

## Build Quiz



Build



Preview



Summary



Rebuild

### quiz 4



This quiz has 88 submissions. Editing a question after participants have taken the quiz will cause multiple versions of a question to be shown in the results. If the participant did not see a version of the question, "N/A" will be shown as their response. Learn more about [how results are affected](#).

Add questions or general content to your survey by selecting an item from the drop-down menu and clicking "Add". [View examples of question types](#).

Add item: Short response



at end of survey



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Position 1: Multiple choice - one answer (button)

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#### Question

What makes a drug a "drug" includes

- I. that it is recognized in an official compendium.
- II. that it is intended for use in treatment of disease.
- III. that it is intended to affect structure or function of the body.

#### Answers

- a. I only
- b. III only
- c. I, and II
- d. I and III
- e. I, II and III

Required: 

Point value: 1

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Position 2: Multiple choice - one answer (button)

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#### Question

A cosmetic is not a drug because

#### Answers

- it is intended for a trivial disease.
- it is intended for cleaning, beautifying, and promoting attractiveness.

#### Feedback

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed introduced into, or otherwise applied to the human body or any part thereof for cleansing

beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

Required:

Point value: 1

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◆ Position 3: Multiple choice - one answer (button)

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**Question**

The FDA has penalties for:

- I. adulteration.
- II. misbranding.
- III. overcharging of patients.

**Answers**

- a. I only
- b. II only
- c. I and II only
- d. I and III only
- e. I, II and III

**Feedback**

Note: Sponsors are sometimes allowed to charge for investigational drugs (almost never) and investigational medical devices (more common), but only to the extent that the charge is for the cost of research and production: 21CFR312.7(d)(3) Noncommercialization of investigational drug. Under this section, the sponsor may not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling the investigational drug.

Required:

Point value: 1

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◆ Position 4: Multiple choice - one answer (button)

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**Question**

Pharmaceutical compounding:

- I. is outlined in FDA's "9 points of light".
- II. questions are jurisdiction of State Boards of Pharmacy.
- III. Presumes a prescriber-patient-pharmacist relationship.

**Answers**

- a. I only
- b. III only
- c. I and II
- d. I and III
- e. I, II and III

Required: 

Point value: 1

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◆ Position 5: Multiple choice - one answer (button)

[Hide question details](#)[Edit](#) [Preview](#) [Copy](#) [De](#)**Question**

Many pharmacies lose their licenses secondary to fraudulent billing procedures.

**Answers**

- a. True.  
 b. False.

Required: 

Point value: 1

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◆ Position 6: Multiple choice - one answer (button)

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Fraudulent billing procedures have root causes that include:

- I. Complacency.  
II. Limited governance and oversight.  
III. Lack of rigorous risk assessment.

**Answers**

- a. I only  
 b. III only  
 c. I and II only  
 d. I and III only  
 e. I, II and III

Required: 

Point value: 1

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◆ Position 7: Multiple choice - one answer (button)

[Hide question details](#)[Edit](#) [Preview](#) [Copy](#) [De](#)**Question**

Purposeful Fraud includes:

- I. dispensing generic Rx for brand Rx.  
II. dispense one strength and bill for another.  
III. "Ghost" patients.

**Answers**

- a. I only  
 b. III only  
 c. I and III only

- d. I and II only
- ✓  e. I, II and III

Required:

Point value: 1

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◆ Position 8: Multiple choice - one answer (button)

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**Question**

From FDA's perspective, a drug is differentiated from a medical device because

- I. manufacturer's intent that the article modify form and function of the body
- II. manufacturer's intent that the article be used in the diagnosis, cure, mitigation, treatment or prevention of disease
- III. article's attributes do not achieve their primary intended purpose through chemical action within or on the body

**Answers**

- a. I only
- ✓  b. III only
- c. I and II only
- d. I and III only
- e. I, II and III

**Feedback**

21USC321 (h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Required:

Point value: 1

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◆ Position 9: Multiple choice - one answer (button)

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**Question**

Whether a practice is considered treatment or research:

- I. depends on intent of provider.
- II. depends on novel nature of practice.
- III. depends upon whether it is supervised by IRB.

**Answers**

- a. I only  
 b. III only  
 c. I and II only  
 d. I and III only  
 e. I, II and III

Required:

Point value: 1

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◆ Position 10: Multiple choice - one answer (button)

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**Question**

The Belmont Report differs from the "Georgetown mantra" in that it fails to mention:

**Answers**

- a. Autonomy  
 b. Beneficence  
 c. Justice  
 d. Nonmaleficence

Required:

Point value: 1

Total points: 10

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