HSC 335 -- Pharmaceutical Policy (Fall 2020)

Week 5 Questions

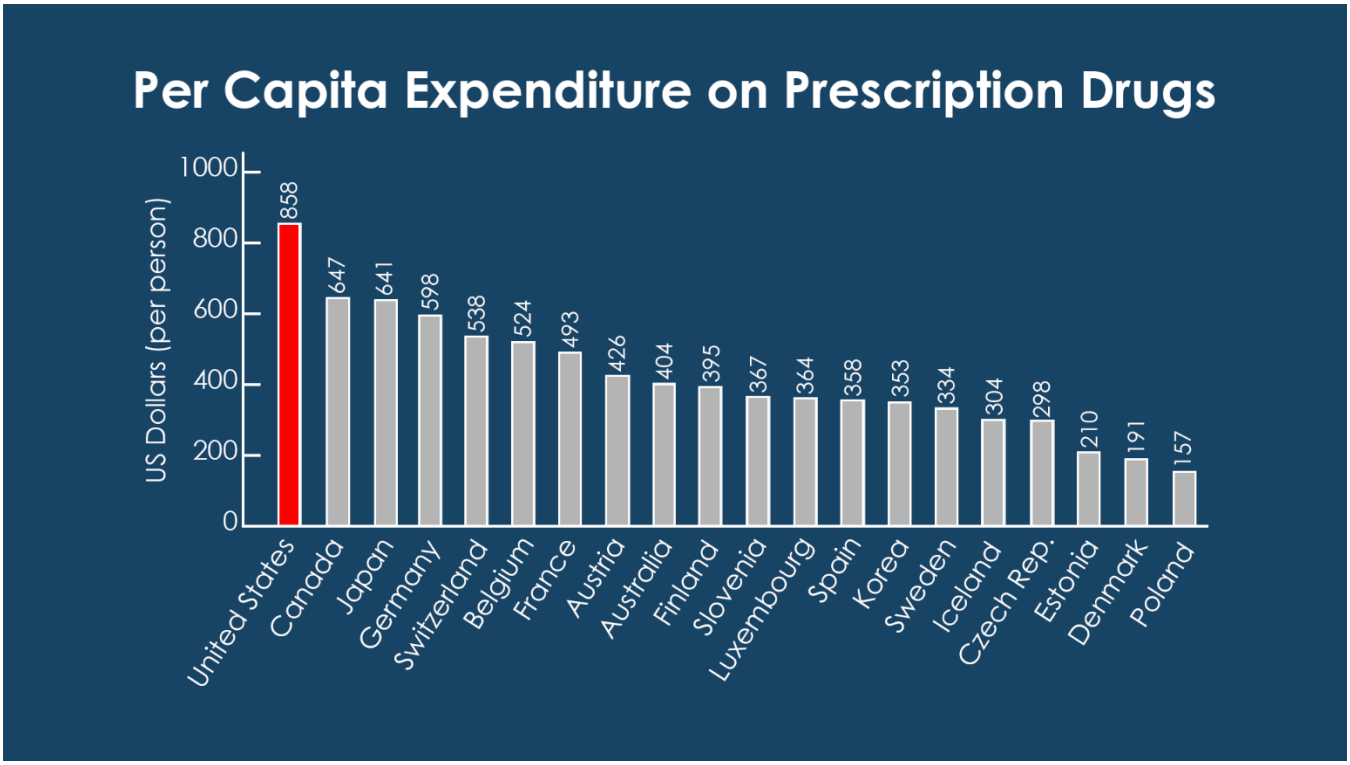
<u>Deadline:</u> September 24, 2020 at 2:45pm (submit via Slack DM)

Name:

What We Pay and Implications

<u>Question 1</u>

The graph shows annual per capita spending on prescription drugs in 20 industrialized countries.



Based on the data presented here, patients in the US spend more than twice as much on prescription drugs when compared to patients in _____ of the other industrialized countries on the graph.

- ☐ 35%
- ☐ 50%
- ☐ 65%
- ☐ 90%

Question 2

Over the past decade, brand-name drug prices have grown by a similar percentage to other health care goods.

- ☐ True
- ☐ False

Question 3

After accounting for rebates, US drug prices are comparable to those in other countries.

- ☐ True
- ☐ False

Question 4

Rising drug prices have contributed to increasing government spending on Medicaid and Medicare.

