1.

i. Please read this article and answer the questions below:

A. At what types of companies do the authors say most pharmaceutical innovation takes place, and what about this environment leads to the innovation?

They found that emerging start-ups with low annual sales discover more than half of all newly approved drugs. The environment in these smaller companies attracts top scientific talent, where the most creative scientists work with more freedom. This results in increased innovation that is further encouraged (monetarily) through stock options as opposed to modest end of year bonuses.

B. What do the authors say is the real barrier to innovation in pharmaceuticals, and how does this impact the way that big pharmaceutical companies get many of their products?

They say that the real barrier is the FDA's high regulatory costs, as these innovative smaller companies can't always afford to conduct the large billion-dollar clinical trials required for approval. This positively impacts bigger companies who treat these smaller companies like 'farm teams', buying off their best drugs. The FDA's costs for approval result in big pharmaceutical companies getting many of their products from the innovative emerging start-ups discussed in part (i).

ii. Read these two articles and answer the questions below:

C. According to the article, how much does a single pill cost, and how much does the full treatment cost (note the full treatment cost isn't explicitly given, but the pill must be taken daily for the duration of treatment, which is given)? How much income did the hepatitis C pill generate for Gilead in just a three month period (a "quarter")?

They report that the list price is about $1000 a day for a 12-week long treatment plan. This totals to $84,000 total for the treatment. For the second quarter, the pill itself generated $3.5 billion, and Gilead reported a total profit of $3.66 billion for the quarter.

D. Who is Pharmasset, and what is their relationship to Gilead and the hepatitis C pill? Describe how the hepatitis C pill story either supports or goes against the main argument in "No, Big Pharma's High Prices Don't Drive Innovation"

Pharmasset is a small company with no commercial products that developed the drug that Gilead was interested in. Gilead acquired the company for around $11 billion. The main argument in "No, Big Pharma's High Prices Don't Drive Innovation" is that high drug prices are not necessary for innovation because many breakthrough drugs are developed by smaller companies, not large corporations. This argument is clearly supported by Pharmasset's story, as Gilead literally bought the company and its innovation to be able to produce the Hepatitis C drug. This story also supports the argument as Gilead charges so much for the drug, prioritizing profit. The buying of an innovative company for pharmaceutical progress supports the main argument from the first presented article.

2. Please read this article and answer the following questions:

A. What do "high upfront costs" and "low incremental costs" mean, and how is this relevant to the authors' ideas regarding international disparities in pharmaceutical prices?

High upfront costs refers to large initial investments required before a drug can be made available. This includes the R&D phase, patenting, trials, and other approval costs.These costs must be incurred before any revenue is generated. Low incremental costs refers to the relatively small additional cost needed to produce each unit. This includes manufacturing the actual drugs. Wealthier countries like the US lack strict price controls, leading to higher drug prices, but low incremental costs make it economically viable to sell drugs at lower prices in poorer countries. This maximizes revenue while maintaining access across different income levels.

B. The authors argue that the lower prices of pharmaceuticals in other countries are due to the certain actions of other countries. What are these actions taken by the other countries, and what do the authors say would happen with pharmaceutical innovation if the US took these same actions (and why)?

They say that these countries have 'monopsonistic government agencies' that negotiate drug prices with pharmaceutical companies, forcing them to accept lower prices. These agencies have the attitude that if they can't afford it, then their citizens can do without it. Less investment in research and development would lead to fewer medical breakthroughs worldwide as drug companies recoup R&D costs primarily through high US prices. Specifically, they say "If we pay, we get new lifesaving medicines. If we don't, we don't".

C. Describe how the authors' argument aligns with Immanuel Kant's universality formulation of moral theory: "I ought never to act except in such a way that I could also will that my maxim should become a universal law". Hint: Kant is saying that the test to see if an action is immoral is to see what would happen if everyone did this action; an action is immoral if the benefit obtained by doing the action only occurs if other people are NOT doing the action. An example of this is cheating in school -- if it were well known that everyone cheats, then no one would pay consideration to grades and there would be no benefit from cheating.

The author's argument aligns with this by suggesting that if every country imposed strict price controls on pharmaceuticals, then the system of drug innovation would collapse, making such actions immoral under Kant's framework. Under Kant's formulation, price controls are immoral if they rely on others not doing the same. Just as cheating in school only benefits a student because most others don't cheat and grades are valued, price controls in one country only work because other countries pay full price. Ultimately, the authors argue that U.S. high drug prices are necessary for global medical progress, and that universal price controls would create a self-defeating system.

3.

A. What are the factors the authors list that favor taking into account patient views in drug approval decisions? What are the factors the authors list that oppose taking into account patient views in drug approval decisions?

The authors say that patient input is most valuable in close cases where data and regulatory frameworks fail to indicate whether or not a drug should be approved. They also say that taking patient opinion will avoid making false generalizations about patient preferences. Next, they argue that the urgency of current patients will result in the FDA pushing immediate access to drugs, benefiting future patients as well. Finally, they say that using patient views will help with risk analysis, and can also give context to patients' clinical trial data. In opposition, they say that patient desperation means nothing in the face of crushing reality. Also, they mention that patient choice can result in high risk with low reward, and that giving them choice gives patients hope which is then exploited for commercial benefit.

B. Describe how the authors' approach can be considered to follow Aristotle's Golden Mean approach to ethics. Hint: Aristotle's Golden Mean is the most influential version of virtue ethics. In this approach, virtues lie on a golden mean in between two extremes which are vices. As examples, courage is a virtue that lies as a golden mean between cowardice and recklessness, and generosity is a virtue that lies as a golden mean between stinginess and extravagance.

