

## Prescription Drug Affordability Initiative Frequently Asked Questions (FAQs) HB 631/666 and SB 415/437

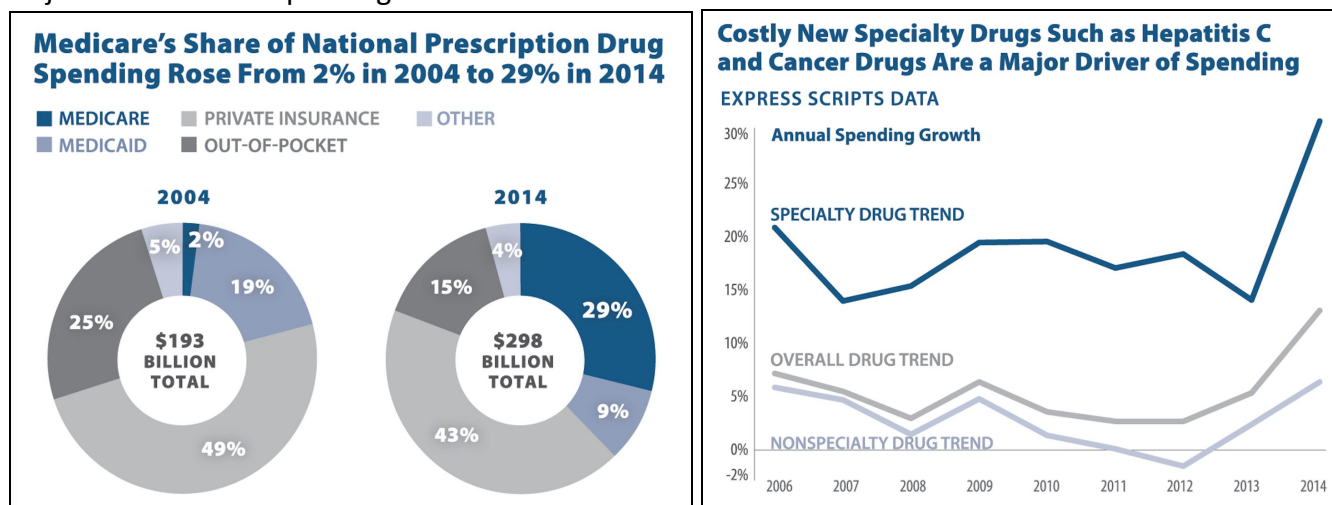
### ***The coalition proposes HB 666 and SB 437***

- Requiring pharmaceutical and biotechnology corporations to disclose the factual basis of prices for expensive prescription drugs - including generic, brand-name, and specialty drugs - in a timely fashion, including profits and the amounts spent on production, research, and marketing;
- Requiring manufacturers of expensive drugs to provide public notice before increasing the wholesale price of any name-brand or specialty drug by 10% or more annually, or by 15% over a two-year period so that consumers can plan for such price increases; and

### ***The coalition proposes HB 631 and SB 415:***

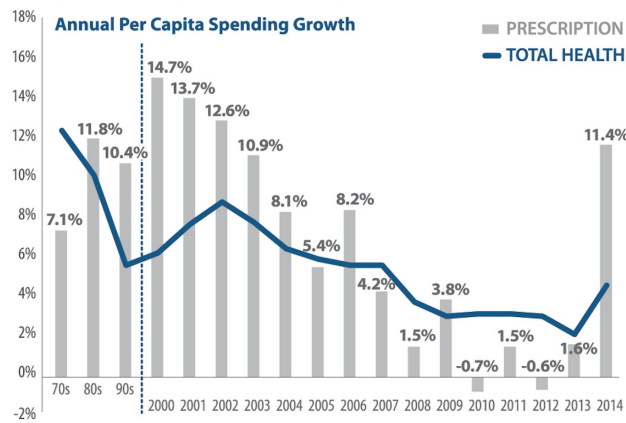
- Authorizing the Maryland Attorney General to take legal action to stop price gouging of essential generic drugs by pharmaceutical corporations.