- ☐ True
- ☐ False

A Patient's Perspective

Now that you have a sense of the scope of the issue, let's talk with someone who as a patient has struggled with high drug prices—and in response formed an organization to represent patients in advocating for changes to the way drugs are priced in the US. We are pleased to be joined by David Mitchell, president and founder of Patients for Affordable Drugs, who will share what he's learned from his experiences as a patient and through the work of his organization.

Question 5

Describe one thing you learned from the discussion on high drug prices with David Mitchell. Please also post your comment on the appropriate section of the #discussion channel on Slack and comment on at least one other student's post.

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.

Generic Drug Approval Process

Generic drugs are bioequivalent versions of brand-name drugs that have similar clinical effects and enter the market once the exclusivity period for a brand-name drug has ended. The availability of generic drugs can substantially lower drug prices.

- What is a generic drug?
- How has regulation of generic drugs changed since earlier in the twentieth century?

Question 6

In the US, state laws that prohibited pharmacists from dispensing generic drugs in place of brand-name drugs were common before the 1962 Kefauver-Harris Amendments.

- ☐ True
- ☐ False

Question 7

A generic drug is a non-interchangeable version of a brand-name drug made by different manufacturers.

- ☐ True
- ☐ False

Question 8

Which three of the following were major components of the 1984 Hatch-Waxman Act?

- ☐ It created a patent challenge process to ensure that brand-name manufacturers did not extend their patent-protected market exclusivity periods indefinitely.
- ☐ It incentivized the creation of biosimilar drugs to mimic biologic drugs by providing tax breaks to manufacturers.
- ☐ It streamlined the process for approving generic drugs, reducing the burden on manufacturers to carry out large-scale clinical trials.
- ☐ It provided market exclusivity periods to run concurrently with the life of the patents for new brand name drugs.
- ☐ It offered tax subsidies to all manufacturers of new generic drugs.

The Hatch-Waxman Act and Drug Product Selection Laws

When you go to the pharmacy in the US, there is a good chance that your prescription will be filled with a generic drug, if one is available; indeed, generics account for about 90% of all filled prescriptions in the US. The growth of the generic drug industry was stimulated by the Hatch-Waxman Act of 1984, which allowed generic drugs to have a streamlined development and approval process. In addition, state drug product selection laws facilitate the substitution of generic drugs for their brand-name counterparts at the pharmacy, making it easier for patients to obtain them. Think about your own experiences taking prescription drugs and consider the benefits that generic drugs provide to patients and the effects that they have on the pharmaceutical market as a whole.

- What are the requirements for a generic drug to be considered interchangeable with its brand-name counterpart?
- How do drug product selection laws impact the generic drug market in the US?
- What effect does the availability of generic drugs have on the pharmaceutical market?

Question 9

Which three of the following must be true of a new generic drug for it to be approved as potentially interchangeable by the FDA?

- ☐ The generic drug must have the same active ingredient and dosage form as the approved brand-name drug.
- ☐ The generic drug must have the same rate and extent of absorption as the brand-name drug.
- ☐ The labeling must be consistent with the labeling for the brand-name drug.
- ☐ The generic drug must be cheaper than the brand-name drug.

Question 10

There is strong clinical evidence that brand-name drugs and generics are equally safe and effective.

- ☐ True
- ☐ False

Question 11

What are Drug Product Selection laws?

- ☐ Laws that allow pharmacists to substitute FDA-approved generic drugs for brand-name versions when filling prescriptions.
- ☐ Laws that verify the quality standards for prescription drugs.
- ☐ Laws that give patients greater latitude to choose between brand-name and generic drugs.
- ☐ Laws that govern how government-funded drug research projects are chosen to be brought to market.

Question 12

Which **three** of the following are true of generic drug availability?

- [ ] It promotes innovation by brand-name drug manufacturers.
- [ ] It reduces the need for prescriptions.
- [ ] It saves money for consumers and the health care system.
- [ ] It improves prescription adherence.
- [ ] It immediately lowers drug prices 50% or more, on average.

Patent Challenge Process

Most drugs are protected by a key patent, usually on the active ingredient, which is obtained shortly after the drug is discovered. However, after a drug looks successful, brand-name manufacturers obtain dozens, or even hundreds, of additional patents relating to the products, which could serve to extend the drug's exclusivity period longer than the remaining term on the key patent. To obtain market entry, generic drug manufacturers often have to challenge the validity of these patents in court. A trend in recent years has been for brand-name manufacturers to settle these cases with generic manufacturers, resulting in agreements in which the generic manufacturer agrees not to market a generic drug in exchange for some valuable consideration from the brand-name manufacturer. Let's take a closer look at some of these issues in the video that follows.

