An Understanding and Implications of the Cost Drivers in the Drug Supply Chain

By

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The Pharmaceutical Industry Labor-Management Association (PILMA) is a partnership of unions and companies that work together on key state and national issues affecting organized labor and the biopharmaceutical industry. PILMA is focused on maintaining much-needed employment and leadership in the U.S. and recognizes that a vibrant domestic biopharmaceutical industry providing innovative, affordable medicines is vital to the American people and the nation.

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The opinions expressed herein are those of the author.
All errors are our own. Funding for this study was provided by PILMA.

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ACKNOWLEDGMENTS

An examination of a topic as broad and complex as the various elements of getting prescription drugs from concept to patient offers a variety of opportunities for the message to get lost in the details. To help prevent that to the greatest extent possible, I had the exceptional fortune to have the advice of Candace DeMatteis, Managing Director, Policy Breakthroughs LLC, and Jessica Fink, Vice President, Groundswell Communications, whose suggestions have made this document a more concise read, and Saumil J. Pandya, Deputy Vice President, Policy and Research at PhRMA for his technical assistance in the preparation of the final report, all of whom deserve my gratitude in helping to clearly convey its message.

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EXECUTIVE SUMMARY

The Pharmaceutical Industry Labor Management Association (or PILMA) is proud to offer this assessment of the current drivers inherent in the drug supply chain which contribute to the overall costs of getting our country's prescription drugs to the consumer.

The U.S. spends more on prescription drugs than any other country. It is also the leading source of the industry's research and innovation. Advances in the treatment of both acute and chronic conditions and the general demographic shifts, in part as a result of these advances, means that a greater number of us will survive to advanced ages when more people need the products this industry provides. These advances have come at an increasing cost. The discovery of new cures for diseases such as hepatitis C, advances in the treatment of immune system diseases and the evolution of entirely new categories of extremely effective, but more narrowly targeted drugs to treat cancer and other life-threatening diseases based on patients' own genetic makeup (biologics and biosimilars) have all contributed to these costs.

Much, if not the majority, of the focus of the media, legislators and regulators has been on the manufacturers; however this is an industry with a host of other players in the "drug supply chain," each of which has a distinct role and many of whom play an outsized role in the cost drivers relative to their additive value in getting these life-saving medicines from the manufacturers to the ultimate consumer. To the extent possible, this study will focus on their relative roles and estimated influence on such costs. It is important to note, however, that because of the lack of transparency in their contracting policies and language, it is virtually impossible to precisely quantify the full impact of each of these players at this time.

Over the past several generations, spending for prescription drugs has moved away from a direct purchase by the end consumer to one covered by other third-party payers primarily through plans sponsored by employers and government programs for the indigent, elderly and disabled. As such, the true costs to the consumer have become less transparent.

These trends have resulted in the need for plan sponsors to better control the costs of such coverage. Entire industries have sprung up to meet these market needs. With a growing list of possible drugs, the local pharmacies needed a way to meet the demands of their customers without having to maintain excessive inventories of drugs that may not be requested very often. As payers grew concerned over increasing costs, another new industry was born of consultants known as pharmacy benefit managers (or "PBMs) who would negotiate with the manufacturers for volume discounts and by providing an opportunity for reduced competition or exclusivity on evolving drug formularies. The same approach of negotiating discounts through control of markets applied to the development of mail order distribution systems for chronic medications and limited participating lists of pharmacies where these and drugs to treat acute conditions could be purchased.

As these relationships became more mature, many of the details of the financial arrangements became more obscure. Instead of simply negotiating a price based on a discounted percentage off Average Wholesale Price (AWP), the addition of rebates, both drug specific and more general, based on meeting volume targets and even more impervious contracting formulae, made it increasingly difficult for payers to understand what they are paying for these goods. For many, simply knowing that these third-party intermediaries were negotiating discounts below what they would have to pay without them was sufficient for some payers and was encouraged by the PBMs. Without very clear oversight, contracting models such as "spread pricing" (the difference between what the PBM pays the dispensing pharmacy and what is billed to the payer) have created new incentives for the way PBM agreements are structured which do not always align with the best interests of either the patient or the ultimate payer, but yield massive profits for the PBM industry. While reported earnings by the dominant firms are quite modest, an independent analysis conducted by Bernstein Research has estimated the EBITDA profitability (earnings before interest, taxes, depreciation and amortization) of the PBMs at 85%. Governments have also complicated this system by imposing mandatory discounts and rebates on many of the drugs purchased under their programs. Pricing by other providers based on the level of clinical supervision necessary for the administration of drugs has also opened new opportunities for price mark-ups.

As the cumulative prices continue to rise for the research and development, manufacture and distribution of drugs and all of the intermediary services described above, payers at all levels have become increasingly aware of the need to better control costs in this aspect of health care.

In the pages which follow, the magnitude of these changes, the respective roles of the various parties who participate in the drug supply chain, and the recent efforts, especially by the federal government to attempt to reduce the costs of prescription drugs for both the federal budget and for those individuals whose out-of-pocket costs, including premiums also continue to rise, will be examined.

Among the items to be covered are:

- An overview of PILMA, its members and the strategic relationship between the industry and the labor organizations which comprise its membership.
- The various "links" that comprise the drug supply chain and their respective roles.
- The current public policy concerns as expressed by the Trump administration over the costs and inflationary trends of prescription drugs primarily with respect to their impact on Federal Medicare and Medicaid programs.
- An examination of the historical rise and current level of spending in the U.S., in terms of gross spending, as a percentage of total health care costs and GDP and on a comparative level with other developed nations.
- A discussion of the evolution of health benefit designs for prescription drugs,
- An assessment of how the various links' participation affects the pricing of the drugs to be acquired and how the numerous definitions of price affects the reimbursement levels paid to the various links in the supply chain and, ultimately, the cost to the consumer.
- Finally, several examples of pricing variability by specific links in the drug supply

chain, some of which have been characterized as clearly abusive and which have resulted in legislative and/or regulatory intervention.

These elements lead to several key findings:

- Retail drug expenditures that have gone from $2.2 billion to an estimate of approximately
  $360.2 billion from 1960 to 2018, largely as a result of:
    - the types of new drugs and the way they are produced
    - the way plans are designed
    - the way products are purchased
    - the intervention of third-party payers and
    - the proliferation of players in the drug supply chain.
- Certain abusive practices, as well as the lack of transparency and full disclosure of the terms and conditions of payments by and to certain links in the drug supply chain (especially PBMs), have drawn the attention of the government and other entities demanding greater transparency in contracting and, at the state level, imposition of changes in prescription drug pricing.
- Wide variation in pricing, especially for generic drugs, has resulted in more direct intervention by some state Medicaid programs including replacement of "spread pricing" practices with pricing based on the National Average Drug Acquisition Cost price plus an administration fee.
- The magnitude of such variations is breathtaking, reflected in numerous studies, including one in which a "basket" of five commonly prescribed drugs were priced in a variety of areas with the resulting variation of pricing ranging from a low on-line of $66 to a high of nearly $900 for the same five drugs when purchased at two of the largest chain pharmacies.
- The use of spread pricing in state Medicaid programs continues to invite abusive practices as demonstrated by a case study of the evolution of Gleevec from brand to generic which showed that, despite a decline of 89% from brand pricing, many Medicaid plans continue to pay prices for generic equivalents that almost equal the brand cost, prompting investigation and intervention by several state enforcement agencies.
- Alternative pricing models can yield significant savings as demonstrated by New Jersey by legislating and implementing a state-of-the-art "on-line auction" of access by qualified PBMs to provide prescription drug coverage to the 750,000 current and retired state employees and their dependents which is projected to save the state an estimated $1.6 billion or 18% of the state's prescription drug costs through 2020 without reducing benefits or increasing out-of-pocket costs to participants.

In the end, the recurring theme is one of a need for greater transparency in contracting and pricing in this industry. With federal and state governments either legislating or mandating through executive order wholesale changes in the way prescription drugs are priced and paid, it is apparent that change is forthcoming. As with any such change, it will be far better for the supply chain vendors whose business model is most at risk to devise new pricing schemes

which better reflect the added value of the services provided to address these concerns, than to wait until more draconian structures are imposed.

WHO IS PILMA?

The Pharmaceutical Industry Labor-Management Association (PILMA) is a coalition of pharmaceutical manufacturers and labor organizations in the building and construction trades whose symbiotic relationship recognizes the contributions of each to the other. Formed in 2003, the coalition recognizes the benefits derived from jobs created by the industry's employment of skilled union tradesmen and women to build and maintain the specialized facilities in which the industry conducts its research, perfects and ultimately manufactures the nation's prescription drugs. The partnership is further enhanced by the fact that union represented active and retired skilled workers and their families are customers and beneficiaries of the medicines produced by the pharmaceutical industry. They are among the segment of the workforce with comprehensive employee health benefits, including prescription drug coverage, many of whom receive such benefits through jointly managed multiemployer health and welfare plans. They are also among the portion of the workforce which still participates in traditional defined benefit pension plans whose investment portfolios include significant ownership positions in pharmacy industry stocks.

To provide context for these observations, the approximately 3,000 multiemployer health benefit plans are an important source of coverage for as many as 26 million active and retired American workers and their dependents across the economy. Similarly, the investment portfolios of the nearly 1,400 multiemployer defined benefit pension plans represent nearly one-half trillion dollars of available capital to ensure the retirement income of approximately 10.4 million participants and their families.

Since its inception, PILMA members have joined together to: support policies that represent the shared interests of its stakeholders; conduct educational sessions for its members; sponsor research on issues of common concern; and actively advocate on behalf of these issues, as deemed appropriate.

WHO ARE THE "LINKS" IN THE DRUG SUPPLY CHAIN?

