Breakthrough medications offer tremendous clinical benefits for patients,

but there is little understanding as to how pharmaceutical manufacturers establish their prices. The current method upon which prescription drugs are priced in New York is broken and unsustainable for consumers trying to afford health care. Per capita drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index.¹ Further, PricewaterhouseCooper's Health Research Institute estimates that 18 percent of medical spending is attributable to prescription drugs.² This paper examines current trends in the marketplace and outlines a series of sensible approaches that policymakers should consider to address rising pharmaceutical prices and keep life-saving therapies available to patients.

KEY TAKE AWAYS

- Average wholesale drug prices have increased by over 200% for 20 different prescription drugs since January 2017.
- Between 2010 and 2015, 47 widely used generic drugs had a price increase of over 100% at a single point in time.
- The average annual cost of therapy for a specialty drug rose by almost \$35,000 between 2006 and 2015.
- Nine out of ten pharmaceutical manufacturers spend more on marketing than research.

POLICY RECOMMENDATIONS

- Increase price transparency manufacturers are not required to disclose or justify why drugs are priced as high as they are.
- Limit the use of manufacturer coupons coupons actually increase overall spending on prescription drugs.
- Require prior notice before large prescription drug price increases.

¹ "The High Cost of Prescription Drugs in the United States – Origins and Prospects for Reform" JAMA. 2016; 316(8):858-871.

² PwC Medical Cost Trend: Behind the Numbers 2018 https://www.pwc.com/us/en/health-industries/health-research-institute/behind-the-numbers/reports/hri-behind-the-numbers-2018.pdf

PRICE INCREASES - MORE THAN A FEW BAD APPLES

An analysis by Pharmacy Benefits Consultants found average wholesale drug prices for 20 common prescription drugs have increased by more than 200% from January 2017 to March 2018. The largest increase was for SyerDerm, a prescription skin cream, which increased by 1,468%. During this same time period, 39 other drugs had a price increase of at least 100% and many high-cost, high-use drugs experienced increases as well that greatly contributed to overall spending. Prices for Humira, the most widely used drug in the world, increased by 19%, Ebrel by 19%, and Revlimid by 20%. The analyses also showed that the prices for opioids such as OxyContin and Percocet increased by 20% or more.

A March 2018 report from the Senate Homeland and Government Affairs Committee Minority Office indicated the "prices for each of the 20 most prescribed brand name drugs for seniors have increased dramatically every year for the past five years" at a rate that is "approximately ten times higher than the average annual rate of inflation." From 2012 to 2017, "twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50%" while six out of the top 20 had price increases of more than 100%. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477% over a five-year period. The report also found that although 48 million fewer prescriptions were written for the top 20 most commonly prescribed brand-name drugs for seniors between 2012 and 2017, their total sales revenue increased by almost \$8.5 billion during the same period.

Annual Price Increases of Most Commonly Prescribed Brand-Name Drugs				
Product	2012 Annual Weighted Average WAC Price	2017 Annual Weighted Average WAC Price	Average Annual Percent Change (2012-2017)	Percent Change (2012-2017)
Advair Diskus	\$227.60	\$360.86	10%	59%
Crestor	\$349.31	\$615.65	12%	76%
Januvia	\$306.58	\$517.91	11%	69%
Lantus	\$121.88	\$250.24	15%	105%
Lantus Solostar	\$144.15	\$354.12	20%	146%
Lyrica	\$264.43	\$600.35	18%	127%
Nexium	\$256.99	\$368.85	7%	44%
Nitrostat	\$15.91	\$91.76	42%	477%
Novolog Flexpen	\$131.95	\$313.05	19%	137%
Premarin	\$255.94	\$554.60	17%	117%
Proair Hfa	\$39.96	\$54.05	6%	35%
Restasis	\$167.62	\$321.26	14%	92%
Spiriva	\$244.77	\$348.30	7%	42%
Symbicort	\$206.05	\$293.46	7%	42%
Synthroid	\$96.35	\$153.82	10%	60%
Tamiflu	\$97.94	\$143.18	8%	46%
Ventolin	\$34.67	\$50.68	8%	46%
Voltaren Gel	\$35.86	\$50.96	7%	42%
Xarelto	\$258.82	\$449.51	12%	74%
Zetia	\$225.63	\$483.71	16%	114%
Zostavax	\$1,044.36	\$1,363.08	5%	31%

