Chapter 2: Drug Design, Testing, Manufacturing, and Marketing
Multiple Choice Questions

1. Correct Answer: c
Question Feedback: Stem cells are immature cells that are capable of differentiating into any type of body tissue.
2. Correct Answer: b
Question Feedback: The chemical name of a drug accurately describes its molecular structure and is commonly used by drug companies and researchers, but is too lengthy and complicated for everyday use by health professionals.
3. Correct Answer: b
Question Feedback: In the distant past, designing a new drug by changing the molecular structure of an existing drug was a slow process of trial and error, using intuition and molecular models made from wood and wire.
4. Correct Answer: b
Question Feedback: Using computers to manipulate chemicals at the molecular level and design new drugs involves molecular pharmacology, the study of the chemical structures of drugs and their actions at the molecular level within a cell and even the DNA within the molecules.
5. Correct Answer: c
Question Feedback: In 1982, human insulin (Humulin) became the first recombinant DNA technology drug to be approved by the FDA.
6. Correct Answer: a
Question Feedback: Information from the human genome has led to the development of the subspecialty areas of pharmacogenetics and pharmacogenomics in research and drug design.
7. Correct Answer: b
Question Feedback: From the moment of its discovery or design, every drug has a chemical name that is assigned by the International Union of Pure and Applied Chemistry (IUPAC0.
8. Correct Answer: d
Question Feedback: The trade name of a drug is registered with the U.S. Patent Office as a registered trademark.
9. Correct Answer: c
Question Feedback: In 2001, the first embryonic stem cell was manipulated to become a mature blood cell.
10. Correct Answer: c
Question Feedback: During phase III, the drug is administered to several hundred or several thousand ill patients in exactly the same way (dosage, route of administration, frequency, etc.) it will be used once it is on the market.
11. Correct Answer: b
Question Feedback: The 10-digit code, given in three segments, identifies the drug company (first segment), the drug's specific strength/dose (second segment), and the package size and type (third segment).
12. Correct Answer: d
Question Feedback: Once the FDA gives final approval for drug marketing, the drug company creates a trade name or brand name.

13. Correct Answer: c
Question Feedback: The brand name or trade name of a drug is registered with the U.S. Patent Office as a registered trademark.
14. Correct Answer: a
Question Feedback: The spelling of a trade name never indicates the length of the drug's patent. Tip 5: The drug manufacturer selects a trade name that indicates the ingredients or source of the drug. Tip 2: The drug manufacturer selects a trade name that indicates what disease condition or symptom the drug is being used to treat. Tip 7: The drug manufacturer selects a trade name that indicates how often the drug is to be taken.
15. Correct Answer: b
Question Feedback: Tip 7: The drug manufacturer selects a trade name that indicates how often the drug is to be taken. Lithobid: Lithium drug given twice a day (*b.i.d.* is a Latin abbreviation that means *twice a day*).
16. Correct Answer: b
Question Feedback: Toxic side effects are observed during animal testing. It is not a way in which drugs are created or designed.
17. Correct Answer: b
Question Feedback: In addition, double-blind studies with the drug and a placebo are performed, in which neither the patients nor the physician-investigators know which patients are receiving the drug and which patients (the control group) are receiving the placebo.
18. Correct Answer: c
Question Feedback: A drug company is protected by a 17-year patent on any new drug that is approved by the FDA.
19. Correct Answer: b
Question Feedback: There are three phases of human testing, which are known as clinical trials.
20. Correct Answer d
Question Feedback: Recombinant DNA technology (rDNA) is also known as *gene splicing* or *genetic engineering*. The DNA segments are then spliced together (recombined) with the DNA in a bacterial cell.
21. Correct Answer: d
Question Feedback: Chemical analysis of a drug done in a laboratory in test tubes is known as *in vitro* testing (*in vitro* is Latin for *in glass*). Testing carried out in animals or humans is known as *in vivo* testing (*in vivo* is Latin for *in living*).
22. Correct Answer: d
Question Feedback: Drug companies use different types of inert ingredients (binders, fillers), as well as different preservatives, antioxidants, and buffers in a drug that can affect the bioavailability.
23. Correct Answer: b
Question Feedback: The drug company, together with an organization known as the United States Adopted Names (USAN) Council, determines a second name for the drug—its generic name.
24. Correct Answer: c
Question Feedback: The drug's original trade name can only be used by the original drug company. It cannot be used by other drug companies, even after the patent expires. When

