Drug Regulation and Control

Chapter Outline

- Drug Regulation
- Behind-the-counter Medications
- Sample Labels
- Controlled Substances
- Public Safety
- Law and the Technician

Brief History of Statutory Pharmacy Law

- In the **19th century,** drugs in the United States were unregulated.
  - Medicines did not require proof that they were either safe or effective.
  - Most agents contained a high content of alcohol.
  - Some caused injury or death.

Pharmacy Law - 1906

- To combat abuses in both formulation and labeling, in **1906** the U.S. Congress passed the first of a series of landmark 20th century laws to regulate drugs.

Pure Food and Drug Act of 1906

- The purpose was to prohibit the sale of **adulterated** or **misbranded** food and drugs.
  - **Adulterated** is impure by adding extraneous, improper, or inferior ingredients.
  - **Misbranded** to brand or label misleadingly or fraudulently.
- **Labels could not contain false information** about the drugs' **strength and purity.**
- Proved unenforceable and new legislation was required.

Harrison Tax Act 1914

- Established that manufacturers, pharmacists, importer, and physicians prescribing narcotics should be **Licensed** and required to **pay a tax.**
- The law enacted in response to growing opiates and cocaine-containing medications.

Food, Drug, and Cosmetic (FDC) Act of 1938

- **Sulfa poisoning** caused the death of 107 people primarily children.
  - Due to untested sulfanilamide concoction.
  - In response to this event, FDC was introduced.
- **FDC** is the most important piece of legislation in pharmaceutical history.
- Required only that drugs be **SAFE** for human consumption before marketing.

FDC Act of 1938

- Gave FDA the **power to conduct inspections** of manufacturing plants to ensure compliance.
- Act applied to interstate transactions, as well as to intrastate transactions.
- FDA required pharmaceutical manufacturers to file a **new drug application (NDA)** with each new drug before marketing.

Durham-Humphrey Amendment of 1951

- States that drug containers do not have to include "adequate directions for use" as long as they include
  - "**Caution: Federal Law Prohibits Dispensing Without Prescription.**"
  - Now, "**Rx Only.**"
- Distinguished between
  - Legend **(prescription)** drugs.
  - **Over-the-counter (OTC)** (non-prescription) drugs.
- Authorized
  - Verbal prescriptions.
  - Prescription refills.

Kefauver-Harris Amendment of 1962

- Extended the FDC Act of 1938 to require that
  - Drugs not only be **safe** for humans but also be **EFFECTIVE.**

Kefauver-Harris Amendment of 1962

- Requirement of drug manufacturers:
  - An investigational new drug application **(INDA)** with the FDA before initiating a clinical trial in humans.
  - Once proven safe and effective, manufacturer may submit an **NDA** seeking approval to market the product.

Poison Prevention Packaging Act of 1970

- Passed **to prevent accidental childhood poisonings** from prescription and nonprescription products.
- Enforced by the **Consumer Product Safety Commission (CPSC).**

Poison Prevention Packaging Act of 1970

- Requires most over-the-counter (OTC) and prescription drugs to be packaged in **child-resistant containers.**
  - **Cannot** be opened by 80% of children under five.
  - **Can** be opened by 90% of adults.
- Patients may request a non-child-resistant container; other exceptions are provided for by law.

Comprehensive Drug Abuse Prevention and Control Act of 1970

- Commonly referred to as the **Controlled Substances Act (CSA).**
- Created to combat and control drug abuse and to supersede previous federal drug abuse laws.
- Created the **Drug Enforcement Administration (DEA)**, an arm of the Department of Justice.
  - Charged with enforcement and prevention related to the abuse of controlled substances like many narcotic pain medications.

CSA – 1970

- Classified drugs with potential for abuse as **controlled substances.**
- Ranked controlled substances into **five categories**, or **schedules.**
  - Ranging from those with great potential for abuse **(Schedule I)** to those with little potential **(Schedule V).**

CSA - 1970

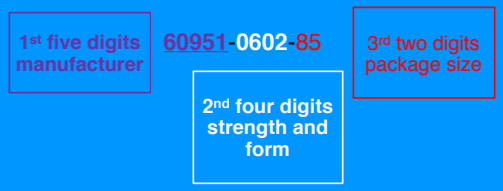
Schedule	Medical Use	Examples
I	For research only – **not approved for human use**	Heroin, LSD
II	Dispensing severely restricted	Morphine, oxycodone, amphetamines
III	Prescriptions can be refilled up to 5 times in 6 months	Codeine with aspirin, anabolic steroids
IV	Same as for Schedule III	Benzodiazepines, meprobamate
V	Some sold w/o a prescription; must be 18	Liquid codeine combination preps.

