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HOUSE OF REPRESENTATIVES

COMMONWEALTH *of* PENNSYLVANIA

House Democratic Policy Committee Hearing
Subcommittee on Progressive Policies for Working People

Pricing out Pennsylvanians: How to Drive Down Drug Prices
Monday, July 12, 2021 | 1 p.m. to 3 p.m.

Representative Emily Kinkead • Representative Eddie Day Pashinski
Representative Elizabeth Fiedler, Chair

1:00 p.m. PANEL ONE:

Sean Zmenkowski, Constituent Services Advisor
Representative Kinkead's District Office

Q & A WITH LEGISLATORS

1:30 p.m. PANEL TWO

Jessica Brooks-Woods, President & CEO
Pittsburgh Business Group on Health

Patrick Keenan, Director of Consumer Protections and Policy
Pennsylvania Health Access Network

Kristin Parde, Deputy Vice President
State Policy, PhRMA

Q & A WITH LEGISLATORS

2:00 p.m. PANEL THREE

Jane Horvath, Principal
Founder, Horvath Health Policy

Drew Gattine, Senior Policy Fellow
National Academy for State Health Policy

Jennifer Reck, Project Director
Center for State Prescription Drug Pricing, National Academy for State Health Policy

Kyle McCormick, Owner
Founder, Blueberry Pharmacy

Q & A WITH LEGISLATORS

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HOUSE OF REPRESENTATIVES
COMMONWEALTH *of* PENNSYLVANIA

I suffer from a life-destroying disease called Diabetes. According to The American Diabetes Association, in 2018 one in ten people had diabetes in the United States, and one in four seniors. They counted over 34 million constituents suffering from diabetes, of which over 26 million were diagnosed, and over 7 million were undiagnosed. It's probability only grows with age. The percentage of Americans age 65 and older remains high, over 26%, which is over 14 million seniors (diagnosed and undiagnosed) [ADA [ww.diabeties.org](http://www.diabeties.org)]. A population dependent on pensions, savings, social security, and Medicare, one in four of our seniors' lifespan may simply come down to luck of the draw.

In addition, 1.5 million Americans are diagnosed with NEW cases of diabetes every year. Lurking on the edge of those diagnosed, in 2015 a total of 88 million Americans age 18 and older had prediabetes. [ADA www.diabetes.org]

Cultures around the world—including locations as disparate as India, China and Greece—have been reporting cases since 552 BCE, when it first surfaced in Egypt. According to these reports, no matter where it occurred, adults and children who developed this disease were expected to have very short and painful lives. So short, in fact, that some cultures began going so far as to treat it with poisons to provide 'a quick and painless alternative.' But despite its age, and although prognoses have improved over centuries, there is still no cure.

By 1922, as medical science advanced, we began harvesting insulin. When Fredrick Banting, Charles Best, John Macleod, and J.B. Collip developed this life-saving process, it saved so many lives that they were awarded a Nobel Prize for the work they did. These early scientists felt that profiting from such a vital treatment was both unethical and inherently wrong. As such, these men refused to patent the insulin-harvesting process. Instead, they sold it to the University of Toronto for the not-so-princely sum of \$1.00 to ensure that insulin could be affordable and effectively mass produced. To say that the world of medicine and diabetes treatment has changed in the past 100 years is a massive understatement.

Today, only four major corporations exist in the world who hold patents for insulin—a medication that people literally depend upon for day to day living. Corporations are permitted by law to increase the cost of this medication at will, netting obscenely inflated profit margins... margins that will keep increasing until those that most need the drug die and are no longer there to purchase it. Because insulin has become so expensive, many of us are often forced to skip doses of insulin because taking the prescribed amount of their medication has become entirely cost prohibitive.

As a diabetes patient skips doses, they begin suffering from other medical issues, such as Diabetic Ketoacidosis, and treating these related issues costs even more money to the patients, hospitals, and even insurance agencies. These costs, in effect, sparks an Ouroboros cycle of patients refusing to seek medical help because of the overwhelming cost, which causes more and more problems, until they absolutely must seek the help,

go broke and then die... or are forced to seek government program assistance because they have no choice, can't work, and are so unhealthy they are never able to get their lives back onto a "normal track".

In my own life, almost every decision I have made in the workforce has been based upon how much the price of my prescriptions will cost. Just last year, I had the option to become an assistant manager at my previous job, but had to turn it down because the salary I was offered—without comparable insurance—would be too much to qualify for Medicaid coverage but too little to cover my insulin needs. With the costs of my medication, rent, utilities, and groceries, I would have had to use a credit card to afford the medications I needed to keep me alive. I wish I could say that was an isolated situation, but it was not; this was the third time in the past four years that I was forced into debt to cover costs, or simply to go without.

In January of 2018 I was forced to go without. I lost the job that provided me with life-sustaining insurance. Although I signed up for the state's Medicaid program, it took two months to receive assistance, so during that seemingly endless window, I had to ration all my medications. I limited the daily insulin that I take through a pump, and instead of changing my pump sites every three days as prescribed, I had to keep the pump sites in for a week at a time, putting me at risk of infection. The same went for the Synthroid that regulates my thyroid to produce the correct levels of hormones. I rationed my psych medication that treats my depression, a

common occurrence in diabetic populations. Likewise, I was only able to check my blood sugar once a day, instead of eight.

My health was failing after two months of scarcity and no Medicaid support. When I finally found a job with insurance, my Hemoglobin B1C was at 12—more than five points higher than/nearly double what a diabetic’s “healthy” maintenance level should be. A high HB1C can cause blindness, necrosis, and other debilitating damages to all body systems. While I was able to get the HB1C back down quickly, it took four months for my thyroid to return to normal, healthy levels. So many others are not this fortunate- I was lucky that my insurance through my short-term job allowed me to afford all of the necessary appointments and tests that kept me alive, and I was eventually able to restore my health equilibrium.

That simple two month gap kept my body from functioning correctly for four months. I developed stress induced fluid-filled cold sores in my eye from the common herpes simplex virus. The two times this occurred placed me in the hospital for a total of 10 days (a week for the first time, and three days for the second time). I can add that to my pile of 15 plus emergency hospital stays in my 31 years that relate directly to diabetes

When I finally did receive insurance, I contacted my different doctors and asked them to send in my insulin prescriptions since with my new plan I could now afford them. Without insurance in 2019, the cost for a single vial of Humalog insulin was \$332 (in 2021 the cost as of writing this is \$275),

with each 10 mL vial being used up in 7 days (I use 2.5 mL every three days). When buying a single vial of insulin, I knew I could not afford this for long--I would have been forced to spend \$830 every month in 2019 (\$686 in 2021). I am personally relieved to see my costs trending downward, but despite that, the costs of insulin alone are still wildly unaffordable.

If I were to add the cost of an insulin pump of \$7,000 that lasts 4 years, and supplies starting at \$202 per month, the monthly cost for only my diabetes treatment was \$1,037 per month in 2019. This totals to \$12,444 a year, not including tax or the insulin pump itself. A person who would be making \$15 an hour doing a 40 hour work week in one month would make only \$2,400. My \$1,037 cost—which I need to spend just to stay alive--would be almost half of my wages.

I survive financially only because of my insurance plan provided through my current job which does not offer me an insurance option, and allows me to qualify for Medicaid. Unfortunately, many are not that lucky to get decent insurance, and without it their sentence is pain and death.

Testimony – Rx
July 12, 2021

Jessica Brooks, President & CEO
Pittsburgh Business Group on Health

To the Members of the PA House Democratic Policy Committee, thank you for the opportunity to share employers' perspectives about the crucial effort to address the impact of the high cost of prescription drugs on families, companies and communities.

My name is Jessica Brooks and I serve as the president and CEO of the Pittsburgh Business Group on Health, a non-profit, employer-led business coalition based in Pittsburgh. Our mission is to protect the ability of employers to provide high-quality, equitable and affordable healthcare for their employees and their families so Pennsylvania can thrive and its future prosperous.

A question: At what point will we realize the quality of one's life is greater than what any pharmaceutical company's profit should be? Each year we – the coalitions representing thousands of small, medium and large employers – experience rising costs in health insurance. Not only do the monthly premiums increase, but the pharmaceutical copays, deductibles and out-of-pocket maximums are, in many cases, extraordinary and unsustainable.

At times, these costs are so extreme, employees – the backbone of America – find themselves purchasing supplemental health insurance products as a layer of protection to offset deductibles, should a member of their family become ill. And what about those who need their medications but cannot afford them? Often this population is being forced to choose between putting food on the table or maintaining prescribed medications in the hopes of sustaining – or saving – their lives.

Each year, employers are tasked with reviewing the benefits they offer their employees. Trends around coverage decisions, along with patterns of high-use medications and therapies drive the change in cost to employers and, essentially, to the employees.

Moreover, each year the increase in the cost of pharmaceuticals outpaces the general increase in healthcare medical spending dollars. For example:

- The cost of pharmaceutical medications has grown 19 percent from 2017-2019 as compared to 6 percent for medical spending
- Pharmacy costs have grown from 22 percent to 28 percent of the total healthcare dollar spent
- Specialty medication accelerated by 39 percent from 2018-2019. Depending on it being billed under pharmacy or medical benefits, as well as the location where service is performed – contributing to large variances in costs

- For every \$1 million spent on pharmacy costs, 3 percent is spent on higher cost drugs, which have no additional clinical value. In fact, the Pacific Business Group, among other employer and advocacy groups, have identified more than 400 medications as wasteful, including, for example:
 - Diabetes Insulin treatment Humalog Kwik Injection pen is \$1,000 vs. Novolog Flexpen \$580 (42 percent higher)
 - Diabetes Metformin 1,000 mg extended-release tablets is \$2,700 vs. Metformin (2) 500 mg extended-release tablets at \$26 – 100X higher
 - Insulin is a life-saving drug. Private and public insurance should treat it as such with low co-payments that remain predicable. The rebate system is a major driver of insulin's rapidly increasing cost to people struggling to live with diabetes. (Rebates represent more than 70 percent of the list price for insulin). There should be an end to the rebate system under private and public insurance and for drug companies to reduce prices and limit subsequent price increases to the Consumer Price Index.
 - Duexis for pain relief \$450 vs. Ibuprofen + Famotidine \$51 – 9X higher

Reality: the high price of prescription drugs and their cost to consumers have gone unaddressed for far too long while American families have watched their elected leaders allow politics to overcome meaningful progress. As representatives of America's employers, who, in turn, hire, train and empower their employees as consumers, patients and taxpayers, we are cognizant of this moment in time – a critical inflection point, the need to end the pharmaceutical industry's anticompetitive behaviors and unjustified, egregious pricing, which makes drugs unaffordable.

To date, 28 states, some with multiple coalitions, have signed a letter to Congress asking members support legislation to reduce drug costs. Represented states include Alabama, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Minnesota, Missouri, Montana, Nevada, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Wisconsin, and Wyoming.

This isn't new information. But today, employers are faced with even new burdens surrounding pharmaceutical costs, particularly for specialty medications as employers bear witness to seeing small numbers of people continue to drive dramatic increases in pharmacy spending. Add in the lack of visibility regarding specialty medication billed through medical and a problem becomes worse. Recent gene therapy drugs are even more concerning as they are often approved by the Food and Drug Administration FDA very limited research, the price tags are virtually unaffordable and there are few partnerships employers trust to help them understand the value and decide coverage for these drugs. The price tags often affects both employer and patient (or employee/member) spending (especially with high deductible plans).

Most employer-led business coalitions continue to educate members on potential strategies and listen to their concerns. For some employers (usually large and/or paternal), the question is *how* to afford these therapies. However, for others the question is *CAN* we afford these therapies.

Further compounding the challenge is the issue of accurate data to drive good decisions. Some employers collect their own data. Others utilize data partners, such as Innovu, and trust what they are receiving. However, as has been the case, when employers are forced to use the data from their health plans or Pharmacy Benefit Manager, they lack the confidence the data is a true reflection of the impact to their companies or employees/members.

Education is a key component in resolving the crisis some believe we are barreling towards, when in reality we are already in it. The Consolidated Appropriations Act legislation, which has specific requirements for pharmaceuticals, as well as eliminating vendor gag clauses, is a good starting point, but we need processes employers can follow to comply with new law.

Utilizing the services of companies, such as RightRx, education is offered to both the prescriber and patient. The knowledge of the pharmacist and pricing as well as dosing options is also key in cost savings. Collaboration by all parties, when the situation allows, can be the first step in keeping costs down with the ultimate shared goal of providing the most effective medication at an affordable rate.

Reduction in drug pricing has been on the proverbial table of legislators for nearly *four* decades. It is time to act. America's workforce and their families can wait no longer.

Stakeholders in our nation's Capitol have been vocal about the need to address drug costs and have been putting the pieces together behind the scenes to get ready to pass legislation. Now we must throw our full efforts forward so that legislation becomes law.

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Testimony before the Pennsylvania House Democratic Policy Committee Hearing on Impact of High Prescription Drug Costs on Pennsylvania

July 12, 2021

Good afternoon and thank you Chairman Bizzarro and Representatives Kinkead, Pashinski, and Fiedler for holding this hearing today. My name is Patrick Keenan, and I am the Policy Director for the Pennsylvania Health Access Network. Our mission is to achieve a day when all Pennsylvanians have affordable, high quality, and equitable healthcare. And we recognize that we are far from that reality at the current moment. Every year, we talk to over 10,000 residents of the commonwealth from roughly 61 or 62 of its 67 counties and assist people with problems including unaffordable medical bills, problems accessing providers, long travel or wait times for care, denials of medically necessary care, and many other similar issues. We also assist people in enrolling in health insurance coverage through our state-based marketplace, Pennie, as well as in public coverage options like Medicaid and the Children's Health Insurance Program. All of these experiences show us just how much Pennsylvania families, seniors, and small business owners struggle to access healthcare.

To add additional depth to our understanding of the struggles faced by everyday Pennsylvanians, PHAN has worked closely with Altarum's Healthcare Value Hub to do the first ever survey of healthcare affordability in Pennsylvania with a representative sample, first in 2018 and most recently in 2020. The findings are compelling:

- **1 in 2 Pennsylvania adults experienced a hardship or affordability burden due to the high cost of healthcare in the past year.** This number is astounding. There are very few issues that affect half of the adult population in Pennsylvania. Given this prevalence, it is important for lawmakers to focus on healthcare.
- **44% of Pennsylvania adults had needed medical care interrupted by a cost burden in the past 12 months.** Again, a significant number of individuals are foregoing care ordered by a doctor because they cannot afford it. This has serious repercussions for an individual's health and costs us more in the long term when people forego care and end up sicker and requiring more costly forms of care.
- The cost of prescription drugs created one of the largest affordability burdens, causing **1 in 5 of all Pennsylvania adults to cut pills in half, skip doses, or not fill a prescription.** Prescription medications are often the frontline treatment for preventing or managing serious health conditions. Given the widespread nature of cost barriers, it is critical we think about solutions.
- **51% of all respondents reported being worried about affording prescription drugs.** Worry varied significantly by income group, with residents in households making less than \$50,000 per year being almost twice as worried as those in households making more than \$100,000 per year. This points to a serious health equity issue as well as

one that affects seniors on fixed incomes and many hardworking families struggling to make ends meets.

- **The rate of people not filling a prescription, cutting pills in half, or skipping doses is nearly twice as great in rural communities (28%) compared non-rural communities (17%).**
- **1 in 4 Pennsylvania adults got the care they needed – including prescription drugs – but struggled to pay the resulting bills.** Included in this number is the 8% of Pennsylvania adults who used up all of most of their savings, the 7% who put off payments for basic necessities like food, heat, or housing to afford care, and the 6% of adults who racked up large amounts of credit card debt or borrowed money to pay for care. People should never have to choose between basic needs and medical care, or jeopardize their financial stability to avoid sickness.

Simply put, many Pennsylvania families, seniors, and individuals are on the brink of personal and financial disaster just because they are sick and need care.

The average older Pennsylvanian takes between 4 and 5 brand name prescription drugs regularly. The average annual cost of these drugs is 20% higher than the average senior's income. For our older adults who have worked hard all of their lives, the uncertainty and worry about not having a prescription drug due to cost is all too real. Many of these adults are faced with the stark realities described in the survey.

Not only are Pennsylvania families hit hard when they go to get care, but often they are losing out on increased wages and further economic growth because of how the high and rapidly rising cost of drugs hits their employers. A recent national survey of small business owners shows that 89% of small business owners think prescription drug costs are too high and 55% of small businesses providing coverage to employees have had to delay growth opportunities because of rising healthcare costs. The survey goes on to detail how small employers are dropping coverage, scaling back on benefits, raising prices, holding off on hiring new employees, or limiting wage growth or increasing employee contributions. Essentially, the backbone of the Pennsylvania economy is buckling under this kind of pressure.

To be fair, healthcare costs in general are rising, not just the cost of prescription drugs. However, prescription drugs account for a significant portion of rising healthcare costs. Estimates from the Commonwealth's insurance regulator along with national estimates show that prescription drugs make up between 20 and 25% of healthcare spending in Pennsylvania. Often, we see big healthcare entities, including the pharmaceutical industry, point fingers at other entities and push blame onto them. Now is the time to end that blame game. There is no question that pharmaceuticals play a significant role in healthcare and healthcare spending and Pennsylvanians deserve transparency, accountability, and oversight.

Because of these conditions, Pennsylvanians – overwhelmingly and across party lines – want state elected officials to take actions.

- When asked about the top three healthcare priorities the government should work on, at the top of the list (51%) was addressing high healthcare costs, including prescription drugs.

- Of more than 20 options, Pennsylvania adults put drug companies at the top of the list of those who are charging too much money (70% overall, 71% Republicans, 69% Democrats, 69% nonaffiliated).
- Pennsylvanians support a wide array of state-level policy solutions to address prescription drug pricing issues:
 - “The government should prohibit drug companies from charging more in the U.S. than abroad.” 89% overall, 91% Republicans, 90% Democrats, 86% nonaffiliated.
 - “The government should require drug companies to provide advanced notice of price increases and information to justify those increases.” 89% overall, 87% Republicans, 91% Democrats, 88% nonaffiliated.
 - “The government should create a Prescription Drug Affordability Board to examine the evidence and establish acceptable costs for drugs.” 87% overall, 84% Republicans, 92% Democrats, 84% nonaffiliated.