The authors advocate for a balanced approach to drug approval. Their opinion lies between cowardice (Ignoring patient perspectives entirely) and recklessness (Relying solely on patient separation without scientific rigor). In the former extreme, the patient could l;ose their life due to closed mindedness, while in the latter the patient could lose their life due to unforeseen consequences. The Golden Mean in this context is a middle path, where the FDA listens to patients but still upholds high scientific standards to ensure drugs are both safe and effective.

C. What do the authors say in regard to the "something is better than nothing" point of view?

The authors say that the FDA should resist the urge to follow this approach. It is understandable for desperate individuals to want this approach, but they say that the FDA following this affects the drugs and clinical information. Having the FDA act as a 'gatekeeper' encourages manufactures to establish that their drugs are safe and effective before they can be marketed.

4.

A. How many different prices, on Medicare plans, were found for the generic version of the breast cancer drug Tykerb? What were the low and the high prices? What was the range of prices for CVS Caremark alone?

There were 460 prices found for the drug. The prices range from a low of $1,392 to a high of $12,145. The average low is $4,817, and the average high is $6,504. The price range for CVS Caremark is from ~$3,100 to ~$7,000.

B. What is the reason given in the article for these big drug price variations?

They say that medicare divides coverages into 34 regions around the US and that health plans have to submit separate buds for each region. They also say that PBM's inconsistent way of arriving at drug prices makes medicare look less trustworthy and more like a gamble. Taking into account dispersed medicare regions and PBM practices, the article sums up these variations byu stating that the reason for such huge differences is "America's complicated drug-reimbursement system which uses middlemen to negotiate prices".

5. Please watch this video and answer the following questions:

A. Consider a customer buying soda in a store like CVS. Describe the supply chain, including all parties involved and the transfer of goods and payments between parties.

The parent company manufactures the soda and sends it to a retailer who then sells it to a customer. The retailer then uses the money the customer paid for the beverage to pay the parent company back for manufacturing the goods.

B. Now consider a customer buying a prescription drug in a store like CVS. Who are the parties in this supply chain?

Those involved in the supply chain are pharma companies (drug makers), wholesalers (distributors) who sell to pharmacies, insurance companies, and pharmacy benefit managers (middle men; PBM).

C. Who does a pharmacy benefit manager work for, and what is their job role?

They work for insurance companies, big employers, and government agencies. Their job is to bring down the cost of drugs for their employers by negotiating with pharma companies with rebates.

D. What is the formulary, and how do its tiers relate to the co-pay that a customer must pay? How does the rebate affect the tier? What tier do pharma companies want their drug on, and why?

A formulary is the list of drugs the insurance company covers. Each tier represents what portion of the list price the patient pays versus what the insurance company pays. The highest tier is the lowest amount the patient pays, and the lowest tier is the highest copay for the patient. Higher rebates result in higher tiers for the drug on the formulary. Companies want high placement on the formulary (higher tier) as more people will buy it so that they make more money on average for large needed groups.

E. What reason did the pharma companies give for raising list prices, and what did they say was the role of the pharmacy benefit manager in this regard? What was the response from the pharmacy benefit managers?

They say that they need to raise the list prices to meet the demands of the higher rebates imposed by the PBMs. They say you get no uptake and poor finances from not raising the list prices. Ultimately this is to protect their sales and profits. The PBMs say that the companies don't have to raise drug prices to boost bottom lines and that rebates reduce costs, not inflate them. They say that rebates reduce insurance payments and thus customers don't need to pay large premiums.

F. Data is shown in the video that the average price paid for some drugs has not really been increasing, even though the list price is increasing. But some people are nonetheless adversely affected by this system -- who are these people and why are they adversely affected?
The patient ultimately ends up being affected by this adversely, where they have to pay closer to the list price, not the price that the insurance company is responsible for after the rebates. Specifically, patients without (good) insurance or those that have high deductibles sometimes have to pay the entire list price due to insurance companies' role in pricing. Different people with different insurance plans pay different amounts for different drugs.

6. This press release from the Federal Trade Commission in July 2024. claims that prescription drug middlemen are "squeezing Main Street pharmacies". Describe how these drug middlemen are doing this.

The report found that PBMs (the middlemen) have enormous power over accessibility and cost of drugs, as well as having large influence over independent pharmacies by imposing unfair, arbitrary, and harmful contractual terms. They can do this because they are well integrated with the nation's largest health insurers and specialty and retail pharmacies. This vertical integration and high degree of consolidation in the market results in a significant increase in power. Integrated PBMs have the ability and incentive to prefer their own affiliated businesses, creating conflicts of interest that can disadvantage unaffiliated pharmacies which increases prices. The report also finds that PBMs use harsh contracts to disadvantage smaller, unaffiliated pharmacies. Finally, PBMs negotiate rebates conditioned on limiting access to lower-cost generic competitors. These issues compound in the PBMs effectively squeezing Main Street pharmacies, increasing prices and punishing patients nationally.

7. Which of the factors mentioned above do you find most convincing in explaining the high drug prices in the US, and why do you think that is?

I think the most convincing factor is the supply chain combined with PBMs. According to the report discussed in number 6, this factor seems most compelling. PBMs are reported to have widespread influence over availability and pricing. Availability is a driving economic force when it comes to driving up prices. Moreover, PBMs act out of self interest to drive the profits of their supervising companies up. They act with disregard to the patients and consumers, and do everything in their power to increase profits. This, combined with the supply chain scenario described in number 5 leads to the high drug prices in the US, in my opinion. Ultimately, PBMs are ultimately forcing pharmacies and drug manufacturing into corners where prices need to go up in order to keep profits high. This is at the cost of people's wallets.