- What is a patent?
- How do key patents on active ingredients differ from secondary patents?
- How does the Hatch-Waxman Act encourage generic manufacturers to challenge drug patents held by brand-name manufacturers?

Question 13

The 1984 Hatch-Waxman Act granted 180 days of exclusivity to reward generic manufacturers that:

- [ ] Brought their drug to market by successfully challenging drug patents held by a brand-name manufacturer.
- [ ] First filed an Abbreviated New Drug Application (ANDA) with the FDA once a brand-name drug's patents expired.
- [ ] Conducted more rigorous bioequivalence testing than mandated by the FDA.
- [ ] Focused on manufacturing drugs for rare diseases.

Question 14

Branded firms win most lawsuits against generic manufacturers asserting the validity of so-called "secondary" patents.

- ☐ True
- ☐ False

Brand Name Reasons - What People Think

Now we'll shift our focus to reasons why people think prescription prices are high. One claim is that high drug prices are needed to support development of new, innovative drugs. What do you think of this claim? What proportion of their revenue do you think large pharmaceutical manufacturers spend on research and development? Submit your answer to the poll below, and see how your answer compares to those of everyone else.

Before you watch the video: take a guess - what do you think?

Large pharmaceutical manufacturers in the United States spend X% of their revenue on research and development, as compared to about Y% on marketing and administration.

- ☐ X = 5-10; Y = 10-20
- ☐ X = 10-20; Y = 20-30
- ☐ X = 20-30; Y = 20-30
- ☐ X = 20-30; Y = 30-40
- ☐ X = 30-40; Y = 10-20
- ☐ X = 30-40; Y = 20-30

Another claim is that the price of a drug reflects the costs of its research and development, including failures. As you watch the video, think about the relationship between the price of a drug and a company's research and development costs, and how research and development costs are determined. Are these costs truly reflective of how much companies spend on drug development?

Question 15

The price of a drug is a function of its research and development costs.

- ☐ True
- ☐ False

Question 16

Which two of the following are reasons the $2.6 billion estimate of the cost of drug development is suspect?

- [ ] The study used a high cost of capital.
- [ ] The analysis was not based on publicly available data.
- [ ] The study included clinical trial costs as a factor in drug pricing.
- [ ] The study looked at a disproportionately high number of oncology drugs, which typically cost more than other prescription drugs.

The Effect of Monopolies

After a new drug is FDA-approved, manufacturers are able to charge high prices for them because they are granted a period of market exclusivity – essentially a government-sponsored monopoly. In this video, we'll take a look at two main sources of this market exclusivity. As you watch, keep the following questions in mind.

- What is patent term restoration?
- What other protections can be applied to prescription drugs? How long do they last?
- What is the outcome of having two different types of market exclusivity that oftentimes overlap?

Question 17

Which of the following inventions would likely be ineligible for a patent?

- [ ] A newly synthesized cholesterol-lowering drug
- [ ] A new use of an existing drug
- [ ] A new abuse-deterrent formulation of an opioid
- [ ] An updated process for manufacturing a drug that followed a published process for producing a similar drug

Question 18

Patent term restoration allows drug manufacturers to extend the length of one key patent to account for the time a drug was in clinical trials and FDA review.

- [ ] True
- [ ] False

Question 19

Only new drugs with patents are guaranteed any legal protection from generic competition.

- [ ] True
- [ ] False

Question 20

What is the approximate median period of market exclusivity for widely-used new drugs?

- [ ] 5 years
- [ ] 10.5 years
- [ ] 12.5 years
- [ ] 20 years

Negotiating Power and Intermediaries

Brand-name manufacturers have monopoly power and can set a price at whatever the market will bear. The US market for prescription drugs is extremely inefficient. In this video, we'll look at how the diffuse network of public and private payors can try to reduce the amount that they pay for prescription drugs. A key role is played by pharmacy benefits managers, which negotiate drug prices with pharmaceutical companies.

- What power do public programs like Medicare, Medicaid, and the Veterans' Administration have to negotiate for lower prices on prescription drugs?
- What is the role of pharmacy benefits managers in the pharmaceutical market?

Question 21

A new cancer drug is found to be no more effective than other available drugs but extremely expensive. Which of the following payers can refuse to cover the drug?

- [ ] Veterans Administration
- [ ] Medicare Part B
- [ ] Medicare Part D
- [ ] Medicaid
- [ ] All of the above

Question 22

Medicaid programs cannot negotiate drug prices because they already receive a guaranteed statutory discount. This ensures that they pay the lowest price offered on the private market.