In closing, I want to spend some time examining the Prescription Drug Affordability Board. What Pennsylvanians want to see is lower costs at the pharmacy and this is the only solution that can actually do that and continue to keep other out of pocket costs, like premiums, in check. Not only is it a consumer-friendly solution, but it is one that would actually increase the accessibility of high cost medications, and, in doing so, would likely broaden the profitability of pharmaceutical manufacturers. The board would pursue targeted, precise actions that would correct market failures, ones that no other entity have the possibility of correcting on their own. Those opposed to this limited intervention portray it as “government rate setting” or “socialized medicine” and they talk about it as “unconstitutional.” None of these things are actually true. Three states – Maryland, Maine, and Colorado – are implementing these kinds of boards and dozens of other states are seeking to implement them. This is because these boards are the commonsense solution that citizens are demanding. They are fair and equitable to all parties involved. They deliver the transparency, accountability, and oversight necessary to ensure these vital pharmaceuticals – often developed through significant taxpayer support for research and development – are available to all who need them. Because, as is frequently said, “prescription drugs don’t work if people can’t afford them.”

Thank you again for covering this important topic. I’m happy to take questions and would like to point out that the Prescription Drug Affordability Board is soon to be introduced by Representative Frankel as House Bill 1722. On behalf of those struggling desperately for their medications, I’d ask you to consider supporting this critical legislation, and in doing so, would also help small business owners, local hospitals, county governments, and even taxpayers here in the Commonwealth. Again, I appreciate your time today.

Contact: Patrick Keenan, Policy Director, Pennsylvania Health Access Network, patrick@pahealthaccess.org, (717) 322-5332

**PENNSYLVANIA HOUSE DEMOCRATIC POLICY COMMITTEE
Subcommittee on Progressive Policies for Working People**

**Testimony of Kristin Parde
Deputy Vice President, State Policy
Pharmaceutical Research and Manufacturers of America (PhRMA)**

July 12, 2021

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Testimony
Pennsylvania House Democratic Policy Committee
Subcommittee on Progressive Policies for Working People
July 12, 2021

Thank you, Chairman Bizzarro, Representative Kinkead, Representative Pashinski and members of the committee for inviting me to join you today. My name is Kristin Parde and I am testifying on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”). PhRMA is a voluntary nonprofit organization representing the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of Pennsylvania’s economy and its economic competitiveness. The sector directly accounts for 46, 830 jobs in Pennsylvania and supported an additional 207,046 jobs.¹ These jobs generate over \$67.3 billion in economic output.² In addition, the biopharmaceutical industry invests heavily in Pennsylvania’s capital expenditures. Between 2015 and 2020, this included: 48 major (+ \$5m) projects, \$3.6 billion in capital, 7.3 million labor hours with Pennsylvania building and construction trades unions, and more than \$85 million in union earnings.³ We appreciate our many partnerships in Pennsylvania.

My testimony today will cover several topics per the request of the committee, including prescription medicine costs, research and development, accessibility issues for patients, and policy solutions.

The State of Pharmaceutical Research & Development in the United States

The research and development process for new drugs is lengthy and costly, with a high risk of failure. From drug discovery through FDA approval, developing a new medicine takes, on average, 10 to 15 years, and costs \$2.6 billion⁴. Fewer than 12 percent of the candidate medicines that make it into Phase 1 clinical trials are ultimately approved by the FDA⁵.

In addition, the cost of drug development has more than doubled over the last 30 years. Many factors are driving up the costs of biopharmaceutical R&D, including increased clinical trial complexity, larger clinical trial sizes, more data sources to integrate, greater focus on targeting chronic and degenerative diseases, and higher failure rates for drugs tested in earlier-phase clinical studies.⁶ Ongoing investment in research and development depends on the commercial success of a few products that must make up for all the rest, including those that never reach the market. Average returns on R&D investments have been declining. Accounting for uncertainty and risk, biopharmaceutical profits are in the middle range among industries.

Despite these challenges, the pharmaceutical research and development pipeline is robust. In the last decade alone, biopharmaceutical companies invested half a trillion dollars in R&D, and these investments are yielding results, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.⁷ As a result of this tremendous progress, many diseases previously regarded as deadly are now manageable and potentially curable. Last year alone, the cancer death rate saw the biggest one-year drop in

history.⁸ Today, there are more than 8,000 medicines in development around the world.⁹ Across the medicines in the pipeline, 74% have the potential to be first-in-class treatments, representing entirely new approaches to treating a disease.¹⁰ The future has never been brighter as researchers explore new frontiers that just a few years ago may have been regarded as science fiction, but now transform patients' lives.

Prescription Medicines: Costs in Context

We are in a new era of medicine where breakthrough science is transforming patient care. In 2020 alone, 53 new medicines were approved by the FDA. Even as many new treatments reached patients, **growth in brand medicine prices declined by 2.9 percent and total net spending on prescription medicines remains in line with inflation at 0.8 percent.**¹¹ Over the next five years, net medicine spending is projected to increase 0 to 3% annually.¹² In 7 of the last 10 years, retail prescription medicine costs grew more slowly than total health care costs and on average, spending growth for retail prescription medicines has been lower than the total health expenditures.¹³ While rarely reported, it is clear that prescription medicine costs are a small and stable share of overall health care spending, accounting for just 14% of total U.S. health care spending and remaining consistent over time.¹⁴ In addition, prescription medicines account for a small share of total Medicaid spending. Between 2019 and 2021 retail and nonretail prescription medicines will account for less than 9% of total Medicaid spending.¹⁵

Prescription medicines also play a significant role in controlling overall health care costs. Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization. Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges. Likewise, better use of medicines, such as improved adherence to needed treatments, offers the opportunity for improved results for patients and an estimated \$213 billion per year in health care savings.¹⁶ **Researchers have found that every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated \$3 to \$10 dollars in savings on emergency room visits and inpatient hospitalizations.**¹⁷ Conversely, it is well established that medication nonadherence is associated with poor clinical outcomes and higher overall health care costs.¹⁸

An integral component of understanding the cost and value of prescription drugs is the pharmaceutical lifecycle and the role of generic medicines. More than 9 in 10 prescriptions (91%) filled in the United States are for generic medicines¹⁹. U.S. brand medicine sales are projected to be reduced by \$128 billion due to competition from generics and biosimilars between 2021 and 2025.²⁰ There is no similar type of cost containment for other health care services.

Pharmaceutical Costs: The Patient Experience

Despite current cost trends, consumers continue to struggle with both affordability and access to their needed medicines due in large part to changes to insurance benefit design and the failure of manufacturer rebates and discounts to directly lower patients' out-of-pocket drug costs. This is reason why your constituents are struggling to afford their medications even when they pay for insurance coverage.

Insurers and PBMs have increasingly shifted more health care costs to patients through high deductibles and coinsurance which have grown sharply in recent years.²¹ **Commercially insured patients with a deductible have seen their out-of-pocket costs for brand medicines increase 50% since 2014.**²² Research by the Peterson Center on Healthcare and Kaiser Family Foundation, found a 205% change in payments on patient out-of-pocket

spend on deductibles and a 74% change in out-of-pocket payments on coinsurance among large employer health plans between 2007 and 2017.²³ **Further, use of deductibles and coinsurance has increased particularly acutely for new medicines that represent the most innovative therapies and often treat the sickest patients.**

Patients with deductibles and coinsurance typically pay cost sharing based on the undiscounted list price of a medicine rather than the negotiated net price.²⁴ This is significant as manufacturer rebates, discounts, and other reductions in price have more than doubled since 2012, totaling \$187 billion in 2020.²⁵ And this is the reason that patients continue to see their costs rise as prices remain stable. They are being asked to bear more of the burden while other members of the supply chain are absorbing the discounts. Nearly half of all spending on brand prescription medicines goes to entities other than the biopharmaceutical manufacturers who researched, developed, and manufactured the medicines.²⁶ PhRMA has long been concerned that health plans and PBMs are not making these substantial rebates and discounts directly available to patients, leaving patients paying deductibles and coinsurance that do not reflect the net cost of these therapies to their plan.

This practice of calculating patient cost sharing and deductibles based on list price rather than discounted or net price can result in a plan or PBM realizing a net gain when a prescription is filled. For example, imagine a patient enrolled in a high-deductible health plan who takes a medication with a list price of \$400. The patient's health plan has negotiated a 55% rebate, which substantially reduces the cost to the plan. However, because the patient has not yet met his deductible, his plan does not provide any coverage for the prescription, and the patient's bill reflects the medication's full list price of \$400. Despite paying nothing for this patient's insulin, the plan still collects the rebate, earning over \$220.²⁷ In essence, plans and PBMs have historically "double dipped." Not only do they receive manufacturer rebates, rather than allowing them to be carried forward to patients—but they also calculate cost sharing and deductible obligations based on a list price that does not reflect the actual cost that has been incurred by the plan or PBM for the drug. **This does not happen with any other health care service. If you go to the emergency room while in your deductible phase, you pay the rate your insurance company has negotiated with the hospital, not the hospital list price.**

Instead of sharing the full benefit of discounts on the price of medications with the patient at the pharmacy counter, plans sometimes apply negotiated rebates to reduce premiums for all enrollees. Putting aside that the fraction of retained rebates that plans use toward reducing patient premiums is not always significant or adequate, this also creates fundamental mis-incentives with respect to plan design: **It means that the sick are subsidizing the healthy.** As the actuarial firm Milliman has pointed out, the practice results in a system of "reverse insurance" where payers require sicker patients using brand medicines with rebates to pay more out-of-pocket, while rebate savings are spread out among all plan enrollees in the form of lower premiums.²⁸ Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the opposite of how health insurance is intended to work. This means that patients taking medicines with large rebates are subsidizing coverage for other beneficiaries—which is effectively a tax on the sick.²⁹

In addition to affordability challenges, high cost-sharing is a threat to patient access and health. A substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.³⁰ For beneficiaries with a serious illness or multiple chronic conditions, out-of-pocket expenses for prescription medicines can easily add up to many thousands of dollars annually, resulting in patients with

chronic or life-threatening illnesses such as diabetes, schizophrenia, multiple sclerosis, and cancer walking away from the pharmacy counter without filling vital prescriptions.

For example, one published study found that where beneficiary cost sharing exceeds \$250, 71% of new specialty prescriptions were abandoned.³¹ Even among patients with debilitating or life-threatening illnesses, abandonment rates were alarmingly high. For example, more than 6 out of 10 new oncology prescriptions and more than 7 out of 10 new antipsychotic and multiple sclerosis prescriptions were abandoned at the pharmacy counter when their cost sharing exceeded \$250. These rates of medication nonadherence raise fundamental concerns about patient health and safety, as well as costs for the broader health care system.

Policy Proposals and Price Controls

Legislation attempting to address prescription drug affordability has been prolific in recent years. **Unfortunately, many of the proposals fail to address the actual issue of patient affordability and access and instead rely on a common theme of instituting government price controls.** Regardless of the terminology employed – Upper Payment Limit, Unsupported Price Increase, Rate Setting – these policies focus on restricting the wholesale acquisition cost of medicines without acknowledging the dynamics of the United States pharmaceutical supply chain and the impact of price controls on medication access and future innovation. Research shows that “[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures.”³²

Price Controls Limit Access

Many arguments in favor of price controls, seek to draw a comparison between pharmaceutical prices in the United States and those in foreign countries. However, foreign governments that utilize price controls also rely on rationing care in their own countries. Government price controls go hand-in-hand with access restrictions and delays.

American patients have faster access to more medicines than patients anywhere else in the world, and doctors and patients work together to decide which medicine is right for them. In countries that use international reference pricing and other government price controls, patients can access fewer new medicines and face long treatment delays. Research shows that U.S. patients enjoy earlier and less restrictive access to new therapies,³³ a finding that is reinforced by the U.S. Department of Health and Human Service’s (HHS) own analysis of Medicare Part B drugs, which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have single-payer health care systems.³⁴ The U.S. has access to nearly 90% of all medicines launched between 2011 and 2020, while just 64% are available in Germany, 60% in the U.K., 52% in Japan, 48% in France, 48% in Canada, and 38% in Australia. Even when medicines are available, it often at a significant delay. In countries with government price controls in the marketplace, such as the United Kingdom, it can take over a year from the time a drug is approved to the time it is available to patients. Some countries have a delay of over 3 years for a cancer drug to be available to patients.³⁵

Many state pharmaceutical price control proposals rely on cost-effectiveness analysis (CEA) which utilize discriminatory Qualified Adjusted Life Years (QALYs). Developed from population averages, QALYs ignore important variability in patients’ individual needs and preferences and are acknowledged by experts to discriminate against people with disabilities by placing a lower value on their lives. A report issued by the National Council on Disability in 2019 “found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates

about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used.”³⁶

Even proposals that do not specifically reference QALYs or CEA can implicate their discriminatory impact by relying on prices set in other countries. In countries that rely on CEA to determine coverage and payment, many patients face significant restrictions on access to treatments, including those diagnosed with cancer, diabetes, and rare diseases. A recent analysis noted that these types of cost-effectiveness assessments and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of the patients.³⁷

Price Controls Raise Constitutional Concerns

Efforts to enact government price controls on brand medicines also raises constitutional concerns under the Supremacy Clause because price controls restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention and states are not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia*, 496 F.3d 1362 (2007), the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on brand drugs, reasoning that the D.C. law conflicted with the underlying objectives of the federal patent framework by undercutting a company’s ability to set prices for its patented products. The court’s decision state that “[t]he underlying determination about the proper balance between innovators’ profits and consumer access to medication ...is exclusively one for Congress.”

Price Controls and Competition

Competition is a hallmark of the US prescription medicines market. Negotiating power is concentrated among a few pharmacy benefit managers (PBMs), which forces new and existing medicines to compete for coverage and increases the likelihood of excluding medicines from coverage altogether. The built-in cost containment of the prescription medicine lifecycle remains unique in health care, where new medicines eventually lead to lower-cost generics and biosimilars that bring long-term value to patients and the health care system. Competition between brand competitors and the dynamics of the pharmaceutical patent lifecycle create an environment that inspires innovation.

From time to time, arguments are made that drug manufacturers should be regulated as public utilities, such as an electric distribution company, like PPL or PECO in Pennsylvania. This line of thinking is based on an inherently false equivalence. In general, a public utility has a monopoly on the service it provides. Public utilities are essentially guaranteed a profit for providing the same service year over year, such as the transmission and distribution of electricity from a deregulated generation plant to an end customer. In contrast, the cornerstone of the pharmaceutical industry is competition and this competition spurs innovation without which an individual company would not thrive.

In fact, the biopharmaceutical industry is one of the most innovative, research and development driven in the world. The innovative nature of the pharmaceutical industry is what made it uniquely prepared to take on the challenges of the Covid-19 world-wide pandemic and successfully develop vaccines and therapeutics to combat the virus. America’s biopharmaceutical companies leveraged decades of experience researching other viruses and providing critical infrastructure and capabilities to overcome the pandemic and its consequences. In times

like these where Americans are facing a high degree of uncertainty, the contributions of the biopharmaceutical industry are providing critical support not only to the health of patients but to the health of our economy.

Proactive Policy Solutions to Address Patient Access and Affordability

Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy. PhRMA is working to improve the health care system for patients by supporting policies that lower out-of-pocket costs, while avoiding those that reduce patient access and limit much needed medical innovation. We are willing to work with all stakeholders to deliver a stronger, more resilient, affordable, and equitable health care system for all. There are many policy options to accomplish these goals but today I am focusing on several of the state proactive policies that directly impact patient costs and affordability at the pharmacy counter.

Share the Savings with Patients at the Pharmacy Counter

This year, the state of West Virginia became the first state in the nation to enact legislation ensuring that patients will benefit from rebates at the point of sale. PhRMA has long advocated for sharing directly with patients at the pharmacy counter the \$187 billion in rebates and discounts given by biopharmaceutical companies to the government, issuers, plans, and PBMs. Sharing negotiated rebates with patients is an important step toward improving medicine affordability and ensuring patients can access the medicines they need. Actuarial research shows the tangible impact of calculating patient cost sharing based on net price rather than list price: patients enrolled in plans with high deductibles and coinsurance could save between \$145 and \$800 annually.³⁸ Importantly, requiring PBMs to calculate cost sharing based on net price will have minimal and manageable impact on premiums (actuarial research conducted by Milliman estimates that premiums may increase by one percent or less).³⁹

Ensure Cost-sharing Assistance Applies to Deductibles

Health insurance carriers and PBMs are increasingly adopting policies, often referred to as “accumulator adjustment programs” (AAPs), that block manufacturer cost-sharing assistance from counting towards a patient’s cost-sharing obligations. Patients subject to AAPs have a significantly greater risk of treatment discontinuation and lower refill adherence. By implementing legislation to require that all third-party cost-sharing assistance be counted toward a patient’s deductible and out-of-pocket maximum, states can help consumers better afford their medicines and provide patients immediate relief from rising out-of-pocket costs. To date, 11 states have enacted legislation banning the use of accumulator adjustment programs.⁴⁰

Cover Medicines from Day One

Insurers are increasingly requiring patients to pay high deductibles before receiving coverage of their medicines. This can lead to patients rationing or not taking their medicines at all and suffering devastating consequences to their health. States can help patients immediately by requiring that certain medicines be covered by insurers from day one without subjecting patients to deductibles. The Internal Revenue Service recently issued guidance allowing high-deductible health plans to exclude certain drugs, such as those for the treatment of some chronic conditions, from requirements that deductibles be met before those medicines are covered. Because of the federal guidance, states can now require plans to exclude those medicines from the deductible in high - deductible health plans. States may also choose to require other state-regulated plans to eliminate deductibles for all drugs. While health insurance companies would still have flexibility to offer different plan designs, limiting

or eliminating deductibles in this way could help smooth out patients' expenditures over the calendar year and could provide immediate relief to patients at the pharmacy counter.

Offer Lower, More Predictible Cost-sharing Options

Patients need more choices when it comes to their medicine coverage. States can require health insurers to offer at least some health options that exclude medicines from their deductibles and offer set copay amounts instead of forcing patients to pay an amount based on the full list price of their medicines. Cost-sharing should not be so burdensome that it prevents patients with insurance from accessing necessary prescription medicines. Similarly, several states have enacted legislation to place hard-dollar monthly caps on patient out-of-pocket costs for state-regulated plans in the commercial market. While California has a broad requirement, other state caps focus on specialty drugs or insulin products.

Constituent Resources: Medication Access Tool

In closing, I want to highlight a tool that the industry has developed to assist consumers in accessing more information about their pharmaceutical benefit and specifically affordability assistance. The pharmaceutical industry has a responsibility to not just develop treatments and potential cures, but to also help patients access them. The industry recently launched the Medicine Assistance Tool (MAT), to make it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable. In light of the pandemic, America's biopharmaceutical companies are individually expanding their programs to help more patients during these uncertain times. MAT matches patients with resources and cost-sharing programs that may help lower out-of-pocket costs regardless of insurance status. MAT can be accessed at www.MAT.org.

