis of theft and loss reports
- More frequent cyclic inspections
- Scrutiny of renewals
- Requirement of SOMS from distributors/wholesalers
- Requirement of SOMS from Manufacturers; review of chargeback data

Indicators of Potential Future DEA Action

- DEA communicates with customers or suppliers
- DEA delays renewing registration
- DEA issues administrative subpoena
- Warrant from federal magistrate judge
- DEA delays granting additional registration; weeks, months or longer
- DEA requests voluntary surrender
- Complaint letter from AUSA
- Order to Show Cause re: application for renewal
Possible DEA Actions

- Letter of Admonition
- Administrative actions against DEA registration
  a. Order to Show Cause:
     - Seeks to revoke or deny registration
     - Notice and opportunity for administrative hearing
  b. Immediate Order to Show Cause:
     - Suspends registration while administrative proceedings pending
     - DEA must demonstrate continued registration poses imminent danger to health or safety
- Civil Action—Civil penalties (up to $10,000 or $25,000 per violation)
- Criminal prosecution

RX Drug Abuse Problem

- Prescription drug abuse is the fastest growing drug problem in the U.S. – epidemic proportions.
  - Increase among younger population – access to medicine cabinets
  - Abuse population seeking legitimate drugs
- The increase in prescription drug abuse is not from direct theft or diversion, but from new schemes devised by criminals to get access to controlled substances under the guise of legitimate medical practice.
- Was dominated by use of fictitious prescriptions by rogue Internet pharmacies, which became problematic between 2004 and 2008 – individuals who did not have a medical need for such medicine or were able to receive the medication without proper medical supervision.
Current Trend - RX Drug Abuse Problem

- Current problems relate to concerns about overprescribing of pain drugs by licensed practitioners leading to abuse and diversion.

- Florida Pain Clinics:
  - ground zero in the prescription drug abuse epidemic.
  - An oxycodone 30 mg. tablet that cost a patient $1.75 to $2.50 could be re-sold on the street in Florida for $7 to $15 or re-sold outside Florida for $25 to $30 (or $1 per mg.).
  - The full complement of "cocktail" medications (oxycodone 15 mg., oxycodone 30 mg., alprazolam and carisoprodol) could be re-sold for $650 to $1,000.
  - "Patients" traveled to pill mills in Florida from Georgia, Kentucky, Tennessee, Ohio, Massachusetts and West Virginia.

NEW PROBLEM/NEW TARGETS

- DEA historically viewed medical practitioners as the "gatekeepers" who determined through examination, administering, dispensing and prescribing which patients legitimately needed controlled medications.

- However, as the current prescription drug abuse problem began escalating in about 2005, DEA turned its attention to accountability higher up the supply chain, focusing on pharmacies, distributors, manufacturers and others, targeting high volume ordering and dispensing.

- DEA focused on pharmacies/pharmacists and distributors as controlled substance gatekeepers holding them accountable for dispensing pursuant to prescriptions not issued for legitimate medical purposes.

Evolving DEA Enforcement Approach
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- DEA’s past approach – frequent registrant communications; work with registrants to help them comply with requirements under the CSA, and work up from the least onerous sanctions to the more punitive ones if registrants continued to fail to comply.

- DEA now – More enforcement action even for minor violations; order to show cause for registration revocations; pressures registrants to voluntarily surrender registrations; seeks significant civil penalties not as an alternative, but in addition to, revocation or surrender.

DEA’s Perception of Industry

- DEA believes it has adequately warned the industry about issues regarding prescription drug abuse.

- Industry has ignored these warnings or failed to take appropriate action to stop diversion and abuse (likely because of pursuit of profits.

- DEA needs to be more aggressive to ensure compliance
Tactical Diversion Squads

- DEA expanded the number of Tactical Diversion Squads ("TDSs") deployed around the country to disrupt diversion schemes; there are now 48 TDSs nationwide.

- TDSs are comprised of DEA diversion investigators who have received diversion training, with DEA special agents and state and local law enforcement officers, many of whom have not.