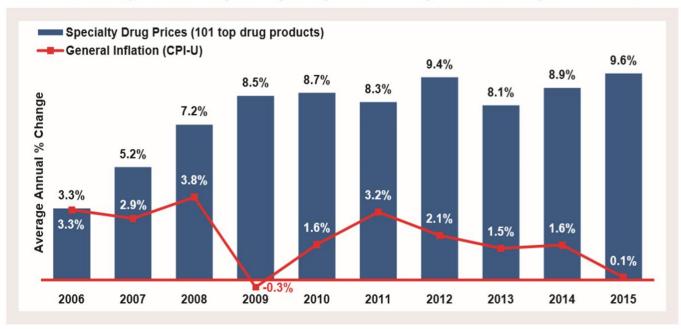
SPECIALTY DRUGS

Specialty drugs, while not precisely defined, generally include drugs used to treat complex, chronic conditions and require special administration, handling and patient care management. In 2015, retail prices for 101 widely used specialty prescription drugs increased by an average of 9.6% — the highest average annual increase since at least 2006. In contrast, the general inflation rate was .01% over the same period. The average annual cost for one specialty medication used on a chronic basis was \$52,486 in 2015. This cost was:

- Slightly less than the median US household income (\$55,775);
- More than twice the median income for Medicare beneficiaries (\$25,150); and
- More than 3 ½ times higher than the average Social Security retirement benefit (\$16,101).

Further, the average annual cost of therapy for the specialty drug products used to treat chronic conditions rose by almost \$35,000 between 2006 and 2015. The average annual price of therapy for specialty prescription drugs was nine times higher than the average annual price of therapy for brand name prescription drugs, and 100 times higher than the average annual price of therapy for generic prescription drugs.

In 2015, Average Annual Specialty Drug Price Change Was the Highest since 2006

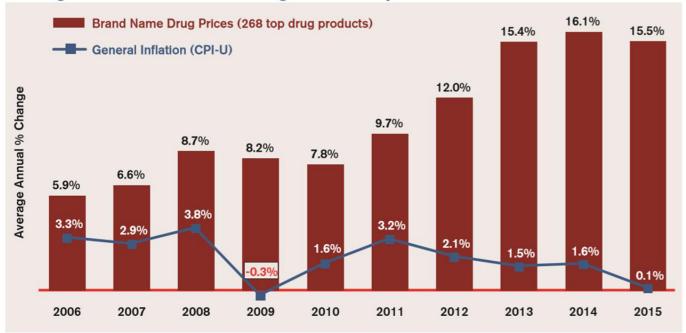


Source: AARP Public Policy Institute, September 2017

BRAND NAME DRUGS

In 2015, retail prices for 269 widely used brand name prescription drugs increased by 15.5%. In contrast, the general rate of inflation rate was .01% over the same period. The average annual cost for one brand name medication used on chronic basis was more than \$5,800 in 2015, almost \$1,000 higher than the average annual cost of therapy in 2014. For the average consumer who takes 4-5 brand name prescription drugs on a chronic basis, the annual cost of the same therapy would have been more than \$26,000 during 2015 – more than the median annual income for Medicare beneficiaries.

Average Annual Brand Name Drug Prices Compared to Inflation from 2006 to 2015



Source: AARP Public Policy Institute, September 2017

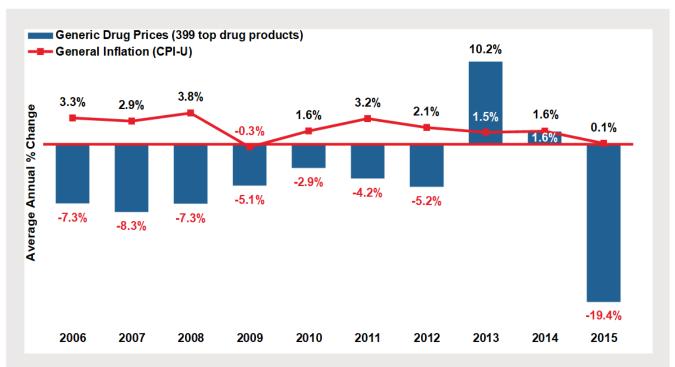
GENERIC DRUGS

Generic drugs have long been a means of helping consumers and payers reduce prescription drug costs, and currently account for more than 85% of all retail prescriptions filled in the US. In 2015, retail prices for 399 widely used generic prescription drugs fell by an average of 19.4%. In contrast, the general inflation rate was .01% over the same period. The average annual generic drug price decrease in 2015 was the largest decrease since at least 2006. The 2015 decrease in prices followed two consecutive years (2013 and 2014) where generic drug prices increased by an average of 10.2% and 1.6%, respectively.

