Objectives

- Review the history of federal drug laws.
- Review guidelines for the Controlled Substance Act.
- Discuss the migration to electronic prescriptions.
- Cite drugs added to Controlled Substances schedule.
- Discuss Ryan Haight Act in reference to internet pharmacies.

Introduction & History

- The sale and distribution of drugs in the US is primarily controlled by two major legislative acts:
  - Federal Food, Drug and Cosmetic Act (FDCA)
  - Federal Controlled Substances Act (CSA)

History of Coca Cola

- The beverage was named Coca-Cola because, originally, the stimulant mixed in the beverage was coca leaves from South America.
- In addition, the drink was flavored using kola nuts, also acting as the beverage's source of caffeine.
- The first serving in 1886 cost US$0.05. Pemberton called for five ounces of coca leaf per gallon of syrup, a significant dose, whereas, in 1891, Candler claimed his formula (altered extensively from Pemberton's original) contained only a tenth of this amount.
- Coca-Cola did once contain an estimated nine milligrams of cocaine per glass, but in 1903 it was removed.
Controlled Substances Act (CSA)

- Concerned with the prevention and control of the abuse of certain drugs called “controlled substances”
- Dept. of Justice and FBI established the Drug Enforcement Administration (DEA)
- Supplemented by the PPPA and the Federal Hazardous Substance Act

Electronic Prescriptions

- On March 31, 2010, DEA published in the Federal Register the Electronic Prescriptions for Controlled Substances interim final rule
- Became effective June 1, 2010. The rule provides practitioners with the option of writing prescriptions for controlled substances electronically and also permits pharmacies to receive, dispense, and archive these electronic prescriptions.

Health Care Financing Administration (HCFA)

- Control drug distribution and utilization for federal funding in Medicare and Medicaid programs
- In many cases state law is more stringent than Federal law and must be complied with in addition to Federal law

Legislative Purposes

- During 19th century there was no regulation of the sale of drugs in the USA
- Opium was readily and legally available OTC in pharmacies, grocery, general stores and mail order businesses
- Labels did not require a list of contents
- “Miracle cures” contained opium, alcohol, coca leaves and caffeine
- Addiction to opiates and fatal delays in seeking medical help
Opium
- Chinese Opium House
- Harvesting Opium

From the Poppy plant

Opium Derivatives
- Opium
- Heroin
- Opiates: morphine, codeine, thebaine
- Semi-synthetic opiates (opioids): hydrocodone, hydromorphone, oxycodone, and oxymorphone

Federal Food and Drug Act of 1906
- This act prohibited adulterated and misbranded food or drugs from interstate commerce

Sulfanilamide Disaster of 1937
- Sulfanilamide – first of "miracle drugs", "sulfa powder" was used to prevent infection in wartime
- Sulfanilamide + ethylene glycol (antifreeze and deadly poison) – resulted in 107 deaths
- Resulted in FDCA of 1938

Food, Drug and Cosmetic Act of 1938
- Required:
  - that drugs be adequately tested for safety
  - A label, packaging insert, proof of safety, directions for use
  - Warning label for "narcotics"
  - Included cosmetics

Durham-Humphrey Amendment of 1951
- Exempted certain drugs from the requirement that their labeling contain adequate directions for use
- Caution: Federal Law prohibits dispensing without a prescription – was created
- Legend become an eponym for a major drug classification
Thalidomide Disaster 1962

- Thalidomide (a sleeping pill) was discovered to be teratogenic in the first trimester of pregnancy
- After many lawsuits the Kefauver–Harris Amendments resulted

Kefauver–Harris Amendments of 1962

- Provided for the registration and inspection of manufacturers and their sites.
- Addresses issues of effectiveness and safety

Comprehensive Drug Abuse Prevention and Control Act of 1970

- Gathered together all of the federal laws dealing with narcotic drugs, stimulants, depressants, and abused “designer drugs”
- Formed the DEA
- Controls matches each drug’s potential for abuse

Drug Enforcement Administration

- DEA is the lead Federal law enforcement agency responsible for enforcing the Controlled Substances Act (CSA).
- Established in 1973
- In carrying out its mission, DEA cooperates with other Federal agencies

Orphan Drug Act of 1983

- Provides tax incentives and limited exclusive license to manufacturers of drugs of rare diseases and conditions

Anabolic Steroids Control Act of 1990

- Places anabolic steroids under the control of the CSA
  “Any drug or hormonal substance related to testosterone that promotes muscle growth”
Omnibus Budget Reconciliation Act of 1990 (OBRA ’90)

