UNIT 1
MEDA 1406 Basic Pharmacology
INTRODUCTION TO PHARMACOLOGY

Chapter 1
Learning Objectives

- Describe the origin of the words pharmacology, drug, medicine, and other words related to specialty fields within pharmacology.
- Describe the three general medical uses for drugs.
- Give the origin and meaning of the symbol Rx.
- Name at least five drugs historically derived from plant, animal, or mineral sources that are still in use today.
- Describe the process of the preparation of drugs in the 1800s to early 1900s.
- Name 10 major pharmaceutical milestones that have occurred since the 1800s.
Learning Objectives

- Describe the use of mislabeled and dangerous drugs and the problem they presented in the past for consumer safety.
- Describe the origin and content of the various drug laws.
- Describe the function of the Food and Drug Administration (FDA) with respect to approving or removing drugs from the market.
- Differentiate between prescription and over-the-counter (OTC) drugs.
- Define *schedule drugs* and describe the five categories of controlled substances.
- Define *orphan drugs*.
Pharmacology
Pharmac-(pharmakon (medicine or drug) -ology (the study of)the study of drugs

- Define Pharmacodynamics
  - the mechanism of action by which drugs produce their effects (desired or undesired) based on time and dosage

- Define Pharmacogenetics
  - how the genetic makeup of different people affects their responses to certain drugs

- Define Pharmacokinetics
  - how drugs move through the body in the processes of absorption, distribution, metabolism, and excretion.

- Define Pharmacotherapy
  - using drugs to affect the body therapeutically.
Pharmacokinetics

- **A** Absorption-the process of a substance entering the blood circulation.
- **D** Distribution-the dispersion of substances throughout the fluids and tissues of the body.
- **M** Metabolism-alterations that substance undergoes within the body.
- **E** Excretion-the removal of the substances from the body.
Medical Uses For Drugs

- State three medical uses for drugs
  - prevent disease
  - diagnose disease
  - treat symptoms, signs, conditions, diseases

- The study of these uses is known as pharmacotherapy.
Drugs in Ancient Times

- The symbol **Rx**
  - Latin word for *recipe* (meaning *take*)
  - indicates a prescription

**Activity break!**

- Give an example of a drug from ancient times
Modern Drugs Derived From Natural Sources

- Drugs from plants
- Drugs from animals
- Drugs from minerals

Activity break!
- Give an example of a drug from one of the above sources
Mislabeled and Dangerous Drugs

COCAIN TOOTHACHE DROPS
Instantaneous Cure!
PRICE 15 CENTS.
Prepared by the
LLOYD MANUFACTURING CO.
219 HUDSON AVE., ALBANY, N.Y.
For sale by all Druggists.
(Registered March 1885.) See other size.

COCOA-COLA
SYRUP AND EXTRACT.
For Soda Water and other Carbonated Beverages.
This "INTELLECTUAL BEVERAGE" and TEMPERANCE
DRINK contains the valuable TONIC and NERVE STIM-
ULANT properties of the Coca plant and Coca (or Kola) 
nuts, and makes not only a delicious, exhilarating, 
refreshing and invigorating Beverage, (dispensed from 
the soda water fountain or in other carbonated bev-
erages), but a valuable Brain Tonic, and a cure for all 
nervous affections — SICK HEADACHE, NEURALGIA, 
HYSTERIA, MELANCHOLY, &c.
The peculiar flavor of COCA-COLA delights every 
palate; it is dispensed from the soda fountain in same 
manner as any of the fruit syrups.

Am. J. Ph.] 7 [December, 1801

BAYER Pharmaceutical Products
HEROIN—HYDROCHLORIDE
is pre-eminently adapted for the manufacture 
of cough elixirs, cough balsams, cough drops, 
cough lozenges, and cough medicines of any 
kind. Price in 1 oz. packages, $4.85 per 
ounce; less in larger quantities. The effi-
cient dose being very small (1/3 to 1/24 gr.),
it is

The Cheapest Specific for the Relief of Coughs
(In bronchitis, phthisis, whooping cough, etc., etc.)
WRITE FOR LITERATURE TO
FARBENFABRIKEN OF ELBERFELD COMPANY
SELLING AGENTS
P. O. Box 2160
40 Stone Street, NEW YORK
Drug Legislation and Drug Agencies

The Food and Drugs Act of 1906
- Insured strength, quality and purity of drugs
  - 1912 amendment required accurate labeling
  - only drugs listed in the United States Pharmacopeia or National Formulary could be prescribed

The Food, Drug, and Cosmetic Act of 1938
- FDA
- 1951 Durham-Humphrey Amendment
- 1962 Kefauver-Harris Amendment
- drugs show that they are safe and effective before being marketed
- manufacturers report adverse side effects
Drug Legislation and Drug Agencies