All but one of the 399 generic prescription drug products in the study's market basket had at least one retail price increase between 2010 and 2015. Forty-seven widely used generic drug products had an extraordinary price increase – that is, a price increase that exceeded 100% at a single point in time. The average annual cost for a generic medication used on a chronic basis was more than \$520 in 2015.

Understanding what is driving the recent retail price increases for some generic prescription drugs, as well as how these factors might be mitigated, will become more important as more brand name drugs and biologicals enter the market with unusually high prices.

Average Annual Generic Drug Prices Declined Substantially in 2015 After Two Consecutive Years of Price Increases



Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Policymakers should consider regulatory and legislative action that balances the need for pharmaceutical innovation with the need for improved health and the financial security of consumers and taxpayer-funded programs like Medicaid and NYSHIP.

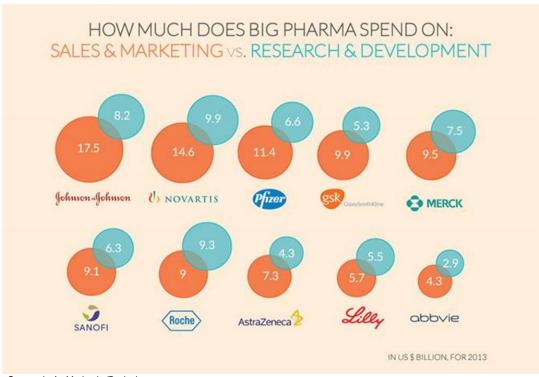
THE RESEARCH & DEVELOPMENT FALLACY OF RISING PRICES

Prescription drug manufacturers justify their pricing decisions by citing industry-funded research that claims that it costs \$2.6 billion to bring a new drug to market, although a November 2017 study in the *Journal of the American Medical Association* found that the median cost of developing a cancer drug was about \$648 million. Further, there is a growing body of evidence showing that manufacturers' marketing costs are greater than R&D costs. Analysis from the Global Data research firm found that nine of the big ten pharmaceutical manufacturers spend more on marketing than on research.

Despite claims that high drug prices are necessary based on the costs associated with R&D, there is virtually no public data showing a link between prices and the cost of development. In fact, in many instances the pharmaceutical manufacturer is not the actual developer of the drug. For example, a small biotech company that received the majority of its funding from the National Institutes of Health (NIH) conducted R&D for Solvaldi. The

biotech company was then acquired by the current manufacturer, which recouped the cost of the acquisition in one year of sales by pricing the drug at \$1,000 per pill while spending nothing on R&D.

Without increased transparency into how prescription drugs are developed — including the amount spent on research and development — and how the drug is ultimately priced, there is no way to ascertain that the drug's price is reasonable.



Source: León Markovitz/Dadaviz

AFFORDABILITY - BALANCING INVESTMENT

As the health care system in New York drives to deliver high quality care at a higher value through the Delivery System Reform Incentive Payment (DSRIP) program, and promote the use of value based payments (VBP), the same must be done for pharmaceuticals. To address the high cost of prescription drugs in New York there must be more done to assess the effectiveness of different treatment options. Currently, there is insufficient evidence as to how new, and often expensive, drugs compare with older interventions. In New York, pharmaceutical manufacturers are allowed to set their prices without any justification or disclosure as to how the initial price of the drug was chosen, or why the price of the drug was increased.

Increased transparency provides consumers, providers, government and health plans with the knowledge that they currently lack in assessing which treatments and drug regimens work, and which are less effective. The ability to analyze drug prices and underlying costs that drive pricing is critical to informing the development of policies that will ensure access to affordable medications. Health plans, hospitals, and physicians are all required to periodically submit extensive cost and quality data to regulators. The Affordable Care Act (ACA) has increased transparency across our health care system but, unfortunately, not regarding prescription drug costs and pricing.