Thank you again for the opportunity to testify today. We look forward to continuing to work with members of this committee on approaches to address patient access and affordability and preserves the innovation of tomorrow's cures.

¹ TEconomy Partners, The Economic Impact of the Biopharmaceutical Industry. U.S. and State Estimates. Report prepared for PhRMA in September 2019 and reflects 2017 data.

² Ibid.

³ Institute for Construction Economic Research and Pharmaceutical Labor-Management Association, An Analysis of Construction Spending in the Pharmaceutical & Biotech Industry, 2015-2020. June 2021.

⁴ PhRMA adaptation of DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Econ.* 2016;47:20-33.

⁵ Food and Drug Administration (FDA). U.S. Food and Drug Administration drug approval process. <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf>. Accessed May 2017.

⁶ DiMassi JA, Grabowski HG, Hansen RW. Innovation in the Pharmaceutical Industry: new estimates of R&D costs. *J Health Econ.* 2016;47:20-33 Previous research by DiMasi and Grabowski estimated the average R&D costs in the early 2000s at \$1.2 billion in constant 2000 dollars (see DiMasi JA, Grabowski HG. The cost of biopharmaceutical R&D: is biotech different? *MDE Manage Decis Econ.* 2007;28:469-479). That estimate is based on the same underlying survey as estimates for the 1990s to early 2000s reported here (\$800 million in constant 2000 dollars) but is updated for changes in the cost of capital.

⁷ PhRMA annual membership survey. Washington, DC: PhRMA; 2007-2020.

⁸ Facts and Figures 2019: US Cancer Death Rate has Dropped 27% in 25 Years, Cancer.org. Available at <https://www.cancer.org/latest-news/facts-and-figures-2019.html>.

⁹ Adis R&D Insight Database. 2020.

¹⁰ Analysis Group. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, July 2017.

¹¹ IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May 2021.

¹² Ibid.

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- ¹³ Centers for Medicare & Medicaid Services. National Health Expenditures Data.
- ¹⁴ Altarum Institute. “Projections of the Non-Retail Prescription Drug Share of National Health Expenditures.” August 2020
- ¹⁵ PhRMA Analysis of Centers for Medicare and Medicaid Services’ 2019 to 2028 National Health Expenditure Data and Altarum Institute. “Projections of the Non-Retail Prescription Drug Share of National Health Expenditures.” August 2020.
- ¹⁶ IMS Institute for Healthcare Informatics, *Avoidable Costs in US Healthcare: the \$200 Billion Opportunity from Using Medicines More Responsibly* (Jun. 2013), available at: <https://www.quotidianosanita.it/allegati/allegato4982969.pdf>.
- ¹⁷ M.C. Roebuck et al. “Medical Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending.” *Health Affairs*, January 2011
- ¹⁸ Boswell KA, Cook CL, Burch SP, et al. Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review. *American Journal of Managed Care*. 2012;4(4):e97-e108.
- ¹⁹ Fein, A. “The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” Drug Channels Institute. March 2021.
- ²⁰ Ibid.
- ²¹ The share of patient out-of-pocket drug spending represented by coinsurance more than doubled over the past 10 years in the commercial market, while the share accounted for by deductibles tripled. Claxton G., Levitt L., Damico, A., Cox, C., Kaiser Family Foundation, “*Examining High Prescription Drug Spending for People with Employer-Sponsored Health Insurance*” (Oct. 27, 2016) available at: <http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/>.
- ²² Devane, K. Patient Affordability Part One, The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018.
- ²³ Rae M, Copeland R, Cox C; Peterson Center on Healthcare and Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. Peterson-KFF Health System Tracker. Published August 14, 2019. Accessed April 2020. <https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage>.
- ²⁴ Devane, K. Patient Affordability Part One, The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018.
- ²⁵ Fein, A. “The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” Drug Channels Institute. March 2021.
- ²⁶ Berkeley Research Group, “The Pharmaceutical Supply Chain: Revisited,” January 2020.
- ²⁷ For illustrative examples of the flow of payment for prescription medicines across the supply chain, see PhRMA Press Release, “*Follow the Dollar*” (Nov. 2017), available at: <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf>.
- ²⁸ Girod CS et al. “*2017 Milliman Medical Index*,” (May 2017), available at: <http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>.
- ²⁹ Girod CS et al. “*2017 Milliman Medical Index*,” (May 2017), available at: <http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>.
- ³⁰ IMS Institute for Healthcare Informatics, “*Emergency and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans*” (Sept. 2015); Doshi JA, Li P, Huo H, et al. “*High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia*” *American Journal of Managed Care*. 2016;22(4 Suppl):S78-S86; Brot-Goldberg ZC, Chandra A, Handel BR, et al. “*What Does A Deductible Do? The Impact of Cost Sharing on Health Care Prices, Quantities, and Spending Dynamics*,” NBER Working Paper 21632, October 2015; Eaddy MT, Cook CL, O’Day K, et al. “*How Patient Cost Sharing Trends Affect Adherence and Outcomes*,” *Pharmacy & Therapeutics*. 2012;37(1):45-55.
- ³¹ Amundsen Consulting, “*Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment*,” (Nov. 2017); see also Doshi, JA., Li, P, Huo, H, et al. “*Medicare Part D Cost sharing And Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients*” *Value in Health*, 2016;19(3):78-86; Doshi, JA, Hu, T, Li, P, et al. “*Specialty Tier-Level Cost sharing and Biologic Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis*” *Arthritis Care & Research*, 2016.
- ³² Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation. Sept. 9, 2019. Available at <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures>.
- ³³ IQVIA Institute, *Global Oncology Trends 2017, Advances, Complexity and Cost*, May 2017.
- ³⁴ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.
- ³⁵ The United States v. Other Countries: Availability of Cancer Medicines Varies. Available at <https://www.phrma.org/en/Fact-Sheet/The-United-States-vs-Other-Countries-Availability-of-Cancer-Medicines-Varies>
- ³⁶ National Council on Disability, “Quality-Adjusted Live Years and the Devaluation of Life with Disability.” November 6, 2019 (cite cover memo).
- ³⁷ Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.
- ³⁸ Bunger A, Gomberg J, Petroske J. “*Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums*” (Oct. 12, 2017), available at: <http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market>.
- ³⁹ Bunger A, Gomberg J, Petroske J., “*Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums*” (Oct. 12, 2017), available at: <http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market>.
- ⁴⁰ Arkansas, Arizona, Connecticut, Georgia, Illinois, Kentucky, Louisiana, Oklahoma, Tennessee, Virginia, West Virginia, and Puerto Rico.



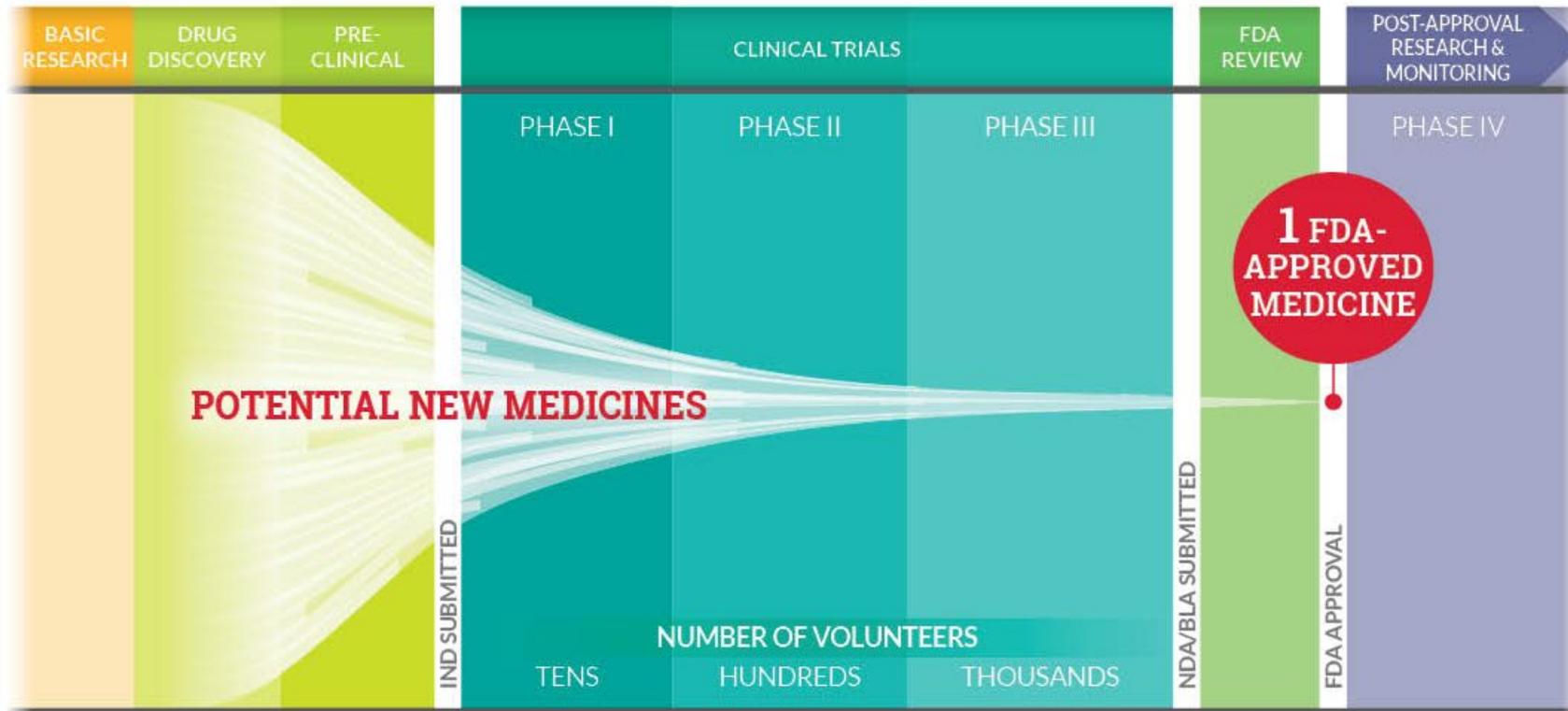
House Democratic Policy Committee

Kristin Parde, Deputy Vice President, State Policy

July 12, 2021

The R&D Process for New Drugs Is Lengthy and Costly, with a High Risk of Failure

From drug discovery through FDA approval, developing a new medicine takes, on average, 10 to 15 years and costs \$2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials are approved by the FDA.



Key: IND=Investigational new drug application, NDA=New drug application, BLA=Biologics license application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

We are in a New Era of Medicine Where Breakthrough Science is Transforming Patient Care

53 New Medicines Were Approved by the FDA in 2020



Cancer Death Rate

Cancer death rate posts biggest one-year drop ever



Game Changer

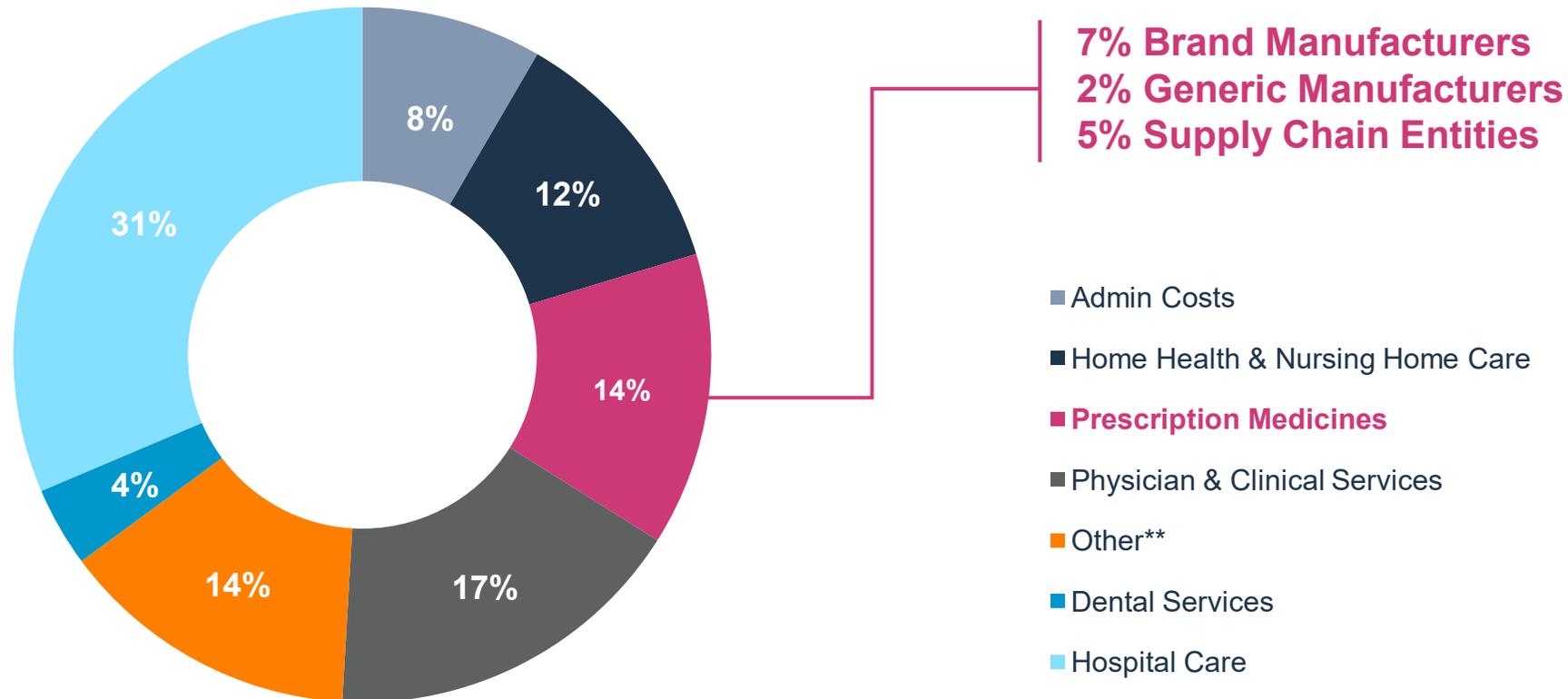
Newly approved drug being called 'game changer' for people who suffer from hemophilia



Coronavirus Vaccine

Reasons for hope: the drugs, tests and tactics that may conquer coronavirus

Spending on Retail and Physician-administered Medicines Represents Just 14% of Health Care Spending



Though Growth in Medicine Prices and Spending Remains in Line With Inflation, Many Patients Still Struggle to Afford their Medicines

Brand Medicine Prices

Medicine Spending



declined

2.9%

in 2020

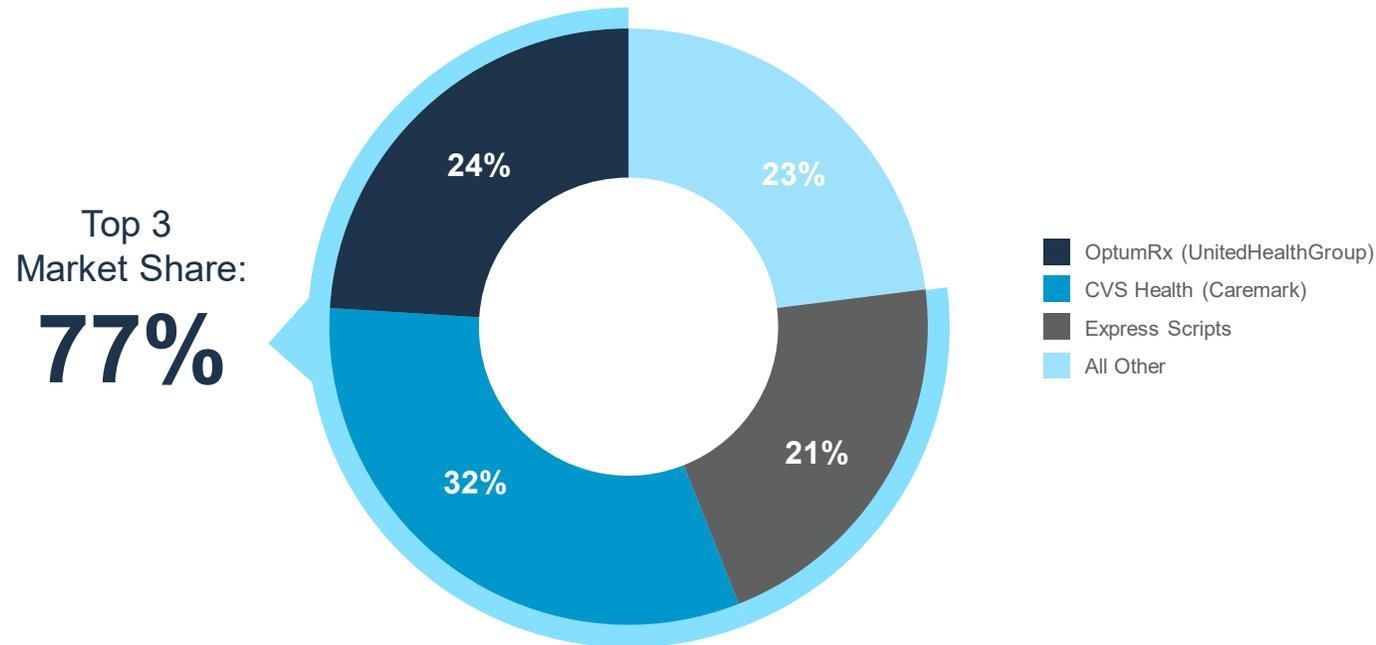
grew

0.8%

in 2020

Insurers and PBMs Have a Lot of Leverage to Hold Down Medicine Costs

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs).