the patent expires, any other drug company can manufacture that drug under its original generic name or under a new trade name.
25. Correct Answer: b
Question Feedback: The therapeutic index (TI) indicates the relative margin of safety between the dose that produces a therapeutic effect and the dose that produces a lethal effect in animals.
26. Correct Answer: d
Question Feedback: In 1982, human insulin (Humulin) became the first recombinant DNA technology drug to be approved by the FDA.
27. Correct Answer: a
Question Feedback: Tip 9: The drug manufacturer selects a trade name that indicates the strength of the drug. Bactrim DS is a double-strength dose of the antibiotic drug.
28. Correct Answer: c
Question Feedback: In 2001, the first embryonic stem cell was manipulated to become a mature red blood cell. This breakthrough ignited a controversy over the use of human embryonic cells in stem cell research. Umbilical cord blood can also be used for stem cell therapy, but only if the umbilical cord is saved and preserved after birth. Now, it is known that stem cells can be harvested from the patient's own bone marrow or blood. This approach has no ethical concerns; it also involves no chance of tissue rejection because the stems cells are harvested from the patient.
29. Correct Answer: b
Question Feedback: When the Human Genome Project was completed in 2000, the map of all 3.2 billions parts of the human genome had been deciphered.
30. Correct Answer: a
Question Feedback: The chemical name is commonly used by drug companies and researchers, but is too lengthy and complicated for everyday use by healthcare professionals.
31. Correct Answer: a
Question Feedback: Tip 3: The drug manufacturer selects a trade name that indicates what part of the body is being treated. Dermasil is a lotion for the skin.
32. Correct Answer: c
Question Feedback: Drug manufacturers who agree to test their new drugs on children so that pediatric doses can be standardized, receive a six-month extension on the standard 17-year patent on new drugs.
33. Correct Answer: d
Question Feedback: Placebos are commonly sugar pills or injections of sterile normal saline solution.
34. Correct Answer: d
Question Feedback: The manufacturing process also includes securing the drug in an appropriate container. This could require adding a packet of a desiccant (a moisture-absorbing silica gel), if necessary.
35. Correct Answer: d
Question Feedback: The drug companies and the FDA continue to monitor the effectiveness and safety of approved drugs. This is known as post-marketing surveillance.
36. Correct Answer: a
Question Feedback: A placebo is sterile water or normal saline, not a new drug

discovered in the environment. A placebo is a drug form that exerts no pharmacologic effect, no therapeutic effect, and has no side effects when administered.

37. Correct Answer: d

Question Feedback: Dextrorotary drugs (such as dextromethorphan) and levorotary drugs (such as levothyroxine) are examples of isomers that are rotated and are the right-facing mirror image compared to a related isomer (*dextr/o-* means *right*.)

38. Correct Answer: d

Question Feedback: A computer can display the molecular structure of any drug from a listing of thousands contained in its database. The computer can also identify those chemicals that would probably not be successful in treating a particular disease before time and money are invested in extensive testing. With computers, researchers can study any molecule, rotating it in three dimensions on the computer screen.

39. Correct Answer: d

Question Feedback: Drugs created through recombinant DNA technology include recombinant human erythropoietin, recombinant human growth factor, recombinant clotting factors, and others.

True/False Questions

40. Correct Answer: True

Question Feedback: An isomer is a drug that has the same chemical formula (same types and numbers of atoms in its molecule) as another drug, but has those atoms arranged in a different way.

41. Correct Answer: True

Question Feedback: Once a drug has received its final approval from the FDA, its ingredients, doses, manufacturing process, labeling, and packaging cannot be changed.

42. Correct Answer: False

Question Feedback: The advertising of over-the-counter drugs is regulated by the Federal Trade Commission. The advertising of prescription drugs is regulated by the FDA based on the Federal Food, Drug, and Cosmetic Act.

43. Correct Answer: False

Question Feedback: Some trade name drugs are difficult to spell because drug manufacturers are not held to any linguistic standards.

44. Correct Answer: False

Question Feedback: No matter how a drug was originally discovered or designed, it must be thoroughly tested by the drug company before it can be marketed. It is tested to determine the drug's effectiveness and safety according to certain guidelines specified by the FDA.

45. Correct Answer: True

Question Feedback: Generic drugs, as well as trade name drugs that are in the same drug form and have the same dose strength—even if they are from different drug companies—must all contain exactly the same active drug ingredient and must be able to be administered in exactly the same way.

46. Correct Answer: True

Question Feedback: A drug company is protected by a 17-year patent on any new drug that is approved by the FDA. This means that, during those 17 years, no other company can manufacture or market an identical drug. However, part of the 17-year patent period is used up during the testing process before the drug is even approved.