In a system as complex as health care, even the prescription drug supply chain component, there are numerous players - "links" in the chain - and factors that contribute to costs. These include, but are not limited to:

- Manufacturers -who are responsible for research, innovation (especially most recently through the evolution of biologic and bio-similar classes of drugs which bring highly effective, targeted treatments to more narrow patient classes), testing, compliance with federal health and safety statutes and regulations, clinical trials, patent application and

protection, and creation and maintenance of highly sophisticated production systems and facilities;

- Wholesalers – who purchase bulk quantities to resell to other participants in the supply chain with less capacity to negotiate and store large inventories and who may pay rebates to pharmacies on many, but not all prescription drugs;

- Pharmacy Benefit Managers – who aggregate purchasers (health insurers, benefit plans (including multiemployer plans), purchasing coalitions, and others) to provide market leverage in negotiation of drug pricing with manufacturers. Their role also includes such other services as providing mail order prescriptions, creation and maintenance of a variety of formularies governing which drugs in which therapeutic categories are covered. They also negotiate discounts and rebates to be paid by manufacturers, some or all of which may be shared with the entities they represent under their purchasing agreements. Unfortunately, the terms of such agreements tend to be opaque and are often guarded as proprietary, making it difficult for the payers to fully comprehend. The PBM also sets the prices they pay to the pharmacy for covered drugs as well as the prices billed to the payer under "spread pricing" (the difference between the amount Pharmacy Benefit Managers (PBMs) pay pharmacies for a drug and the amount they charge their clients) essentially setting their own compensation;

- Specialty facilities – including hospitals, oncology, fertility and other specialty practices and clinics, and others which prescribe and administer drugs requiring clinical supervision to administer;

- Retail Pharmacies – from large national chains, to small community pharmacies, to increasingly integrated conglomerates, which provide retail prescriptions at widely varying prices. Pharmacies negotiate participating agreements with PBMs to gain access to markets which may otherwise be closed to them, as well as discounts, rebates and administrative and dispensing fees.

The following graphic provides a general description of the current distribution system as understood by HHS.

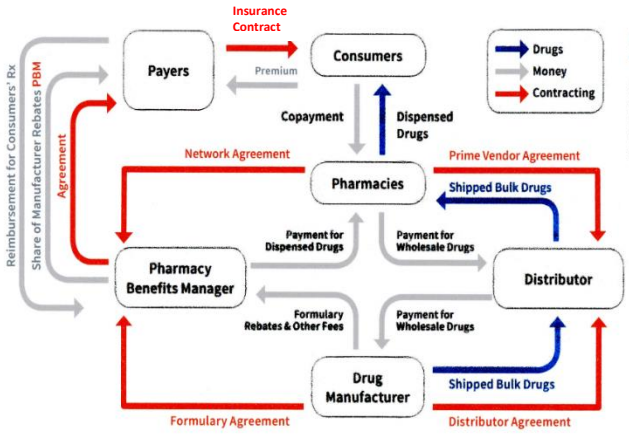

FIGURE 1

ADAPTED FROM: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016.

Azur, P. 12.

BACKGROUND

CURRENT POLICY FOCUS ON DRUG COSTS

The current apprehension over the increasing cost of prescription drugs is a growing concern. In recent years, the media has focused significant attention on the increase in prescription drug costs as a major contributing factor to rising health care costs. The outcry has been sufficient to garner the attention of the White House, with the Trump Administration promising to reduce prescription drug prices and reduce out-of-pocket costs. In a report issued in May 2018 titled "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"[1] the Administration's assessment of the problem was summarized as follows:

> *When it comes to the cost of prescription drugs, our healthcare system faces four major challenges: high list prices for drugs; seniors and government programs overpaying for drugs due to lack of the latest negotiation tools; high and rising out-of-pocket costs for consumers; and foreign governments free-riding off of American investment in innovation…. This blueprint is a historic plan for bringing down the high price of drugs and reducing out-of-pocket costs for the American consumer.*[2]

In launching the Administration's initiative, the President held meetings with industry leaders culminating in both a roll-back in announced price increases, deferral of others and additional proposals by the Department of Health and Human Services to address this problem[3]. Among those proposals is the elimination of rebates, including the possible repeal of the safe harbor from federal anti-kickback rules. As HHS Secretary testified at a hearing of the Senate Finance Committee on June 26, 2018 -

> *"…Everybody in today's system makes money as a percentage of list prices, including pharmacy benefit managers, who are supposed to keep prices down. Everybody wins when list prices rise except the patient… More fundamentally, we may need to move toward a system without rebates, where PBMs and drug companies negotiate fixed-price contracts. Such a system's incentives, detached from artificial list prices, would likely serve patients far better.*"[4]

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[1] Azur II, Alex M. The U.S. Department of Health & Human Services. *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. 11 May 2018. Washington, DC. Page 5.
[2] Ibid. p. 7.
[3] Datapoint. U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. "Prescription Pharmaceutical Price Changes since the Release of the President's Drug Pricing Blueprint." August 21, 2018, p.2.
[4] Azur, Alex, III. "Testimony from Alex Azur on President Trump's Drug Pricing Plan Before the Committee on Finance." June 26, 2018.

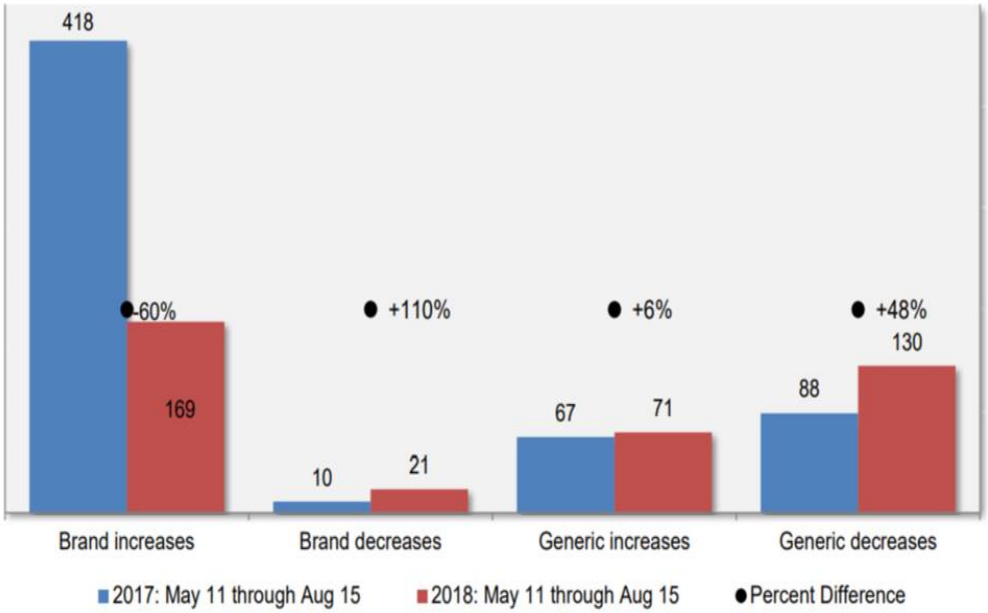
In July 2018, the industry concurred with the need for an alternative pricing structure that uncouples drug supply chain vendor compensation from the list price; suggesting instead that any new model should better reflect the value of the services provided.[5]

To further expand on the Administration's proposal to control drug costs, HHS released its' "Report on the First 100 Days of Action on the American Patient First Blueprint" on August 20, 2018 that offered a short-term critique of the Administration's success in reducing the price of drugs and out-of-pocket costs in comparison with the same period one year earlier. As shown below, that report stated that the Administration's actions had resulted in:

1. *60% fewer brand-drug price increases compared to the same period in 2017; and*
2. *54% more generic and brand-drug decreases compared to the same period in 2017*[6]

It should be noted that while the price reductions described in the Secretary's report received only passing mention in the media on publication, much greater attention was paid by the media to the price increases adopted at the beginning of 2019.

Chart: Price Changes by Product, Post Blueprint Period in 2017 compared to the Same Time Period in 2018



[5] Ubl, Stephen J. Press Release by PhRMA "Our industry agrees with the Administration that the status quo is not working in the best interest of patients and our health care system needs to change. Delinking supply chain payments from the list price will be disruptive and requires our companies and others to adapt, but it is necessary to improve patient affordability. We hope realigning these incentives will result in a greater shift toward value and lower costs for patients." July 16, 2018. P.1.

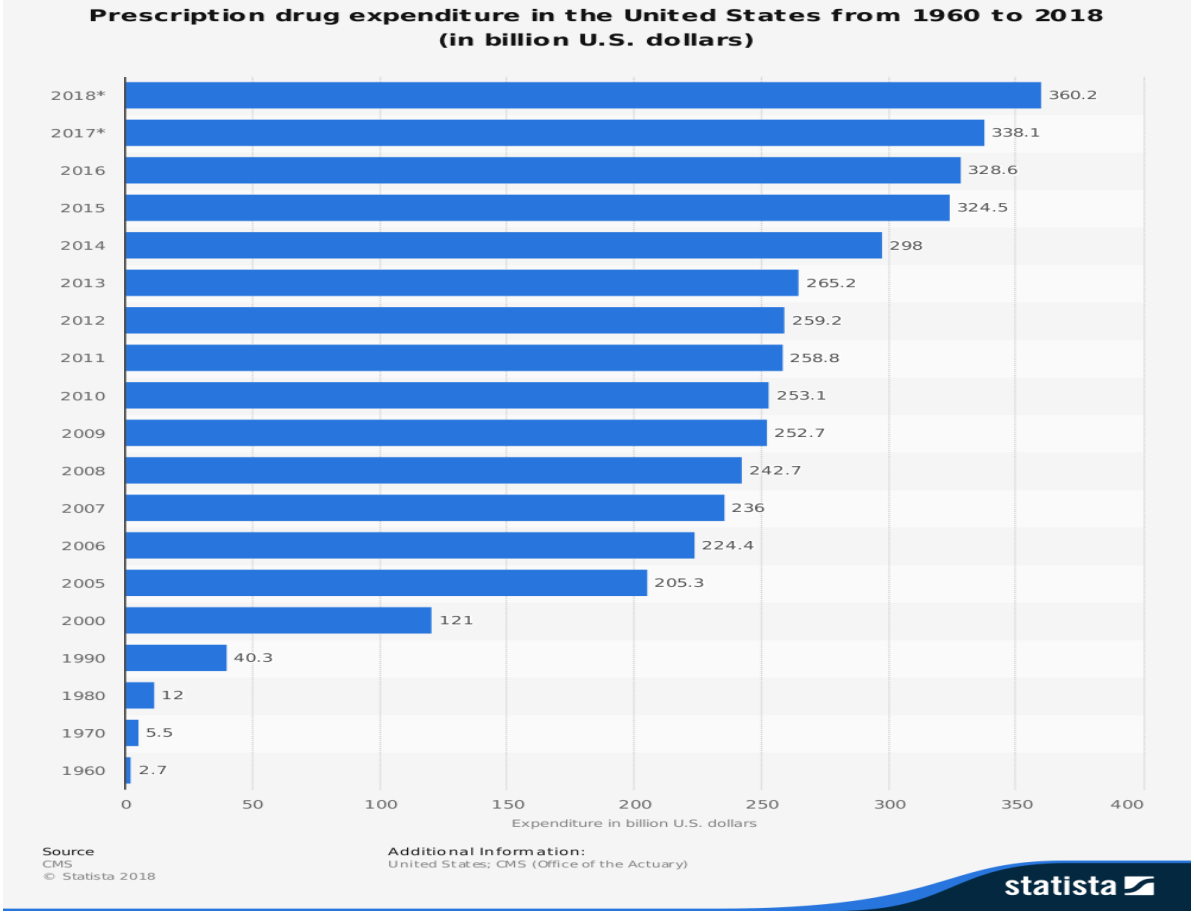
[6] Best, Dan. "Report on 100 Days of Action on The American Patient First Blueprint." *US Department of Health and Human Services,* August 20, 2018, p2.