Insurers determine:

FORMULARY

if a medicine is covered

TIER PLACEMENT

patient cost sharing

ACCESSIBILITY

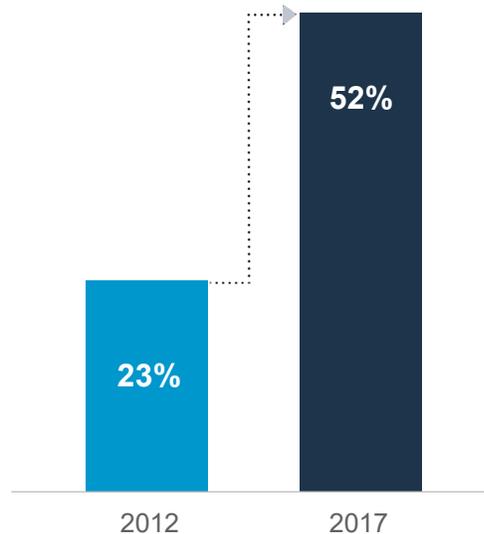
utilization management through prior authorization or fail first

PROVIDER INCENTIVES

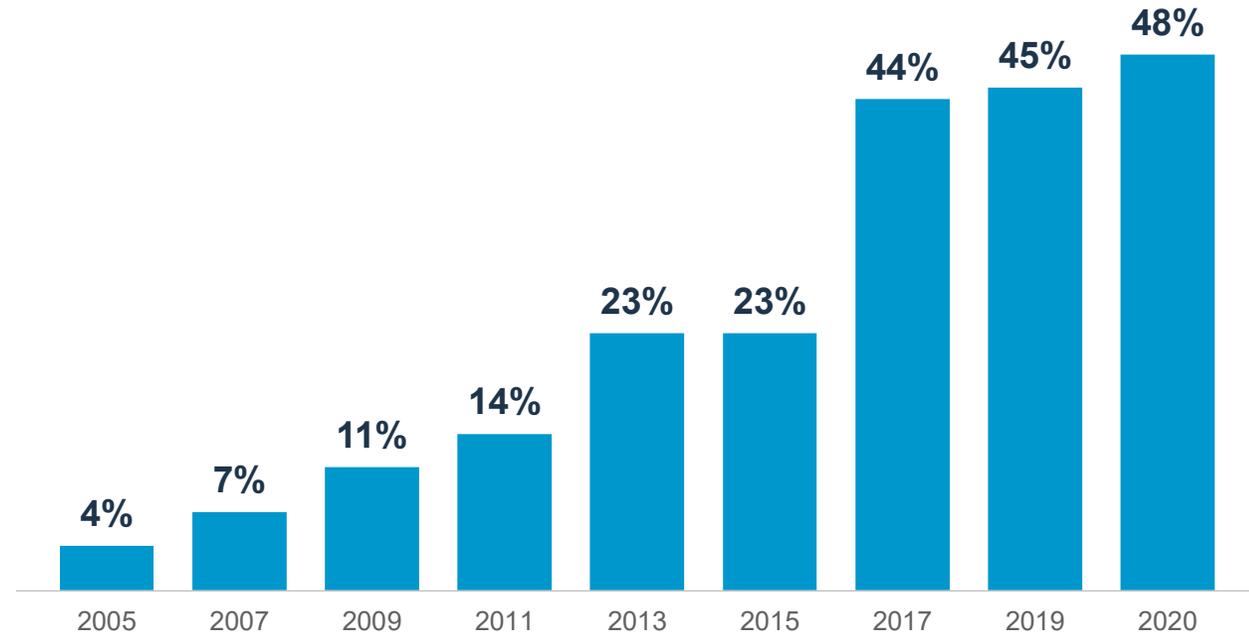
preferred treatment guidelines and pathways

Insurers are Increasingly Shifting Costs to Patients Through the Use of Deductibles and Coinsurance

Percent of plans with deductibles on prescription drugs

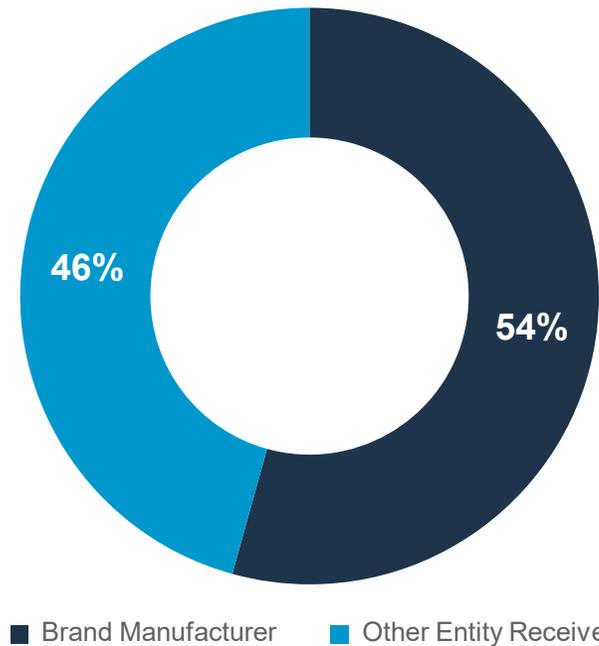


The use of four or more cost-sharing tiers is becoming more common on employer plans



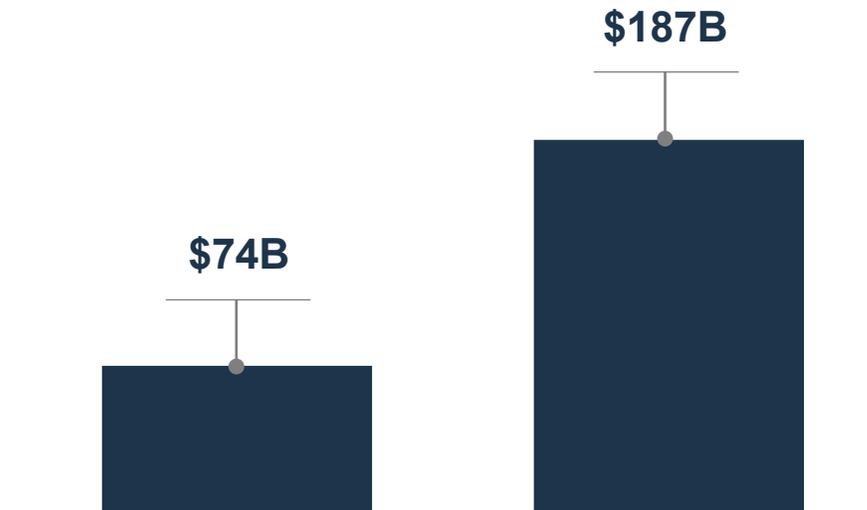
Nearly Half of Spending on Brand Medicines Goes to Entities Other Than the Manufacturers Who Developed Them

Percent of Total Spending on Brand Medicines Received by Manufacturers and Other Entities, 2018



Source: Berkeley Research Group, 2020.

Rebates, discounts, fees and other price concessions have more than doubled since 2012

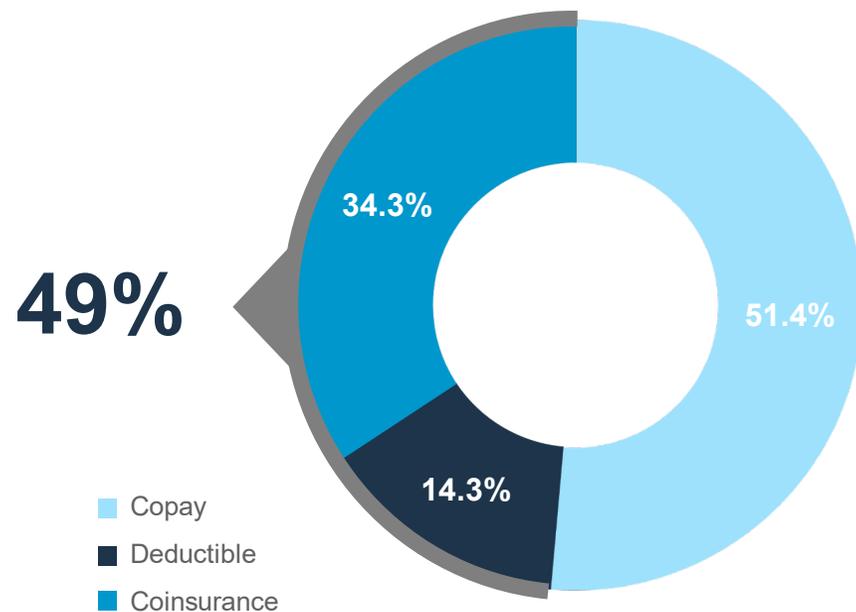


Source: Drug Channels Institute, March 2021.

Too Often, Negotiated Savings Do Not Make Their Way to Patients at the Pharmacy Counter

Half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price

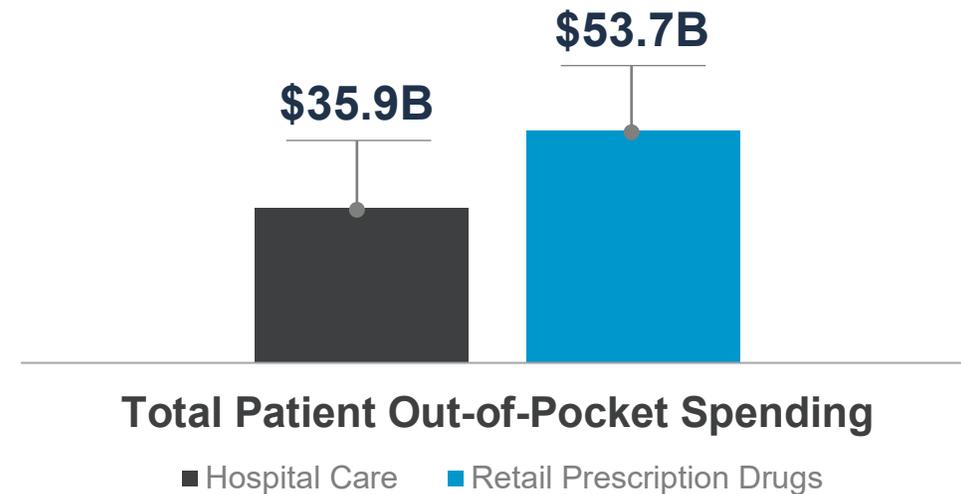
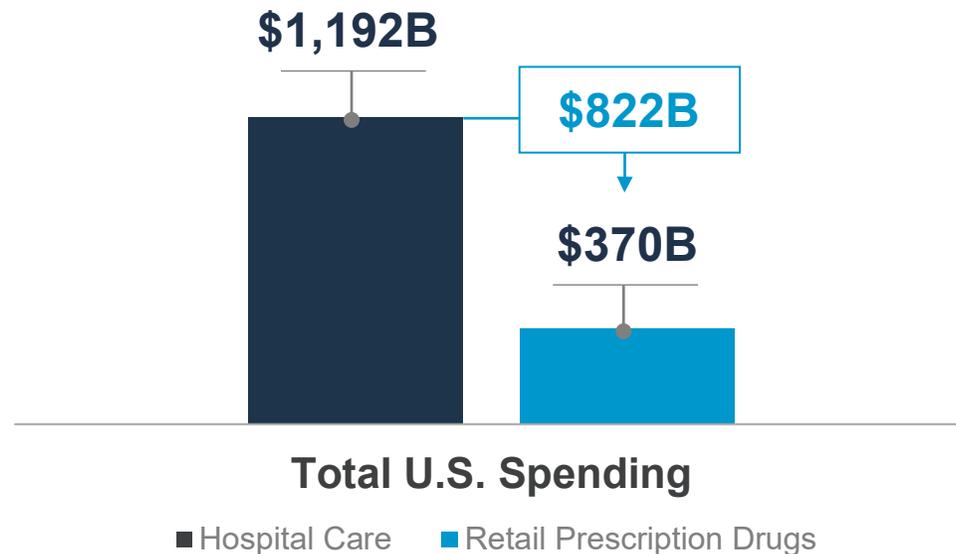
Cost sharing for nearly 1 in 10 brand prescriptions is based on list price



Patients Face High Out-of-pocket Costs at the Pharmacy Counter Even Though Total Spending on Other Parts of the Health Care System is Far Higher

Hospital spending is much higher than prescription drug spending.

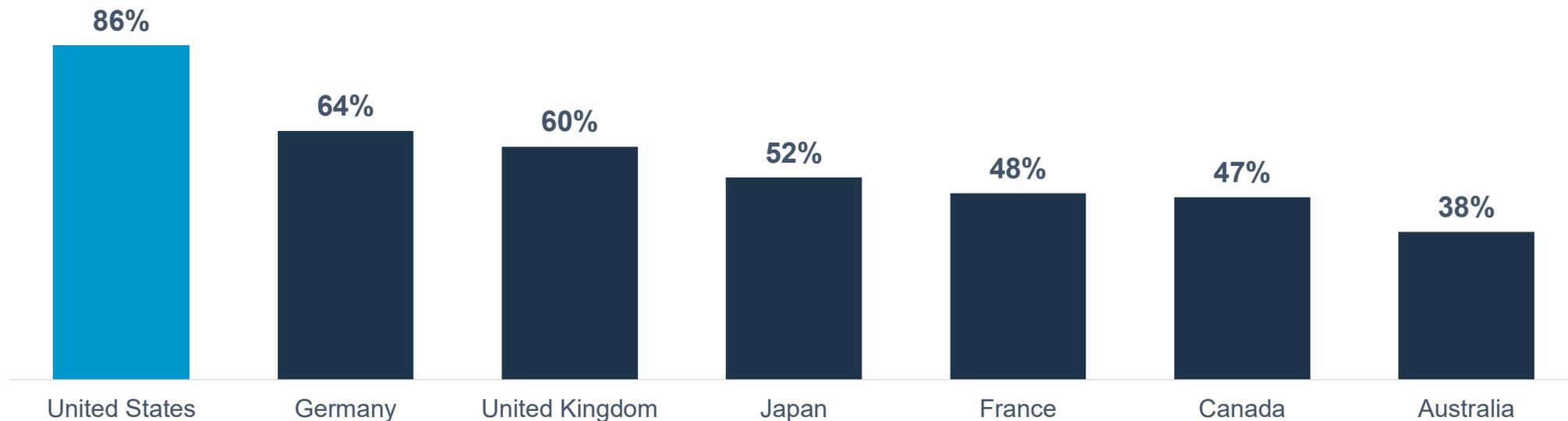
Yet patients pay more out-of-pocket for medicines than for hospital care.



More Medicines are Available to U.S. Patients as Compared with Other Countries that Set Prices Artificially Low

The 5-year survival rate for all cancers is 42% higher for men and 15% higher for women in the U.S. than in Europe.

Number of New Medicines Available by Country, 2011-2020

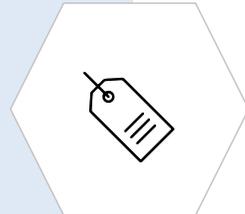


Common-sense, Patient-centered Reforms to Make Medicines More Affordable



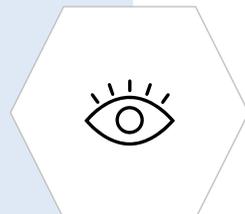
Modernize Medicare

- Improve affordability in Part D
 - Cap out-of-pocket costs
 - Lower cost sharing
 - Spread costs across the year
 - Pass savings onto patients
- Reduce costs in Part B
 - Bring prices in Medicare Part B closer to what commercial insurers pay



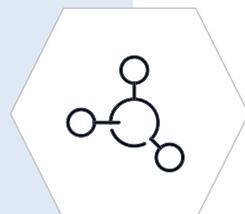
Make Insurance Work Like Insurance

- Cover medicines from day one
- Make out-of-pocket costs more predictable
- Ensure cost-sharing assistance applies to deductibles
- Share the savings with patients at the pharmacy counter



End Misaligned Incentives & Foster Competition

- Tie middlemen fees to the services they provide, not list price of a medicine
- Foster the competitive market for medicines while providing incentives for continued biopharmaceutical innovation



Protect the Safety Net

- Maintain coverage of medicines in Medicaid
- Drive oversight and transparency of the 340B program to ensure it helps the patients it was intended for

Working Together on Policies that Help Patients Pay Less

Patients Pay Less

Share the Savings

- Patients benefit from negotiated rebates and discounts at the pharmacy counter

Make Coupons Count

- Ensure cost-sharing assistance applies to deductible
- End use of accumulator adjustment programs

Insurance Should Work Like Insurance

- Cover medicines from day one
- Make out-of-pocket costs more predictable

PhRMA Created the Medicine Assistance Tool, or MAT, To Help Patients Navigate Medicine Affordability

MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

The Medicine Assistance Tool Includes:

A search engine to connect patients with

900+

assistance programs offered by
biopharmaceutical companies, including
some free or nearly free options



Resources to help patients
navigate their insurance coverage



Links to biopharmaceutical
company websites where
information about the cost of a
prescription medicine is available

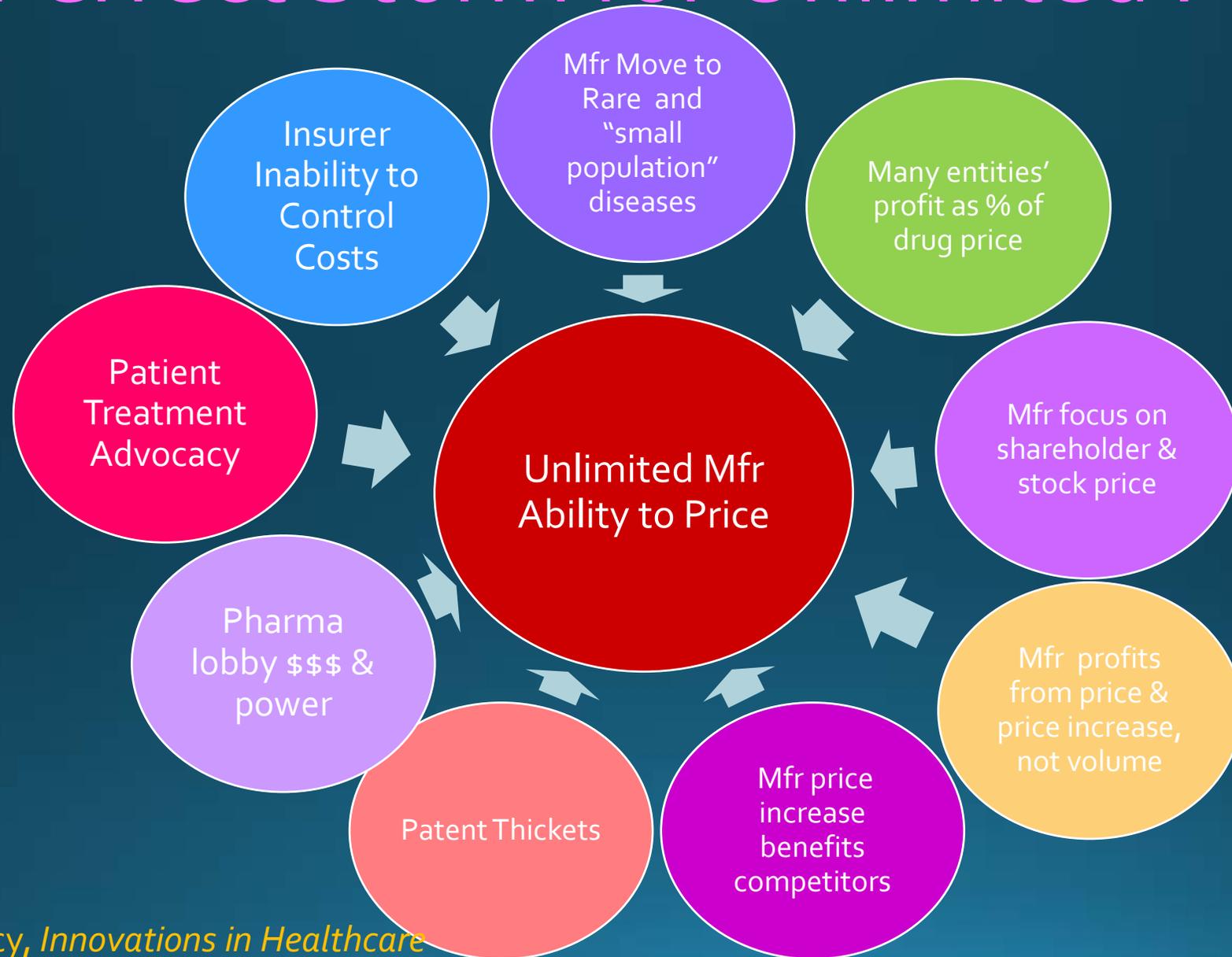
Kristin Parde
Deputy Vice President, State Policy
kparde@phrma.org

7/12/2021

Jane Horvath

How Pharma Gets to Price Like This

The Perfect Storm for Unlimited Pricing



Industry Move to Small Population Treatments

- A specific industry strategy to pursue treatment areas where insurer cost containment power is reduced, and patient advocacy is high.