Drug Listing Act of 1972

- Gives the FDA the authority to compile a list of currently marketed drugs.
- Each drug is assigned a unique and permanent product code
  - Known as a **National Drug Code (NDC).**
  - **Eleven characters** that identify manufacturer or distributor, drug formulation, size and type of packaging.
- FDA requests, but does not require, that the NDC appear on all drug labels.

National Drug Code (NDC Number)

- Identification number assigned by the manufacturer to a drug product.
- Has 3 sets of numbers.



1976 Medical Device Amendment

- **The Medical Device Amendment** requires pre-market approval of safety and effectiveness of life sustaining and life supporting **medical devices**.

Orphan Drug Act of 1983

- An **orphan drug** is intended for use in a few patients with a rare disease or condition.
  - Developing such a drug would be prohibitively expensive, given the small market.
- The Orphan Drug Act encourages the development of orphan drugs by:
  - Providing tax incentives.
  - Granting manufacturers exclusive license.
- Over 250 orphan drugs have been approved by the FDA.

Drug Price Competition and Patent-Term Restoration Act of 1984

- Also called **Hatch-Waxman Act.**
- Allows substitution of brand name products with generic drugs.
- Once the original patent expires, any manufacturer may market a generic drug.
  - FDA approval is required to market a generic
  - Generic is less costly than the brand name.

Drug Price Competition and Patient-Term Restoration Act of 1984

- A given drug typically has several names.
  - **Generic name** is a common name given to a drug regardless of brand name.
  - One or more **brand names** under which the manufacturer markets a drug.
- Example

• Ro 18-0647	Research #
• Tetrahydrolipstatin	Non-official generic
• Orlistat	Approved Generic
• Xenical	Trade Name (Brand)
• Alli	Trade Name (OTC)

Prescription Drug Marketing Act of 1987

- **PROHIBITS**
  - **Re-importation** of a drug into the United States.
- **PROHIBITS**
  - Sale or trading of **drug samples.**
- **PROHIBITS**
  - **Distribution of samples** to persons other than those licensed to prescribe them except by mail or by common carrier.

OBRA-90

- ***Omnibus Budget Reconciliation Act of 1990***
- Requires states to establish standards for Drug Use Review (DUR) by the pharmacist.
- Requires pharmacists to **offer counseling** to **Medicaid** patients.
- 45 states implemented counseling for all patients.
- Requires a manufacturers **rebate** to state Medicaid program between the manufacturer's best price for a drug (typically the wholesale price) and the average billed price.

HIPAA of 1996

Health Insurance Portability and Accountability Act

- Defines the scope of health information that may or may not be **shared** among health care providers without patient consent.

FDA Modernization Act

- Authorizes fees to be added to a new drug application (NDA) process to accelerate the review and approval process for new drugs.
- Updates the labeling on prescription medications
  - Products labeled are **"Rx Only."**
  - New labeling requirements were implemented in 2004.

The FDA's Center for Drug Evaluation & Research (CDER)

- Provides an Index to **Drug-Specific Information** with patient, consumer and healthcare professional information sheets, including FDA Alerts.
- Works with drug manufacturers to develop risk management programs for drugs with FDA.
  - Alerts, such as the **iPLEDGE program for Accutane**.

New Drug Approval Process

- **All new drugs** require FDA approval before they can be marketed in the US.
- To receive approval, new drugs must be shown to be **SAFE** and **EFFECTIVE** and its benefits **OUTWEIGH** its risks.
- **Drug manufacturers** and not the FDA is responsible for proof.
- This process will be the subject of our next class.

Look Alike and Sound Alike Drugs

- Federal laws require containers **NOT to look like another drug**, however some drug names may look alike or sound alike.
- Example:
  - Kapidex: used to treat heartburn/reflux
    Confused with:
  - Casodex (sound alike) Prostate cancer
  - Kadian (look alike) Morphine for pain

Over-the-Counter (OTC) Drugs

- OTC drugs must be approved by the FDA .
- Can be used upon the judgment of the consumer **without a prescription** from a physician.
- Generally, OTC drugs are intended for short term use.

Over-the-Counter (OTC) Drugs

- There are **over 100,000 OTC drugs in 80 therapeutic categories.**
- The manufacturer has to follow a format called **drug monograph** to be able to market with proper label including:
  - Active ingredient
  - Direction for use
  - Amount of drug contained
  - Warnings
  - Expiration date

Sample OTC Label

Drug Facts

Active ingredients (in each extended-release bi-layer tablet) — **Purpose**

Dextromethorphan HBr 60 mg ..... Cough suppressant
Guaifenesin 1200 mg ..... Expectorant

Uses
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use
- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product
- do not use more than directed

Drug Facts (continued)

Stop use and ask a doctor if
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information
- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
- store at 20-25°C (68-77°F)

Inactive ingredients carbomer homopolymer type B; D&C yellow #10 aluminum lake; hydroxyethylcellulose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions? 1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

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Behind-The-Counter OTC Medications

- Medications sold without a prescription, but with **RESTRICTION** on their sales.
- Kept behind the pharmacy counter.
- Examples
  - Pseudoephedrine
  - Some Codeine containing cough preparations

Exempt Narcotics

- Sold by a pharmacist without a prescription.
  - E.g. Codeine containing cough syrups.
- Only pharmacists can approve their dispensing.

