US ERA ARCHIVE DOCUMENT

Drug Enforcement Administration

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Mission of the Diversion Control Program

 To prevent the diversion of legitimately produced controlled substances and listed chemicals while ensuring adequate supplies for legitimate needs

Controlled Substances Act (CSA) of 1970

- Provides for a 'closed' system of distribution
- Monitors controlled pharmaceuticals from production to end use, to limit diversion
- Is intended to ensure adequate supply to meet legitimate medical need
- Authority derived from 3 international drug treaties:
 - Single Convention of 1961 (narcotics)
 - Psychotropic Convention of 1971 (psychotropics)
 - UN Convention Against Illicit Traffic in Narcotic Drugs & Psychotropic Substances of 1988 (Article 12 - chemicals)

Three Basic Drug Categories

- Over-the-Counter (OTC)
- Prescription: non-controlled substances
- Prescription: controlled substances
 - Drugs having abuse potential
 - DEA is responsible for control

Drug Scheduling Criteria

Schedule I

- High abuse potential
- No accepted medical use
- No accepted safe use

I - Heroin, LSD, Marijuana

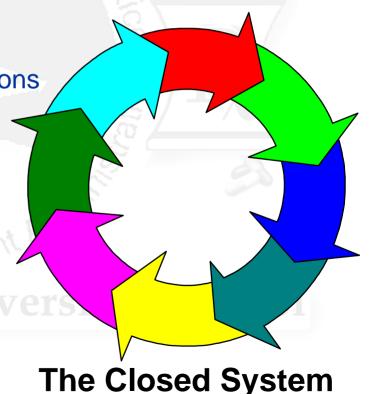
Schedule II - V

- High to low abuse potential
- Accepted medical use
- Physical or psychic dependence

- II Dilaudid, morphine,OxyContin, methylphenidate
- III Tylenol # 3, anabolic steroids
- IV Alprazolam, diazepam, phentermine
- V Codeine Cough Preparations, Lomotil

Tracking the Flow of Controlled Substances

- Registration Requirements
 - Type A (physicians, retail pharmacies)
 - Type B (manufacturers, distributors)
 - Chemical handlers
- Record Keeping Requirements
 - Order forms/invoices/prescriptions
 - Theft/loss forms
 - Drug destruction forms
- Inventory Requirements
 - Initial inventory
 - Biennial inventory
 - ARCOS reporting
- Security Requirements



Points of Penetration Within the Closed System

- Practitioners
 - Illegal distribution
 - Self abuse
- Pharmacists
 - Illegal distribution
 - Self abuse
- Employee pilferage
 - Hospitals
 - Practitioners' offices
 - Nursing homes
 - Retail pharmacies
 - Manufacturing/distribution facilities
- Patients
 - Individual
 - Organized drug ring

Drugs

Diverted

Drugs

Registration Facts

- Who Must Register?
 - All handlers of controlled substances in the U.S.
- Many Levels
 - Manufacturer, importer, exporter
 - Distributor, reverse distributor, researcher, analytical lab
 - Narcotic treatment program
 - Hospitals/clinics, retail pharmacies, teaching institutions
 - Practitioners (physicians, dentists, veterinarians)
 - Mid-level practitioners (nurse practitioners, physician assistants, optometrists, animal shelters)

Registrant Population July 6, 2005

Retail Level Registrants Wholesale Level Registrants Total CSA Registrants

1,183,197 12,112 1,195,309

RETAIL LEVEL		WHOLESALE LEVEL	
Retail Pharmacy	63,556	Manufacturer	505
Hospital / Clinic	15,568	Distributor	791
Practitioner	993,026	Reverse Distributor	40
Teaching Institution	480	Researcher	7,607
Mid-Level Practitioner	110,567	Analytical Lab	1,547
		Importer	166
		Exporter	262
		Narcotic Treatment Program	1,194