- Contains amendments to Medicare/Medicaid programs
- States must require pharmacists who provide services under the program to offer elaborate consultative (counseling) services

New Drug Procedures

- All new drugs must be approved by the FDA as being both safe and effective before they can be imported, transported in interstate commerce, or commercially marketed

New Classes of Prescribers

- Traditionally – MDs, surgeons, Doctors of Osteopathy, Dentists, Podiatrists, Vets
- New – RN Practitioners, PAs, Naturopaths, Pharmacists (limited by states)

Patient Information

- A printed informational brochure must be given to any patients on oral contraceptives
- All controlled substance drugs and all prescription drugs are subject to special packaging requirements

POISON PREVENTION PACKAGING ACT

- Exceptions: sl doses of Nitroglycerin
- Sl & chewable forms of Isosorbide Dinitrate
- Erythromycin Ethylsuccinate granules for po suspension
- Anhydrous Cholestyramine in powder form
- All ud dose forms of Potassium supplements

Patient Information/PPPA

- Bethamethasone tablets
- Pancrelipase preparations
- Prednisone tabs w/no more than 105mg
- Mebendazole tabs w/no more than 84mg
- Colestipol in powder form w/no more than 5g
Exceptions to the PPPA

- Non-child-resistant containers may be dispensed if:
  - The prescriber authorizes it
  - The patient requests it

  **Purpose:** to make the medications easily available to the elderly and handicapped

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Pharmacy Vial caps

- Child resistant caps
- Non-resistant caps

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Recalls

- **Class I Recalls** – for products that will cause serious or fatal consequences
- **Class II Recall** – for drugs or devices that may cause serious but reversible health effects
- **Class III Recall** – for products not likely to cause adverse health consequences

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Federal Controlled Substance Act

- This established a "closed system" for the distribution of drugs and other substances of abuse
- Controlled substances can only be distributed by persons who are registered with the DEA

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Forms for Registration

- Form 224 – to manufacture or distribute
- Form 224 – to dispense
- Form 363 – to conduct a narcotic treatment program to be a "compounder"

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Schedules of Controlled Substances

- **C-I** – has a high potential for abuse
- Has no currently accepted medicinal use in treatment in the US
- **Examples:** opiate derivatives – heroin, normorphine, PCP, ecstasy, GHB
- Opiates – trimeperidine
- Hallucinogens – STP, LSD, marijuana, mescaline
- **C-I** – may not be prescribed
Substance Abuse Stats

- More young Americans die from drugs than suicides, firearms, or school violence;
- The only disease that affects more people than substance abuse in America today is heart disease;
- Substance abuse is the single largest contributor to crime in the United States;
- In the latest year measured, the direct cost of drug abuse was estimated at $52 billion, with indirect costs of $128 billion.

Proceedings to Add, Delete, or Change the schedule of a drug

- May be initiated by the (DEA), the Department of Health and Human Services (HHS), or by petition from any interested party, including:
  - The manufacturer of a drug
  - A medical society or association
  - A pharmacy association
  - A public interest group concerned with drug abuse
  - A state or local government agency
  - An individual citizen

Gamma-Hydroxybutyric acid (GHB) is another name for the generic drug sodium oxybate. Xyrem® (which is sodium oxybate) is the trade name FDA-approved prescription medication.

- It was placed on Schedule I of the Controlled Substances Act in March 2000. However, when sold as GHB products (such as Xyrem®), it is considered Schedule III, one of several drugs that are listed in multiple schedules.

Schedules of Controlled Substances

- **CII** – has a high potential for abuse
- Has a currently accepted medical use in treatment
- Abuse may lead to severe psychological or physical dependence
- Examples: opium, extracts of opium, cocaine, morphine, amphetamine, methamphetamine, secobarbital, methadone, Opium poppy capsules, poppy heads
- Dispensed with a non-refillable written prescription

Methadone

- Methadone is a synthetic (man-made) narcotic.
- Origin - German scientists synthesized methadone during World War II because of a shortage of morphine.
- Methadone was introduced into the United States in 1947 as an analgesic (Dolophine).
- Amidone, Chocolate Chip Cookies, Fizzies, Maria, Pastora, Salvia, Street Methadone, and Wafer
Street names for various narcotics/opioids
- Smack, Horse, Mud, Brown Sugar, Junk, Black Tat,
- Big H, Paregoric, Dover's Powder, MPTP (New
- Heroin), Hillbilly Heroin, Lean or Purple Drank, OC,
- Ox, Oxy, Oxy cotton, Sippin' Syrup
- Ite term “narcotic” comes from the Greek word for “stupor”
- D, Dillies, Dust, Footballs, Juice