Examples

- Rare diseases – 25M people/330M total population (rare disease affects <200000 people)
 - Cancer – 1.7M people
 - COPD – 16M people
 - Lupus – 1.5M people
 - MS -- 1M people
 - Epilepsy – 3M people
 - Sickle Cell – 1M people
- **49M/330M = >15% of population and counting**
 - Pricing model will generate phenomenal/unaffordable costs

Who Benefits From High Drug Prices?

- Entities that benefit from high prices often oppose policy that reduces Rx costs
 - Manufacturers
 - Wholesalers
 - Research Centers/Universities
 - Pharmacy Benefit Managers
 - 340B Entities (hospitals and others)
 - Pharmacies (notably chain pharmacies)
 - Physician Specialists (depending on the reimbursement formula)

How the Industry is Incentivized to Focus on Stock Price

(and makes company revenue performance so critical)

- **Pharma:**

- Merck CEO 2018: \$21M total compensation
 - \$ 1.61M Salary
 - \$19M stock, pension, perks
- J&J CEO 2018: \$20M total compensation
 - \$1.6M Salary
 - \$14M stock and options
 - \$ 4.4M pension, other benefits, perks
- Many levels of pharma leadership compensated with stock grants
- **Similar situations in other industries but there is more pressure on product price in those industries.**

Result of Industry Use of Price and Price Increases to Meet Wall Street Expectations

BCBS Study shows *price* drives spending rather than *utilization volume* (more prescriptions) for branded products

Drug Type	Annual Utilization Δ	Annual Price Δ	Annual Spending Δ	Cumm Spending Δ 2010-2016
Generic	9%	0%	9%	64%
Brand	-6%	17%	10%	76%

BCBS Blue Health Intelligence Report: Rising Cost for Patented Drugs Drive Growth of Pharmaceutical Spending in the US

Growing Literature on Sales Volume v Price in Industry Revenues

The Contribution Of New Product Entry Versus Existing Product Inflation In The Rising Costs Of Drugs *Hernandez, Good, Cutler, Gellad*

Health Affairs January 2019

Findings:

“The rising costs of generic and specialty drugs were mostly driven by new product entry, whereas the rising costs of brand-name drugs were due to existing drug price inflation.”

Competition Does Not Reduce Prices

Does competition equal lower prices? MS drugs defied cost logic as challengers swarmed in

by [Kyle Blankenship](#), Fierce Pharma, Aug 29, 2019

“The average price of self-administered disease-modifying therapies for MS quadrupled between 2006 and 2016 as a rush of competitors flooded the market, according to a new study published in JAMA Neurology.”

Prices Increases Even Benefit Competitors

High Launch Prices and Price Increases Clear a Price Path for Therapeutic Branded Competitors

Patented Innovator Drug	\$\$\$ Launch Price	\$\$\$\$ Price Increase	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Patented Therapeutic Competitor		\$\$\$\$ Launch Price	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Generic #1					\$\$\$\$\$ Launch Price	\$\$\$\$\$\$ Price Increase	\$\$ Price Decrease
Generics #2 & 3							\$\$ Launch Price

Patent Thickets Delay Competition by Decades

Patents are 20 years in the absence of system abuse

1	AbbVie HUMIRA	2	Biogen/Genentech RITUXAN	3	Celgene REVLIMID	4	Amgen ENBREL
	CONDITION(S) TREATED: Arthritis		CONDITION(S) TREATED: Cancer		CONDITION(S) TREATED: Multiple Myeloma		CONDITION(S) TREATED: Arthritis
	NUMBER OF PATENT APPLICATIONS: 247		NUMBER OF PATENT APPLICATIONS: 204		NUMBER OF PATENT APPLICATIONS: 106		NUMBER OF PATENT APPLICATIONS: 57
	NUMBER OF PATENTS ISSUED: 132		NUMBER OF PATENTS ISSUED: 94		NUMBER OF PATENTS ISSUED: 96		NUMBER OF PATENTS ISSUED: 41
	PRICE CHANGE SINCE 2012: +144%		PRICE CHANGE SINCE 2012: +25%		PRICE CHANGE SINCE 2012: +79%		PRICE CHANGE SINCE 2012: +155%
	YEARS BLOCKING COMPETITION: 39		YEARS BLOCKING COMPETITION: 47		YEARS BLOCKING COMPETITION: 40		YEARS BLOCKING COMPETITION: 39
	ON THE U.S. MARKET SINCE: 2002		ON THE U.S. MARKET SINCE: 1997		ON THE U.S. MARKET SINCE: 2005		ON THE U.S. MARKET SINCE: 1998

Source: www.i-mak.org August 2018

Industry Spending to Thwart Change

- **Pharma Lobby Power -2020**

- Federal (all companies and trade assn spending) \$161.5M
- State (total all companies and trade assns.) ~\$5M

Source: [OpenSecrets.org](https://www.opensecrets.org)

- **Pharma funds disease groups/patient advocacy groups which align with key industry coverage/payment policy views**

- \$680M to patient groups in 2018 – **by just 6 companies**

Source: Fierce Pharma 10/9/2019

Lots of Room for Lower US Prices & *continued* R&D

- Top pharma companies spent \$56B more on stock buybacks and dividends than they spent on R&D in last 5 years (US House Govt Oversight Comm 7/2021)
- Pharma return on investment is \$14:1 for cancer drugs (WHO 2018)
- R&D of \$7.2B for 10 cancer drugs, revenue of \$67B (JAMA 9/2017)
- US-based Rx companies earned 176% of their *worldwide* R&D budget from just the portion of US prices that are above the prices charged in other countries (Health Affairs Blog 3/2017)
- Large pharmaceutical manufacturers could absorb an 11% profit reduction and still have a more effective return on capital compared to other industries (West Health, 11/2019)

Rules of Thumb for Market Change

- **Price has to be transparent**
 - On-invoice discounts and prices – minimize rebates
 - Lower price/cost must get to the pharmacy counter
 - If pharmacy is paying and billing high cost, system cannot really change
- **Focus on Affordability, Not Value**
 - Every drug is valuable, if not invaluable, to the patient for whom it is intended
 - Every invaluable drug is not affordable
 - Affordable pricing expands access, value-based pricing likely will not.

Thank You!

Drugs Don't Work if People Can't Afford Them

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Testimony of Jane Horvath

Before the Pennsylvania House Democratic Policy Committee

Prescription Drug Market Dynamics and the Need for Public Policy

July 12, 2021

Thank you, Madam Chair and Members of the Committee for the opportunity to testify on prescription drug cost containment policy. This is an important and complex issue that touches virtually all of us. We all need to understand more about the pharmaceutical marketplace to identify policies most able to help individual consumers.

I believe any state or federal policy to constrain prescription drug costs must think about 'affordability' for the consumer and the healthcare system. An effective policy will that helps consumers and the larger healthcare system, will need to accomplish the following:

- Create cost transparency and cost certainty for patients, purchasers, and payers.
- Move transparent lower costs through the supply chain to the consumer at the point of service.
- Reduce the need for rebates for drugs because a lower cost is moving through the supply chain.

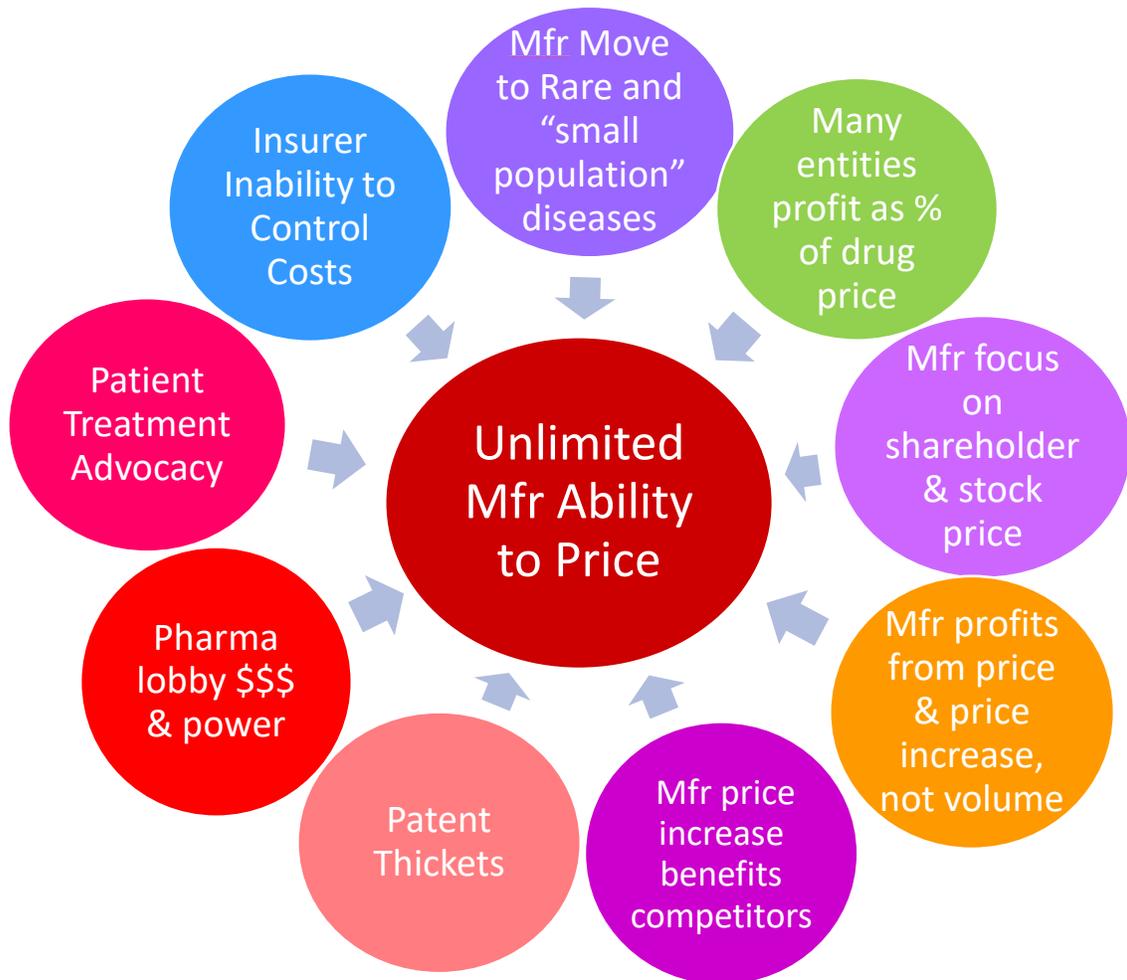
By way of background, I have worked with states on prescription drug costs for many years. I represented the Medicaid Directors when the Medicaid rebate program was created. I am supported by non-profit foundations to consult with state policymakers on prescription drug policy. I also spent more than ten years working in the pharmaceutical industry. I have deep respect for the work of the industry, but the business model is broken, and I do not see a path forward other than public policy to address the problems.

I want to start today with two facts today that can help in our understanding of high drug costs.

- 1) Outpatient retail prescription drugs were [10 percent](#) of total personal healthcare spending in 2019. Retail drug spending grew [5.7 percent in 2019](#) (\$370B); that growth trend is expected to continue for the next several years. What is alarming is that this analysis does not include costly biologics and gene therapies administered by healthcare professional rather than dispensed in pharmacies.
- 2) Also important is that net prescription drug costs consume 22 percent of our healthcare premiums,ⁱ exceeding the proportion of premium spent on inpatient hospital services.
- 3) State taxes support some or all the pharmacy benefits for as many as 25-30 percent of residents in many states.ⁱⁱ State governments and state residents have a large stake in constraining drug spending.

As the amazing biopharmaceutical science and technology rapidly evolve to produce meaningful products, society's inability to manage the costs of these products without significant trade-offs inside and outside of healthcare has grown even faster than the technology.

How We Got Here in Pharmaceutical Pricing



This graphic summarizes the component factors that create the situation we have today in biopharmaceutical pricing.

What follows are some key industry business strategies that we need to understand to create change.

I would like to briefly describe each of the components of the drug price/drug cost dilemma. Finally, I would like to make the case for government policy in ways that support continued treatment breakthroughs while assuring that people who need a drug can afford that drug. I think an optimal policy is a Prescription Drug Affordability Board.

Small Population Disease Treatments

The industry now favors a focus on conditions that afflict small populations. There are specific regulatory approval pathways to expedite approval for many of these drugs and manufacturers understand that it is more difficult for insurers to manage utilization and costs of new treatments that serve small groups of people with high unmet needs. Addressing unmet medical needs is very important, but there are pricing abuses associated with this trend... extraordinarily costly oncology products that provide small benefits over existing therapies and new million-dollar treatments for rare diseases, most of which do not have long term outcomes data. We accept costly products that treat a small group of people as justifiable, but the challenge for us is that, taken together, about 15 percent of the US population has rare and other small-population conditions that will be treated with very high-cost products.ⁱⁱⁱ

“[SANOFI CEO] HUDSON SAID HE EXPECTS SALES OF SANOFI’S VACCINES BUSINESS TO GROW AT MID-TO-HIGH SINGLE DIGITS. IT [THE COMPANY] WILL FOCUS ON ONCOLOGY, HEMATOLOGY, RARE DISEASE, NEUROLOGY, AND THE CHINESE MARKET, WHERE SANOFI HAS BEEN STRONG. IT WILL GIVE TOP PRIORITY TO SIX EXPERIMENTAL DRUGS, INCLUDING TWO FOR HEMOPHILIA AND SINGLE ENTRANTS IN RARE DISEASE, CANCER, INFECTION, AND MULTIPLE SCLEROSIS. THAT TRANSITION WILL COME AT A COST. SANOFI WAS BUILT ON PLAVIX, ONE OF THE BEST-SELLING HEART DRUGS EVER. IT CURRENTLY SELLS LANTUS, A LONG-ACTING INSULIN THAT WAS THE BEST-SELLING INSULIN IN THE WORLD. BUT SANOFI WILL EXIT RESEARCH IN DIABETES AND CARDIOVASCULAR DISEASE, FINISHING STUDIES ON A MAJOR DIABETES MEDICINE IT IS DEVELOPING WITHOUT PLANS TO BRING IT TO MARKET.” STAT NEWS 12/9/2019

Who Benefits from High Drug Prices?

- Manufacturers – establish the list price/wholesale price
- Wholesalers – attach small markup to large product sales volumes
- Research Centers/Universities – conduct bench science to develop promising molecules (often with federal funding) that they patent, and then lease or sell rights to manufacturers who commercialize the molecule. Royalties can be based revenue, which is based on price.
- Pharmacy Benefit Managers – obtain rebates (some of which is shared with insurer clients). Rebate revenue increases as prices increase. (PBMs do not finance pharmacy reimbursement, they pay pharmacies, but the insurer reimburses the PBMs for that pharmacy payment.)
- 340B Entities (safety net providers and others) – buy low prices drugs through the federal 340B program and ‘sell high’ when charging insurers market rates for dispensed drugs.
- Pharmacies – chain pharmacies that can purchase large volumes acting as their own distributors.
- Physician Specialists –depending on the specialty and the insurer reimbursement formula.

Who Does Not Benefit from High Drug Prices?

- Patients – Cost sharing for insured patients is based on the market price. Uninsured also pay market prices.
- Insurers -- High patient out of pocket costs are a symptom of the problem, not the problem. Rebates offset the high cost of drugs, but higher prices with higher rebates does not make the net expense more affordable.
- Government Health Programs – state employee benefits, corrections, even Medicaid which benefits from rebates but still reimburses pharmacies and other providers at high market rates.

Industry Focus on Stock Price

The industry is laser focused on maintaining and increasing their stock price. This has lots of ramifications for society and patients. Industry CEO and C-suite leadership compensation is tied to stock price; stock grants are a significant part of executive compensation. Most recently, a [Congressional report](#) found that among 14 large drug companies, spending on stock buybacks and dividend payouts exceeded spending on research and development by \$56B. Stock buybacks reduce the number of shareholders and raise the value of each stock unit – growing executive compensation. The report expects that companies will spend \$1.5 trillion on buybacks and dividends in the next decade. Additionally, Wall Street seems to value high unit prices more than low prices, and rewards price increases more than strong sales.

Business Model Based on Price and Price Increases, Not Sales Volume

A 2018 BCBS Intelligence Report found that among enrollees, utilization of brand drugs *declined* annually by 6% while net spending on brand products *increased* annually at 10% due to average brand drug price increases of 17%. More recently, the medical journal, [Neurology](#), found that Medicare spending for neurological conditions grew 50% between 2013 and 2017 but the number of prescriptions grew only 8%. There is a growing body of literature about this phenomenon, including most recently a congressional report that found that Teva and Celgene repeatedly raised prices to hit revenue targets and meet Wall Street expectations – representative of an industry that relies on high prices and price hikes to produce revenues. The old business model was to *sell* more drugs, which meant that prices had to be reasonable to hit sales targets. It used to be that increasing sales produced the revenue. Today, prices and price increases produce the revenues even at the expense of reduced sales.

The PBM business model, hospital business models, and chain pharmacy business models reinforce the incentive for high prices. The recent US Senate Finance Committee [investigation](#) into insulin pricing highlights the variety of misaligned incentives that benefit the participants in the pharmaceutical market but undeniably harm patients.