Drug companies refuse to acknowledge the impact of **escalating drug prices** on patients and American businesses. There is mounting public pressure for policymakers to take action, but manufacturers continue to divert attention away from the root of the problem – the underlying cost of prescription drugs. Medicare's share of national prescription drug spending rose from **2%, or \$3.86 billion, in 2004** to **29%, or \$86.42 billion, in 2014**.<sup>1</sup> Costly new specialty drugs such as Hepatitis C and cancer drugs are major drivers of this spending increase.<sup>1</sup>

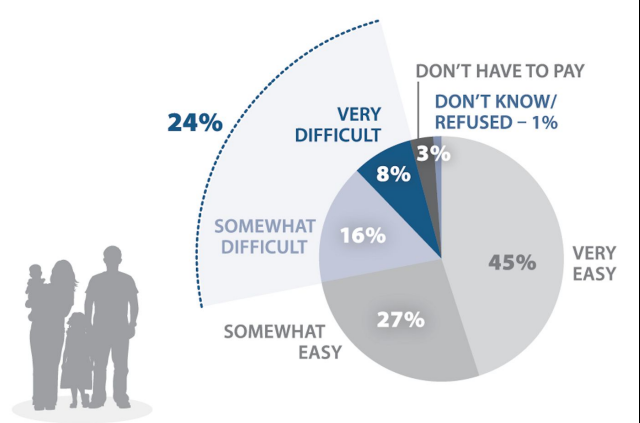


However, these price increases are not limited to specialty drugs. Some generic drugs have also seen large price increases in the last decade.<sup>11</sup>

### After Several Years of Modest Growth, Prescription Drug Spending Rose Sharply in 2014



### Nearly 1 in 4 People in the United States Taking Prescription Drugs Report Difficulty Affording Them

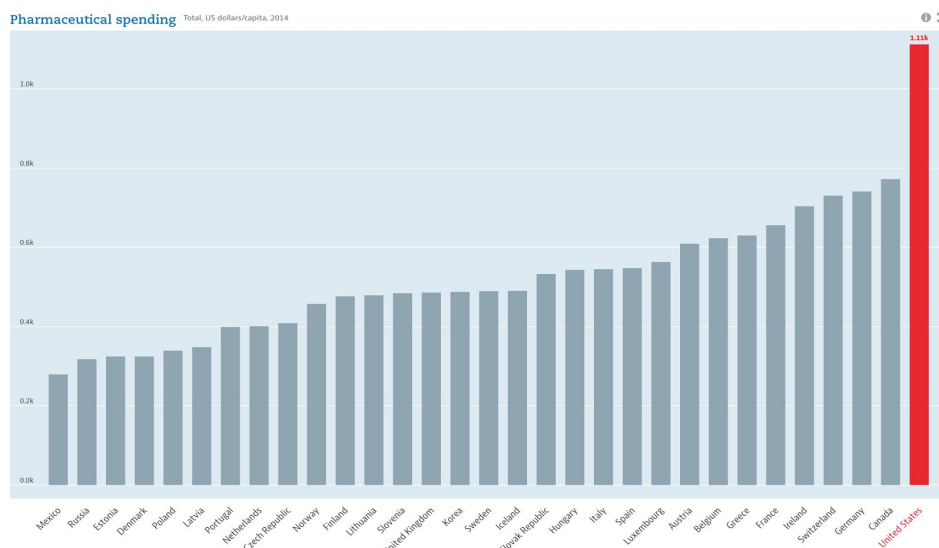


## Prescription Drugs

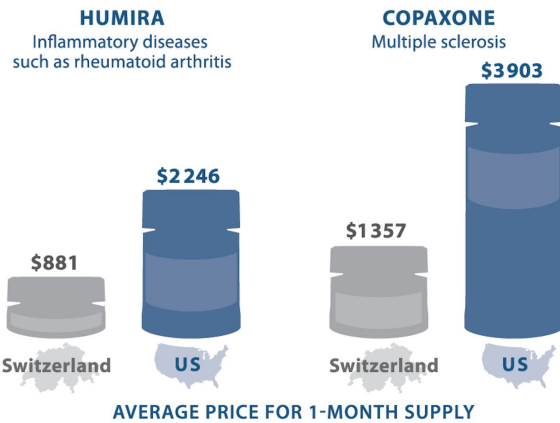
### Why do these bills target prescription drugs instead of other health care costs?