While these summary statistical results appear impressive, these data are missing quantitative assessment of what is included. A more in-depth analysis of its real significance will be set out below (see Drug Pricing and Price Variability).

HEALTH CARE COSTS, COVERAGE AND PLAN DESIGN

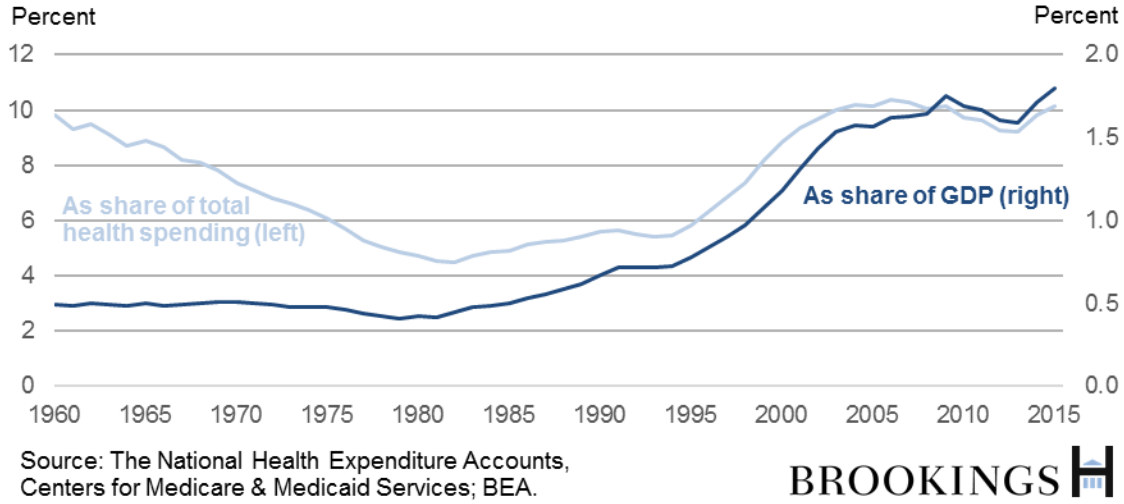
Prescription Drug Costs

The Centers for Medicare and Medicaid Services (CMS) has estimated the total cost of prescription drugs in the US will have risen from approximately $5 billion in 1960 to $360.2 billion in 2018. This is approximately 9.8% of the estimated National Health Expenditures for 2018 of $3.675 trillion.



Brookings has estimated that spending for prescription drugs net of discounts and rebates totaled $325 billion in 2015, or 10% of national health care expenditures. The growth of retail prescription spending from 1960 to 2015 is illustrated below:

Figure 1: Retail prescription drug spending

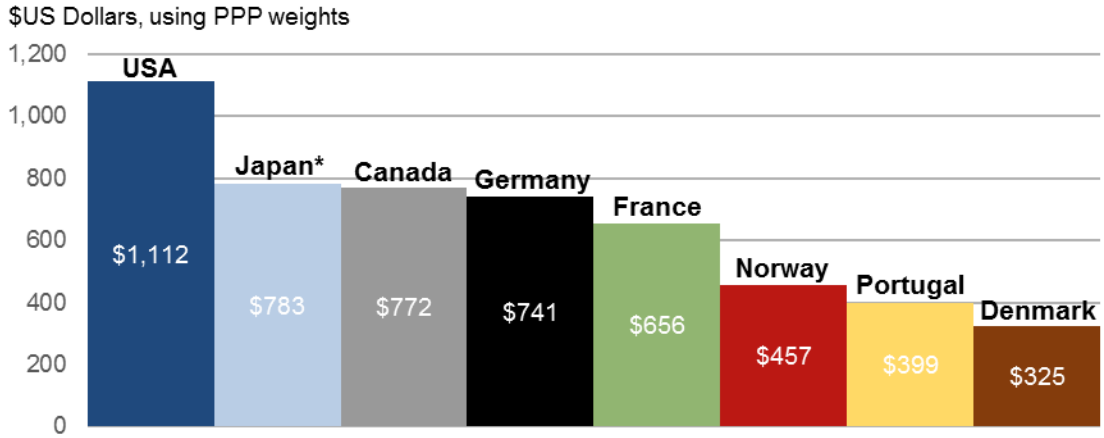


Source: The National Health Expenditure Accounts, Centers for Medicare & Medicaid Services; BEA.

BROOKINGS

Brookings also reported that, on a per capita basis, the U.S. far outpaces the spending of any other country for prescription drugs.

Figure 2: Per Capita Retail Drug Spending in 2014, by Country



Source: OECD, pharmaceutical spending.
Note: Includes prescription & over-the-counter. *Data from 2013.

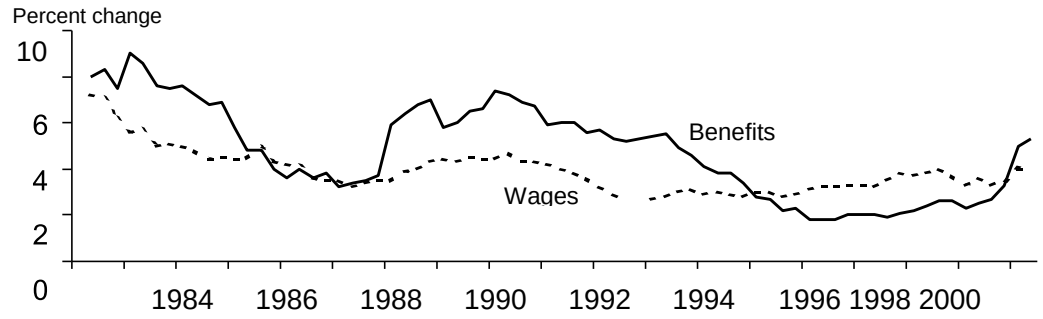
BROOKINGS

The historic growth in prescription drug expenditures reflects more than changes emanating from the evolution of the pharmaceutical industry and the drug supply chain and includes advances and innovation in the health care delivery system generally as well as the growth and importance of the public and private third-party payment industries.

EVOLUTION OF NEGOTIATED HEALTH CARE COVERAGE IN THE U.S.

Looking back to the origins and expansion of employer sponsored third party payment for health care, many "fringe" benefit plans provided limited coverage, and, with notable exceptions,[7] almost exclusively for hospital care. For most, however, commercial health insurance was often referred to simply as "hospitalization." Doctor visits, prescription drugs, dental and vision benefits and many of the other aspects of comprehensive health benefits coverage to which workers have become accustomed became mainstream over the subsequent decades as the economy expanded, creating work opportunities and generating greater contributions to health and welfare trust funds. As with many of the workplace improvements workers take for granted today, labor unions sought out ways to increase their value to members by expanding their negotiated benefits packages to include more of these "fringe" benefits. The two charts below show annual percentage changes in employer wage and benefit costs. The first, which shows the relationship between wage and benefit increases from 1982 to 2000, reflects the rampant overall inflation and interest rate spikes across the economy during the early and then again (to a somewhat lesser degree), in the late 1980s.

CHART 1. **Annual percent change in employer cost for wages and benefits, 1982-2000**



Source: WIATROWSKI, WILLIAM J. The National Compensation Survey: Compensation Statistics for the 21st Century. Compensation and Working Conditions Winter 2000. p.5.

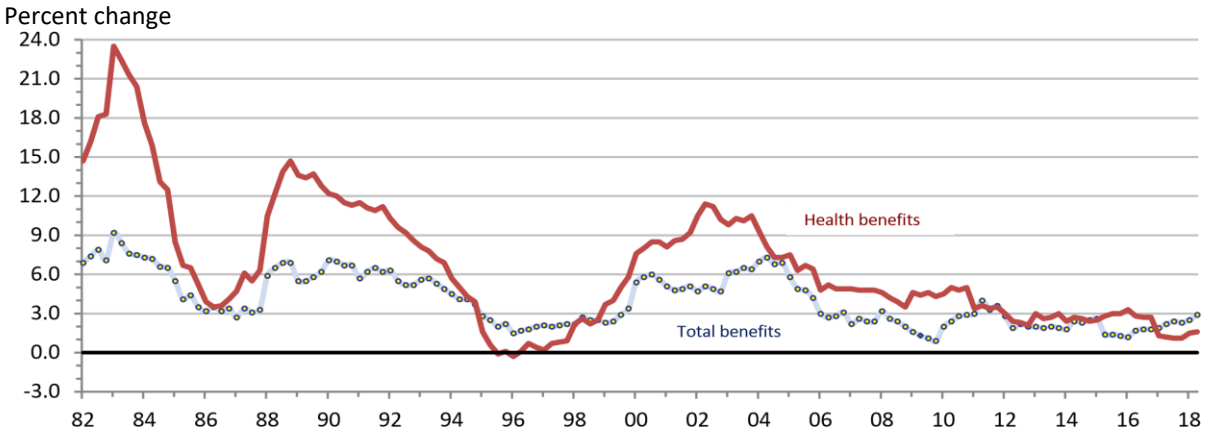
[7] The United Mine Workers of America (UMWA) Health and Welfare Fund, one of the largest multiemployer funds in history, covered almost all health care costs for covered workers in the bituminous coal industry from "cradle to grave" beginning with their "1947 Fund" which was created as a result of the Krug-Lewis agreement ending the Army seizure of the mines during their national strike over a failure to reach agreement over provision of health and pension benefits. Lack of adequate controls on spending, however, caused these funds to be restructured under the subsequent "1950 Fund." In response to third world conditions in Appalachia and far ahead of their time, they created a series of Area Medical Offices led by former public health services physicians, built a chain of hospitals – the Appalachian Regional Hospitals – in the coal fields during the 1950s and 60s, negotiated cost based per diem arrangements with hospitals and retainer agreements with physicians rather than paying fee-for-service and built and/or deficit fund multiple ambulatory care clinics. They also created one of the first mail order drug programs and one of the first formularies for determining which drugs would be covered through that program.

