Drug Money Part 2: A Look at 2017 State Legislative Efforts to Reduce Prescription Drug Prices

By: Katie Beyer, Student Fellow

INTRODUCTION

It is no secret that drug prices have been rising at an alarming rate. In fact, spending on prescription drugs rose 12.4% in 2014 and 9% in 2015.[1] In 2015, the U.S. spent \$457 billion on prescription drugs, which accounted for 16.7% of overall healthcare services.[2] In 2016, Americans filled 4.4 billion drug prescriptions, at a total cost of approximately \$400 billion.[3] On average, Americans spend \$1,370 out of pocket on prescription drugs per year. [4] With an average annual price increase of approximately 10% over the past three years, drug price increases continue to outpace inflation, which is growing at a rate of 2.3%.[5] These high drug costs affect nearly half of all Americans, with 49% of Americans reporting that they used at least one drug in the past 30 days. These prescription drug users experienced a 208% rise in the prices of the most popular brand name drugs from 2008 - 2016 . [6]

The rising cost of life-saving medications is particularly alarming. Bavencio (a cancer drug) costs about \$156,000 a year per patient. [7] A new muscular dystrophy drug introduced last year costs \$300,000 per year. [8] Daraprim, a popular drug used by AIDS patients spiked from \$13.50 to \$750 per prescription. [9] The cost of insulin, now more than \$700 per patient, tripled between 2002 and 2013 and the cost of an EpiPen spiked 500% since 2007. [10]

So what can be done? With little assistance from the federal government, states are taking matters into their own hands. In 2017, 43 states introduced legislation aiming to combat high drug prices. Arkansas, Delaware, Idaho, Kentucky, Dakota, Ohio, and South Dakota were the only states that stayed silent. As of July 2017, seventeen states passed bills and five states still have bills pending, which is a great improvement from 2016 state efforts. Last year, only ten introduced legislation requiring pharmaceutical companies to disclose research and development costs.[11] Vermont was the sole state to enact its legislation. [12] In 2017, the Massachusetts legislature lead the charge and introduced ten bills with the purpose of lowering drugs costs. California, Maine, Maryland, New York, and Oregon followed closely behind.

This Issue Brief explores 2017 state legislative efforts to reduce drug prices. Section I begins with an overview of California legislation. Section II discusses transparency initiatives, the predominant type of legislation introduced in 2017. Section III analyzes measures aiming to directly control drug prices. These bills include allowing the substitution of biological equivalents, prohibiting pharmaceutical managers from price gouging, and creating state commissions to negotiate pricing standards. Finally, Section IV summarizes an assortment of other types of drug price regulation bills. These include bills aimed at prohibiting and gifts from pharmaceutical manufacturers, regulating conflicts of interest issues with pharmacy benefit managers ("PBMs") and pharmaceutical producers. The last section also shows which states introduced legislation regulating PBM and pharmaceutical practices. In addition to a describing different types of legislation, we have created <u>interactive maps</u> detailing relevant state legislation.

I. CALIFORNIA'S PHARMACEUTICAL LEGISLATION

California has five active measures related to reducing drug costs. Together these bills seek to 1) Improve price transparency 2) Regulate PBM reporting practices and price control[3] Prohibit drug manufacturers from giving or receiving benefits to others associated with pharmaceutical distribution | and 4) Strengthen intra-agency collaboration on drug cost saving strategies. The most high-profile measure, SB 17, requires prescription drug manufacturers to notify direct purchasers at least 90 days before raising the wholesale acquisition cost of a prescription drug by a certain threshold. Under this transparency bill, pharmaceutical firms must justify price increases for certain prescription drugs. Current California law allows pharmaceutical companies to increase prices of their most widely used drugs without explanation.[13] SB17 could help reduce price increases by informing consumers what they are really paying for.

Another important measure, <u>AB 265</u>, prohibits drug manufacturers from offering coupons on expensive prescriptions when there are cheaper drug options available. Health experts claim forbidding these coupons would make it more difficult for drug companies to spike their prices.[14] The use of coupons leads to more purchases of expensive drugs, which increases insurance plan and premium costs.[15] Democratic law makers are hopeful that this bill will limit expensive drug use and in turn reduce patient spending.

II. STATE PRICE TRANSPARENCY EFFORTS

As you can see from our <u>maps</u>, the most prominent type of state legislation introduced during 2017 seeks to improve drug price transparency. Most current health plans offer little information about drug costs. Additionally, minimal information is publicly available about the amount pharmaceutical companies are charging for rebates and payments. Both the average ingredient cost and the

manufacturer's net revenue remain confidential.[16] This lack of information makes it difficult to determine if companies are raising their prices inappropriately.[17] In response to these transparency problems. states introduced 28 bills requiring pharmaceutical companies to disclose research and development costs or to notify state department officials of specified increases in drug prices. However, only <u>four states</u> Florida, Louisiana, New Jersey and North Carolina — enacted prescription drug transparency legislation and only another four - California, Maine, Massachusetts, and Washington still have active legislation. States that have successfully implemented drug price transparency measures have improved manufacturer and visibility and distributor accountability.