Exempt Narcotics

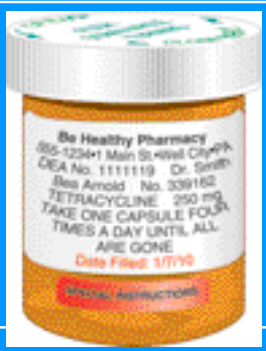
- Purchasers have to:
  - Be at **least 18 years old.**
  - Provide **identification**
  - Document the sale in a **bound record book**
    - Name and address of the purchaser
    - Drug name and quantity, date
    - Name or initial of the pharmacist

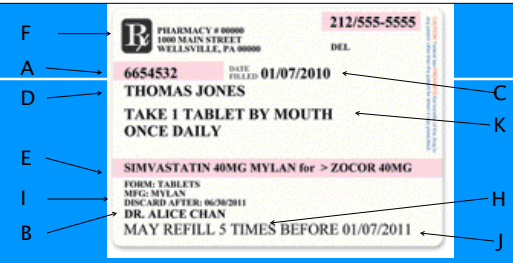
Product Labeling

- **Package Insert** – is prescription information on the drug product.
- Comprehensive information
- **Intended for health care professionals** who prescribe or dispense the product
- We will return to this later in the course

Manufacturing Label

Prescription Bottle





A: Rx number
B: Prescribing physician
C: Date
D: Patient Name
E: Drug Name, strength, dosage form
F: Pharmacy Name, Address, phone number
G: Quantity
H: Number of refills remaining
I: Manufacturer of the drug
J: Expiration date
K: Directions for use

Food and Drug Administration (FDA)

- Primary responsibility and **authority is to enforce** the law and create regulations to assist in providing the public with safe drug products.
- Requires all manufacturers to file applications for investigation studies and **approval of new drugs.**

Food and Drug Administration (FDA)

- Oversees **the recall** of dangerous products.
- Has **no legal authority** over the practice of pharmacy in each state (is a responsibility of the **BOARD OF PHARMACY**).

Public Safety

- FDA approval process is quite thorough, but it is impossible to fully prove a drug's safety.
- The FDA has several options if it determines that a marketed drug presents a risk of illness, injury, or gross consumer deceptions.
- FDA can **seize** the drug, **stop** distribution, or may **issue a recall** of the drug.

Public Safety

- Adverse Effect
  - Unintended effect of a medication that is negative or in some way injurious to a patient's health.

Recalls

- **Removal of a drug from the market.**
  - Can be prescription or over-the-counter from the market.
  - Can be from the public or healthcare professionals
  - Adverse drug effect can be reported to the Manufacturer or to the FDA.

Recalls

Steps

1. FDA will contact the manufacturer.
2. Manufactures contact wholesalers, retailers, and all consumer levels.
3. Personal phone calls are made or letters are sent to customers.
4. Recalls are listed publicly.
5. Listed in the weekly FDA enforcement report.

Types of Recalls

Class I:
Serious adverse effects or death.

Class II:
Cause temporary but reversible effects.

Class III:
Not likely to cause adverse effects.

MedWatch

- A voluntary program which allows any healthcare professional to **report an adverse event** that is suspected of being associated with the use of an FDA-regulated product.
- Includes product problem, or medication error.

MedWatch

- Designed to detect effects not identified from research studies.
- Manufacturers must file a report if an adverse drug reaction is reported.
- Reports can be made.
  - Phone **1-800-FDA-0178**
  - Mail
  - Online www.fda.gov/Safety/MedWatch/default.htm

Vaccine Adverse Event Reporting System (VAERS)

- **Vaccine Adverse Event Reporting Systems (VAERS)**
  - MedWatch does not monitor vaccines.
  - Performed by VAERS.
  - Post-marketing surveillance system operated by the FDA and the Centers for Disease Control (CDC).
- Report
  - **(1-800-822-7967),** online, or submitted by mail on a downloaded form.

Law and the Technician

- Federal laws provide foundation for the state laws which governs pharmacy practice.

State Laws

- Responsible for **licensing** of all prescribers and dispensers.
- Each state enacts laws governing the **manufacturer, distribution, prescription, and dispensing** of prescription drugs.