The second, taken from the Bureau of Labor Statistics National Compensation Survey shows the significance of the increase in health benefits cost relative to the percentage increase of total benefits cost from 1982 to July 2018.

Employment Cost Index

Health Benefits **National Compensation Survey**
July 2018 **www.bls.gov/ect**

Private industry, 12-month percent change in employer costs, total benefits and health benefits



As plans expanded to include prescription drug coverage, the normal pattern was to add it as an additional benefit with a separate, usually modest copayment. Sometimes coverage was limited to mail order for chronic conditions (see footnote 6). As time went on, however, the benefit was expanded to include retail coverage for acute drugs. As prescription drug coverage became more expensive, many groups, especially many multiemployer plans, realized that greater savings could be realized by leveraging their numbers through purchasing coalitions. These coalitions proliferated in the late 1980s and 1990s. Because drug coverage was considered more of a commodity than other types of benefits, many began with the joint purchasing of prescription drugs. Typically, the coalition would retain a consulting firm which would conduct a search through competitive bidding to select a pharmacy benefit manager who would negotiate discounts (usually a percentage off the Average Wholesale Price (AWP)), a participating network and their formulary. This model was then adopted for the joint solicitation and contracting by members of the coalitions on an "a la carte" basis which included a variety of benefit classes including managed care products and inpatient participating lists. Over the years since this model was implemented, the importance of the PBM's role as contracting intermediary has evolved and become more entrenched, even as their contracting methods have become less transparent.

While these coalitions began at a local level, they often saw attrition from some of their original members as some international unions established vertically integrated joint pharmacy purchasing arrangements for their local unions. Prescription drug coverage was an important

feature of plans, especially those which provided (usually heavily subsidized) retiree health coverage. As time went on prescription drug coverage became increasingly important for the over-65 retirees as Medicare did not cover prescription drugs until January 1, 2006 pursuant to the passage of the *Medicare Modernization Act* of 2003.

Since that time, and especially since the Great Recession of 2008 – 2009, subsidized retiree health benefits, especially for Medicare eligible retirees and their dependents have become the subject of greater scrutiny by active workers and the bargaining parties. This scrutiny was a logical result of the additional cost pressures imposed on actives in companion multiemployer defined benefit pension plans which suffered a median asset loss of 22.1%. Given the revised pension funding rules that were enacted in the Pension Protection Act of 2006, many of those same active employees saw their pension contributions double or more while seeing their own accrual rates for future service cut by half or more. As the younger active workers saw their own retiree benefits reduced significantly, while being asked to continue to heavily subsidize the health benefits of pensioners who are currently receiving higher benefits than they expect to earn in retirement, the predictable result was the beginning of a degree of intergenerational resentment. As the economy has improved and work has become more plentiful, this resentment has subsided somewhat, but is still a factor in determining the allocation of the negotiated wage package.

With Medicare having been expanded for post-65 retirees, many of the agreements negotiated after the recession significantly reduced or eliminated subsidized retiree health coverage for this class of retiree. This trend is expected to continue. In its recent study on health care cost trends, The Segal Company observed, with respect to the marketplace changes occurring through the recent acquisitions of Express Scripts by Cigna and AETNA by CVS, and the closing of the "donut hole" in 2019, that sponsors of post-65 retirees should "re-evaluate any Medicare Supplemental retiree plans they may have."[8]

More recently, other plan design alternatives, including high-deductible plans with complementary Health Savings Accounts (HSAs) have become more prevalent across the majority of employer sponsored health benefit programs, although less so in the multiemployer community. First came increasing deductibles; then came different deductibles for brand and generic drugs to steer participants to lower price generics. Then plans adopted copayments which were based on a percentage of the purchase price. Now some of the new plan designs have a separate drug deductible, or require that medical plan deductibles be met before any plan coverage is applied. Some economists argue that such a design will reduce overall costs by increasing the insured's "skin in the game," an argument which, in practice, is seriously flawed. Instead of sharing in the estimated rebates paid to private payers to reduce the costs of medicines for chronic conditions such as diabetes, asthma, Hepatitis C and high cholesterol by between 30 and 70%, in fact, some of the more egregious third-party contractual requirements result in the consumer paying the pharmacy list price which does not include any rebates or discounts to the patient. Such excessive costs defeat the purpose of providing prescription drug benefits to treat

[8] Segal Consulting. Data: Practical Research for Multiemployer Plans. "Increases for Medical and Rx Costs Expected to be Lower in 2019." Fall 2018, p. 8.

acute and better manage chronic conditions, as high out-of-pocket costs, including copayment and deductibles, are likely to result in "prescription abandonment."[9] When that happens, patients are unable to remain compliant with the management of their underlying chronic condition, thereby increasing the likelihood of incurring acute episodes of care and driving up the medical coverage costs for physician and inpatient care.

RISING RATES OF CHRONIC CONDITIONS

The management of chronic conditions is an important consideration in any examination of cost trends in the U.S. The U.S. National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) defines a chronic disease as one that lasts *"1 year or more and requires ongoing medical attention or limit[s] activities of daily living or both. Chronic diseases such as heart disease, cancer and diabetes are the leading causes of death and disability in the United States."*[10] Chronic disease also accounts for:

- seven out of every ten deaths in the U.S. annually;
- six in ten Americans who have at least one chronic disease;
- four in ten Americans who have at least two chronic conditions.

In addition to the obvious health and quality of life benefits derived from prescription drug therapies, research strongly suggests that patient compliance with chronic disease management prescription regimens can contribute to savings in other aspects of treatment. For example:

- Between $100 and $300 billion of avoidable health care costs have been attributed to nonadherence in the U.S. annually, representing 3% to 10% of total U.S. health care costs.[11]
- Use of statins reduces hospital admissions for heart failure by 10%.[12]

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[9]Shrank, William H., Niteesh K. Choudhry, Michael A. Fischer, Jerry Avorn, Mark Powell, Sebastian Schneeweiss, Joshua N. Liberman, Timothy Dollear, Troyen A. Brennan, and M. Alan Brookhart. "The Epidemiology of Prescriptions Abandoned at the Pharmacy." *Annals of Internal Medicine* 153, no. 10 (November 16, 2010): 633.

[10] Centers for Disease Control and Prevention. https://www.cdc.gov/chronicdisease/about

[11]http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Institute/RUOM-2013/IHII_Responsible_Use_Medicines_2013.pdf. IMS Institute for Healthcare Informatics Avoidable costs in US health care. 2013.

[12]Ramsey, David. Citing Preiss, David, M.D. Institute of Cardiovascular and Medical Sciences, University of Glasgow, UK as presented at the 83rd Annual Congress of the European Atherosclerosis Society (EAS) March 21-25, 2015, Glasgow, Scotland, UK Glasgow - *"The 10 percent reduction in hospital admission for heart failure could easily be an underestimate of the true effect, given that the trials were only 4 years duration on average, and the data only related to first heart failure events. With emerging data showing accrual of benefit from statins in the long-term, the 10 percent reduction is just the beginning of benefit from statin therapy. Additionally, if all heart failure admissions were taken into account, we suspect that the benefit would be much larger,"*

- Non-adherence to Type II diabetes medication management can result in hospital costs that are 41% higher than for patients who are compliant.[13]

The purpose in reviewing the evolution of these plan designs is to underscore that multiemployer and other employer sponsored plans, both health and pension plans, have evolved to provide economic security for working Americans who understand the fundamental concept of insurance, wherein greater protection against unforeseen and potentially catastrophic expenses can be ensured by the group much better than the individual. Whether it involves protecting workers from the types of expenses that arise from a serious illness, or the risk of poverty that accompanies the kinds of economic downturn which threatens the solvency of their pension plans, these plans are important. Nevertheless, they also understand that excessive benefit costs deplete the value of their negotiated wage package. Stated more precisely, the more of their paychecks that go to the benefit package, the less one gets for the other aspects of life; therefore, there is a very real incentive to control costs.