State transparency efforts have targeted both PBMs and drug manufacturers. The majority of state transparency bills would require the state to identify high cost prescription drugs and monitoring cost increases in one form or another. Most of these bills also required that manufacturers justify and explain the reasoning behind sharp increases. To date, Louisiana is the only state in 2017 to establish a Drug Review Committee. Louisiana HB 436 compels the Drug Review Committee to publish price information on a newly created website. Some states attempted to improve price transparency on by requiring drug manufacturers to submit price increase reports directly to the Attorney General. State legislation seeking to shed light on PBM negotiated prices, such as New Jersey AB 4438, compelled PBMs to disclose pricing information to health plan customers.

Transparency initiatives are the easiest measures to pass and is also the most logical place to start to lower prescription drug costs. However, transparency alone is not sufficient. Effective transparency policies will publicly provide information on rebates and prices paid by payers. Most 2017 transparency measures require pharmaceutical companies to

Pharmaceutical companies have voiced their concern against these measures claiming they will fail to show true market prices. Educating consumers and policymakers on the disparity between a drug's production cost and list price will hopefully put pressure on manufacturers to sell their products at a more reasonable value. Furthermore, increasing price transparency does not prohibit negotiation of prices and should also motivate PBMs to negotiate lower rebates.

III. LEGISLATION TO CONTROL DRUG PRICES

When new drugs are patented, the drug manufacturer of the patented brand name drug controls both the price and available supply. [18] The patent holder has a monopoly over the drug for 20 years. [19] When patents expire, drug manufacturers are able to produce and distribute generic drugs on the market at a lower cost. [20] These drugs frequently average 80 to 85 percent less than the branded drug originals. [21] Unfortunately, the number of drugs coming off patent is decreasing at a rapid rate. [22] In 2017, \$11.1 billion worth of pharmaceuticals will go off patent. [23] This is a 41.3% decrease from 2016. [24] Fewer patent expirations means fewer generic drugs will enter the market. [25]

In 2017, states sought to encourage pharmacists to substitute lower price equivalent drug products or interchangeable biological products known as biosimilars or biological equivalents for expensive brand named products. Most states already allow generic substitution for regular chemical compounds. Like a generic drug, a biosimilar is proven to be an effective substitute for an existing approved innovative biological product. [26] However, active ingredients in biosimilars and the original biological product are not identical, which leads to unique therapeutic options for each patient. [27] Twelve states — Alaska, Illinois, Iowa, Maryland,

Massachusetts, Michigan, Minnesota, New Mexico, New Nork, South Carolina, Vermont, and Wyoming — introduced legislation authorizing pharmacists to substitute expensive biologic prescriptions for more affordable biological equivalents. Only Iowa, Maryland, Minnesota, and Wyoming enacted the legislation. Montana and West Virginia tried to catch up with the rest of the states by introducing legislation allowing pharmacists to substitute a therapeutically equivalent generic drug for a higher priced brand name drug. Unfortunately, both measures failed.

Currently, 182 drugs on the market are no longer patent protected and do not have associated generic drugs available. [28] Without generics or biological equivalents, manufacturers can take advantage of natural monopolies and increase or maintain patent-era prices. [29] One way states are trying to solve this problem is to create effective monitoring and oversight programs to regulate competition in pharmaceutical markets. [30] Six states, Maine, Massachusetts, New Mexico, Oregon, and Pennsylvania — proposed legislation establishing a commission to lower drug prices by negotiating price concessions for bulk purchasing or by helping to reimburse purchasers for high costs. Massachusetts SB 635 is the only active measure as of July 2017.

Anti-price gouging measures give states the authority to take action against unconscionable price increases for essential, off-patent medications. However, federal legislation regulating pharmaceutical selling practices will likely be more effective as the most recent enacted bill faces constitutional challenges.[31] In May 2017, Maryland signed HB 631/SB 415 into law, prohibiting price gouging on essential off-patent or generic drugs. The law allows the Maryland Attorney General to prosecute pharmaceutical producers that raise the non-competitive off-patent drugs prices inappropriately. A market is deemed noncompetitive if three or fewer manufacturers are actively participating in it.[32]

Connecticut, Maine, New York, and Rhode Island introduced similar bills, but did not enact them during this session.