Prescription drugs are the focus of these bills because:

1. The U.S. spends **more on pharmaceuticals per capita** than **any other country** in the Organization for Economic Co-operation and Development (OECD) (see bar graph below).<sup>4</sup>
2. Prescription drugs account for **21.4%** of overall health care expenditures among the U.S. population, and of those incurring medication expenses, the average annual expense is **\$1,432**.<sup>24</sup>
3. **24%** of Americans taking prescription drugs have difficulty affording them<sup>1</sup>
4. Prescription drug spending is **growing faster** than other health costs. In 2013-14, prescription **drug spending increased by 13%**<sup>5</sup>, while hospital and physician services, and overall health care expenditures grew by 4% and 5%, respectively.
5. Spending on **specialty medications** increased by **30.9%** in 2014.<sup>25</sup>
6. **75%** of Maryland voters are **personally concerned** about the cost of prescription drugs.<sup>21</sup>
7. **25 cents** of every **\$1** spent on ACA private health plans in Maryland is on **prescription drugs**.<sup>3</sup>



### Many Specialty Drugs Are Priced Higher in the United States Than in Other Developed Countries



### Most People in the United States Favor Action to Keep Drug Prices Down

PERCENTAGE WHO SAY THEY FAVOR EACH OF THE FOLLOWING:



Why do these bills require reporting of prescription drug price increases?

- If you are struggling to afford prescription drugs, wouldn't you want to know **when the price is going to increase** so that you could plan accordingly?
- The notification of price increases is meant to **help patients directly**. It gives them time to **speak with their physician** and to **consider alternative medications** that are just as effective and cheaper.

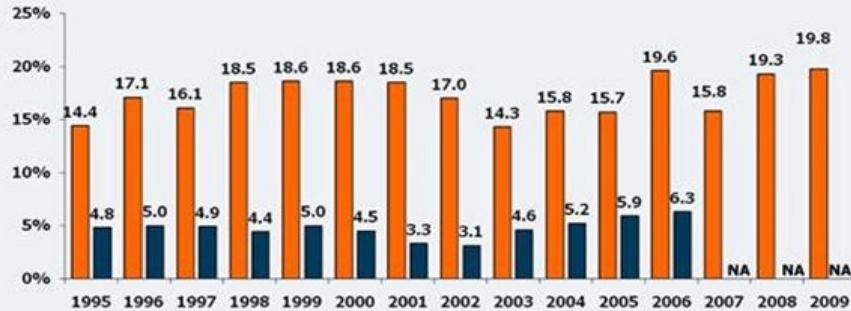


### Pharmaceutical Corporations

Drug innovation is a complex process that takes time. How should pharmaceutical corporations be compensated?

- Drug corporations are currently well compensated and consistently have **three times higher net profit margins** than the median profit among Fortune 500 Firms (see graph below)<sup>16</sup>
- Despite claiming high profits are necessary to offset the cost of research and development (R&D), pharmaceutical corporations spend almost **twice as much on promotion** than R&D.<sup>26</sup>
- Out of the **top 100** pharmaceutical companies, **89** spent more on Sales and Marketing than on R&D in 2015.<sup>7</sup>
- Drug corporations also **do not bear all the costs** of drug development. Public-sector research institutions contributed to the discovery of up to **21.2%** of new drug applications approved by the Food and Drug Administration (FDA) from 1990-2007 and have a **disproportionately larger therapeutic effect**.<sup>27</sup>
- Approximately **84%** of **basic science research** that helps to elucidate the underlying biological mechanisms of disease, is funded by the government and taxpayers.<sup>9</sup> Without this basic science research, the applied research for drug development would not be possible.

## Profitability of Pharmaceutical Manufacturers, 1995-2009



Note: Percent is the median percent net profit after taxes as a percent of firm revenues for all firms in the industry. NA = no longer available.