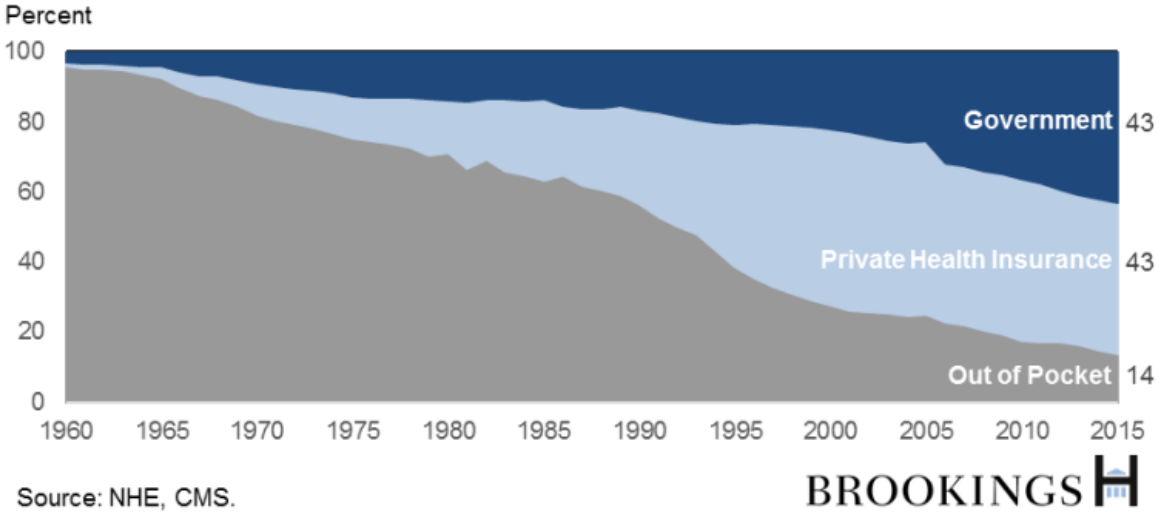
This begs the question: what <u>is</u> the real price for prescription drugs and who pays it? In the end, how the pie gets divided among those in the supply chain is a relative matter. To the end payer, what portion of the net costs are paid to any specific link in the supply chain is less important than the bottom line cost they are to bear. However, for payers with a fiduciary obligation with respect to payments they authorize on behalf of those who entrust them with the responsibility to pay reasonable fees, (e.g. multiemployer plan trustees), the objective is to pay a fair price to those who perform a necessary function. In order to understand whether that objective is being met, much greater transparency of the function and price for each of the component parts of the supply chain is required.

WHAT PRICE IS PAID, BY WHOM, TO WHOM, FOR WHAT?

The evolution of the cost shift away from the consumer paying the bulk of the costs of prescription medicines can be seen in the following illustration:

[13] Egede LE, Gebregziabher M, Dismuke CE, Lynch CP, Axon RN, Zhao Y, Mauldin PD. Diabetes Care. *Medication nonadherence in diabetes: longitudinal effects on costs and potential cost savings from improvement.* 2012 Dec; 35(12):2533-9. As cited in Lugo, Aurel O. and McGuire, Maura J. Dovepress. Risk Management and Healthcare Policy 2014 7: 35 – 44. *Adherence and health care costs. "…in a longitudinal 4 year study of 740,195 veterans with type II diabetes, Egede found that nonadherent patients can have annual inpatient costs 41% higher compared to adherent patients, and concluded that significant costs could be aavoided by increasing adherence."*

Figure 3: Retail prescription drug spending by source of funds

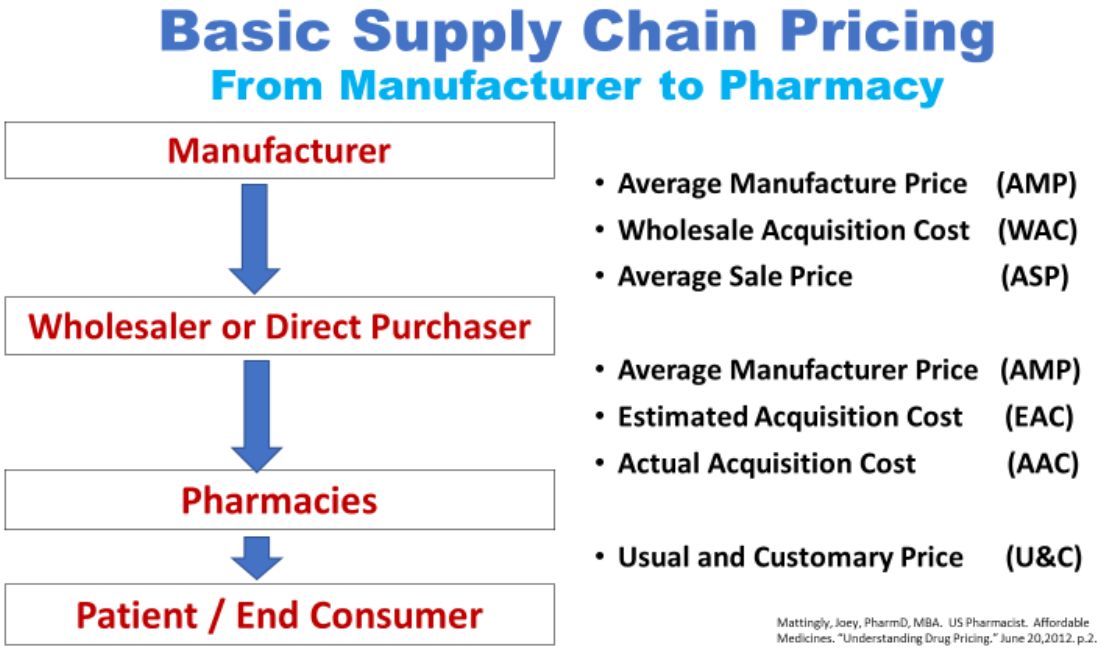


Over the past several decades, there has been a growing consensus that the rate of growth in health care spending is unsustainable. This sentiment was one of the primary motivating factors in the passage of the *Patient Protection and Affordable Care Act*. Because the complexity of the massive health care industry makes it difficult to determine effective, comprehensive solutions, prescription drug spending has become an increasingly popular target. In crafting an effective plan to help contain the rate of increase the obvious next step would be to determine the reasons behind this trend. While that sounds simple enough and is certainly a logical approach, that is where simplicity and logic end.

In this context the traditional economic notion that price is a function of supply and demand is anything but clear for a host of reasons. For example, to answer the question of "What is the price?" one must first answer another question: "Which one?" There are a variety of price definitions which, on first impression appear self-explanatory. A list of eleven different pricing terms and acronyms appears in the attached glossary. These include: National Average Drug Acquisition Price (NADAP), Wholesale Acquisition Cost (WAC) and Average Wholesale Price (AWP), all of which have meaning in specific contexts. In practice, however, such "prices" may actually be used more as point of departure from which discounts or rebates begin, rather than an ultimate determinant of what is paid for any specific drug.

Mattingly offered the following illustration of the pricing applications that are used at the various stages of the supply chain[14]:

[14] Mattingly, Joey, PharmD, MBA. U.S. Pharmacist. Affordable Medicines. "Understanding Drug Pricing". Prospect Kentucky, June 20, 2012, p. 5.



Likewise, the determinants of supply and demand are not set by the manufacturer or the ultimate consumer. As with many decisions in health care, these matters are most strongly influenced by other parties whose expertise or economic power are far more significant than either of the two most obvious players. Wholesalers negotiate discounts with manufacturers based on volume purchases and PBMs negotiate rebates and discounts and determine which drugs appear on formularies to be used by their clients and which will limit the choices of prescribing physicians. Both of these groups will exert much greater influence than the prescribing physicians or the patient on the question of supply and demand.

Consumers of health care are among the most likely to defer their decisions to others because of the importance of the outcome of such decisions and their own lack of essential knowledge about the clinical services under consideration. Instead, the ultimate consumer will generally rely on the guidance of their physician in decisions regarding their own, or a family member's health care. Because of their lack of clinical expertise, they will instead focus on other questions in making their purchasing decisions: Is the illness or injury life threatening? Is this the best, most effective treatment? Will the recommended treatment result in a speedy cure without side effects or lasting physical damage? These questions extend beyond questions of prescription drugs to other elements of the health care delivery system. Is the treatment a long-established modality, or is it experimental or groundbreaking? Is the recommended physician, facility, or drug truly "the best," or is it "the best alternative on a specified participating list or formulary" which has been determined by others for whom a number of factors take priority, wherein quality or appropriateness may not be most important?

These questions are compounded even more by injecting the questions of how much the recommended services cost and who ultimately pays? In the first instance, when it is a life-threatening matter, cost is often only a consideration when the answer is "more than you can

afford to pay." Because of the involvement of third-party payers, the number of other stakeholders which are involved as intermediaries, government policies that dictate mandatory rebates, alternative pricing models, use of narrow participating lists or formularies and/or opaque contracting practices, the answer may be nearly impossible to discern and, to the end user, more or less important depending on how much economic exposure he or she may have. From a public policy perspective, however, or that of any entity with limited resources – whether that is an individual who has no alternative payment source, an insurer, or group of plan trustees charged with ensuring that they are appropriately discharging their fiduciary duties - it is imperative that decisions regarding payment of services are rational which means that those individuals making such decisions are able to make informed decisions.[15]

To put it bluntly, the morass described above provides the backdrop to this latest policy issue paper from PILMA. At the heart of the criticism of prescription drug pricing is a fundamental lack of understanding of the roles of the various players and factors that influence pricing.

