

HSC 335 -- Pharmaceutical Policy (Fall 2020)

Week 7 Questions

Deadline: October 8, 2020 at 2:45pm (submit via Slack DM)

Name:

Marketing Medications

There are many important differences between the prescription drug market and other consumer markets. As a consequence, promotion of pharmaceutical products is regulated differently than promotion of other kinds of products. While other manufacturers must simply be truthful and non-misleading in their advertisements, pharmaceutical manufacturers have heightened responsibilities. In this video, we'll look at some of the special rules that apply to drug manufacturers, and their consequences for both the pharmaceutical industry and consumers.

- What is "commercial speech"?
- Why are prescription medications regulated differently from other consumer goods?
- What are the benefits of and criticisms against the standards applied to marketing of prescription medications?

Question 1

Which of the following is the most precise definition of "commercial speech"?

Communication about political topics

Communication from business entities to consumers

Communication that proposes a commercial transaction

Communication from business entities to government regulators

Communication between two business entities irrespective of topic

Question 2

Which of the following is **NOT** a reasonable justification for FDA regulatory oversight of prescription drug promotion?

FDA oversight provides an incentive for manufacturers to subject their claims to rigorous scientific evaluation.

FDA oversight helps restrict the free flow of useful information to patients.

FDA oversight helps protect patients from being misled into using products that are not appropriate for them.

Question 3

Pharmaceutical manufacturers argue that FDA rules related to drug marketing unfairly limit their ability to disseminate truthful information about their products.

True

False

Labels, Labeling, and Advertisements

To understand current rules about drug marketing, it is important to understand what kinds of information are available to physicians and consumers about a particular drug, and where that information is found. As you watch the video, consider how information relating to the use, benefits, and risks of prescription drugs is balanced and how each appears in a drug's label, labeling, and advertisements.

- What is the difference between a drug's label, its labeling, and advertisements for the drug?
- What information must be included in advertisements for prescription drugs?

Question 4

Any written, printed, or graphic matter that accompanies the drug is considered the:

Labeling

Advertisement

Appendix

Question 5

What does the FDA call the warning that is intended to be the most visually prominent warning found on drug labeling?

Boxed warning

Critical warning

Cautionary warning

Boldface warning

Question 6

Which of the following is **NOT** a requirement for consumer-directed prescription drug advertisements?

Promotional claims in advertisements must be consistent with a drug's labeling.

Advertisements must contain a summary of the drug's known risks as described on its labeling.

Advertisements must demonstrate a fair balance between descriptions of a drug's benefits and risks.

Advertisements must acknowledge the FDA's role in monitoring promotional claims.

Types of Physician Marketing

Pharmaceutical manufacturers seek to influence physician prescribing practices in a number of ways, by hiring sales representatives to meet physicians in their offices, providing free samples of the medicine or coupons for patients to use, and developing promotional materials highlighting why a physician would want to prescribe the product. As we start to think about marketing to physicians, ask yourself:

- How much money do pharmaceutical manufacturers spend on different types of marketing?
- How do pharmaceutical sales representatives influence physician prescribing practices?

Question 7

Pharmaceutical manufacturers spend more money on direct-to-consumer advertising than on promotion directed to prescribers.

True

False

Question 8

Targeted visits by pharmaceutical sales representatives to physician offices are also known as:

Physician detailing

Direct-to-consumer advertising

Physician advocacy

Institutional consultation

Question 9

Studies show that food and other gifts provided by sales representatives along with promotional messages to physicians are expected to have what impact?

They increase the likelihood of the promotional message affecting prescribing practices.

They have no impact on physician prescribing practices.

They can impact physician prescribing practices, but only above a certain threshold (e.g., 25 meals per year).

They are often rejected by the prescriber.

Regulating Physician Marketing

Marketing to physicians can be regulated by federal and state legislation, FDA rules, and individual organizations such as payors or academic institutions. We'll review several laws relating to physician marketing and other sources of regulation in this area to see how they affect interactions between pharmaceutical manufacturers and physicians.

- What is the FDA's role in regulating marketing by pharmaceutical manufacturers?
- What are the goals of the Physician Payments Sunshine Act?

- Why have states and organizations modified their policies relating to interactions between physicians and pharmaceutical manufacturers in recent years?