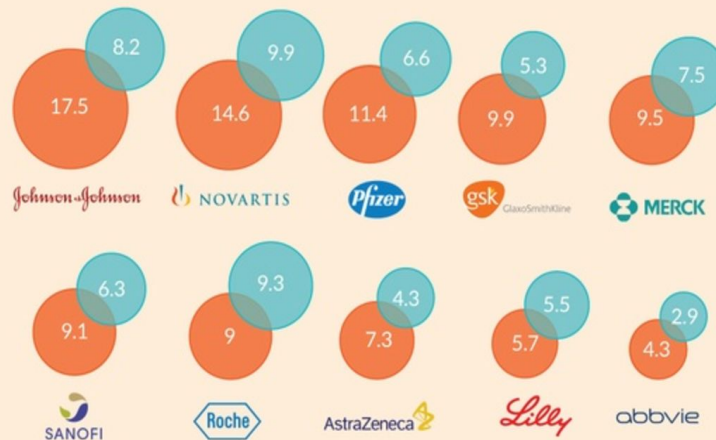
Source: Kaiser Family Foundation and Sonderregger Research Center, Prescription Drug Trends: A Chartbook Update, November 2001, Exhibit 4.11, at <http://www.kff.org/insurance/3161-index.cfm>, updated with data from *Fortune*, *Fortune* 500 Industry Rankings: April 14, 2003, Vol.147, No.7, p. F-26; April 5, 2004, Vol. 149, No.7, p. F-26; April 18, 2005, Vol. 151, No.8, p. F-28; April 17, 2006, Vol.153, No.7, p. F-26; April 30, 2007, Vol.155, No.8, p. F-32; 2007 and 2008 numbers from *Fortune* 500 online at <http://money.cnn.com/magazines/fortune/>; 2009 numbers from personal communication with *Fortune* magazine.

■ Pharmaceutical Manufacturers  
■ All Fortune 500 Firms



## 9 Out Of 10 Big Pharma Companies Spent More On Marketing Than On R&D

HOW MUCH DOES BIG PHARMA SPEND ON:  
SALES & MARKETING vs. RESEARCH & DEVELOPMENT

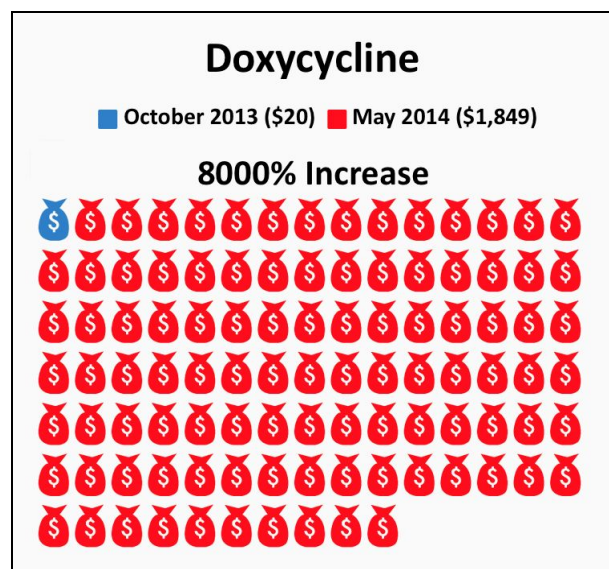


IN US \$ BILLION, FOR 2013



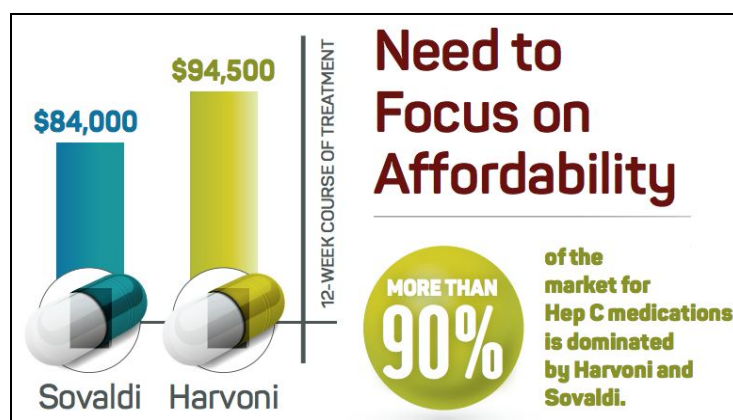
**Drug companies make life-saving drugs, so why does this bill only deal with the cost and not the value of a life?**