DRUG PRICING AND PRICE VARIABILITY

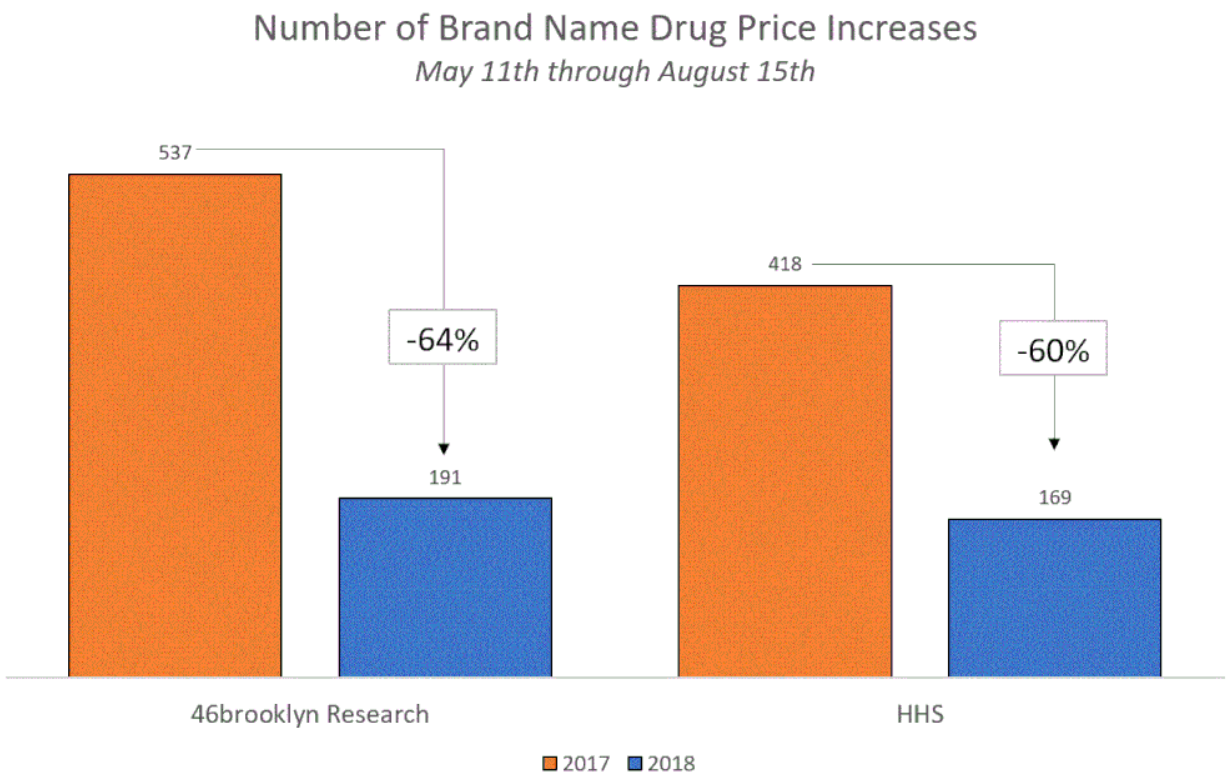
As noted above, the Trump Administration has made control of prescription drug costs a priority, citing significant reductions in the number of brand name price increases and a higher percentage in both brand and generic drug price decreases in 2018, compared with the same period a year earlier. But it is necessary to take a deeper dive into what those changes mean to determine the relative success of those policies in controlling prices. In order to confirm and quantify the story behind the claims, 46brooklyn Research LLP[16] used NADAC pricing experience for the two periods and discovered some interesting results. For their analysis, a price change was defined as any movement of 0.5% in week-to-week pricing.

With respect to their findings, 46brooklyn's analysis showed even more price reductions (64% vs. 60%) than were reported by HHS.[17]

[15]Azur II, Alex M. *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. The U.S. Department of Health & Human Services. 11 May 2018. Washington, DC. Page 11. The Trump Administration acknowledged that "[c]onsidering fiduciary status for Pharmacy Benefit Managers" was one of its' "further opportunities" in evaluating "incentives for lower list prices," similar to what was done by the Department of Labor in the area of defined contribution pension plans several years ago.

[16] www.46brooklyn.com/research/2018/9/6/analyzing-hhs-100-days-of-action-report[10/8/2018 12:50:21 PM]

[17] 46brooklyn Research, LLP. Analyzing HHS' 100 Days of Action Report



Source: Prescription Pharmaceutical Price Changes since the Release of the President's Drug Pricing Blueprint; 46brooklyn Research

They then set out to analyze the impact of these changes. Using the Medicaid State Utilization Database for five states – New York, Texas, Florida, North Carolina and Massachusetts – which had reliably reported data, it was determined that when compared to the previous quarters, the year-to-year comparisons showed that price increases for inflation dropped from $26 million in 2017 to $8.5 million in 2018.[18]

While policy makers and the media refer to the problem of drug costs, they typically do not differentiate between the various elements of the drug supply chain, so it is important to examine all of the links in the chain to determine what contributes to price movement.

INDUSTRY OUTLIERS

While manufacturers generally represent a part of the drug supply chain which do not engage in what many would call price gouging, there are some notable examples where price has drawn widespread criticism. Two such notable examples are Sovaldi by Gilead, which is used in the treatment of Hepatitis C whose initial pricing was the subject of much debate; and the EpiPen, manufactured by Mylan, a drug which has long been used for the delivery of epinephrine used to

[18] 46brooklyn Research, LLP. Analyzing HHS' 100 Days of Action Report

treat severe allergic reactions, which adopted price increases that many considered to be excessive.

Sovaldi was approved in December 2013 as a cure for hepatitis. While the benefits are literally life-saving, the price tag on introduction of $1,000 per day or $84,000 for a twelve-week course of treatment (before any rebates) was viewed as excessive and drew considerable criticism. It was even the subject of a Senate investigation. Rather than meeting its promise of being the public health landmark achievement of a generation, because of the price considerations payers imposed severe restrictions on who could receive it. Although the company management acknowledged that they may not have handled the pricing announcement as tactfully as they might have, they were adamant that the product was appropriately priced, given the success of the treatment and the cost of the alternatives (liver transplant).[19]

In September 2018, Gilead announced that it would be marketing a generic equivalent years ahead of the patent expiration and that the price would be one-fourth to one-third that of the brand name drug. This development will go far towards striking a balance between pricing that recognizes the benefits of such a groundbreaking treatment while enabling greater access to it by patients whose lives can literally be saved by making the drug more affordable to payers.

The story of Epi-Pen is slightly different, but the public backlash was much the same. In 2016 CBS news reported that the life-saving product on which many families had come to rely to respond to severe allergic reactions had increased its price 480% since 2009, from $100 to $600 for a two-pen pack, even though the actual ingredient costs remained only "a few bucks."[20]

SPECIALTY DRUG ADMINISTRATION

Not only are there large price disparities between brand and generic versions of the same drugs, pricing of the same drugs can vary immensely based on the point of sale and/or administration. According to a study conducted by Moran Company, data reported to CMS by 3,792 hospitals for 2016 showed that the average markup by hospitals for medicines is 479%. A majority of hospitals (53 percent) reported a markup of 200% to 400%. There were others, however, that reported even higher markups, with 17% reporting a 700% markup and 8% reported 8% reported markups of over 1000%. It should be noted that most third-parties pay less than billed charges for such items.[21]

[19] Silverman, Ed. Pharmalot. Gilead Fires Back at Medical Journal Report Critical of its Pricing. p.1.
[20] Nair, Vaneta. CBS News. "Rising Cost of Potentially Life-Saving Epi-Pen Puts Pinch on Families." August 16, 2016.
[21] Paavola, Alia. Beckers Hospital Review. "Hospitals Mark up Drugs by 479%: Six Report Findings." September 5, 2018.

Similarly, oncology practices also impose significant markups on drug acquisition costs. While such freestanding clinics provide a less expensive alternative to hospital-based administration of specialty drugs which require clinical oversight, oncologists are quick to point out that they incur additional costs and that a portion of patients' bills (perhaps 5%) are uncollectable.[22] While there are growing incentives to adopt alternative, outcomes-based pricing, that trend is moving slower than many had hoped.[23]

In 2017, specialty drugs accounted for 37.7% of drug spending, with the number expected to increase to 50% by 2018.[24] To put that in context, a study conducted for the AARP Public Policy Institute reported:

> *"…it was noted that the average annual retail cost of specialty drugs used to treat complex diseases (e.g., cancer, rheumatoid arthritis, and multiple sclerosis) presently exceeds the median US household income. The study, which focused on 115 specialty drugs, found that one year's worth of prescriptions for a single drug retailed at $53,384, on average, in 2013. This represented more than the median US household income, double the median income of Medicare beneficiaries, and more than triple the average Social Security benefit for that year.*

SAME DRUGS, WIDE PRICE VARIABILITY

Not all excessive pricing practices involve specialty drugs, however. In a study conducted by Consumer Reports, their representatives researched the retail cash prices for a "basket" of five common drugs from 150 pharmacies in 6 metropolitan areas across the U.S. As they described their findings, "The range in prices they found was stunning." They found they could purchase their "basket" from HealthWareHouse.com, an online pharmacy for ***$66***. At Costco those same drugs cost $105, but at CVS and Rite Aid, two of the nation's largest chain pharmacies, the prices for those same five drugs was closer to ***$900***.[25]

These price variations are not unique. Looking once again at the amounts paid by state Medicaid programs for the same drugs provides an additional and pointed example.

SPREAD PRICING AND MEDICAID

Gleevec (Imatinib Mesylate) is an oral chemotherapy agent. In 2015, it cost $300 per tablet. By 2017, it accounted for nearly half of the $176.7 million spent by state Medicaid programs on oral chemotherapy agents in the U.S., despite the fact that it only represented 1% of the total

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[22] Appleby, Chuck. NCBI. NIH. Biotechnology Healthcare. Payers Costly Battle Against Cancer. June 2005. pp.18 – 25.

[23] Leonard, Dan. Specialty Pharmacy Times. "Aiming for Value Over Volume in Cancer Drug Spending." May 15, 2018.

[24] *Coggins, Mark D., PharmD, CGP, FASCP, Today's Geriatric Medicine."* Specialty Drugs: Growing Segment of Pharmacy Spend.*"* Vol. 9 No. 4 P. 5

[25] Gill, Lisa L. Consumer Reports. "Shop around for Lower Drug Prices: CR's Secret Shoppers Did and the Price Differences Were Remarkable." April 5, 2018.

prescriptions for this class of drugs. That means that in 2017, at over $300 per pill, Gleevec was 83 times more expensive than the average such agent.

The generic equivalent of Gleevec was introduced to an anxious market in February 2016 by Sun Pharmaceutical with a six-month exclusivity period. It quickly became the favored option with PBMs CVS Caremark and UnitedHealth's OptumRx who announced they were moving to the generic early on, capturing 54% of the market in 2016 and ramping up to 79% by the end of 2017.

While the generic version maintained a higher than expected price initially, with the expansion to eight manufacturers currently, the average price per pill fell by approximately 89% to the current level of $33.46 per pill – essentially the textbook case for price reduction upon the maturation of the generic production market. So, one must ask why state Medicaid programs have continued to pay much higher prices for this drug?