Finally, <u>fifteen states</u> have tried to improve prescription drug costs by directly regulating prescription prices. New Hampshire introduced, but failed to pass <u>SB 156</u> mandating that an insured pays the lesser amount between the pharmacy's filing charged and their individual benefit copayment. Other bills require the state to use its negotiating power to obtain the lowest price for all prescription drugs, unless prohibited by federal law. Georgia enacted <u>SB 200</u> that mandates health benefit plans to apply a prorated daily cost-sharing rate to prescriptions that are dispensed in certain circumstances. New York's enacted <u>Budget Bill</u> authorizes the state to identify high-cost drugs, set a value price, and negotiate rebates to achieve the targeted price.

The most effective price control policies will promote competition by allowing new and more drugs to enter the consumer market. As fewer generic drugs are entering the market and fewer band name drugs are going off patent, bolstering competition by providing incentives or allowing new types of drugs such as biosimilars to enter the market is a needed first step to drive down prices for consumers. The most effective policies should aim to proactively monitor and report on how certain drugs are performing and identify anticompetitive behaviors. Greater market competition may also be achieved by waiving newly approved drug fees and providing incentives for generic manufacturers to distribute new drugs in the market. Directly controlling price caps, however is likely not the best solution for creating an equitable competitive market because price controls can diminish incentives for drug manufacturers to develop new types of prescription medication. The National Bureau of Economic Research studied 642 new drugs in 76 countries and found price regulation strongly delays drug launches.[33] At this point, allowing biosimilar use will likely be more effective than regulating costs directly. Currently, state law regarding biosimilar use is very restrictive.[34] Many states have not adopted policies that provide standards for substitution and interchangeability.[35] Removing these barriers to increase biosimilar access will expand patient choice and ultimately improve competition.

Measures directly cutting pharmaceutical profits will face the most amount of challenges. Maryland's anti-price gouging law was immediately challenged by the pharmaceutical industry. The Association for Accessible Medicines filed a lawsuit against the Maryland Attorney General and state health secretary claiming, "manufacturers do not sell their products or make pricing decisions on a state-by-state basis."[36] The complaint also alleged Maryland's law is unconstitutional because it unconstitutionally vague, violates the Due Process Clause under the Fourteenth Amendment, and violates the Dormant Commerce Clause. [37] While it remains to be seen whether these specific claims have merit, similar types of legislation may also face ERISA preemption challenges. ERISA provides uniform federal standards protecting employee sponsored health plans.[38] ERISA's preemption clause prohibits states from enacting laws relating to employer sponsored health plans.[39] Because ERISA preemption generally prohibits states from affecting employer-sponsored health plans by imposing substantial costs or other regulations, it is unclear how state efforts regulating insurance coverage of prescription drugs will play out.

IV. ADDITIONAL BILLS

About 50% of U.S. physicians received some form of compensation from pharmaceutical industries in 2015 totaling \$2.4 billion.[40] In California alone, drug companies spend more than \$1.4 billion a year on gifts for California doctors.[41] Lawmakers hope that regulating gifts from

pharmaceutical companies to doctors will curb drug prices.

This year, Maine enacted <u>LD 911</u>, which forbids a person engaged in the manufacture of prescription drugs to prescribe and administer drugs in the course of that individual's professional practice. California, New Hampshire, and New Jersey introduced, but did not pass legislation that prohibits a person engaged in the manufacture or distribution of prescription drugs from compensating individuals licensed to distribute prescription drugs.

Lastly, legislators sought to regulate PBM and pharmaceutical practices. Generally, three business to business transactions precede the business to consumer sale of pharmaceuticals.[42] Prices are first established after the manufacturers sets a list price.[43] Wholesalers then buy and sell the drug to pharmacies and providers.[44] PBMs and health payers negotiate with manufacturers to create rebates, which are discounted prices from the wholesale acquisition cost.[45] In exchange for negotiating with the manufacturer, PBMs retain a portion of the rebate[46]. The higher the wholesale acquisition cost, the higher the PBMs' retained portion. The rebate amount and the resulting net prices are not publically available.[47]

<u>Seven states</u> — Arizona, California, Georgia, Hawaii, Maine, New Jersey, New York — introduced legislation regulating these transactions. Both <u>Georgia</u> and <u>Hawaii</u> enacted legislation requiring PBMs to obtain registration from the state's insurance commissioner. Georgia's bill also allows the insurance commissioner to create rules and regulations to enforce several PBM practices.

Finally, <u>nine states</u> — Alabama, California, Maryland, Massachusetts, Nevada, New Jersey, Oregon, Texas, and Vermont — introduced legislation separate from the categories described above. Alabama's only prescription price measure would have exempted prescription drugs from business license taxes based on gross receipts. Tennessee passed a bill that

authorizes a person or governmental entity to donate any prescription drug with specified exceptions. Nevada introduced similar legislation. Vermont proposed to delay the requirement that the Department of Vermont Health Access apply for a federal waiver to ensure the continued availability of bronzelevel Exchange plans that meet Vermont's out-of-pocket prescription drug limit.

