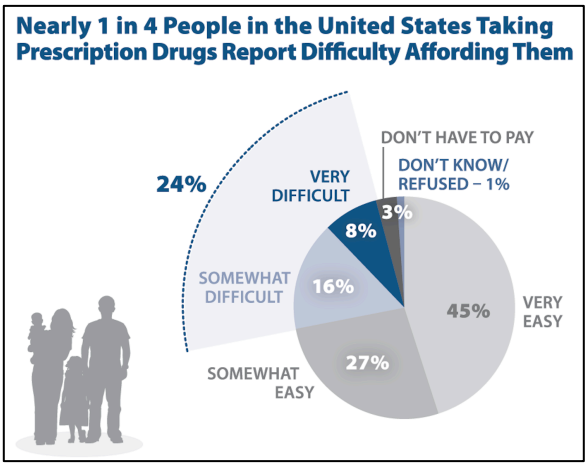
HEALTH CARE for All
MARYLAND CITIZENS' HEALTH INITIATIVE
2600 ST. PAUL STREET BALTIMORE, MD 21218 P: (410)235-9000 F: (410)235-8963 WWW.HEALTHCAREFORALL.COM

Background

Americans pay more on average for prescription drugs than the citizens of any other country.

- Nearly 1 in 4 Americans report difficulty paying for prescription medications.

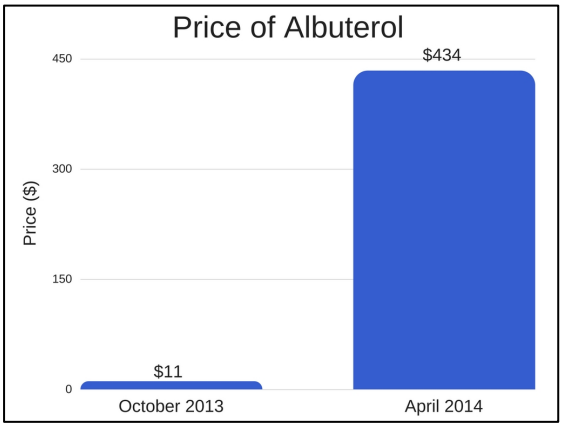


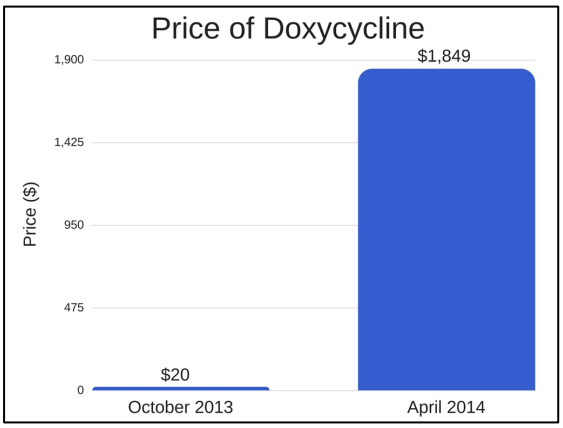
SB 437 Summary

SB 437 introduces transparency into pharmaceutical companies' pricing practices. The bill requires manufacturers of drugs that cost $2,500 per year or more per course of treatment to provide detailed information regarding their cost structure to justify their products' prices and prevent exploitative pricing. Price data indicate that the law would cover many common drugs used for chronic conditions such as cardiovascular disease and diabetes—medications necessary for the average American. While the bill does not directly decrease the price of drugs, it is a first step on the path to lower, fair, and justifiable drug pricing.

Notification of Price Increases

- Retail prices for brand-name drugs increased 130 times faster than inflation in 2015.[1]
- Prices of some generic drugs for common conditions, such as albuterol and doxycycline, increased by 4,000% and 8,000%, respectively, between 2013-2014.[2]





SB 437 requires manufacturers of high-cost drugs to file a notice with the Secretary of Health at least 60 days prior to a price increase of 10% or $2,500 (whichever is less) over a 12-month period, or 15% over a 24-month period. The notice must include specific information pertaining to the history of that drug's pricing and the justification for this particular price increase.

By requiring this information, SB 437 holds drug manufacturers accountable by mandating that they justify price increases. It also allows patients who depend on expensive

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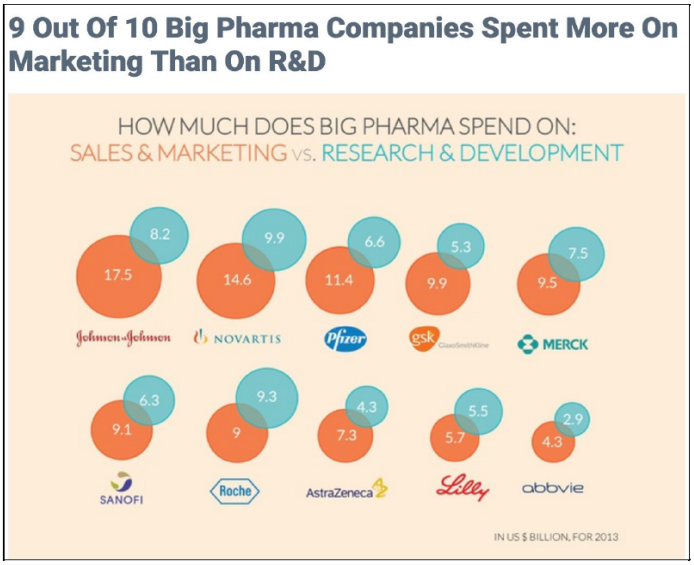
drugs to plan ahead for future price increases, such as switching to less costly drug options if available.