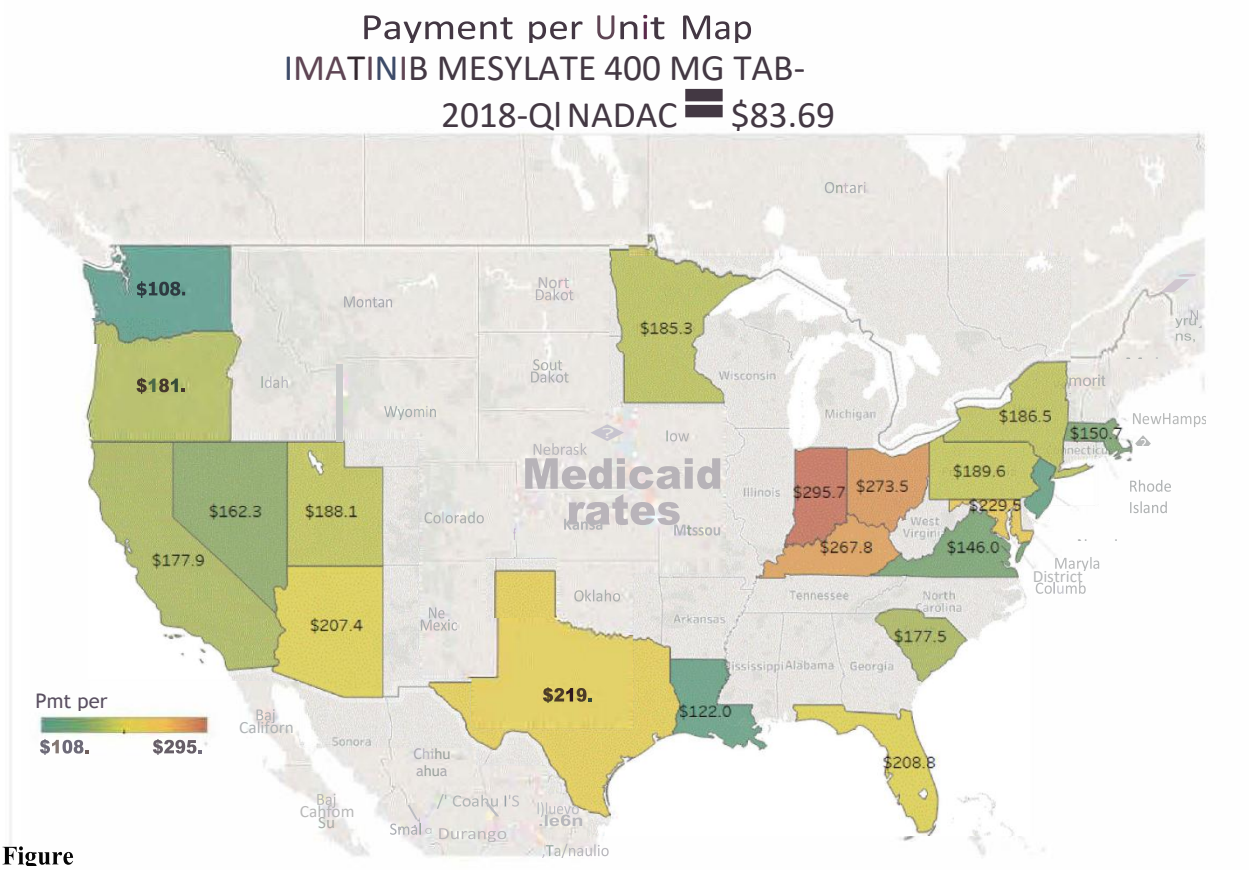
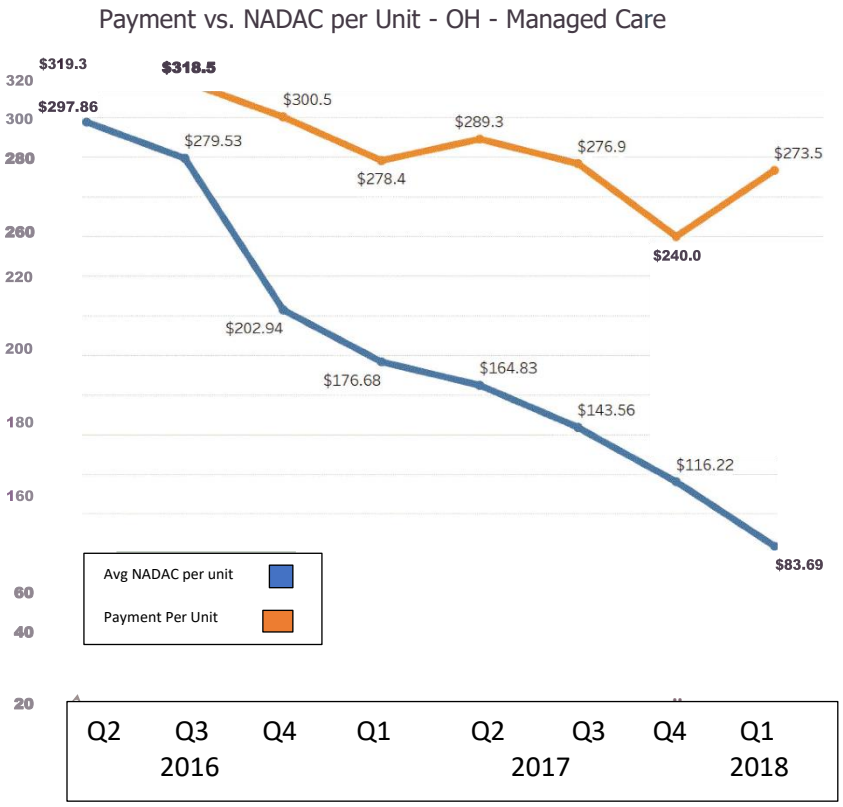


Figure
Source: CMS State Utilization Database: CMS NADAC

Ranging from a low of $108 per pill in the state of Washington to a high of $295.70 in Indiana this graphic demonstrates the variation in pricing paid by different state Medicaid programs where even the lowest price is significantly (29%) higher than the NADAC[26].

On a state specific basis, looking at Ohio, it is clear to see how the difference between the NADAC and the billed price continues to widen (illustrated below). It appears that the reason for this difference is that Ohio's Medicaid program utilized a "spread pricing" methodology. The difference between what a PBM pays a pharmacy and what it charges the payer is known as the "spread."

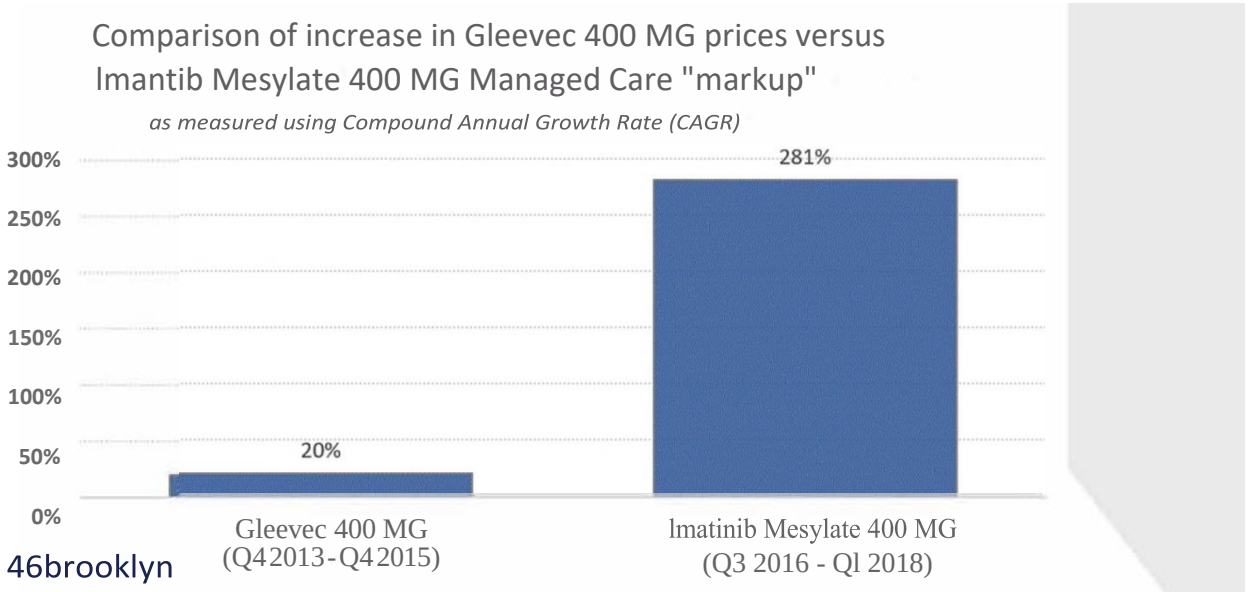
Although the PBM community contends that this method is more predictable than other pricing models, there is evidence that the Ohio PBMs could be retaining as much as 30% of the spread. In 2017, that "spread…[amounted to] $223.7 million or 8.8% of the gross drug spending." [27]



One further observation by 46brooklyn regarding the Gleevec story is worth noting. When the generic production pipeline reached its full complement of eight distinct manufacturers, the compound annual growth rate of the price for the generic equivalent (lmantib Mesylate 400 MG) during its first two years of production dwarfed the increases of the brand Gleevec 400 MG as compared to the two years before patent expiration.

[26] Pachman, Eric and Ciaccia, Antonio. 46brooklyn Research LLP. "The Cancerous Design of the US Drug Pricing System." July 2018. pp. 5 – 7.
[27] Ibid. p.7.

They noted that the generic price increase that took the price from $14.03 per pill to $104.26 in a year and a half (281% annualized) compared to a 20% increase for the brand Gleevec commenting that the mark-up that cost the state Medicaid program $188 for a drug that costs $84 per pill "…makes the brand name inflation seem pretty tame in comparison."[28]



Source: CMS State Utilization Database; CMS NADAC Database;

Other states have uncovered similar situations involving what is being paid to the PBMs and what goes to the pharmacies. In October 2018 the Pennsylvania Auditor General reported on price increases totaling over $1.4 billion in the amount paid by the State Department of Human Services to its PBM in 2017 compared to 2013. It has been difficult for the agency to quantify these differences because they have not always had the necessary data from the pharmacies. Under the new contracts with the Department of Human Services, however, PBMs in Pennsylvania will be required to report both sides of the equation – the amounts paid by the PBM to the pharmacies and the amounts paid to the PBMs by the managed care organizations for the same transactions. In addition, in responding to complaints from pharmacies contending the prices they are paid are often far below what they must pay drug acquisition costs, challenging their ability to stay in business, CVS has been criticized for offering to buy pharmacies shortly after cutting their payment rates. Although they responded that the PBM and pharmacy acquisition lines of business are completely separate, essentially maintaining a firewall between the two, they acknowledged that they have since halted that practice.[29]

[28] Pachman, Eric and Ciaccia, Antonio. 46brooklyn Research LLP. "The Cancerous Design of the US Drug Pricing System." July 2018. p. 7.