*The effect is that the diversion control program is less regulatory in nature and more law enforcement-oriented.*

Latest trends

- Enforcement activities higher up the distribution chain:
- Based on 21 C.F.R. § 1301.74(b) – SOMS regulation expanded far beyond original meaning:
- Distributor initiative – Since 2007 – has resulted in Orders to Show Cause and suspensions of registrations based on at most warnings from DEA
- Manufacturer initiative – DEA now visiting manufacturers.
- Common Carriers – UPS; FedEx … who is next
Suspensive Order Monitoring

- All registrants must maintain effective controls to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels. 21 U.S.C. § 823(a)(1), (d)(1) and (e)(1); 21 C.F.R. § 1301.71(a).
- DEA requires distributors and manufacturers to design and operate a system to disclose suspicious controlled substance orders. 21 C.F.R. § 1301.74(b).
- Distributors must report suspicious orders to DEA. Id.

The regulation broadly and vaguely defines suspicious orders as including “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”
- DEA also requires registrants, before distributing controlled substances, “to make a good faith inquiry” with DEA or the appropriate state authority to determine that the intended recipient is registered to possess controlled substances.
- 21 C.F.R. § 1301.74(a),(b).
DEA’s Expansion of the SOMS Standard for Manufacturers and Distributors

- Increased expectations that manufacturers and distributors will police their customers beyond just monitoring “large orders.”
- Expect policies to involve due diligence of customers (e.g., customer questionnaires, site visits, review customer’s customer).
- Set order thresholds that range from the simple to the highly algorithmic.
- Manufacturers review chargeback data from customers; report same to wholesaler customers.
- Manufacturers and distributors continue to grapple with how to review orders; conduct due diligence.

Areas to Watch

- Quotas
- Registrations
- Increase use of Memoranda of Agreement
Recent DEA Enforcement Matters

- Increase in revocations of physicians and pharmacies, especially independent pharmacies. Some criminal actions.

- CVS (2012) -- DEA served Immediate Suspension Orders on two chain pharmacies in Sanford, Florida, in February 2012; chain lost appeal of suspension (TRO) in district court. DEA subsequently revoked their registrations after an administrative hearing.
  - DEA found that pharmacists abdicated their corresponding responsibility when filled prescriptions for highly abused narcotic controlled substances.

- Top Rx Pharmacy

Recent DEA Enforcement - Practitioners

- Walgreens (2013) – BOTH pharmacies (6) and Florida distribution center.
  - Extraordinary because of DEA position that Walgreen’s DC should have conducted due diligence on its own pharmacies, not ship to those pharmacies and report orders as suspicious to DEA.
  - Walgreens raised for first time issue of legality of monetary penalties.
  - BUT settled in midst of appeal of its Immediate Suspension Order and administrative hearing.
  - $80 million settlement price tag
  - Settlement includes several admissions of liability by Walgreens in settlement.
  - Prospective Compliance Program
Recent DEA Enforcement - Manufacturers/Distributors

- DEA has taken action in last four years against a number of distributors including Cardinal, Masters, NuCare, KeySource, Harvard Drug, McKesson, Amerisource.
- To date, no specific case against a manufacturer based on SOM but increased scrutiny.

What If...

- You operate a common carrier that picks up parcels from and delivers them to a wide range of commercial entities including pharmacies and distributors, and non-commercial entities.
- You are generally unaware of the contents of those parcels….
- What are your controlled substance responsibilities?
Common Carriers

- Common carriers are not required to register with DEA and may lawfully possess controlled substances. 21 U.S.C. § 822(c)(2); 21 U.S.C. 957(b)(1)(B).
- Common carriers and their employees are not “agents” who act on behalf or at the direction of manufacturer, distributor or dispenser. 21 U.S.C. § 802(3).
- Suppliers, not common carriers, are responsible for reporting in-transit controlled substance losses. 21 C.F.R. § 1301.74(c).
- The outside wrapper or container of controlled substances is free of markings so common carriers do not know the contents. 21 C.F.R. 1301.74(e).

But ... Common Carriers Beware!

The UPS Settlement:

- From 2003 to 2010, UPS was on notice through some of its employees, that internet pharmacies were using services to distribute controlled substances in violation of the law
- Forfeited $40 million in payments received from illicit pharmacies
- Acceptance of corporate responsibility
- Implement compliance program to ensure that illegal online pharmacies will not be able to use UPS’s services to distribute drugs
- Cooperated fully in investigation
- FedEx has reported it is subject to DEA probe
Thank You

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