

UT HEALTH SON

**Government
Oversight of
Prescription Drug
Prices**

**GROUP
DEBATE**

PRO ARGUMENT

Group 11

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Lack of regulation leads to price gouging

- Unlike other high-income countries, the US government does not use its bargaining power to negotiate lower prescription drug prices for consumers. Drug companies are free to charge what the “market will bear”. I.e. whatever they want (Fitzgerald, 2019).
 - Price negotiation is left to insurance companies which increases cost sharing for all consumers and makes access to some prescription drugs effectively impossible for the uninsured.
- The federal government does not limit price increases on prescriptions drugs and individual states’ efforts to cap drug prices often don’t make it into law or become tied up in litigation (Padula, 2019).
 - This enables drug companies to increase drug prices virtually without limit and leads to enormous price hikes that can be initiated, literally, overnight.
- There are no federal transparency laws requiring pharmaceutical companies to disclose what costs, such as R&D, manufacturing, marketing, and administration costs, comprise the final drug price (Padula, 2019).
 - This makes it difficult to determine the true value of a drug and makes price negotiation difficult.
 - It also allows drug companies to hide obscene profit margins behind terms like “innovation costs”.
- Consider this example:
 - In 2015 Turing pharmaceuticals purchased the sole means of production and distribution for a generic drug called daraprim.
 - Daraprim is the drug of choice for treating toxoplasmosis and is mostly used to treat this condition in immunocompromised populations such as AIDs and cancer patients.
 - Once Turing was assured that there was no market competition for the drug, they increased the price 5,000% OVERNIGHT.
 - A bottle of 100 pills went from \$1,350 to \$75,000. Nothing about this was illegal, and no one could stop them.

Effect of price gouging on consumers

01

EFFECT

When prescription drug prices suddenly increase, patients face terrible consequences (Fitzgerald, 2019).

02

EFFECT

The Senate Committee on Aging found that after a spike in prescription drug prices, patients:

- experience treatment interruptions
- go without vital medications - often skipping or dividing doses, or hoarding pills
- lose access to medications because insurance companies stop covering them
- worry that they will be denied access to patient assistance programs that make their medications more affordable or free
- switch to alternative drug therapies that may not be as effective or may have increased side effects (Fitzgerald, 2019).

Prescription drug costs are a fiscal challenge for Medicare and Medicaid payers.

The increased prices of drugs are an ongoing concern for people who are on Medicare and Medicaid, especially those with chronic conditions.

BABY BOOMERS ARE ENTERING RETIREMENT AGE IN A HUGE INFLUX. MANY OF THEM ARE OPTING INTO THEIR MEDICARE PART D BENEFITS. IN 2015, THE PART D PROGRAM SPENT \$137.4 BILLION ON DRUGS (DANIEL & BORNSTEIN, 2019).

As of 2018, more than 43 million people were enrolled in a Part D plan. Medicare expenditures account for 29% share of all spending on retail prescription drugs (Daniel & Bornstein, 2019).

MEDICAID HAS ALSO SEEN INCREASES IN PHARMACEUTICAL SPENDING:

Medicaid spending on outpatient drugs increased by 25% (from \$22.4 billion to \$28 billion) between 2013 and 2014 and by another 13% (to \$31.7 billion) between 2014 and 2015 (Daniel & Bornstein, 2019).



These types of unpredictable costs can drive up spending growth and need to be addressed as part of broader efforts to curb the increasing cost of healthcare in the United States. Medicare is the biggest drug and health service purchaser in the US. If it could negotiate, it would have massive leverage. To avoid abusing this massive leverage, it simply automatically gets the lowest price that's not a "bundle" or "sale" price.

Government regulation encourages the companies to research and develop newer, better drugs

Consider the following example:

- In France, the price of a drug is negotiated between pharmaceutical companies and the government. Price is determined based on the therapeutic value (such as mortality, morbidity, side effects) that has been added to the drug compared to the pre-existing one in the market (Rodwin, 2019).
 - If the “new” drug has no improvement compared to the ones in the market, the company must sell at a 5-10% lower price than comparable drugs. On average 51 new drugs get added to this “no improvement” category annually (Rodwin, 2019).
 - If the new drug made major improvements in therapeutic value, it gets the highest price in the market. Only 1.4 new drugs are added to this category annually. However, the price is kept affordable as it’s not allowed to be higher than the highest prices in neighboring European countries (Rodwin, 2019).
- After a 5 year contract the price is reevaluated by comparing it to the new drugs coming into the market and the price is usually reduced (Rodwin, 2019).
 - This helps the best/highest priced drugs be rotated out with even newer/better drugs. In other words, French people who use national health insurance get to use the best drug in the market at a competitive price.
- French government regulation doesn’t allow the pharmaceutical companies to just rely on the drugs that have already been developed. If they want to increase or maintain the revenue coming in, they have to develop newer, better drugs as the price of the old drug gets reduced annually after the 5 year contract is over.

Government regulation will prevent pharma companies from monopolizing the market

- **Currently, pharma companies benefit from patents, which allow them to keep drug prices high and reduce competition at the same time.** Patents provide drug companies protection against others (generic drug companies) from marketing and selling an identical prescription drug for a period of twenty years. Interestingly, drug companies not only patent the original drug but often patent minor changes to the drug such as adding a strip to the coat to prolong market exclusivity (Meller & Ahmed, 2019).
 - For example, the pharma company Sanofi has filed 74 patent applications on Lantus alone, essentially creating a “competition-free monopoly for 37 years” (T1International, 2019).
- **Another tactic to dismiss competitors is the use of Risk Evaluation and Mitigation Strategy (REMS).** By stating “safety concerns”, REMS grant pharma companies the right to refuse to provide samples of their drug products to competitors. Competitors like generic drug companies need drug samples in order to conduct bioequivalence studies to prove the generic drug is the same as the brand drug. In other words, the inappropriate use of REMS delays generic companies from entering the market and limits access to affordable drug prices (Meller & Ahmed, 2019).

Government regulation can promote transparency to reduce prices

- **There are many variables in the supply chain that affect drug prices that remain undisclosed.**
 - Contracts have many restrictions that favor the most expensive of therapeutically equal drugs. Negotiation of these contracts occur behind closed doors, keeping the true cost of prescription drugs hidden or unclear. These deals inhibit cheaper therapies from getting a foothold in the market (Waxman, 2020).
- **Requiring pharmacies, manufacturers, and other players to report costs and compensations will promote fair competition and thereby reduce consumer prices.**
 - Rebates and other hidden costs “can make up to 40 percent or more of a drug’s list price. ... These price concessions corresponded with an 18 percent average annual increase in cost liabilities to taxpayers over the same period” (Waxman, 2020).

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