ASSESSMENT-Law: When is a Medication Not a Drug

1. The term therapeutic claim refers to:

1. A statement that a drug has been approved to treat a disease.
2. A claim that a conventional drug may be used to treat a disease, but which cannot be asserted by homeopathic products nor by supplements.
3. The drug indication that is included in the package insert, but serves no other legal purpose.
4. How a drug affects the normal functioning of an organ.

2. Which of the following is NOT under the jurisdiction of the FDA?

1. Dietary supplements.
2. Tobacco products.
3. Soaps.
4. Medical devices.

3. The Durham Humphrey Amendment to the FDCA:

1. Authorized the FDA to make the distinction between prescription and OTC drugs.
2. Authorized the FDA to make the distinction between conventional (allopathic) and homeopathic drugs.
3. Permitted foods to make health claims.
4. Required drugs to demonstrate safety before they could be marketed.

4. Homeopathic products are legally considered drugs because:

1. They are listed in an official Pharmacopeia
2. They have gone through the FDA approval process.
3. They have a history which predates the current federal drug law.
4. None of these, as they are not considered to be drugs

5. The Homeopathic Pharmacopeia is:

1. A document found as an appendix in the USP.
2. An unofficial resource maintained by the FDA.
3. An independently published resource officially recognized by the FDA.
4. A guide to drug standardization which was eliminated after the Food Drug and Cosmetic Act was enacted.

6. The FDA recently withdrew its compliance guide policy for homeopathic drugs because:

1. Too many manufacturers are not following HPUS quality control guidelines.
2. The homeopathy industry is too small to justify FDA oversight resources.
3. There are concerns that the guide does not follow modern risk-based approaches to regulation and enforcement.
4. There are no reported adverse events due to homeopathic products.

7. The Federal Trade Commission recently made a regulatory decision on homeopathic drugs. What did the FTC do?

1. The FTC mandated that homeopathic drugs need to follow good manufacturing practice standards.
2. The FTC ruled that prescription homeopathic drugs can be sold over the counter.
3. The FTC ruled that the vast majority of OTC homeopathic drugs lack adequate substantiation for their efficacy claims
4. The FTC ruled that they cannot regulate the marketing of OTC homeopathic drugs.

8. Marketing of a homeopathic drug product requires:

1. Formal approval by the FDA taking into account the FDCA’s safety and efficacy standards.
2. Conformance with the standards in the Homeopathic Pharmacopeia.
3. Meeting the approval requirements in the Dietary Supplement Health and Education Act.
4. That homeopathic drugs not be subject to post-market surveillance for safety.

9. The Dietary Supplement Health and Education Act (DSHEA) was enacted in:

1. 1914
2. 1938
3. 1951
4. 1994

10. What was the rationale for the passage of the DSHEA?

1. Congress was concerned that the FDA was being too lax in adequately protecting consumers from the risks of supplements.
2. Congress was concerned about the unsubstantiated health claims being made for foods.
3. Congress wanted to provide consumers with more information about the intended use of dietary supplements.
4. Congress was concerned about herb-drug interactions.

11. Marketing of a dietary supplement product requires:

1. Formal approval by the FDA taking into account the FDCA’s safety and efficacy standards.
2. Conformance with the standards in the Homeopathic Pharmacopeia.
3. The manufacturer to be responsible for determining the safety of supplements.
4. Notifying the FDA of the manufacturer’s intent to market.

12. Which of the following is/are permissible claims for a dietary supplement?

1. Herbal Viagra.
2. Promotes healthy joints.
3. Relieves pain and stiffness of arthritis.
4. All of the above.

13. The burden of proof to demonstrate safety of dietary supplements is:

1. On the manufacturer before the drugs is marketed.
2. On the manufacturer after at least one year of MedWatch reports.
3. On the FDA before the drug can be marketed.
4. On the FDA who must prove a lack of safety after post-marketing surveillance.

14. Which of the following is INCORRECT about safety concerns for supplements?

1. Herbals can interact with prescription drugs.
2. Supplements are organically grown and are therefore free of pesticide residues.
3. Supplements with different combinations of plant ingredients may differ in their pharmacological/clinical activity.
4. The active ingredient in some herbal products may not be known.

15. Which of the following is correct with respect to consumer information about supplements?

1. Consumers know that the FDA does not approve dietary supplements.
2. Consumers rely on the FDA-mandated disclaimer when making a decision to use a supplement.
3. The pharmacist is the most commonly utilized source for consumer information about supplements.
4. Consumers have many misconceptions about the regulation of supplements.

16. The Federal Trade Commission (FTC) regulates the advertising of the following EXCEPT:

1. OTC Drugs.
2. Dietary supplements.
3. OTC homeopathic products.
4. Prescription drugs.

17. What is the most commonly used supplement product in the U.S?

1. Echinacea.
2. St John’s Wort.
3. Multivitamins.
4. Colon cleansers.

18. The FDA announced its intention to strengthen its regulatory oversight of supplements in 2019 due to:

1. Concerns about the safety of supplements.
2. Pressure from health care organizations to make some supplements products prescription only.
3. The growing influence of celebrity endorsements of supplements.
4. Concerns about internet sales.

19. One of the more common and more serious adverse effects due to supplements is:

1. Brain damage.
2. Liver damage.
3. Cancer.
4. Stroke.

20. What is the FDA Medwatch program?

1. A program where health care professionals and consumers can report an adverse event associated with a drug or supplement.
2. A program open only to health care professionals who are required to report an adverse event associated with a drug.
3. A program where health care professionals can access all adverse events about a specific drug submitted to the FDA.
4. A program reporting on drugs currently undergoing clinical trials.