1994: Dietary Supplements and Health and Education Act

- FDA guidelines for herbal products and dietary supplements
Prescription and over-the-counter (OTC) Drugs

- The FDA regulates prescription drugs and OTC drugs
  - Rx drugs
    - defined as those drugs that are not safe to use except under professional medical supervision
    - can only be obtained with a prescription by a healthcare provider whose license permits it
FDA approves a prescription drug being reclassified as an OTC drug if the following criteria are met:

- the indication for the drug’s OTC use is similar to its use as a prescription drug
- the patient can easily diagnose and monitor his or her own condition when using the OTC drug
- the OTC drug has a low rate of side effects/toxicity and a low potential for abuse
- the use of the OTC drug does not require the patient to have any special monitoring or ongoing test

Activity break!

Give an example of a prescription drug that is also available OTC
Schedule Drugs

1970 by The Comprehensive Drug Abuse Prevention and Control Act

- Title II of this Act, The Controlled Substances Act, established the Drug Enforcement Administration (DEA) in 1973 to regulate the manufacturing and dispensing of these drugs.
- Divided potentially addictive drugs into five categories or schedules:
  - Schedule I (C-I)
    - Extremely high potential for abuse-no currently accepted medical use
  - Schedule II (C-II)
    - High abuse potential
  - Schedule III (C-III)
    - May lead to limited dependence
  - Schedule IV (C-IV)
    - Lower abuse potential
  - Schedule V (C-V)
    - Lowest abuse potential
Schedule Drugs

- To prescribe or dispense scheduled drugs healthcare providers:
  - must register with the federal Drug Enforcement Agency
  - be issued a DEA certificate and number
  - provider’s DEA number must be clearly written on any prescription for a schedule drug
Orphan Drugs

- In 1983, The Orphan Drug Act was passed.
  - purpose to facilitate the development of new drugs to treat rare diseases.
  - drug companies are reluctant to spend large amounts of time and money
    - to research and test a drug
    - especially if it will have a limited market
  - The Orphan Drug Act provides special incentives including:
    - grants to offset drug development costs
    - a tax credit that allows up to 75% deduction of the cost of clinical trials
    - streamlined process for obtaining FDA approval
    - exclusive marketing rights for seven years
Chapter 2

DRUG DESIGN, TESTING, MANUFACTURING, AND MARKETING
Learning Objectives

- Name several ways in which drugs are discovered or created.
- Describe how computers facilitate drug design.
- Differentiate between the chemical, generic, and trade/brand names of a drug.
- List at least five things that the trade names of drugs might tell you about those drugs.
- Describe the three phases of the human testing of new drugs.
- Define the phrases *in vitro*, *in vivo*, *clinical trials*, *control group*, *drug patent*, *isomer*, and *placebo*.
Learning Objectives

- Describe how inert ingredients might affect the bioavailability of a drug.
- Describe how direct marketing of prescription drugs has affected consumers and drug costs.
- Give four reasons why a drug might be withdrawn from the market or recalled.
Drug Discovery and Creation

- Drugs are discovered or created in several ways
  - Ancient sources
  - A totally new chemical can be discovered in the environment, from plants, animals, the ocean, or the soil
  - A totally new chemical can be derived from molecular manipulation of a drug that is already in use
  - A totally new chemical can be created through genetic manipulation
  - Stem cell therapy
  - Gene therapy
Drug Names

- Generic
- Trade
- Chemical
- Official

Chemical name:
(1/2)-2-(p-isobutylphenyl) propionic acid

Generic name:
ibuprofen

Trade name:
Motrin

Chemical structure:
Look at the drug label below and answer the following questions:

- What is the name of this drug?
  - Ambien (trade name)
  - Zolpidem tartrate (generic name)

- To what schedule does this drug belong?
  - C-4

- Is this a prescription or an OTC drug? How can you tell?
  - Prescription-”rx only”
Terms Indicating Drug Actions

- **Indications** - what is the drug being used for?
- **Actions** - what cellular changes happen when the drug is used?
- **Contraindications** - when should the drug NOT be used?
- **Cautions** - when should the patient be watched closer?
- **Side effects and adverse reactions** - unpleasant or dangerous effects
- **Interactions** - other drugs or foods that may alter the effect of the drug

**Other headings for drug information:**
- How supplied
- Usual dosage
What is the term that describes the general name assigned to a drug

- chemical name
- trade name
- generic name
Testing of New Drugs

- All drugs must be thoroughly tested
- Tested by the company before marketing according to FDA guidelines
- Testing to determine:
  - drug’s effectiveness
  - drug’s safety
- In vitro testing
- In vivo testing
Testing of New Drugs

- Pharmacodynamics
  - frequency distribution curve
  - half-life
  - median effect dose ($ED_{50}$)
  - median toxicity dose ($TD_{50}$)
  - therapeutic index (TI)