Question 10

The FDA does not have a specific office that has the responsibility for reviewing pharmaceutical advertisements.

True

False

Question 11

The FDA has the authority to require pre-approval of most drug advertisements.

True

False

Question 12

What can be found in the database created by the Physician Payments Sunshine Act? (Select **all that apply**)

A list of physicians who prescribe more brand-name than generic drugs

A documentation of physicians' financial conflicts of interest with the pharmaceutical industry.

A description of the category and amount of a payment made from pharmaceutical manufacturer to physicians.

A description of the evidence linking physicians' financial conflicts of interest to their prescribing practices.

Question 13

In recent years, states and some academic institutions have scaled back previous oversight of physicians' financial relationships with pharmaceutical manufacturers. Which of the following are reasons for these changes? (Select **all that apply**)

Physicians' fears of lost opportunities to interact with pharmaceutical manufacturers' representatives

Evidence that these rules translated into negative clinical outcomes

Lobbying by the restaurant industry based on lost profits from industry-sponsored dinners

Federal court decisions granting greater autonomy to states in legislating conflict of interest laws

Interview with Dr. Shahram Ahari

To get a first-hand perspective on marketing to physicians, we spoke with Dr. Shahram Ahari. Dr. Ahari worked as a pharmaceutical sales representative for Eli Lilly before attending medical school and spoke with us about how pharmaceutical sales representatives use proven sales tactics and extensive databases of information about physicians to influence their prescribing decisions.

Question 14

Identify three new things you learned from the conversation with Dr. Shahram Ahari:

Please also cut and paste your answer to this question into the appropriate section of the #discussion channel on Slack and comment on **at least one other student response.**

Click the checkbox to confirm you've posted and commented on Slack.

What is Academic Detailing?

Dr. Jerry Avorn and colleagues have spent decades developing techniques to guide physicians in one-on-one meetings to make prescribing decisions based on the best clinical evidence available, so that physicians would feel less obliged to listen to one-sided sales pitches by pharmaceutical representatives. They called their approach "academic detailing" to highlight the similarities in its personal approach with pharmaceutical detailing.

- How is academic detailing similar to pharmaceutical detailing? How is it different?
- How does academic detailing differ from other non-industry ways that practicing physicians learn about drug prescribing (e.g. Continuing Medical Education sessions, etc.)?

Question 15

Academic detailing could involve (Select **all that apply**):

Synthesizing literature on the efficacy, safety, and value of treatment strategies for a disease or condition

Disseminating a printed review that describes a drug class's benefit-risk profile

Reviewing misleading aspects of particular pharmaceutical promotional materials

Having one-on-one conversations with physicians about prescribing options and supporting evidence

Giving lectures to large groups of health care providers

Question 16

Which of the following strategies are common to both academic and pharmaceutical detailers? (Select **all that apply**)

- Making visits to physician offices
- Mailing materials to physician offices
- Providing unbiased evidence regarding the clinical use of certain products
- Providing handouts that describe prescribing choices for a given disease or condition

Academic Detailing Successes

Dr. Avorn and his colleagues have assessed the effectiveness of academic detailing in a number of trials that measure its impact on prescribing practices and health care spending. As you watch the following video, consider:

- How does academic detailing seek to change behavior?
- How successful is academic detailing in curtailing inappropriate prescribing practices?
- What is the “return on investment” in academic detailing?

Question 17

Academic detailing pamphlets can help physicians explain prescribing choices to patients

True

False

Question 18

According to one economic review, for every dollar spent on academic detailing, Medicaid saved about _____ in the 1980s.

\$0.10

\$2

\$10

\$100

Question 19

Academic detailing uses “un-advertisements” to: (Select **all that apply**)

- challenge misleading industry claims.
- expose unsafe drug manufacturing practices.
- subconsciously change consumer preferences.
- suggest evidence-based treatment alternatives for a particular disease or condition.

Question 20

Do you think allowing pharmaceutical companies to market **directly to physicians** is a good idea?

Yes

No

Explain your answer:

Please also cut and paste your answer to this question into the appropriate section of the #discussion channel on Slack and comment on **at least one other student response.**

Click the checkbox to confirm you've posted and commented on Slack.