If the high cost of drugs is justified by the investment the pharmaceutical companies have made to develop, manufacture and market these drugs, then the reporting requirements should be pro forma. This will drive better efficiency in the health care system and ensure that the health care dollar covers the most effective, not necessarily the most expensive options.

POLICY RECOMMENDATIONS

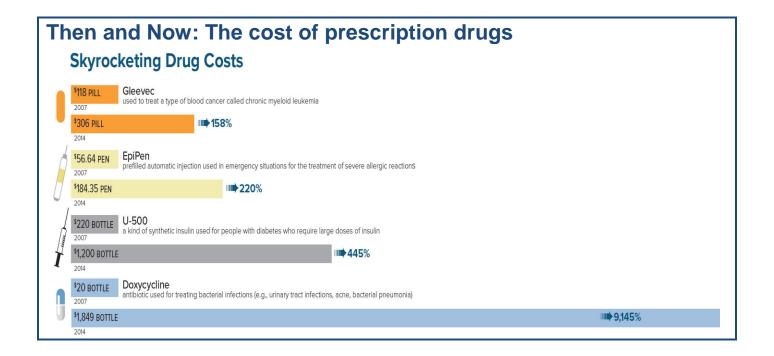
As consumers, employers, providers, health plans, and the state grapple with rising prescription drug costs, greater understanding is needed into how prescription drug prices are set and the rationale for price increases. As increases in prescription drug prices continue to be a major driver of rising health care costs, the following recommendations would provide policymakers and the marketplace with greater accountability and understanding into changes in prescription drug spending to ensure that prices are justified and to make health care more affordable:

PRICE TRANSPARENCY

Consumers, employers, state government programs, providers and health plans must price and budget many months in advance, leaving the health care delivery system vulnerable to uncertainty regarding price changes for existing drugs and the prices of new drugs. Considering the role that pharmaceutical costs have on health care spending, sensible measures should be taken requiring pharmaceutical manufacturers to explain the prices they charge for their products. This should include state reporting on how often the price of the drug has increased and the rationale for the increases, the direct costs associated with manufacturing the drug, such as R&D and materials costs, marketing and distribution spending, net profits, rebates, spending on patient assistance programs and coupons, and other important clinical details that may affect the price of the drug.

EARLY WARNING OF INCREASE IN THE DRUG'S PRICE

Unfortunately, as the price point on new medications goes up, it has also resulted in raising the prices of prescription drugs and treatments that are already in the marketplace. There is little to no information provided by manufacturers to justify these often times substantial increases. Prior to any prescription drug price increase of more than 10 percent of the wholesale acquisition cost (WAC), including cumulative increases that occurred within the previous two calendar years, the manufacturer should provide 60 days' notice of the increase. The notice should require the manufacturer to disclose simple and easy producible information such as the date of the increase, current WAC of the prescription drug, the dollar amount of the future increase in the WAC of the prescription drug, and an explanation on the need for the increase so that consumers, employers, providers, health plans, and the state have notice before the increase takes effect.



LIMIT USE OF MANUFACTURER COUPONS FOR PRESCRIPTION DRUGS

Currently in New York, manufacturer coupons for prescription drugs are prohibited by Medicare and Medicaid. However, in the commercial market their use has proliferated. On the surface, drug coupons appear to benefit consumers by lowering out-of-pocket costs for their prescription drugs at the point of sale. The true impact, though, is that drug coupons steer consumers towards a more expensive brand name medications and away from lower cost generics. While they are marketed as providing a "savings" to consumers, drug coupons drive higher pharmaceutical spending that increases the cost of health insurance premiums with consumers paying more in the end. New York could follow California's lead and prohibit the use of drug coupons when there is a therapeutically equivalent generic drug available. Alternatively, New York could require pharmacies to report when a coupon is used at the point of sale. In doing so, plans are made aware of the actual cost and utilization of coupons so that it can be accurately reflected in premiums and deductibles. This policy does not require a ban on coupons and is a step towards more transparency. Both options work to protect consumers and minimize the detrimental effects of drug coupons on health care premiums.

This issue brief was prepared by the New York Health Plan Association (HPA). Established for the purpose of promoting the development of managed health care plans within New York State, HPA is an industry voice for health care plans across the state. HPA's 28 member health plans share a commitment to meeting the health care needs of New York's residents.