State Laws

- Pharmacists must comply with both federal regulations and regulations in the state in which they practice.
- Such regulations may reside in different departments of the state, such as **the board of pharmacy**, the **department of health**, or **consumer affairs.**

State Boards of Pharmacy

- Composed of leaders from the pharmacy community and the public.
- Activities vary from state to state .
  - Can suspend or issue warnings, revoke pharmacy/ pharmacist/technician license or registration.
  - Provide regulations regarding the practice of pharmacy.

State Boards of Pharmacy & Legal Duties of Pharmacy Personnel

- No statutory federal definition of the role of the pharmacy technician exists.
  - No uniform definition of role and duties of pharmacy technicians from state to state.
  - Roles and duties of pharmacy technicians are changing.

State Boards of Pharmacy & Legal Duties of Pharmacy Personnel

- Requirements for pharmacy technicians vary by state.
  - Some states require licensure or registration with the board.
  - Some states require passing national certification exams.
  - Technicians duties in all states **MUST** be carried out under the direct supervision of a licensed pharmacist.

Law and the Technician

- **Legal liability** means you can be prosecuted for misconduct or negligence.
- **Misconduct** means a wrongful, improper, or unlawful conduct motivated by premeditated or intentional purpose.
- **Negligence** is the most common form of misconduct.
  - Refers to failure to do something that should or must be done.
- **Compliance** is doing what is required.

Law and the Technician

- **Negligence** is the most common form of misconduct.
  - Refers to failure to do something that should or must be done.
    - Incorrect labeling, failure to maintain patient confidentiality.
    - Failure to recognize expired drugs.
    - Calculation errors.
    - Dispensing wrong medication.
    - Incorrect handling of controlled substance.
    - Inaccurate record keeping.

American Society of Health-System Pharmacists (ASHP)

- One of the various professional bodies and associations which set and maintain pharmacy standards.
- Over 30,000 members primarily practice in hospitals.
- Serves as an accrediting organization for pharmacy residency and pharmacy technician training programs.

Drug and Professional Standards

- **United States Pharmacopeial Convention**
  - Independent scientific not-for-profit organization.
  - Sets quality standards for prescription drugs, OTC drugs, compounding sterile products, and dietary supplements.
  - The official publication is the USP (United States Pharmacopeia)
  - Develops authoritative, unbiased information on drug use.

JACHO

- Joint Commission on Accreditation of Health Care Organizations.
- Independent non-profit organization.
- Establishes standards and monitors compliance
- Monitors over 20,000 health care programs.
- Covers hospital, health care networks, HMOs, and nursing homes.

National Association of Boards of Pharmacy (NABP)

- The NABP represents all 50 state boards of pharmacy.
  - Assists in developing, implementing, and enforcing uniform standards.
  - Develops licensing exams for pharmacists.
- Coordinates reciprocation of pharmacist licenses from one state to another.
- Meets regularly to discuss national trends and issues in pharmacy law.

NABP

- Verifies the licensure of online pharmacies.
  - Internet VIPPS® program (Verified Internet Pharmacy Practice Sites).
- NO regulatory authority, unlike the FDA or DEA.
- Coordinates issuance of "NCPDP Provider ID."
  - Assigned a unique number to pharmacies in the United States and territories of the United States.
  - Identifies your pharmacy to health plan claims processors and third party contractors.
- Developed the Model State Pharmacy Practice Act (MSPPA).

Others

- Basic criminal and civil laws apply to pharmacy technicians.
- Crimes like theft, discrimination, sexual harassment, fraud, etc. are punishable just as they would be outside of your job.

Terms to Remember

1. Adverse effect
2. Compliance
3. Controlled substances
4. Dual marketing
5. Exempt narcotics
6. Injunction
7. Legend drug
8. FDA
9. DEA

Terms to Remember

10. Liability
11. NDC (national drug code)
12. Negligence
13. Pharmaceutical equivalent
14. Placebo
15. Product labeling
16. Protocol
17. Recall
18. Therapeutic equivalent

Terms to Remember

- 20. Pure Food and Drug Act of 1906
- 21. Food, Drug, and Cosmetic (FDC) Act of 1938
- 22. Durham-Humphrey Amendment of 1951
- 23. Kefauver-Harris Amendment of 1962
- 24. CSA of 1970
- 25. Poison Prevention Packaging Act of 1970
- 26. Drug Listing Act of 1972

Terms to Remember

- 27. Orphan Drug Act of 1983
- 28. Drug Price Competition and Patent-Term Restoration Act of 1984
- 29. Prescription Drug Marketing Act of 1987
- 30. Omnibus Budget Reconciliation Act of 90 (OBRA-90)
- 32. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

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