Other recent [congressional studies and hearings](#) found high prices and price increases can thwart development of biosimilars and that company revenues are not substantially dedicated to R&D. The reports present evidence that high prices of the first biologic product can make it uneconomical to create a lower cost biosimilar; clinical studies needed for licensing require the use of the original costly product which can mean the biosimilar may not be priced much lower than the original.

Manufacturer Price Increases Benefit Competitors

Does competition equal lower prices? MS drugs defied cost logic as challengers swarmed in

Once only a small group of competitors, the field for multiple sclerosis (MS) therapies has exploded in recent years: By 2016, the number of approved drugs had nearly tripled in just seven years. That's speedy growth, but something else grew faster—those drugs' list prices. The average price of self-administered disease-modifying therapies for MS quadrupled between 2006 and 2016 as a rush of competitors flooded the market, according to a new study published in JAMA Neurology. by [Kyle Blankenship Fierce Pharma](#)

Aug 29, 2019, 5:56pm

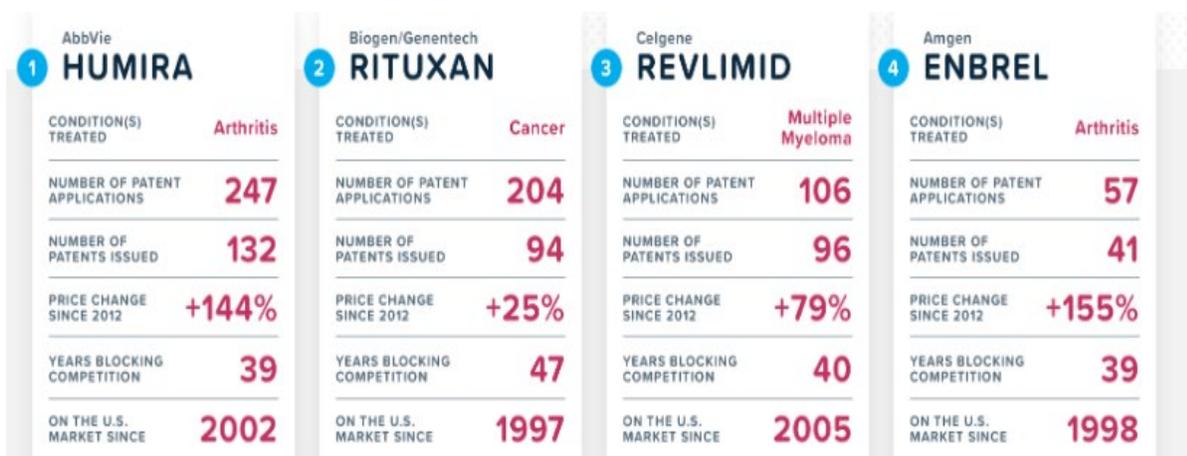
Manufacturers shadow price each other as a recent [congressional study found](#). This shadow pricing practice has been obvious for years and is legal. The first company in a therapeutic class to announce its price increase is followed by therapeutic competitors announcing similar price increases. It is not price competition. Also, price increases of an in-market product provide benefits to the competitor company with a similar product in development as this simple graphic shows.

Patented Innovator Drug	\$\$\$ Launch Price	\$\$\$\$ Price Increase	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Patented Therapeutic Competitor		\$\$\$\$ Launch Price	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Generic #1					\$\$\$\$\$ Launch Price	\$\$\$\$\$\$ Price Increase	\$\$ Price <u>Decrease</u>
Generics #2 & 3							\$\$ Launch Price

Patent Abuse/Patent Thickets Delay Product and Price Competition

When a company returns to the US Patent Office again and again for new patents on an existing product, this “evergreening” extends the monopoly position of a drug and bars market entry of competitors. Humira is a prime example of this practice. Humira is widely used for a host of autoimmune disorders and had annual revenues of \$19.73 billion at an annual cost of \$72,000 in 2019. It has 39 years of patent protection. A product generally has 7 to 10 years of patent protection when it comes to market.

The chart below shows some of the more notorious patent extensions. These are legal but most people agree that the patent system is not intended to provide decades of product monopoly and unfettered price and price increases.



Source: I-Mak August 2018

Industry Lobby Power, Federal and State

The amount the industry spends to lobby federal and state legislators is legendary.

[OpenSecrets](#) tracks federal lobbying money for many industries. They show that industry spent \$161M in lobbying 2020. A recent analysis conducted by STATNews, and National Institute for Money in Politics found that the industry gave over \$5 million to almost 2000 state legislators in two years ending September 2020 (STAT 10/15/2020).

The industry also gives to federal and state candidates and political party committees. The industry is reported to outspend all other industries in most years.

Patient Treatment Advocacy

The [Kaiser Family Foundation](#) has a database of industry giving and patient group reporting for 2015. They tracked industry funding of \$163 million to 650 patient groups. Some groups report the funding on their websites, others do not. Nevada has a law that requires patient advocacy groups to report industry funding.

Insurer Inability to Keep Pace with Industry Business Model Shifts

Insurers and other health benefit programs face a growing challenge of managing prescription drug costs, particularly small insurers such as state employee benefit plans and small group insurers. Insurers know that high patient cost sharing is not optimal for health outcomes but the tools by which to manage the cost of prescription drugs (retail and physician administered) are increasingly insufficient to the task. Insurers must balance keeping premiums affordable for everyone and providing access to new costly treatments for individuals. As mentioned at the beginning, pharmacy costs consume a significant portion of the premium dollar. The pharmaceutical pricing business model is a fast-growing threat to patient access.

Layers of Market Dysfunction

As pharmaceutical companies focused on Wall Street and raised prices to satisfy Wall Street, all sorts of [market dysfunctions](#) were created. It is difficult to catalogue and follow all the dysfunction. But the important point is that the dysfunction started with price maximization strategies of the pharmaceutical industry, which gave rise to the rebate strategy which then created new opportunities for other entities to profit from higher and higher prices. The complexity of rebates then created the need for PBM monitoring companies. High prices and high out of pocket costs resulted in the drug discount card industry. While large PBM, insurer, and drug companies can find ways to preserve their businesses, consumers and patients take more and more of the brunt of the dysfunction.

Conclusion

Today's prescription drug supply and financing systems are byzantine, intertwined, and harmful to consumers.

The pharmaceutical industry speaks about the value of their products. The reality is that any product is of high value to the patient for whom the product improves or extends life. But a valuable or invaluable product is not necessarily an affordable product for the individual or society. No other medical

intervention is priced at its intrinsic value to the individual patient. That is not a functional approach for any medical intervention, including drugs.

Instead of value, we should focus on *affordability* for individual patients and consumers rather than intrinsic patient value. Affordability for individuals is the most important but missing piece of the biopharmaceutical cost policy debate. Affordability should be assessed in the short term, not over decades since healthcare financing is not organized based on treatment effect over decades.

In my opinion, the solution for states is to regulate consumer costs – and do so in a way that gets a lower cost product through the supply chain to the point of service where that cost is the basis of pharmacy drug acquisition, the basis of what a patient pays out of pocket, and the basis for the amount an insurer reimburses.

The industry cannot fix itself at this point. The first mover in a new business model that creates affordability is likely to be punished by Wall Street. The industry cannot act collectively without violating important federal laws. Public policy is needed.

Multiple data driven analyses show that there is room in industry profits and current spending priorities for lower costs while still preserving incentives and financing for research and. Beyond the data, we should realize that a global research and development industry *must* innovate to stay in business. These global corporations continue to innovate and invest in R&D around the globe while successfully managing all different economic pressures and situations. Importantly, lower costs at the consumer level should result in higher utilization – more sales – rather than lost revenues.

ⁱ <https://www.ahip.org/your-health-care-dollar-new-ahip-analysis-shows-where-it-goes/>, accessed 3/15/21

ⁱⁱ The calculation would include State and local government employees and retirees, public school system employees and retirees, prison system employees, dependents, retirees; incarcerated individuals; higher education employees, dependents, and retirees; student clinics; Medicaid enrollees – all as a percentage of the total state population.

ⁱⁱⁱ Cancer – 1.7M people * COPD – 16M * Lupus – 1.5M * MS -- 1M * Epilepsy – 3M * Sickle Cell – 1M * Rare/orphan diseases– 30M



Center for State **Rx** Drug Pricing

*Testimony of the National Academy for State Health Policy
to the House Democratic Policy Committee,
Subcommittee on Progressive Policies for Working People:
How to Drive Down Drug Prices*

State Action on Prescription Drug Pricing July 12, 2021

Chairman Bizzarro, Representatives Kinkead and Pashinski, Members of the Committee,

I am Jennifer Reck, Project Director for the Center for State Prescription Drug Pricing at the National Academy for State Health Policy (NASHP) and I am joined by my colleague Drew Gattine, Senior Policy Fellow at NASHP, former Maine State Representative and Assistant Attorney General. Thank you for inviting us here today to speak on state action on prescription drug pricing.

NASHP is a non-partisan forum of state policy makers that works to develop and promote innovative health care policy solutions at the state level. NASHP believes that when it comes to health care, states are a tremendous source of innovative ideas and solutions. We approach our work by engaging and convening state leaders to identify and solve problems. We conduct policy analysis and research and provide technical assistance to states.

In 2017 NASHP created its Center for Drug Pricing to focus attention on steps that states can take to tackle the spiraling costs of prescription drugs and the impact it has on consumers, the overall cost of health care and state budgets. NASHP's Center for Drug Pricing develops legislative and administrative models for states and provides technical assistance and support to legislators and executive branch leaders who wish to move them forward. When these bills pass, NASHP continues to support states as they are implemented by convening cross-state work groups of implementing states. NASHP currently convenes such workgroups focused on transparency, Canadian importation, prescription drug affordability boards, and reverse auctions.

I'll start by sharing a brief overview of some of the major categories of [enacted state legislation](#) on drug pricing over the past five years and then turn things over to Drew Gattine who will share several newer legislative models NASHP released in the summer of 2020, that were introduced in a number of states in 2021.



STATE DRUG PRICING LAWS: 2017-2021

	2017	2018	2019	2020	2021*	Total	In # of states
Number of states	13	28	37	17	18	48	
Total Laws Enacted	17	45	62	41	38	203	
PBM	7	32	32	20	16	107	45
Transparency	3	4	7	4	6	24	17
Coupons/Cost Sharing**	1	0	4	12	7	24	18
Wholesale Importation	0	1	4	2	1	8	6
Affordability Review	1	0	3	0	2	6	6
Study	0	1	5	1	2	9	7
Volume Purchasing	0	0	2	0	0	2	2
Other	5	7	5	2	4	23	17

*As of July 1, 2021

**There are 18 states with cost sharing caps for insulin.

PBMs

The first and most common area for state legislative action on prescription drugs relates to regulating prescription benefit managers, or PBMs, the middlemen who handle pharmacy claims for plans and negotiate rebates from drug manufacturers, using formulary placement as leverage. PBMs have evolved into a highly vertically and horizontally consolidated marketplace dominated by three big players (CVS Health, ExpressScripts, and OptumRx) and until recently operated without very limited oversight until the last five years when 45 states passed more than 100 laws directed at PBM business practices.

States laws addressing PBMs have come in several waves:

- The first wave included laws with provisions to establish state licensure for PBMs and to extend protections to consumers to limit their costs at the pharmacy counter by banning gag clauses and limiting patient cost-sharing – including a 2020 Pennsylvania law to that effect.
- The second wave extended protections to ensure adequate reimbursement to pharmacies and increased transparency around the extent that PBMs keep or pass through the rebates they negotiate with manufacturers and also prohibiting spread pricing whereby a PBM pays a pharmacy less than it claims from the payer and keeps the difference, or spread, in profit. A 2020 Pennsylvania law prohibited spread pricing by PBMs serving Medicaid MCOs.
- A third and current wave of PBM legislation is taking place now following the December 2020 Supreme Court ruling in *Rutledge vs. PCMA* which established that state regulation of PBMs is not preempted by the Employee Retirement and Income Security Act (ERISA). In other words, this ruling made clear that states can regulate PBMs for both fully



Center for State **Rx** Drug Pricing

insured and self-insured plans as “a form of cost regulation that does not dictate plan choices” and is therefore not preempted by ERISA. In response to this ruling, several states pass laws in 2021 explicitly applying existing PBM regulations to self-funded plans.

Several states have also passed laws enabling reverse auctions for procuring a PBM contract for state employee health plans. Reverse auctions force PBMs to compete each other across multiple rounds of bidding to offer the lowest bid for a contract for a pre-determined set of services. The process enables a state to compare bids across PBMs on an apples-to-apples basis and to secure the lowest qualifying offer. First implemented in New Jersey where it was associated with significant savings compared to their previous contracts, reverse auction laws have since passed in Maryland, New Hampshire, Louisiana, and Colorado.

TRANSPARENCY

The second most active area of state legislation addresses drug price transparency. Seventeen states have passed 24 laws in this area. These laws typically establish a threshold for price increases or launch prices and, if a drug exceeds the thresholds, require manufacturers to report information explaining the prices. NASHP released model legislation in 2019 that extended reporting across the supply chain to include PBMs and wholesalers and offered a set of common data elements to create alignment and to minimize reporting burden across states.

There is some evidence that shining a light on rapid drug price increases helped moderate the extent of those increases over the past few years, as fewer drugs are hitting the reporting thresholds as reported on by states like Vermont and Oregon. High drug launch prices however remain a persistent problem.

PATIENT COST-SHARING / OUT-OF-POCKET CAPS

Another very active area of legislation aims to minimize out-of-pocket spending on drugs, particularly for essential medications such as insulin. There are currently 18 states with laws to establish an out-of-pocket spending cap for insulin. Three of those states, Minnesota, Maine, and Colorado extend out-of-pocket spending limits to ensure emergency access to the uninsured as well. Though out-of-pocket limits do not have the ability to lower the overall costs of drugs, they are effective strategies to help ensure access in the short-term while longer-term solutions are realized.

WHOLESALE IMPORTATION FROM CANADA

In response to the large (200%) gap in drug prices between Canada and the US, many states have explored bills to establish wholesale importation programs from Canada and six states have passed laws to do so with Colorado and Florida being the furthest along with implementation.



Center for State **Rx** Drug Pricing

The federal rule enabling importation – which requires states to establish programs with the ability to deliver safe, cost-saving drugs to consumers, was published in October of 2020. PhRMA has filed a legal challenge against the rule. The Biden administration's response to the complaint argued that PhRMA lacks standing because no state importation program has yet received federal approval and, in the meantime, PhRMA has filed an amended complaint.

Though the savings from Canadian drugs are large, and several states are committed to pursuing them through importation, the federal, regulatory, and international challenges make importation a challenging strategy for states to pursue. To that end, NASHP has also developed model legislation that allows states to import Canadian prices rather than the drug themselves, which you'll hear more about in a moment from my colleague Drew Gattine.

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

A final active area of drug price legislation are prescription drug affordability (PDAB) boards. These boards are tasked with reviewing drugs with high launch prices or high price increases and determining an appropriate, affordable rate for payers within a state. Maryland was the first in nation to pass a PDAB in 2019 and has a legislative process to phase in setting upper payment limits, starting with public purchasers only, pending approval by the state legislature. Maryland was followed by Colorado this session. The Colorado PDAB has existing authority to set upper limits across payers within the states.

States have taken [a range of approaches to PDABs](#). For example, though Maine and New Hampshire also have PDABs, their authority is quite different from the boards in Maryland and Colorado. The Maine and New Hampshire PDAB model does not include setting upper payment limits, but instead focuses on leveraging public purchasing power in order to meet prescription drug spending targets to be established by the boards.

NEW LEGISLATIVE MODELS

In August of 2020, at our annual national conference, NASHP introduced a second generation of model bills. These bills were designed to take what states had learned in the important work around transparency, importation, and affordability and apply those principles in a more direct and immediate way. Although the mechanics of these bills are very different in their operational approach, they are all similar in that:

- They are designed to have a direct and immediate impact on prices by either prohibiting or penalizing price increases or requiring prices to be lowered.
- They are focused squarely on the behavior of manufacturers – who have the ability to raise prices simply because they can. These bills are designed to deter that behavior.



Center for State **Rx** Drug Pricing

- They have broad impact both for government and private payers. To the extent that government programs benefit from these, they will either create savings or generate revenue.
- They were designed so they could be implemented without a great expenditure of state resource. NASHP understands that in some states creating new government programs can be politically difficult and slow in terms of implementation
- By design, the revenue and savings they generate are intended to benefit consumers.

1. An Act to Reduce Prescription Drug Costs Using International Pricing

Compared to citizens of other countries, Americans pay a lot more for prescription drugs and the rising cost of prescription drugs is a huge driver in the overall annual increase in health care costs that Americans experience routinely. Other countries spend less for the same drugs because those countries set rates for prescription drugs. In the United States, rate setting is the norm for many health care services. Public programs like Medicaid or Medicare, and commercial payers routinely negotiate rates or set them via a transparent administrative process. But when it comes to prescription drugs, the United States has a very complicated payment and distribution system that begins with prices set by drug manufacturers.

Some states with the ability to implement drug affordability review boards will set upper payment limits to establish appropriate, affordable rates under the board's direction, however, the process is complicated and requires up-front investment. Some states don't have the infrastructure to do this analytical work. Fortunately, other countries are already doing it and the results of that work are readily and publicly available for states to use.

This bill directs a state to compile a list of the costliest drugs, defined as price times utilization, using a list from the state employee health insurance plan, as the benchmark. This list is then compared to publicly available information from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) and directs that the lowest price becomes the reference rate for payers. The bill applies to state entities other than Medicaid, commercial payers and ERISA plans that chose to participate. (Medicaid was excluded in acknowledgement of the unique design of the Medicaid pharmacy benefit that requires states to cover all drugs in exchange for substantial rebates. Including Medicaid would require up-front agreement by the federal government through either a waiver of state plan amendment.)