- We welcome **more disclosure** on the **evidence-based effectiveness** and price of prescription drugs.
- Meanwhile, many recent spikes in drug prices have been for medications that have been on the market for **years, even decades**. The **value of these drugs remained the same**, but **prices drastically increased**. For example, **Humulin U-500** is a type of insulin that was developed in 1952. Yet the price for Humulin increased **461%** between **2006 and 2014**.<sup>5</sup> Did the drug become **461% more effective**? No, it is the same drug.
- Another example is **Doxycycline**, an antibiotic used since the 1960s that cost **\$20** in October 2013 for 500 pills. Just seven months later, it cost **\$1,849**, marking an increase of more than **8000%**.<sup>10</sup> Did the value of this drug increase by a similar percentage? No.



**Drug pricing is complex. The process from drug discovery to patient utilization involves manufacturers, distributors, PBMs, and pharmacies. Why does the bill only address pharmaceutical corporations, and not other actors?**

- Ultimately, pharmaceutical corporations set the drug price **on what the market can bear** and this dictates the **supply of medications**.
- Often, corporations intentionally select a price point that **only a select proportion** of the population can afford, and this is not necessarily based on the costs incurred for the drug.
- For example, a U.S. Senate Finance committee investigation report found that **Gilead** set the price for **Hepatitis C drug Sovaldi** at **\$84,000** for a **single course of treatment** in order to **maximize revenue**.<sup>16</sup>
- **"Affordable access was not a key consideration in the process of setting the wholesale prices"**.
- The corporation set the price for its first drug with an eye towards a **higher price for its second Hepatitis C drug, Harvoni**.
- The effects of this price structure rippled throughout the system causing a significant financial



burden on **state Medicaid programs, Medicare, and the Bureau of Prisons.**

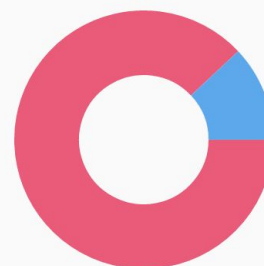
## Generics

### Why are generic drugs included in this initiative?

- While generics cost purchasers and consumers a fraction of the cost compared to brand-name drugs, they account for **88% of prescriptions dispensed nationally**.<sup>17</sup> Therefore, modest price increases in generic drugs can have a **tremendous impact** on overall spending due to purchasing volume.
- Generic drugs have an overall downward price trend, and generally when a generic comes on the market, prices for that drug decrease over time. However, the U.S. Government Accountability Office reports that, **315 out of 1,441, or 22%** of established generics covered by Medicare experienced an **extraordinary price increase of greater than 100% between 2010-15**.<sup>11</sup>
- Of the 351 extraordinary price increases, **48 were above 500%**, with **15 above 1,000%**. This underscores why we cannot underestimate the importance of generic drug pricing.
- Congressional committees held hearings in 2014 and 2015 to investigate price increases in generic drugs, and to identify “**market failures**”. The CEO of Lannett, a company that raised the price of a generic drug to treat heart failure **1000%**, told investors: “*We are an opportunistic company. We see opportunities to raise prices.*”<sup>13</sup>
- He went on to say that because they raised the prices of **75%** of their existing drugs they posted record profits, an increase from **\$4.5 million to \$16.9 million** in just months.
- There have been a rash of companies buying **existing generics** and **dramatically increasing prices**. Currently, pharmaceutical manufacturers can **increase the cost of life-saving medicines to unconscionably high prices** without regulation.
- These bills require **reporting** when there is a **significant increase** in the price of a generic drug, so that purchasers and policy makers can identify market failures when a generic is spiking in price rather than declining.

