



Office of Chief Counsel Diversion and Regulatory Litigation



Agenda

- Who We Are & What We Do
- Immediate Suspension Orders and Orders to Show Cause
- Evidence/Information for Administrative Action
- Diversion Case Trends/Checklist for Cases



Who We Are/What We Do

- Represent DEA in administrative proceedings to revoke or deny DEA registrations to handle controlled substances
- Provide legal advice to DEA personnel related to the regulation of DEA registrants
- 21 U.S.C. § 801, *et seq.* and 21 C.F.R. § 1300, *et seq.*



Diversion is not a Diversion



Tools Available

- Federal Administrative Action
- State Administrative/Regulatory Action
- Criminal Prosecution
- Civil Penalties
- Any combination of the above!



Administrative Remedies

- Orders to Show Cause
- Immediate Suspension Orders
- Letters of Admonition
- Enforcement Hearings
- Memoranda of Agreement



OTSC vs. ISO

- OTSC: Orders registrant to “show cause” as to why DEA should not revoke their registration because it is inconsistent with the public interest
- ISO: Immediately suspends registration *and* orders registrant to “show cause.”
- Both summarize and provide notice of the allegations against the registrant.



Bases for OTSC/ISO: 21 U.S.C. § 824(a)

- 21 U.S.C. § 824(a) (grounds for denial, revocation or suspension of DEA registration)
 - (1) Material falsification of any application required to be filed
 - (2) Convicted of a felony relating to a CS
 - (3) State license or registration suspended, revoked, or denied
 - (4) Committed such acts inconsistent with the public interest*
 - (5) Has been excluded from participation in Medicare



Bases for OTSC/ISO: 21 U.S.C. § 823(f)

- 21 U.S.C. § 823(f) (public interest factors)
 - (1) Recommendation of State licensing board
 - (2) Experience in dispensing CS
 - (3) Conviction record relating to manufacture, distribution, or dispensing of CS
 - (4) Compliance with laws relating to CS
 - (5) Such other conduct which may threaten the public health and safety



ISOs: General Info.

- Requirements
 - Must have a basis to revoke the registration under 21 USC § 824(a) +
 - **“Imminent danger to the public health or safety”** (21 U.S.C. § 824(d))
 - Not defined by statute
 - Why is the standard so important?
 - Deprives an individual of a property right prior to hearing
 - Strictly construed by courts = high bar
 - Challenged by a Motion for a Temporary Restraining Order



ISOs: “Imminent Threat”

- Extraordinary Remedy/Tool
- Threat is to the public health or safety
- Dictionary definitions – *imminent*:
 - “Near at hand; ...impending; on the point of happening....” - Black’s Law Dictionary
 - “About to occur” - American Heritage Dictionary
 - “Likely to occur at any moment”- Dictionary.com



ISOs: ‘Imminent Threat’

From the case law:

- Delay is deadly UNLESS delay can be explained
 - Ongoing Investigation
 - Ongoing Negotiations
- Danger must be significant – risk of death or serious bodily harm
- The danger must be at least as probable as not to occur in the absence of agency action



Evidence: Practitioners

- State Authorization
- Usual Course/Legitimate Medical Purpose
- Violations of State Law
- Such Other Conduct Which May Threaten The Public Health and Safety



Doctors: Building a Case

- Usual Course/Legitimate Medical Purpose:
 - U/C buys
 - Patient interviews
 - PA/Employee interviews
 - Suspicious prescribing patterns
 - State law violations
 - Expert opinion
- Don't prove patient died, prove that the doctor was acting "outside the usual course of professional practice" or prescribing for "other than legitimate medical purposes."



Doctors: Building a Case

- For a legitimate medical purpose and in the usual course of professional practice
 - Inadequate physical exam
 - Inadequate medical history
 - Ignored test results
 - Fee based on drugs prescribed



Doctors: Building a Case

- For a legitimate medical purpose and in the usual course of professional practice
 - Ignoring signs of diversion and abuse
 - Sex for drugs
 - Prescriptions for drug specifically requested by customer
 - Inordinate number of prescriptions for controlled substances



A Meaningful Customer Interview: Doctors

- What did the customer tell the doctor?
 - Request particular drug
 - Indicia of abuse/selling/sharing
- What did the doctor do?
 - Scope of physical examination
 - Medical history
 - Referral for diagnostic testing
 - Urinalysis
 - Medical records
 - Warning about addiction
 - Plan for future treatment



Pharmacies: Building a Case

- U/C buys
- Patient interviews
- Employee interviews
- Suspicious prescribing patterns
- State law violations
- Doctor-Pharmacy connection
- Expert Opinion
- Don't prove they dispensed to addicts, prove that they diverted controlled substances



Pharmacies: Building a Case

- Pharmacies – corresponding responsibility
 - Failing to verify questionable prescriptions
 - Filling prescriptions known to be forged
 - Ignoring the red flags
 - Patients of doctor all receive same drugs
 - Request certain brands/street names
 - Young healthy customers receive narcotics
 - Customers travel great distances



A Meaningful Interview: Employees

- Did the employee have concerns?
 - Voiced concerns ignored
 - Told to follow orders without question
- How did the registrant operate?
 - Same “cocktail” for all customers
 - No physical examinations
 - Cash only
 - Connection between doctor and pharmacy
 - Pharmacy Standards of Procedure



The Hardest Cases

- Doctors – controlled substances must be prescribed and dispensed
 - For a legitimate medical purpose
 - In the usual course of professional practice
- Pharmacies – corresponding responsibility



Legal Keys in Administrative Cases

- Cases are like bread, not wine
- Team = state LE and regulators, DEA enforcement groups, AUSAs, CCD
- Early CCD involvement



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