Referencing a state's rates to Canadian rates should lead to significant savings to the state and to commercial payers. The chart below, using national data, demonstrates the magnitude of the possible savings:



Center for State **Rx** Drug Pricing

Drug Name & Dosage Source: National Average Drug Acquisition Cost (NADAC) data	US Price (NADAC)	Canadian Reference Rate*	Price Difference	Savings off US Prices
Humira syringe (40 mg/0.8 ml) (arthritis, psoriasis, Crohn's)	\$2,706.38	\$541.29	\$2,165.09	80%
1 ml of Enbrel (50 mg/ml syringe) (arthritis, psoriasis, Crohn's)	\$1,353.94	\$272.28	\$1,081.66	80%
1 ml of Stelara (90 mg/1 ml syringe) (arthritis, psoriasis, Crohn's)	\$21,331.28	\$3,267.64	\$18,063.64	85%
1 ml of Victoza (2-pak of 18 mg/3 ml pen)* (diabetes)	\$103.44	\$17.30	\$86.14	83%
Truvada tablet (200 mg/300 mg) (PrEP for HIV)	\$59.71	\$19.78	\$39.93	67%
Xeljanz tablet (5 mg) (rheumatoid arthritis)	\$76.07	\$17.50	\$58.57	77%
Eplcusa tablet (400 mg/100 mg) (hepatitis C)	\$869.05	\$541.32	\$327.73	38%
Zytiga tablet (250 mg) (cancer)	\$87.63	21.47	\$66.16	75%

This bill has been introduced in six states this session. (It was also introduced in late 2020 in Pennsylvania but was not acted upon when the session ended.) In one state where this bill was introduced, the legislature’s [fiscal office estimated](#) that referencing to the Canadian rate could generate upwards of \$50 million in annual savings for the state employee plan alone looking at just the top 20 drugs. In another, NASHP worked with the state to estimate that applying referencing to just the top 23 drugs would save the state employee health plan \$22 million.

The potential value to a state’s residents would be the reduction of the cost of prescription drugs and the requirement that any savings, achieved either by health plans or by state payers, be used to benefit consumers. The bill requires that any savings generated by implementing the reference rates, whether generated by state entities or commercial health plans, be used to reduce consumer health care costs. Lowering the cost of life-saving drugs like Humira – which costs \$2,706 a syringe in the US versus as little as \$541 in Canada – will increase the ability of people who rely on that drug to have better access.

Pharmacy manufacturers, who continue to make profits in Canada and in other countries with lower prices than the US, will still be left with the necessary revenue to invest in research and development and bring new, innovative, drugs to market. The profits that pharmaceutical manufacturers make in the US by charging more to Americans than they do to the citizens of other countries far exceeds their entire global R&D budget. (This does not even account for the billions of direct government support that pharmacy R&D receives from the National Institute of Health.)

2. An Act to Protect Consumers from Unsupported Price Increases on Prescription Drugs

The dramatic annual increases in the price of prescription drugs are a significant driver in the unsustainable cost of health care for Americans. Sometimes price increases can arguably be justified by changes in the market, or an increase in the cost of production or by a reassessment of the clinical value of the product. In many cases, however, they are not. Often drug



Center for State **Rx** Drug Pricing

companies raise their prices on life-sustaining products simply because they can and because they know that in a market that does not effectively regulate price they can increase prices at a rate that far exceeds inflation.

NASHP knows that states are interested in tackling this problem. As my colleague Jennifer Reck noted, states with transparency laws on the books have been tracking and gaining a better understanding of drug price increases. This model bill builds on that foundation by taking the next step in enabling states to take action against manufacturers hiking prices without justification. The annual report prepared by the Institute for Clinical and Economic Research (ICER) represents a credible, unbiased, well informed, freely available basis for this action.

Each year ICER undertakes an assessment of a small number of high-cost drugs that have increased their price far beyond the rate of inflation. ICER then conducts a thorough review of available evidence to determine whether there is any clinical evidence to support those sharp price increases. This process is entirely transparent and documented and manufacturers of the products are invited to participate. ICER's complete methodology is published and available online. https://icer.org/wp-content/uploads/2020/10/UPI_Revised_Protocol_20200715.pdf

ICER's process also allows interested parties, like states, to nominate drugs for review. For ICER's most recent report, several states, in an effort coordinated by NASHP, nominated Enbrel which ICER determined was the number one drug last year contributing the most to excess spending due to an unsupported price increase.

Once ICER's review is completed it publishes a detailed report documenting the drugs that it has determined have had large price increases without any justifying clinical evidence. In its most recent report ICER identified seven drugs that accounted for \$1.2 billion in additional US drug spending. Over the past three years, the ICER report has identified over \$6 billion in price increases that are not justified based on just 12 high priced drugs.



Treatment	Primary Uses	2018-19 WAC Increase	2018-19 Net Price Increase*	Increase in US Drug Spending Due to Net Price Change (in Millions)
Enbrel® (etanercept, Amgen)	Arthritis, psoriasis	5.4%	8.9%	\$403
Invega Sustenna®/ Invega Trinza® (paliperidone palmitate, Janssen)	Schizophrenia	6.8%	10.7%	\$203
Xifaxan® (rifaximin, Salix)	E. coli	8.4%	13.3%	\$173
Orenzia® (abatacept, Bristol-Myers Squibb)	Rheumatoid arthritis	6.0%	7.4%	\$145
Tecfidera® (dimethyl fumarate, Biogen)	Multiple sclerosis	6.0%	3.7%	\$118
Humira® (adalimumab, AbbVie)	Chron's disease, ulcerative colitis, rheumatoid arthritis	6.2%	2.0%	\$66
Vimpat® (lacosamide, UCB)	Epilepsy	7.0%	5.6%	\$58

A copy of the most recent ICER report is available at https://icer.org/wp-content/uploads/2020/11/ICER_UPI_2020_Report_011221.pdf.

ICER’s methodology for identifying unsupported price increases does not involve the use of cost-effectiveness research or the use of Quality-Adjusted Life Years (QALYs).

The bill directs a state to look at the ICER report as a guide. It puts the manufacturers of a small number of high-priced drugs on notice that if they raise their price above the rate of inflation without new clinical evidence justifying those price increases, they will be penalized. The bill sets the penalty at 80% of the revenue from the drug above the base price plus inflation. Manufacturers are required to report each year of the sales volume and pricing per unit so the state can determine the penalty.

The bill requires revenues be deposited into a dedicated account to be used by the state to offset the costs to consumers.

3. An Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs

While the unsupported price increase model described above focuses on a small number of high-cost drugs, including brand name drugs, price increases have a significant impact in the generic market also.



Center for State **Rx** Drug Pricing

There are a number of examples spikes in the prices of generic drugs, some of them notorious. We all remember the outcry in 2015 when Turing Pharmaceuticals raised the price of Daraprim from \$13.50 to \$750 per pill. But this isn't the only egregious example:

- In January 2019 Fluoxetine, a generic version of the antidepressant Prozac, jumped from \$9 per bottle to \$69, an increase of \$60 or 667 percent;
- In February 2019 Guanfacine, a generic treatment for high blood pressure and ADHD, jumped from \$29 to \$87 per bottle, an increase of \$58 or 204 percent; and
- In April 2019 Azacitidine, a generic version of the chemotherapy drug Vidaza, jumped from \$105 to \$210 per vial, an increase of \$105 or 100 percent.

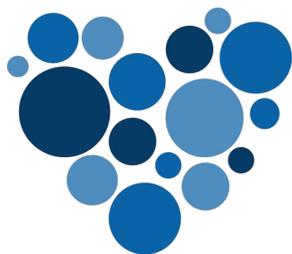
This model would make these and similar examples of price gouging illegal. Specifically, generic or off-patent drugs with price increases over 15% in a year, or over 40% in three years, would be referred to the state Attorney General for investigation. If found to have engaged in price-gouging, a company would have to roll back the inflated prices and pay back their profits from price gouging – either directly to consumers when possible, or to the state for consumer relief.

As you may be aware, a previous price-gouging bill enacted in Maryland was struck down by the Fourth Circuit. When NASHP created the model act, it worked with a team of legal experts (including a former Maryland Assistant Attorney General who worked on the original case) to address the specific points of law raised by the court. To that end, this bill includes language making it clear that it applies to in-state transactions only, in order to avoid violations of the dormant commerce clause. It also requires drug wholesalers to maintain a registered agent in-state. It is also designed to be very specific in scope to avoid any challenge based on vagueness. It is designed to apply only to generic and off-brand drugs in order to avoid any possible argument that the limit on price increases infringes the owner of any patents.

As the Committee explores options for addressing high prescription drug prices in Pennsylvania, NASHP is available to support your work. Prior to drafting its latest round of model legislation, NASHP engaged with a team of legal experts so that possible legal challenges were understood and accounted for. NASHP understands that efforts by states to protect their citizens by curbing pharmacy costs will be opposed by manufacturers and their allies. In order to support the work of states, NASHP has made our [legal analysis](#) available on our website. The NASHP website also contains other [materials](#) (model legislation, written Q&A, blog articles, etc.) that may be useful material for the Committee. Thank you.

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Blueberry
pharmacy

The Blueberry Pharmacy Story

*Potential solutions to save Pennsylvanians
money on prescriptions*

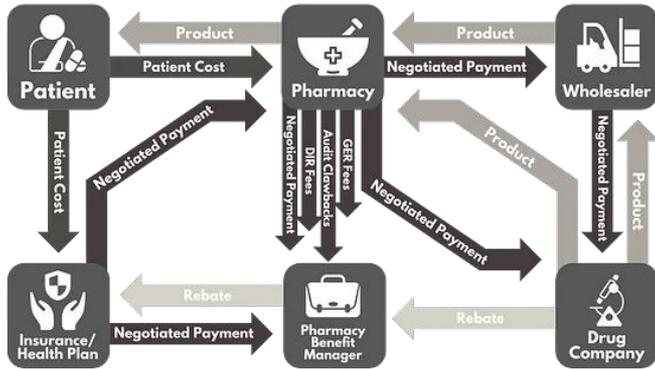
2 out of 4

pharmacies I've worked at
have closed





Traditional Model



Our Model



HOW WE PRICE DRUGS



+ \$3.00 dispensing fee + \$10.00 dispensing fee

=

\$18.06

Member Price

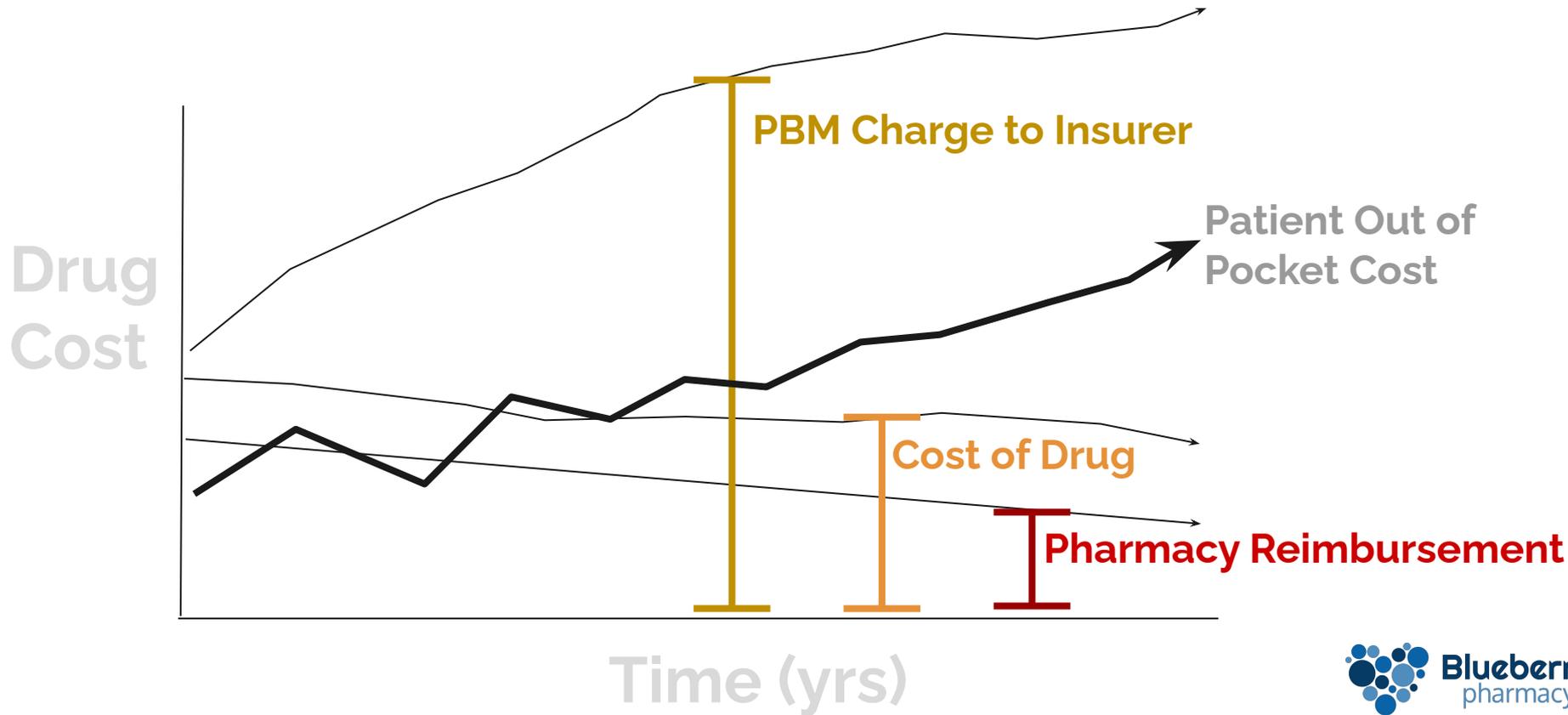
\$25.06

Non-Member Price

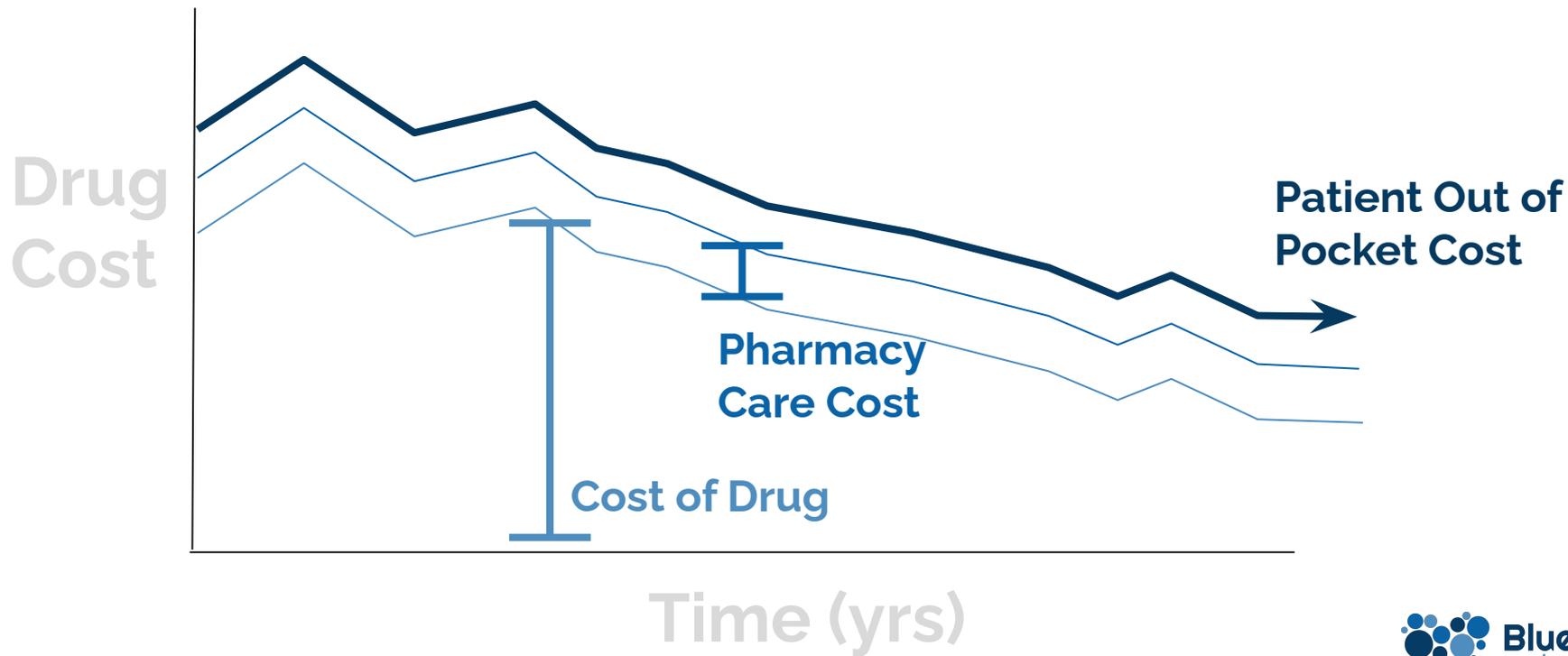


*Based on 30 tablets purchased on 4/9/2021. Manufacturer Aurobindo. Includes 5% markup for shelf-life costs, credit card fees, etc. Actual price may vary based on acquisition cost, manufacturer, etc

RISING DRUG COST - Greedy profits without patient value

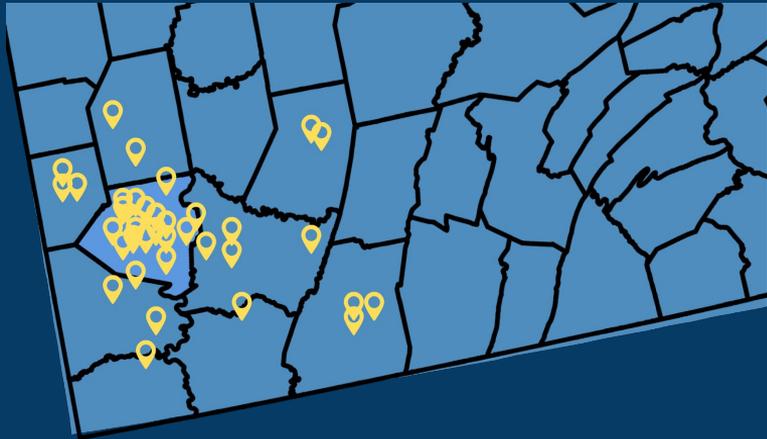


COST-PLUS MODEL - transparency for all stakeholders





1000+ patients



\$150,000+
estimated yearly
savings

Testimony Before the House Democratic Policy Committee

Cost of Prescription Drugs

Kyle McCormick, Blueberry Pharmacy
July 12, 2021

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Introduction

My name is Kyle McCormick. I entered practice as a pharmacist at an independent pharmacy 7 years ago and recently ventured into ownership, opening Blueberry Pharmacy in March 2020.

First, I appreciate the Committee's focus on prescription pricing for Pennsylvania's residents, a topic that drives my daily work. Thank you also for inviting me to share solutions we have implemented over the last year in West View, a small borough north of Pittsburgh. We have directly saved patients and residents over \$150,000 in actual costs.

Hoping to provide context and background to Blueberry Pharmacy's unique model, I will begin with my story.