CONCLUSION

In 2017, state legislative efforts demonstrate the nation's strong desire to reduce prescription drug prices. The states introduced 111 bills this year with the sole purpose of lowering drug costs, which comparatively is a dramatic increase from the ten bills introduced in 2016. State legislators show no signs of slowing down in 2018 and will likely continue to tackle recent spending trends. For an additional resource, follow the National Academy for State Health Policy for real time state legislative action on pharmaceutical prices. Stay tuned for future trends and news on pharmaceutical costs and competition!

REFERENCES

- [1] Centers for Medicare and Medicaid Services, National Health Expenditure Fact Sheet, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.
- [2] Office of the Assistant Secretary for Planning and Evaluation, Observations on Trends in Prescription Drug Spending,

 1 https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf (March 8, 2016).

- [3] Steven Lieberman and Paul Ginsburg, Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients? The Brookings Institute (June 2017).
- [4] Sean Williams, The Average American Spends This Much on Prescription Drugs Each Year, The Motley Fool, Dec. 12, 2015, https://www.fool.com/investing/general/2015/12/12/the-average-american-spends-this-much-on-prescript.aspx.

[5]

https://www.bcbs.com/the-health-of-america/reports/rising-costs-patented-drugs-drive-growth-pharmaceutical-spending-us.

[6] Id.

[7] Editors of AARP, Why Drugs Cost So Much, AARP Bulletin 2 (Robert Love ed., 2017).

[8] Id.

[9] Id.

[10] Id.

[11] Ameet Sarpatwari, Jerry Avorn, and Aaron Kesselheim, State Initiatives to Control Medication Costs — Can Transparency Legislation Help?, The New England Journal of Medicine, 2301, 2302 (June 2016).

[12] Id.

[13] Alexei Koseff, Your Drug Costs Might Drop if Lawmakers can Agree on why They're so High, The Sacramento Bee, May 29, 2017,

http://www.sacbee.com/news/politics-government/capitol-alert/a
rticle152922344.html

[14] Melody Petersen, How Free Coupons for Patients Help Drugmakers Hike Prices Up by 1,000%, L.A. Times, Dec. 5, 2016, http://www.latimes.com/business/la-fi-prescription-drug-coupon

```
s-20161204-story.html.
[15] Id.
[16] Lieberman and Ginsburg, supra note 3 at 1.
[17] Id.
[18] Editors of AARP, supra note 6, at 3.
[19] Id.
[20] Himanshu Gupta, Suresh Kumar, Saroj Kumar Roy, and R.S.
Gaud, Patent Protection Strategies, Journal of Pharmacy and
Bioallied Sciences, Feb. 2010, at 1.
[21] Food and Drug Administration, Facts About Generic Drugs
(2012).
[22] Kelly Barnes et al., Medical Cost Trend: Behind the
Numbers 2018, 13 (2017).
[23] Id.
[24] Id.
[25] Id. at 14.
[26] AMGEN Biosimilars, What Are Biosimilars? Unique
Therapeutic Options for Patients (2017).
[27] Id.
[28] Henry Waxman et al., Getting to the root of High
Prescription Drug Prices, The Commonwealth Fund, July 2017, at
4.
[29] Waxman et al., supra note 19, at 4.
[30] Id.
[31] Jeremy Greene and William Padula, Targeting
```

Unconscionable Prescription-Drug Prices — Maryland's Anti—Price-Gouging Law, The New England Journal of Medicine, 101, 102 (July 2017).

[32] Id.

[33] Iain Cocburn, Jean Lanjouw, Mark Schankerman, Patents and the Global Diffusion of New Drugs 1 (2014).

[34] Waxman et al., supra note 28 at 24.

[35] Id.

[36] Kimberly Leonard, Maryland 'Price Gouging Law' meets Immediate Legal Challenge, Washington Examiner (July 17, 2017),

http://www.washingtonexaminer.com/maryland-price-gouging-law-meets-immediate-legal-challenge/article/2628431

[37] Id.

[38] National Academy for State Health Policy, ERISA Preemption Primer 1 (2009).

[39] *Id.* at 2.

[40] Dennis Thompson, Survey Reveals How Many Doctors Receive Money, Gifts from Drugmakers, CBS News (May 3, 2017), http://www.cbsnews.com/news/doctors-receive-money-gifts-from-drugmakers-pharmaceutical-companies/.

[41] Sophia Bollag, California Bill Would Ban Drug Company Gifts to Doctors, US News & amp|World Report, (May 18, 2017), https://www.usnews.com/news/best-states/california/articles/2017-05-18/california-may-bar-drug-makers-from-giving-doctors-gifts.

[42] Lieberman and Ginsburg, supra note 3, at 6.

[43] Id. at 7.

- [44] Id.
- [45] Id.
- [46] Id.
- [47] *Id.* at 8.