Schedules of Controlled Substances
- C-III – potential for abuse less than C-I, C-II
- Abuse may lead to moderate or low physical dependence or high psychological dependence
  - Examples: Nalorphine, chlorphentermine, glutimide, anabolic steroids, Norco
- It is possible for a controlled substance to appear in more than one schedule: the schedule related to the amount of drug in the formulation

Schedules of Controlled Substances
- C-IV – low potential for abuse relative to the drugs in C-III
- Has a currently accepted medical use in treatment in the US
- Abuse may lead to limited physical dependence or psychological dependence
  - Examples: Phenobarbital, Placidyl, Librium, Valium, Talwin, Lyrica
Schedules of Controlled Substances

- **C-V** – has a low potential for abuse relative to C-IV
- May lead to limited physical or psychological dependence
- **Examples:** Anti-tussive (Robitussin AC) or anti-diarrheal (Lomotil)
- May be sold w/out a prescription

Record of Sales of C-V substances

- Sale to be made by a pharmacist
- **Purchaser** – must be 18 years old; possess a driver’s license
- No more than 8 ozs. Or 48 dosage units of any substance containing OPIUM in any 48-hr period may be sold
- No more than 4 ozs. Or 24 dosage units of any other controlled substance in any 48-hr period may be sold

The Combat Methamphetamine Epidemic Act of 2005

- Signed into law March 9, 2006 and went into effect on March 9, 2006
- Primarily affect persons selling products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**CV DRUGS**

**Confidential Pharmacy Log**

**Faces of Meth**

Bann, Bikers Coffee, Black Beauties, Chalk, Chicken Feed, Crack, Crystal, Glass, Go-Go, Himplon, Ice, Meth, Methlabs, Quick, Poor Man’s Cocaine, Shabs, Shards, Speed, Stone Top, Tnts, Trush, Twack, Upper, Vitamins, Vidrio, Yaku, and Yellow Bam

**Meth Mouth**
Cannabis & Cannabinoids

- The DEA proposes placing five synthetic cannabinoids into Schedule I of the CSA
- The Drug Enforcement Administration decree states that "marijuana has no currently accepted medical use"
- Synthetic THC (delta-9 tetrahydrocannabinol), the active ingredient in marijuana, has been available in pill form since 1986.

Obtaining Controlled Substances

- **Order forms** – C-I, C-II – DEA Form 222 (can be obtained electronically)
- Do not erase on these forms
- C-III, C-IV, C-V – exempt from federal forms (separate po order)

Ryan Haight Act

- On October 15, 2008, the President signed into law the **Ryan Haight Online Pharmacy Consumer Protection Act of 2008**
- This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy
- Designed to combat the proliferation of so-called "rogue Internet sites"

Inventory Requirements for Different Schedules

- **C-I or C-II** – there must be an exact count or measure
- C-III, C-IV, C-V – an estimated count is sufficient unless the container hold more than 1000 units, in which an exact count is necessary
- Inventories must be kept at the registered location for 2 years

Filing Methods

- **C-II** – only
- C-II, C-IV, CV – together
- All other prescriptions
- **OR**
- C-II – only
- C-II to C-V and all others

Verification of a DEA number

- **Formula for verification:**
  - Add: 1st + 3rd + 5th digits
  - 2(2nd + 4th + 6th) digits
  - Add the first total to the second total
  - Rightmost digit of the result should correspond to the 9th digit of the DEA number
- **Example DEA Number:** AJ 3274658, Robert Jones, MD
Refills for C-II
- Except for an emergency the C-II prescription should be in writing
- No refills allowed

Refills for C-III, C-IV, CV
- Prescription maybe oral or written (must be reduced to writing within 72 hours)
- Refill no more than 5 times
- No more than 6 months after date of issue
- Refill amount cannot exceed amount initially prescribed

Disposal of Unneeded Controlled Substances
- DEA Form 41
- DEA specifies manner of disposal
- In front of two witnesses
- Forward drugs to a state agency
- Hold until DEA can witness destruction
- Ship to the DEA

Theft of Controlled substances
- DEA form 106 (triplicate)
- Report the theft to the DEA and local police
- Report culprit (if known) to the employer and security
- PENALTY – 1 year imprisonment and/or $5000.00 fine for simple possession
- Not less than 20yrs, forfeiture of property for dealing drugs

Disposal of Drugs