### % of National Prescriptions

■ Generic Drugs (88%) ■ Brand Name Drugs (12%)



### Extraordinary Price Increases for Generic Drugs

■ >100% n=288 ■ >500% n=48 ■ >1000% n=15





## Transparency

### How would transparency make prescription drug prices more affordable for the public?

Large purchasers of prescription drugs, including the state Medicaid program and private insurers, enter into negotiations with drug corporations or their proxies. Prices are not set in stone, and purchasers negotiate discounts, rebates, and other contract terms to lower the price of drugs. Therefore, having **transparency on the cost of prescription drugs** will **assist purchasers with negotiations**.

For example - In 2012, Sanofi began selling a colon cancer drug **Zaltrap**, which **cost twice as much** as its competitors on the market. Physicians at Memorial Sloan Kettering Cancer Center in New York refused to use the drug because it was too expensive and did not offer any additional survival benefit. The corporation **responded by reducing the price by half**.<sup>18</sup>

This initiative also gives large purchasers **advance notice** of extraordinary price increases so they can attempt to negotiate a fair price. Purchasers may also decide that the price increase is reasonably justified based on submitted information. However, if a price increase is **too steep**, the advance notice gives purchasers **time to find alternative drugs** or to exclude the product from their formulary. The structure of this notification is based on the advance notice health plans and insurers are required to give purchasers before a rate change.

Consumers will benefit when **entities purchasing their drugs** have **more information** and are better able to negotiate drug prices as a result of transparency. Currently, the lack of price transparency and the complex supply chain make it difficult for even the largest purchasers to get reasonable prices on drugs. Consumers will also benefit because **drug prices are pushing up premiums**, so even if a consumer does not use any prescription drugs this will help contain the prescription drug cost driver.

We believe these measures will **deter drug corporations from charging prices they cannot justify** and will give us the opportunity to **decide if the prices charged are justified**. We all have the right to know how much of the unaffordable price of critical drugs is a result of marketing and profits as opposed to reasonable research, development and production costs.

### Is the information requested by this initiative proprietary or a “trade-secret” ?

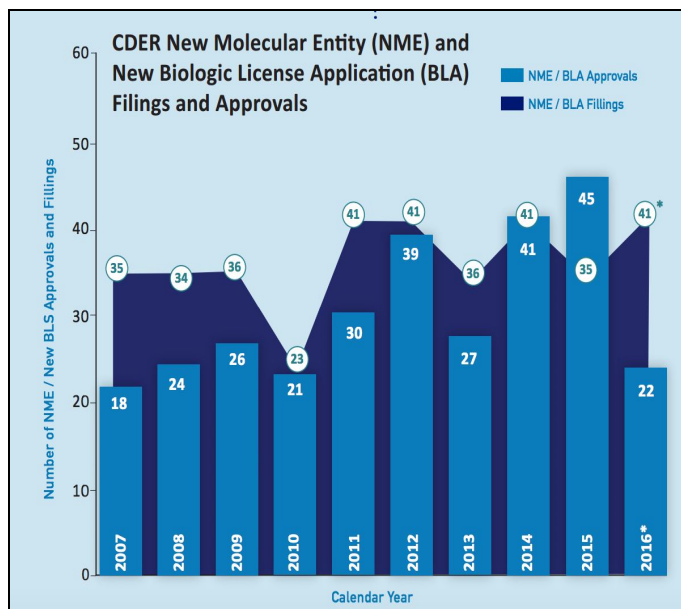
This bill requires disclosure of many kinds of information, and represents an important first step in enhancing transparency. It builds directly on the government’s inherent authority to require disclosure of information in the public interest, ranging from ingredient disclosures to SEC filings. Some of this **information already exists in the public domain** (though the bill helpfully makes it easier to access). Other information, such as research and development costs, is less comprehensively public but also **may not hold economic value for competitors**—an important element of a trade secret. In addition, by requiring all companies to abide by certain disclosures, the bill would create a level playing field. Any **lawsuit challenging this bill would face serious legal and political obstacles**.

### Should we consider the list price or net price of a drug when it comes to price transparency?

- Drug corporations set the **list price** and this is what all negotiations are based on. Therefore, it is **necessary to consider the list price**.