- [ ] True
- [ ] False

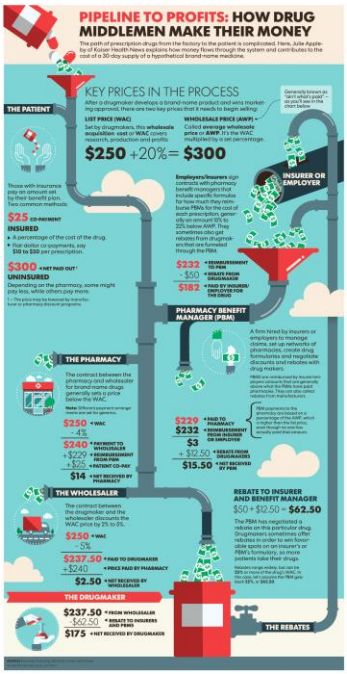
Question 23

Which of the following is/are true regarding pharmacy benefits managers? (Select all that apply.)

- [ ] They serve as intermediaries on the part of health insurers to administer pharmaceutical coverage.
- [ ] They manage the benefits of pharmacy employees.
- [ ] They negotiate confidential rebates with pharmaceutical companies.
- [ ] They are non-profit entities that advocate for improved benefit management in the health care sector.

Pharmacy Benefits Managers

The infographic below, by Julie Appleby of Kaiser Health News, describes how pharmacy benefits managers, which act as middlemen between insurance companies and pharmaceutical companies, are able to make profits by negotiating prices and rebates in a process that is often hidden from consumers. To view more clearly, download the PDF here.



Prescribers and Patients

The pharmaceutical market is distinctive in part because the physicians who make decisions about what drugs to prescribe are not responsible for paying for those drugs, while those who are responsible for paying for drugs often have limited knowledge of their options and most have insurance that covers the majority of the price. This leads to a dysfunctional price negotiation dynamic that favors the monopolist pharmaceutical manufacturers. As you watch the following video, consider:

- What roles do physician and patient behaviors play in affecting drug prices?
- What are the effects of drug coupons and samples on the prices of prescription drugs?
- What effect does direct-to-consumer marketing of prescription drugs have on drug prices?

Question 24

Which of the following statements is true about prescription drug coupons?

- [ ] They incentivize use of low-cost, safe, and effective generic drugs.
- [ ] They help sustain higher drug prices overall.
- [ ] They lower the amount that insurers must pay.

Question 25

As of 2018, how many countries other than the US allowed broad direct-to-consumer marketing for prescription drugs?

- [ ] 0
- [ ] 1
- [ ] 5
- [ ] 20

Question 26

In the US, pharmaceutical industry spending on marketing to physicians is about double the annual spending on marketing to patients.

- [ ] True
- [ ] False

Possible Solutions

US policymakers have been working on strategies to lower prescription drug costs for the last 5 years. In this video, we will take a look at some options and their potential consequences.

- What actions can the government take to lower the costs of prescription drugs?
- What are the benefits and risks of these ideas?

Question 27

Which condition is a necessary part of the federal government invoking "government patent use" to find alternative, lower-cost manufacturers of patented brand-name drug products?

- ☐ Public demand for lower drug prices must be high.
- ☐ Reasonable compensation must be made to the patent holder.
- ☐ Drug research must have been paid for using taxpayer money.
- ☐ The brand-name manufacturer must have been negligent in monitoring post-approval use of the drug.

Question 28

Which of the following are benefits of government-funded drug cost-effectiveness assessment? (Indicate **all that apply**.)

- ☐ Better informing insurance coverage determinations to promote high value care
- ☐ Educating physicians and patients about the value of medication choices
- ☐ Creating an organization to override FDA regulatory authority
- ☐ Giving current pharmaceutical company CEOs with real-world experience an opportunity to sit on the assessment group and oversee change in industry

Patient Perspective on Solutions and Limitations

We now return to our conversation with David Mitchell, who will share his thoughts about some of the reasons for high drug prices, and what strategies Patients for Affordable Drugs supports for lowering them. In particular, please consider how strategic manufacturers are in their outreach efforts, and how P4AD weighs the various ideas being proposed to lower prices.

Question 29

Describe one thing you learned from the discussion on solutions and limitations with David Mitchell. Please also post your comment on the appropriate section of the #discussion channel on Slack and comment on at least one other student's post.

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