47. Correct Answer: False
Question Feedback: Just because a drug has been approved by the FDA and is on the market does not guarantee that it will remain on the market indefinitely.
48. Correct Answer: True
Question Feedback: Many drugs still in use today were originally derived from plant, animal, or mineral sources hundreds or even thousands of years ago.
49. Correct Answer: True
Question Feedback: The Recombinant DNA Advisory Committee is a group of physicians and pharmacists who review the clinical trials of genetically engineered new drugs and make recommendations to the FDA.
50. Correct Answer: True
Question Feedback: The animal phase of drug testing precedes testing on humans.
51. Correct Answer: False
Question Feedback: During the animal phase of drug testing, the pharmacodynamics of the drug are explored.
52. Correct Answer: True
Question Feedback: The higher the therapeutic index, the more desirable it is, because it indicates that the drug has a wide margin of safety.
53. Correct Answer: True
Question Feedback: While it is physiologically impossible for a placebo to exert any pharmacologic effect, patients often report a decrease in certain types of symptoms and can even experience "side effects" when given a placebo.
54. Every drug company must provide the FDA with a complete list of all prescription drugs they currently have on the market.
True Feedback: Correct!
False Feedback: This is a true statement.
Question Feedback: Every drug company must provide the FDA with a complete list of all of the prescription drugs they currently have on the market.
55. Correct Answer: False
Question Feedback: In a double-blind study with the drug and a placebo, neither the patients nor the physician-investigators know which patients are receiving the drug and which patients (the control group) are receiving the placebo.
56. Correct Answer: False
Question Feedback: In a double-blind study with the drug and a placebo, neither the patients nor the physician-investigators know which patients are receiving the drug and which patients (the control group) are receiving the placebo.
57. Correct Answer: True
Question Feedback: The power of suggestion can produce changes within the body that closely mimic the pharmacologic action of an actual drug.
58. Correct Answer: False
Question Feedback: Recombinant DNA technology (rDNA) is also known as gene splicing or genetic engineering. Gene therapy was the result of deciphering the human genome.
59. Correct Answer: True
Question Feedback: A drug company may evaluate thousands of different chemicals before finding one that moves successfully through all phases of testing and is finally

approved by the FDA for release and marketing.

Short Answer Questions

60. Correct Answer: vector

    Question Feedback: In gene therapy, a normal version of the gene is linked to a harmless virus, known as a vector that carries the gene into body cells affected by the disease.

61. Correct Answer: Investigational New Drug

    Question Feedback: Feedback: When animal studies are completed, the drug manufacturer submits an IND application to the FDA. The abbreviation IND stands for Investigational New Drug.

62. Correct Answer: clinical trials

    Question Feedback: There are three phases of human testing, which are known as clinical trials.

63. Correct Answer: placebo

    Question Feedback: A placebo (drug form that exerts no pharmacologic effect, therapeutic effect, or side effects when administered) is often used in double-blind studies during phase III.

64. Correct Answer: New Drug Application

    Question Feedback: Once phase III is completed, the drug company submits all of its documentation on the drug to the FDA in a New Drug Application (NDA) and waits for a final FDA decision for approval or denial.

65. Correct Answer: direct-to-consumer

    Question Feedback: Direct-to-consumer (DTC) marketing has become common, beginning with magazine ads and moving to television.

66. Correct Answer: bioavailability

    Question Feedback: The bioavailability of the active drug ingredient can be particularly crucial in drugs with a low therapeutic index (a low margin of safety between the therapeutic dose and the toxic dose).

    67. Correct Answer: FDA (Food and Drug Administration), DTC (direct-to-consumer (advertising)), TI (therapeutic index), IND (Investigational New Drug), NDC (National Drug Code)

68. Correct Answer: Nose

    Question Feedback: Tip 3: The drug manufacturer selects a trade name that indicates what part of the body is being treated. Nasalcrom is used to treat nasal allergies.

Matching Questions

69. Correct Answer: 1. B 2. E 3. D 4. C 5. A

    Question Feedback: Frequency distribution curve: The number of people who respond or do not respond to the drug and at what dose. Half-life: The time required for the drug level in the serum to decrease from 100 percent to 50 percent. Median effective dose (ED_{50}): The dose at which 50 percent of animals tested show a therapeutic response to the drug. Median toxicity dose (TD_{50}): The dose at which 50 percent of animals tested had toxic levels of the drug. Therapeutic index (TI): The relative margin of safety between the dose that produces a therapeutic effect and the dose that produces a lethal effect in animals.

70. Correct Answer: 1. B 2. B 3. B 4. A 5. C

    Question Feedback: Working with the chlordiazepoxide molecule, the same researcher then derived diazepam (Valium). When researchers added two more sugar molecules to

the molecular structure of erythropoietin, they created the new drug Aranesp. Researchers modified the chemical structure of terfenadine (Seldane) to derive the new drug fexofenadine (Allegra). Human insulin (Humulin) became the first recombinant DNA technology drug to be approved by the FDA. The antituberculosis drug streptomycin was first isolated from the stomach of a sick chicken.

Essay Questions

71. Question Feedback: (1) The drug does not contain the correct amount of active ingredient. (2) The drug does not remain stable until its expiration date. (3) The drug is contaminated with particulate matter from the manufacturing process.

72. Question Feedback: Chemical analysis of a drug done in a laboratory in test tubes is known as *in vitro* testing (*in vitro* is Latin for *in glass*). Testing carried out in animals or humans is known as *in vivo* testing (*in vivo* is Latin for *in living*).

73. Question Feedback: A double-blind study with a drug and a placebo is performed so that neither the patients nor the physician-investigators know which patients are receiving the drug and which patients (the control group) are receiving the placebo. The two groups, the group receiving the drug and the control group, are then compared.