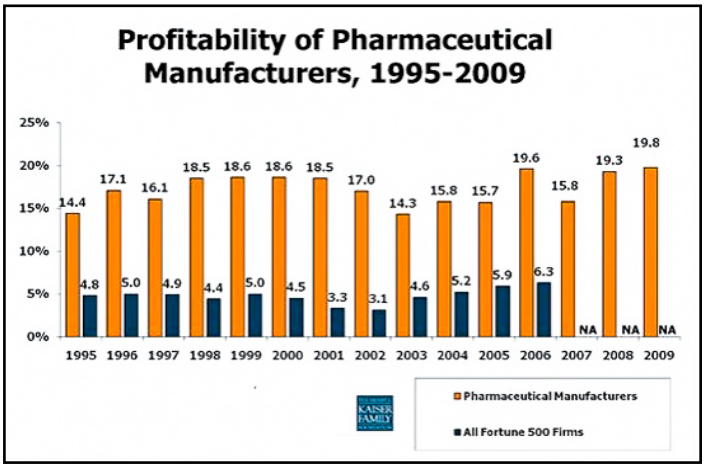
Research & Development Costs

- Many successful drugs sold by major pharmaceutical companies originate from acquisitions of smaller biotechnology companies, who are responsible for most of the major R&D costs.[3]
- From 1988-2005, 49% of all drugs and 65% of the most medically important "priority review" drugs received public research funding.[4]

R&D costs incurred by companies should be compensated by fair prices for their drugs. However, without transparency around these costs, the public cannot know whether drugs are priced excessively.

Taxpayers fund many of the costs of drug research and discovery. SB 437 helps give credit for public investments, and establish benchmarks against which to measure a reasonable price. The law also requires drug manufacturers to disclose how much they, rather than their predecessors, invested to develop the drug and how much of that investment they have recovered.





Manufacturing and Marketing Costs

- Drug coupon programs are typically short-lived, offered once a year, and increase health-care costs long-term.[5]
- One study estimated companies spend twice as much on marketing as they do on R&D, and up to 30% of these numbers are hidden from current reporting requirements.[6]

Pharmaceutical companies say that their central mission is innovation. If so, then they should spend more on researching drugs than on advertising them. SB 437 requires manufacturers to disclose the costs associated with the manufacturing, administration, and marketing of the drug, including any coupons or promotions offered to patients**.** This holds pharmaceutical companies accountable by forcing them to report how much money is spent on advertising compared to R&D. It would also make clear how many patients actually benefit from the coupon programs that are provided by the company.

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Profit Margins

- In 2016, generic and major pharmaceutical companies combined achieved a net profit margin of 55% ranking higher than major banks (23%) and investment managers (29%).[7]

Drug manufacturers enjoy high profit margins relative to many other industries. **SB 437 requires manufacturers of high-cost drugs to provide information regarding the wholesale acquisition prices, revenue, and profits from the sale of the drug.** It will also require manufacturers to clarify their federal, state, and local tax rates and government benefits. The public must have a complete picture of their role in subsidizing the pharmaceutical industry to understand the basis of drug pricing.

Intellectual Property & Regulatory Costs

SB 437 requires disclosure of drug manufacturers' intellectual property rights and associated regulatory exclusivity. Understanding how long a particular company has a monopoly on a drug is crucial to knowing when more affordable generics can enter, as well as how long the manufacturer has to recoup its investment. Also, this information will help illuminate when companies are abusing the patent system by seeking trivial patents just to extend their monopoly. Companies should also have to disclose if they have participated in agreements to delay generic competition, because these may violate anti-trust laws.

Comparative Effectiveness

- Over a 15-year period, the FDA determined that 58% of the new molecular entities brought to market had therapeutic similarities to existing drugs.[8]
- These "me-too" drugs shift R&D investment away from innovative discoveries to conditions that already have treatment options.[9]

Patients should not pay exorbitant prices for drugs that do not offer significant improvements over existing care. SB 437 requires manufacturers to report information regarding a high-cost drug's efficacy in relation to competitive alternative treatments to ensure that society is making the most efficient choices in directing healthcare resources.

Drug Price Transparency Advisory Committee

SB 437 creates a committee to prepare and review the annual reports required by the bill and to ensure that companies comply with regulations. To combat industry influence, these impartial experts will not be affiliated with any drug manufacturer. This committee will help ensure SB 437's transparency requirements prevent drug manufacturers from implementing exploitative and unconscionable pricing practices.

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