

Pharmaceutical Design and Testing

OBJECTIVES/RATIONALE

New pharmaceuticals undergo extensive testing for effectiveness and safety before being approved by the FDA. Students will research and debate ethical issues related to the process of development and production new pharmaceutical agents.

TEKS 121.2 1F, 2E, 7B, 7C

TAKS ELA 1, 3
Science 2

KEY POINTS

Pharmaceutical Design and Testing PowerPoint Presentation

- I. Pharmaceutical Names
 - A. Chemical name- describes its molecular structure and distinguishes it from other pharmaceuticals
 - B. Generic name- is determined by the pharmaceutical company along with the a special organization known as the U.S. Adopted names Council
 - C. Trade names or brand name- the manufacturer selects alone...can become a registered trademark. They are they only one who can advertise and market the pharmaceutical under that name.
 - D. The particular spelling of a brand name pharmaceutical is proposed by a manufacture for one of several reasons.
 1. To indicate the disease process being treated
 - a. Azmacort- treats asthma
 - b. Rythmol- treats cardiac arrhythmias
 2. To simplify the generic name
 - a. Pseudoephedrine to Sudefed
 - b. Haloperidol to Haldol
 - c. Ciprofloxacin to Cipro
 3. To indicate the duration - Slow-K slow release potassium supplement
- II. Pharmaceutical Design
 - A. New pharmaceuticals are discovered in one of two ways
 1. Totally new chemical substance
 2. Derived from molecular manipulation of a current pharmaceutical
- III. Testing
 - A. In vitro- in glass
 - B. In vivo- in living
 - C. many guidelines set by FDA
- IV. Animal Phase
 - A. Precedes human testing
 - B. Watching for toxic effects, side effects, addictions, cancerous tumors or

- fetal deformities
 - C. Calculating the **Therapeutic Index (TI)**.... The difference between the dosage that produces a **Therapeutic Effect** and the dosage that produces a **Toxic Effect**
 - D. NOT always a reliable indicator of how well a Pharmaceutical will perform in humans.
- V. Human Testing – 3 Phases
- A. Phase I- Healthy volunteers used to study a safe dose range, evaluate side effects and establish a correct dosage.
 - B. Phase II - Pharmaceutical is given on an experimental basis to patients with the disease it will eventually be used to treat- done to determine the extent of it's therapeutic effect
 - C. Phase III - Pharmaceutical is administered to several hundreds of ill patients in exactly the way in which it will be used clinically (dosage & route). Comparisons are made to other current pharmaceuticals.
 - 1. Group A
 - a. All patients disorder and receive new pharmaceutical being studied
 - b. Results compared to next two groups for side effects and ability to treat disorder
 - 2. Group B
 - a. All patients have disorder meant to be treated by new pharmaceutical
 - b. All patients receive a placebo and results are compared to other 2 groups
 - 3. Group C
 - a. All patients have disorder meant to be treated by new Pharmaceutical
 - b. Patients will be treated by another pharmaceutical currently being used to treat disorder
- VI. FDA Approval
- A. After reviewing all documentation on the safety and effectiveness of the new pharmaceutical
 - B. May be protected by a patent for up to 17 years

ACTIVITIES

- I. Debate the ethical issues involved in shortening the research period to approve pharmaceuticals for life threatening diseases and disorders.

MATERIALS NEEDED

Computer for power point

ASSESSMENT

HOSA Biomedical Debate Guidelines

ACCOMMODATIONS

For reinforcement, the student will locate and summarize a current event related to an ethical problem in pharmaceuticals.

For enrichment, the student will research and report on an ethical problem related to pharmaceuticals.

REFLECTIONS