### Drug companies are regulated by the FDA. What is the significance of the regulation proposed by this initiative?

- The FDA regulates the safety, efficacy, and security of prescription drugs. They oversee the approval process for new and generic drugs, protecting the health of the public. **However, the FDA does not exercise any oversight over drug pricing.**
- The **State regulates, licenses, or oversees** most aspects of the health care system. For example, hospitals, health plans, insurers, and doctors are licensed, regulated, and required to report varying degrees of information, including price and rates. This protects the public's health while ensuring a functional health care market.
- This initiative **avoids** imposing regulations or licensure on drug corporations, and does not require a new regulatory structure. It simply requires drug corporations to give purchasers, both public and private, advance notice of price increases, similar to what health plans already do.

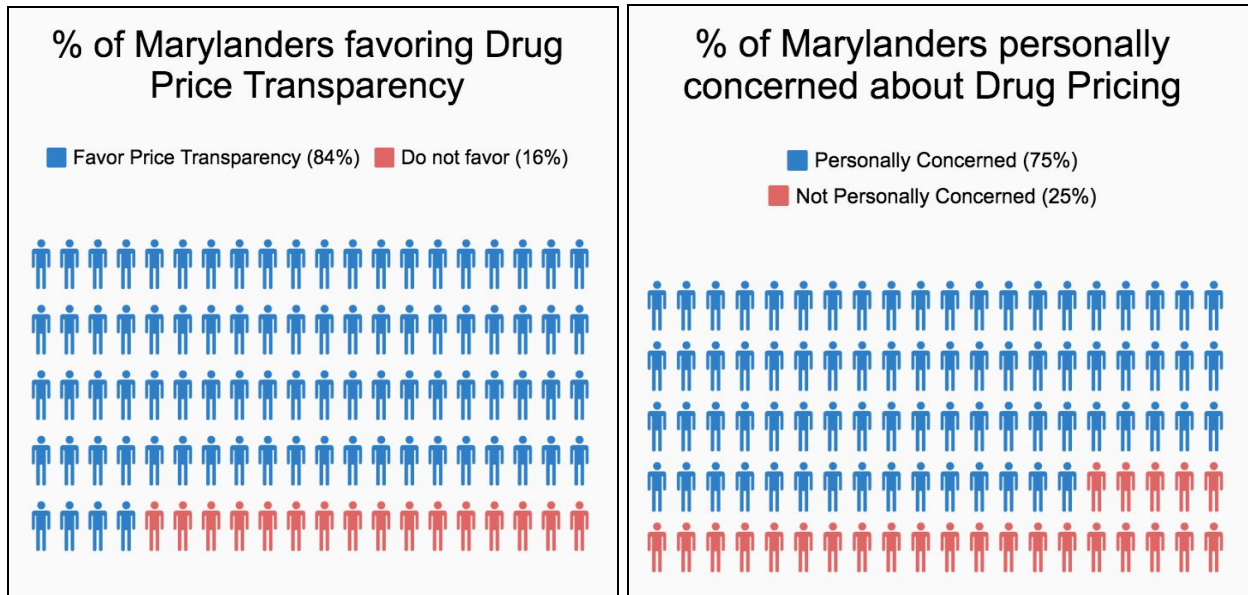


### Why does this initiative call for price transparency of prescription drugs when a similar level of transparency does not exist for other health care services?

We are witnessing a significant **disconnect** between investment in R&D and innovation. The U.S. Government Accountability Office reports a **150% increase in annual-inflation adjusted R&D costs from 1993 to 2004**; however, the number of new molecular entities (NMEs), or innovative drugs that are different than current products on the market, **only increased by 7%.**<sup>19</sup> Furthermore, Over a 15-year period, the FDA determined that **58%** of the new molecular entities brought to market were **similar** to existing drugs on the market.<sup>20,28</sup> In short, just because drugs are being approved does not

mean they are providing a novel value to the public and health of patients. This suggests that there is an issue with R&D productivity. We are not getting a fair return on R&D investment. These findings provide ample reason for us to take a closer look at the industry.