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Testing of New Drugs

- After completion of animal studies
  - company submits an IND (Investigational New Drug) Application
    - contains information about animal trials
    - shows drug not a risk to humans
    - includes information
      - chemistry of drug
      - manufacturing process
Testing of New Drug

- Phases of Human Testing (clinical trials)
  - Phase I
    - 10-100 healthy volunteers
    - Informed consent mandatory
    - Evaluate side effects
    - Establish final, correct dosage
    - Pharmacokinetics studied
    - Generally takes 1½ years
Testing of New Drug

- Phases of Human Testing (clinical trials)
  - Phase II
    - Drug given on experimental basis to 50-500 who have the disease the drug is to treat
    - generally takes 2 years
Testing of New Drug

- Phases of Human Testing (*clinical trials*)
  - Phase III
    - Drug given to 100’s or 1000’s of ill patients in exactly the way (dose, route, freq, etc. in which it will be once on the market)
    - Double blind studies done
Testing of New Drug

- Completion of Phase III
  - drug company submits all documentation to FDA in a New Drug Application (NDA)
  - waits for final FDA decision
    - approval
    - denial
  - only 20% NDA’s receive final FDA approval for marketing
Testing of New Drug

- Once FDA approves
  - ingredients, dosage, manufacturing process, labeling, and packaging cannot change
  - can conduct further clinical trials
    - expand the drug’s use
    - example:
      - Propranolol (Inderal) arrhythmias, HTN, migraine HA
Drug Patents

- Trade name of drug registered with U.S. Patent Office as a registered trademark™
- Under patent, right to advertise and market
- Protected by 17-year patent
- After expiration, competitors can enter the market
  - Drug’s original trade name can only be used by the original company
  - If generic is manufactured, listed under different trade names
Drug Withdrawals and Recalls

- Post-marketing *surveillance*
  - drug companies and FDA continue to monitor the drug after approval
  - some adverse effects become apparent—MedWatch

- A drug recall can be done if drug not meeting standards
  - Responsibility of drug manufacturer to notify physicians, hospitals, and pharmacies of a drug recall
A drug company is assigned the exclusive right to market a drug for a total of 17 years.
Drug Manufacturing

- What the bioavailability of the drug effect can inert ingredients have on how the drug will be
  - Absorbed
  - Distributed
  - Metabolized
  - Excreted
Learning Objectives

- Name eleven forms in which drugs are manufactured
- Describe seven different types of tablets
- Describe the difference between a solution and a suspension
- Name eight different types of drugs that come in a solution form
- Describe how pellets, beads, and wafers are used as drug forms
- Define these words and phrases:
  - ampule
  - elixir
  - lozenge
  - transdermal patch
  - Vial
Drug Forms

- Tablet (tab or tabs)- a solid form
  - scored
  - effervescent
  - enteric-coated
  - slow-release
  - caplet
  - lozenge
  - troche

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Drug Forms

- Capsule (cap or caps)
  - one-piece gelatin shell, liquid inside
  - hard shell in two pieces, powder or granules inside
Drug Forms

- **Ointment**
  - semisolid emulsion of oil
  - water
  - absorbed into the area applied
  - local vs. systemic effect

- **Cream**
  - semisolid emulsion of oil
  - water
  - absorbed into the skin
  - local vs. systemic effect
Drug Forms

- Lotion
  - suspension
    - drug
    - water base
  - absorbed into the skin
  - local vs. systemic effect

- Powder
  - finely ground drug
  - can be found within capsules
  - can be reconstituted
  - sprinkled topically on skin
  - sprayed on skin
  - inhaled into the lungs
Drug Forms

- **Liquid**
  - *aqueous* (Latin word *aqua*) or *viscous* (*nonwatery, thick*)
  - *solutions*
    - drug dissolved in sterile water or saline for injection
    - drug dissolved in a liquid base for topical or oral administration
      - elixirs
      - syrups
      - tinctures
      - liquid sprays
      - foams
      - Mousse
    - drug form remains separate from the base
      - emulsions
      - gels
Drug Forms

- Liquid
  - suspensions
    - Fine, undissolved particles
    - suspended in a water or oil base
    - particles gradually settle
    - important to shake
Drug Form

- **Suppository**
  - solid base of glycerin or cocoa butter containing the drug
  - manufactured in appropriate sizes
    - vaginal
    - rectal
    - adult
    - pediatric
  - can also be inserted into the mouth
Drug Forms

- Transdermal patch
  - patches that contain drugs
  - applied to the skin
  - releases small amount
  - over a period of time
  - exert a systemic effect, not topical

- Pellet, bead, wafer, insert, and device
  - placed within a body cavity
  - slowly releases drug

- Gas
  - inhaled