Background

I started in pharmacy as an intern at Findley's Pharmacy in Somerset, PA. In college, I worked at University Pharmacy at Pitt. Upon graduation with my Doctor of Pharmacy degree in 2014, I completed a residency with Gatti Pharmacy in Indiana, PA, and stayed on as the director of



patient care. While at Gatti Pharmacy, I also worked part time at Hometown Apothecary in New Brighton, PA. As you can tell, I gravitate towards independent pharmacy - our services allow us to focus more on the health and well-being of patients and the community, and provide greater quality care than the average chain or mail order pharmacy. However, despite this, independents have been shutting down: in 2019, Hometown Apothecary closed along with two others in Beaver County. In 2020, Gatti Pharmacy shut its doors, along with two more in Indiana County. An analysis, published in the Journal of the American Medical Association (JAMA), of pharmacy closures from 2009 to 2015 found that independent pharmacy closures were more likely than their counterparts. The analysis also showed pharmacies serving disproportionately low-income, uninsured, and publicly insured at greater risk of closure.¹

You might think the pandemic caused these closures, or declining business and lower customer volume. But in fact, Gatti Pharmacy had increased script count and services in the last few years - 9.8% year over year volume growth in 2018 and 6.9% in 2019. Rather, the reason for closure was because 80% of prescriptions were reimbursed by insurance companies below the cost to dispense. The nationwide average cost to dispense is \$10.93 per prescription² - meaning 4,162 of the 5,203 prescriptions dispensed each month lost the pharmacy money. Sometimes, if losses were excessive, we told patients we were unable to get the medications, and they needed to go elsewhere. In addition to the direct loss of prescriptions being reimbursed below acquisition cost, there were indirect losses. Direct and indirect remuneration (DIR), generic effective rate (GER), and brand effective rate (BER) fees are all fees that are imposed by Pharmacy Benefit Managers (PBMs) up to 6 months after adjudication and make a pharmacy's financial projections and existence a nightmare and a threat, respectively. These fees totaled \$90,000 for Gatti Pharmacy in 2019, double what they were in 2018. Between 2010 and 2019, DIR fees increased by 91,500% according to fiscal year 2022 budget justification sent to congress by Centers for Medicaid and Medicare Services (CMS).³ For context, that exceeds inflation levels seen in housing, education, and macro-level healthcare.

At the same time that PBMs were underpaying the pharmacy and charging excessive fees, we had a patient whose Medicare copay rang up at \$300+/mo for solifenacin (generic Vesicare®) 5mg, which cost the pharmacy approximately \$5 to acquire at the time. At Blueberry Pharmacy, she would have paid just \$6.51 for 30 days - a price irrespective of her employer, income, zip code, age, or insurance. Her experience was not unique; countless patients were, and still are, being overcharged by insurances on generic medications.

Origins of Blueberry Pharmacy

With so many closures and rampant under-reimbursement, why would any sane person open a pharmacy? If patients are being price gouged by insurance copays, yet the pharmacy is losing

¹ Jenny S. Guadamuz, M. S. (2020, January 1). *Assessment of Pharmacy Closures in the United States From 2009 Through 2015*. JAMA Internal Medicine. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2753258>.

² Michos, L. (n.d.). *2020 NCPA Digest*. <https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf>.

³ It's not a Typo: 91,500% Increase in Fees Heaped on Pharmacies. (2021, June 3).

<https://ncpa.g/newsroom/news-releases/2021/06/03/its-not-typo-91500-increase-fees-heaped-pharmacies>.

money, I figured I would just cut out middlemen and sell directly to patients at fair, transparent prices.



Blueberry Pharmacy is, to our knowledge, America’s first and only insurance-free, cost-plus community pharmacy. Our model is simple: patients pay what we pay plus a professional fee. In communicating the model to patients and prescribers, we liken it to car insurance; do you send your gas bill to your insurance company? What about a small dent? No. Why? Because you know it will raise your premiums or that your plan includes a deductible, so you bear the full cost of that minor repair anyhow. What is insurance typically used for? High cost, unknown events such as death, car accidents, significant home repairs, etc. Daily medications to control blood pressure that cost \$0.02 per pill hardly fit the description.

Generic prescription medications are more similar to gas for cars and dents than one might think.

Our Pricing Model

Generic drugs have been in a deflationary period for decades, as prices decline predictably once a drug goes generic.⁴ Additionally, 89% of all prescriptions filled are for generic medications.⁵ For oral medications, Blueberry Pharmacy’s average acquisition cost is around \$0.12 per unit (i.e. tablet, capsule). With our cost-plus formula, which includes a \$3 or \$10 professional fee depending on whether a patient is



⁴ Cheers to the triumphant return of generic drug price deflation. 46 Brooklyn. (2021, July 2). <https://www.46brooklyn.com/news/july-2021-drug-pricing-report>.

⁵ The Generic Drug Supply Chain. Association for Accessible Medicines. (n.d.). <https://accessiblemeds.org/resources/blog/generic-drug-supply-chain>.

a member, that puts the average out-of-pocket cost at just \$6.79/30ct or \$13.79/30ct, respectively. That total is less than most prescription insurance copays and equivalent to two gallons of gas, harkening back to the previous analogy. Adding insurance and other middlemen to such a small transaction guarantees a cost increase.

A breakdown of our structure is as follows:

Non-member: Cost + \$10

Member: Cost + \$3

Membership: \$18 per quarter or \$60 per year

Traditional Pricing Model

A traditional pharmacy typically uses an archaic and opaque price, termed Usual and Customary (U&C). U&C is the amount they bill every insurance plan and even cash-paying patients (hence the need for an entire industry around coupons). U&C is commonly tied to the drug's Average Wholesale Price (AWP) in some fashion. AWP is a fictitious price set by the manufacturers and is in no way tied to actual wholesale prices.

Let's use imatinib 400mg, a cancer-fighting medication, as an example. Its AWP hovers around \$11,000/30ct. Amazon Pharmacy's list price (U&C) is \$8,300/30ct⁶; CVS - \$19,136; Walgreens - \$11,797, Rite Aid - \$10,190.⁷

Blueberry Pharmacy buys this drug for \$50/30ct and sells it to members for \$53.

Martin Shkreli famously took a drug that cost \$13.50/tablet and raised it to \$750/tablet (a 5,455% increase), gaining national scrutiny overnight.⁸ Assuming CVS buys imatinib at a similar price to Blueberry Pharmacy, that's a \$1.60/tablet cost to \$638/tablet markup (39,775%) - a percentage markup far exceeding Shkreli's. The unfortunate reality is that EVERY SINGLE pharmacy that uses an AWP-based U&C does this same thing, and on EVERY DRUG. **Their excuse:** most insurances don't actually reimburse at U&C.

⁶ *Imatinib Mesylate*. (n.d.).

https://pharmacy.amazon.com/Imatinib-Generic-Gleevec-Oral-Tablet/dp/B084BWHVPK?ref=sr_1_1&s=amazon-pharmacy&keywords=imatinib&qid=1625634681&sr=1-1.

⁷ *Imatinib Prices*. (n.d.). goodrx.com/imatinib.

⁸ Pollack, A. (2015, September 20). Drug Goes From \$13.50 a Tablet to \$750, Overnight. *The New York Times*. <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

Our Success Metrics

Direct Savings



\$150,000+
estimated yearly
savings



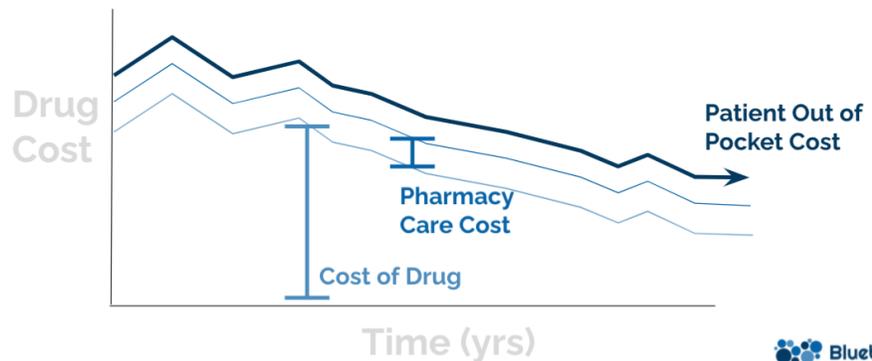
Through our transparent prices and cost consultation services, about 1000 patients have saved a combined \$150,000 in direct costs compared to what they would have otherwise paid through insurance or coupon services. One couple's experience spotlights Blueberry's difference best: a husband and wife were referred to Blueberry Pharmacy for the cost of their generic medication through their marketplace plan. The husband's nebulizer solution copay alone was over \$100 every 3 months. As members, we reduced their generic drug costs - the nebulizer solution is now just \$24 every 3 months. Upon helping with their generics, the wife asked about her insulin which was costing \$100 a month. I got on a 3-way call with her insurance to ask which tier each long-acting insulin belonged to. Through tier and coupon navigation, I was able to call her other pharmacy and have an alternative product adjudicated through at \$5 a month. She reacted to the news with, "Kyle, I've never had someone in healthcare care about me this much before." Three months later, her nurse practitioner called to ask what GLP-1 inhibitor should be added to further target her diabetes. We repeated the same process and got her started on a branded product at just \$10 a month. She followed up a month later to let us know she was down 10 pounds and her blood sugars were headed in the right direction. We weren't done though. Her husband brought up that he hadn't been using his maintenance COPD inhaler due to cost. We repeated the process for him, recommending a change to his pulmonologist that allowed him to get a better, branded product at a \$0 copay. He called 2 days after starting the new medication, simply stating, "I can breathe again." The direct savings on this medication - going from a \$50 a month copay to \$0 - are immediately measurable. What's not as easy, but likely far greater, is the indirect savings on the medical side (prevented hospitalization, improved quality of life, etc.) that resulted from a stage III COPD patient transitioning from non-compliance to compliance.

This is not a singular story; we've been able to help many patients with their brand name medications despite being a pharmacy that specializes in generics. One time, after helping an

uninsured patient get her insulin for \$35, the CVS pharmacist I worked with through the process actually stopped by the pharmacy to express her gratitude, saying, “I want to be able to help each patient at this level, but we just don’t have the time.”

Circling back to the deflation of generic drugs, when the cost of a generic goes down in the traditional system, the patient never benefits - insurance and PBMs do. Blueberry’s cost-plus passes those generic deflation savings on to the patient. Regularly, a patient will have a new, lower price the next time they pick up their prescription.

COST-PLUS MODEL - transparency for all stakeholders



Removing Bloat in the Healthcare System

When generic medications are competing on an open, transparent marketplace, the patient-pharmacist relationship is maintained. The entities disrupted are those adding to the current systemic bloat: Pharmacy Services Administrative Organizations (PSAOs), PBMs (which add nearly \$0.30 in cost to every dollar⁹), insurance carriers (who add cost through premium markups), claim-switch companies, insurance brokers, audit companies, and prescription coupon companies.

Take coupon companies as an example: the largest company in the space, GoodRx, generated \$550.7 million in revenue in 2020¹⁰, taking advantage of a broken pricing system.¹¹ If pharmacies just charge fair and transparent prices to begin with, that is \$550.7 million that could be returned to patients. In fact, prices at Blueberry Pharmacy average 33% below those on GoodRx.

⁹ The Truth About Pharmacy Benefit Managers: They Increase Costs and Restrict Patient Choice and Access. (n.d.). <https://static.spacecrafted.com/ac688f1c94a84b4f9ce116dfbfe818d2/r/bc34e7f27c5e4f59935d4e76f1714073/1/FINAL%20NCPA%20Response%20to%20PCMA%20ads.pdf>.

¹⁰ Hackett, M. (2021, March 12). *GoodRx closes first year as a public company in Q4 2020 earnings call*. MobiHealthNews.

<https://www.mobihealthnews.com/news/goodrx-closes-first-year-public-company-q4-2020-earnings-call>.

¹¹ Fein, A. J. (2020, August 31). *How GoodRx Profits from Our Broken Pharmacy Pricing System*. Drug Channels. <https://www.drugchannels.net/2020/08/how-goodrx-profits-from-our-broken.html>.

Realigning Incentives

In addition to saving patients money, we are able to realign incentives. The decreasing reimbursement due to all the factors discussed previously has forced traditional pharmacies to rely on increasing their volume. This subsequently creates a safety hazard as pharmacists are pressured to dispense increasingly more prescriptions in less time. If not increasing revenue through volume, traditional pharmacies are incentivized to recommend products that reimburse better. Blueberry Pharmacy is not volume driven nor per-product profit driven. Our main source of revenue comes from membership. Membership lowers our cost-plus professional fee to \$3.00, which is profit neutral - it only covers the cost of the time it takes to dispense that particular medication, as well as the prescription vial, lid, label, etc. Therefore, the pharmacy is incentivized to care for patients and retain members, not to fill unnecessary prescriptions. If discontinuing medication is best for a patient, it is best for Blueberry. In fact, our incentive is towards healthier patients, better care and customer service, and lower utilization of the system.

Solutions

Create Generic Marketplace with Fair and Transparent Pricing

Blueberry Pharmacy's progress to date displays early signs of larger-scale successes. We were recently featured nationally in Axios¹² thanks to a report by 46brooklyn¹³ outlining how states could save money by adopting Blueberry's cost-plus formula for generic Truvada® (emtricitabine/tenofovir), a medication that treats HIV. They summarize, "Even if we added a \$10 pharmacy dispensing fee on top of this new ingredient cost, it only brings up the all-in cost of the generic to \$8.4 million, a 97% savings off what Medicaid paid in 2020."¹⁴ Again, savings extend beyond bottom-line prescription costs, as lower consumer costs lead to better adherence and improvement in HIV.¹⁵

A research letter published in JAMA this month also suggests governments, taxpayers, and employers are overpaying for generic medications. Looking at the 184 most common generic medications, researchers found that Medicare overspent relative to the cash price of the medication 43% of the time on 30-day fills and 53% on 90-day supplies.¹⁶

With the growth of FSA/HSA plans, along with yet-developed tools to support a generic marketplace, patients will be able to drive down their own costs by directly purchasing fair and

¹² Herman, B. (2021, May 26). *Why drug-discount programs aren't always a good deal*. Axios. <https://www.axios.com/drug-prices-discount-programs-truvada-goodrx-daf50487-9607-4fb2-a84f-02b1fd7bc37a.html>.
¹³ Pachman, E. (2021, May 26). *Generic Truvada costs less than a dollar. Here's why you're likely paying much more*. 46brooklyn Research. <https://www.46brooklyn.com/news/2020/25/generic-truvada-launch>.
¹⁴ Pachman, E. (2021, July 2). *Cheers to the triumphant return of generic drug price deflation*. 46brooklyn Research. <https://www.46brooklyn.com/news/july-2021-drug-pricing-report>.
¹⁵ https://www.cdc.gov/mmwr/volumes/68/wr/mm6849a1.htm?s_cid=mm6849a1_w
¹⁶ Trish E, Gascue L, Ribero R, Van Nuys K, Joyce G. Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members. *JAMA Intern Med*. Published online July 06, 2021. doi:10.1001/jamainternmed.2021.3366

transparently priced generic medications. They will also be able to find services that best fit their needs and reward innovation in pharmacy models.

Prohibit Rebates with the Brand-name Drug Market

Rebate-driven formulary placements obfuscate the true price of the medication. Taking insulin as an example, it is estimated that the rebated price is actually 75% less. Removing rebates prevents middlemen organizations from taking a piece of the rebate instead of passing it on to the consumer. I am not the expert on this topic, so to dig deeper, I defer to the [research put out by 46Brooklyn](#)¹⁷ and [Drug Channels](#).¹⁸

PBM Oversight

Historically, PBMs existed to facilitate drug utilization review, formulary management, and claims processing. The need for PBMs arose out of a nascence or lack of technology and from an increasing rise in brand prescriptions coming to market. The industry has since largely outgrown these needs. The analogy my colleague uses when describing PBM practices is simple: imagine a new sporting league. Now imagine the league's commissioner is the same entity, sets the rules for the league, owns a team in the league, and referees the games. Would that be a fun sport to watch? That is exactly what happens when CVS Caremark sets reimbursement higher at CVS Pharmacies than at other contracted pharmacies, mandates mail order through CVS Caremark Mail Service for its most profitable medications¹⁹, or only allows 90 day quantities to be dispensed at CVS Pharmacies.

Blueberry's argument is that insurance companies, most especially PBMs, play no role in the generic drug market and only increase the financial burden on all parties. When we actually charge fair and transparent prices, patients can buy on the open market and choose the pharmacy that offers the lowest price, best services, or both. Patients are no longer driven by vertical distribution monopolization to use some chain's mail order service where mailing costs are higher than the item itself and where they cannot even speak to a human being, let alone a pharmacist. One 100-year old Blueberry Pharmacy patient was driven to mail order by her insurance. However, she is near-deaf and near-blind and could not get questions answered or hear well enough to place orders. With Blueberry Pharmacy, she is getting all her prescriptions for less than \$20 a month, along with in-person, verbal education and large Sharpie-printed instructions that she can see. Without vertical monopolies, patients can choose to fill at a pharmacy that offers the services they need, not the one whose logo matches that on their insurance card.

¹⁷ <https://www.46brooklyn.com/research/tag/Rebates>

¹⁸ <https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html>

¹⁹ Fein, A. J. (2019, May 29). *CVS, Express Scripts, and the Evolution of the PBM Business Model*. Drug Channels. <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>.

Digging into PBMs further, here are just some of the practices that need regulation and/or investigation. I'll defer to the [National Community Pharmacists Association \(NCPA\) and Pharmacists United for Truth and Transparency \(PUTT\) expertise on these](#)²⁰:

- Manufacturer rebates to PBMs
- Spread pricing
- Direct and Indirect Remuneration (DIR) fees
- Generic Effective Rate (GER) and Brand Effective Rate (BER) fees
- Per-prescription commissions to brokers
- PBM ownership of pharmacies and distribution monopoly
- Excessive credentialing requirements targeting non-PBM-owned pharmacies
- PBMs ownership of coupon companies
- Gaming quality metrics

Summary

Thank you again for the opportunity to provide testimony on this critical issue. If my experience in pharmacy and at Blueberry Pharmacy have taught me anything, it is that we can have affordable medication and high quality care without the need for (and arguably due to the absence of) middlemen. When patients purchase generic medications in a transparent marketplace, they get better pricing and can seek out the care that suits their needs.

²⁰ *PUTT ON CONGRESSIONAL HEARINGS: FULL PBM OVERSIGHT, TRANSPARENCY REQUIRED IF WE ARE TO FIX OUR BROKEN PRESCRIPTION DRUG SYSTEM.* Pharmacists United for Truth and Transparency. (n.d.). <https://www.truthrx.org/puttstatements/putt-on-congressional-hearings-full-pbm-oversight-transparency-required-if-we-are-to-fix-our-broken-prescription-drug-system>.