**What is the role of government as it relates to negotiations between purchasers and drug manufacturers?**

- The **government and taxpayers pay for basic science R&D** and must **ensure they are receiving a deal that is fair based on their contribution, among other factors.**
- Existing state and federal law have requirements for what can and cannot be in contracts between two parties in the health care arena. The Maryland Insurance Administration has oversight over disputes and contracts between two private parties and hundreds of pages of regulations regarding contract requirements.
- The American economists, Thomas Sargent and Christopher Sims, who won the Nobel Prize in 2011 stated that, **“government must play a strong role in an imperfect market.”**
- The prescription drug market is definitely imperfect, if not broken, given the asymmetry of information, lack of price transparency, complex structure and **lack of free choice**—consumers have to buy what doctors prescribe. For those reasons, legislators need to **carefully monitor** the market to prevent market failure and to protect purchasers and consumers.

## Price-Gouging

### Why is having language against price gouging of generic drugs important?

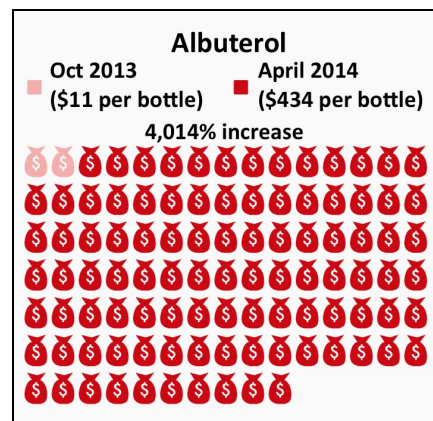
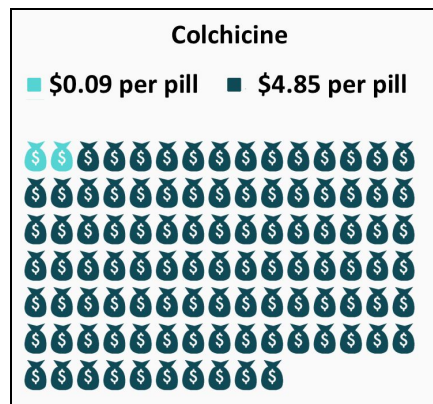
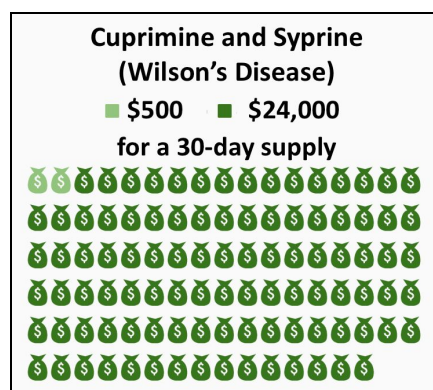
In recent years, extraordinary price increases of 500% or more have become a normal occurrence, even for drugs that have been on the market for years or decades. **The U.S. Senate Special Committee on Aging** recently described some of these price increases as **price gouging** – excessive price increases resulting not from increases in the cost of producing the drug but from a drug company's exploitation of market power.

Here are a few examples:

- 1) **Valeant** raised the prices of **Cuprimine and Syprine**, two drugs that treat Wilson disease, the rare genetic inability to process copper, from about **\$500** to about **\$24,000** for a 30-day supply.<sup>22</sup>
- 2) **Colchicine**, a drug that was widely available as a generic prescription since the 19th century and determined to be effective for the treatment of gout over years of research. URL Pharma raised the price of this drug by more than **5000%**, from **\$0.09** per pill to **\$4.85** per pill, without any additional benefit to the drug.<sup>23</sup>
- 3) **Albuterol**, which is used to treat asthma and other lung conditions, had an average market price of **\$11** in October 2013 for a bottle of 100 tablets. The average price was raised **4014%** to **\$434** in April 2014 for the same quantity.<sup>10</sup>

These findings, paired with the Government Accountability Office report regarding generic drugs under Medicare, indicate that this is not an isolated situation.<sup>11</sup>

**No law currently prevents prescription drug price gouging.** This initiative will give the Attorney General a **new and necessary tool** to combat this emerging trend and will help ensure that extraordinary price increases do not deprive Marylanders of access to essential generic medicines.



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