[29] Dunn, Catherine. The Philaldelphia Inquirer. "Pharmacy Benefit Managers defend their Medicaid role at Pa. State." Updated October 16, 2018.

Pennsylvania lawmakers have also drawn parallels with Ohio and also cited potential problems with spread pricing. State Representative Seth Grove (R- York) asked for a review of the state's experience with spread pricing across all state agencies.[30]

PBM PROFITABILITY

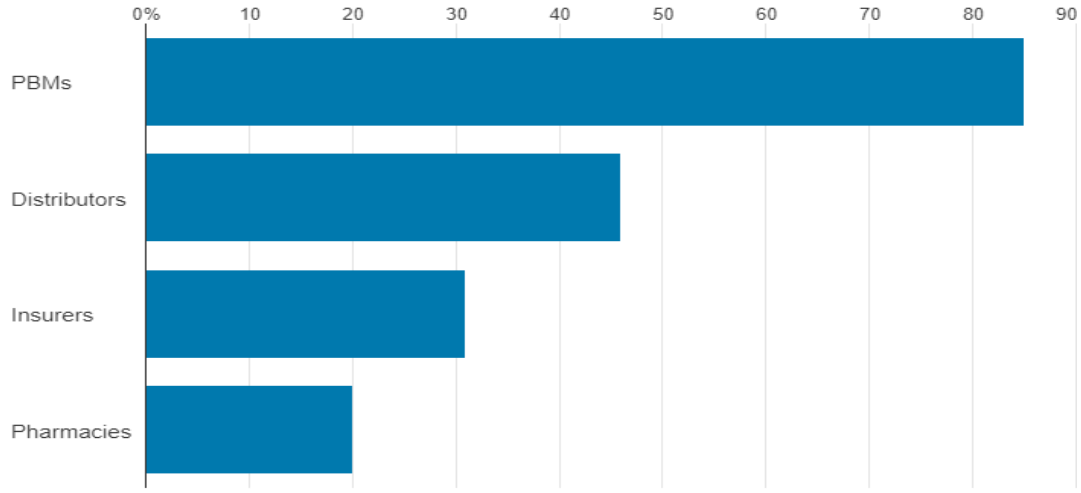
In his February 24, 2018 article in the *Wall Street Journal* "Hidden Profits in the Drug Supply Chain," Charley Grant observed that Pharmacy Benefit Managers are hired to control drug costs through negotiation of discounts and rebates from the manufacturers. He noted that the largest of the PBMs, Express Scripts Holding, was expected to report profits of 4.7%, while CVS Health reported a loss of 0.28% and UnitedHealth Group essentially broke even at +0.06%. He also reported, however, that these numbers appear to significantly understate the companies' true profits, observing that their statement showed gross profits (revenue minus the cost of goods sold) of $1.8 billion on sales of $24.7 billion in the third quarter of 2017. Because PBMs rarely take possession of the drugs, he noted, their fixed costs, overhead, depreciation, amortization and administrative costs are quite low. This observation was supported in another study reported in "Drug Channels" which found that rebates and discounts have more than doubled from $74 billion in 2012 to $153 billion in 2017, concluding that not enough of these rebates and discounts are making it to employers/unions, but are rather being retained by middlemen.[31]

With those considerations in mind, analysts at Bernstein performed their own analysis. Bernstein Research is widely recognized as Wall Street's premier sell-side research and brokerage firm. Their methodology excluded the cost of drugs that are included in their revenue and then "compared the rate at which gross profit converts into earnings before interest, taxes, depreciation and amortization (EBITDA) for pharmacy-benefits managers and other pieces of the drug supply chain, including drug distributors, insurers and pharmacies."[32] Their findings are illustrated in the chart below.

[30] Dunn, Catherine. The Philaldelphia Inquirer. "Is Pa. getting shortchanged on drug costs? Legislators want to know." Updated October 16, 2018.
[31] Fein, Adam J. PhD. Drug Channels. *The Gross-to-Net Bubble Topped $150 Billion in 2017*. April 24, 2018. https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html
[32] Grant, Charley. *The Wall Street Journal* "Hidden Profits in the Drug Supply Chain." February 24, 2018.

Big Profits

Rate at which drug supply chain converts gross profit into Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA)



Source: "Hidden Profits in the Drug Supply Chain"
https://www.wsj.com/articles/hidden-profits-in-the-prescription-drug-supply-chain-1519484401
February 24, 2018, by Charley Grant

Grant concluded:

> *By this analysis, pharmacy-benefit managers are exceptionally profitable; 85% of their gross profit converted into Ebitda over the past two years. Drug distributors converted 46% of their gross profit, while health insurers and pharmacies achieved about 30%. The analysts say these companies benefit from "lack of transparency and misaligned incentives," the latter because they benefit from higher drug prices. Historically those dynamics have been great news for shareholders.*

Price Inflation Protection

In addition to "spread" pricing, "Price Inflation Protection" is promoted as another effective means of restricting the size of annual price increases. Designed as a safeguard to double-digit inflation in list prices, especially for brand name drugs with generics on the horizon, CVS (Caremark) has reported that such price protective provisions have been incorporated in over 90% of their contracts with manufacturers of formulary drugs and that in 2015, such provisions reduced non-specialty brand drug price inflation by 50% and specialty drug trend by one-third.[33] Under these arrangements annual price inflation amounts are negotiated which, if exceeded, would result in additional rebates being paid to the PBM. While it would appear logical that such rebates would be remitted to the plan sponsor, they are not typically shared with the payers,

[33] Roberts, Jon. CVS Health Payer Solutions. "How We Cut Trend by More Than 50%" February 23, 2016

providing yet another opportunity for PBMs profitability as a result of the lack of transparency in pharmacy benefit pricing.[34]

In December 2018, CVS Health introduced yet another price inflation protection model designed to increase price predictability, while better aligning PBM incentives with the plan sponsor's objectives. Under the Guaranteed Net Cost Model, to be implemented in 2019, *"CVS Caremark will pass through 100 percent of rebates to plan sponsor and take accountability for the impact of drug price inflation and shifts in drug mix.*"[35]

ALTERNATIVES TO HELP INCREASE SUPPLY CHAIN TRANSPARENCY AND REDUCE COSTS

The illustrations shown and described above are but a few of the examples of the problems inherent in the current system wherein the current pricing and contracting models inhibit the ability of payers, lawmakers, regulators and even the most informed industry researchers from fully understanding the flow of dollars that allow prescription drugs to get from the manufacturer to the end consumer. Nevertheless, that does not preclude one from concluding that the current system is far from problem free.

While competition is a hallmark of capitalism, the current obscure system of contracting, where pricing and payment arrangements are held to be proprietary; where discounts and rebates intended to lower the cost of drugs to the payer for the benefit of the patient are diverted to a number of links in the supply chain; and where, as described above with respect to the definition of the respective roles of the "Links" in the supply chain,[36] PBMs are able to establish both aspects of the price "spreads" that will ultimately determine the amount of their own compensation, the ability of purchasers to make informed decisions is unintentionally, if not unwillingly, delegated. This is especially true with respect to multiemployer plans whose trustees' obligation to act for the "sole and exclusive benefit" of their participants has, in other circumstances, been interpreted to mean that a failure to be fully informed of the compensation being paid to service providers constitutes a breach of their fiduciary duty.[37] As a result these factors have produced a growing chorus of purchasers, legislators and policy makers alike who are determined to find other, more transparent pricing systems.

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[34]Harman, Matthew PHARMD, MPH. Employers Health Connect, *"What is the Deal With Drug Price Inflation?"* Spring/Summer 2017. Page 10.

[35] CVS Health. "CVS Health Introduces New Approach to Pricing of Pharmacy Benefit Management Services" December 5, 2018.

[36] See Pharmacy Benefit Managers (above) p. 5.

[37] The trustees' fiduciary duty to understand all aspects of the cash flowing through the drug supply chain is analogous to the rules imposed on trustees of defined contribution pension plans wherein the previous practice of simply contracting for bundled marketing, administrative, record keeping and investment services without adequate disclosure of the relationships of the various parties and their respective compensation was determined to be a fiduciary breach. While the Department of Labor has, from time to time revisited this issue with respect to the drug supply chain, no action to impose a similar standard has yet been taken. It is important to note, however, that the list of potential actions which may be taken by the Administration to control drug costs includes this concept.

Policy makers have gotten the message and, at least for a number of state Medicaid programs, have moved to alternative reimbursement models. Private payers are also beginning to examine alternatives. Some of these trends are discussed below.

FEE-FOR-SERVICE

In response to the results of the analysis of Ohio's fee-for-service Medicaid program and CMS' updated methodologies for State Medicaid programs, Ohio and many other states have adopted alternatives to spread pricing (although Ohio will continue to use spread pricing for its Medicaid Managed Care Organization drug purchases). Specifically, Ohio will use the "full pass-through" NADAC plus dispensing fee.

Mississippi has gone one step further by requiring the alternative for both their fee-for-service and managed care components.[38]

OUTCOMES BASED PRICING

In its policy paper "Follow the Dollar," PhRMA reported on the private market's movement to alternative pricing and payment structures. Specifically, they described a system of "Outcome Based Pricing", which better aligns the needs of patients, payers and the biopharmaceutical industry in a variety of clinical circumstances:

> *"As the market begins to move in the direction of a system that better aligns the price of prescription medicines with their value, biopharmaceutical companies are working with private health insurers to implement new payment arrangements for a variety of diseases. Biopharmaceutical companies and health plans are also considering new ways to pay for treatment when a patient needs multiple high-priced, innovative medicines and experimenting with money-back guarantees if a medicine does not work as intended. These new types of arrangements offer the potential to increase the choice of therapy, ensure that patients have affordable access to the newest medicines, and enable our health care system to achieve better outcomes at even more affordable prices."* --
>
> Source: PhRMA. Executive Summary **"*Follow the Dollar.*"** Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines. November 2017. Page 6

LEGISLATIVE / REGULATORY CONSIDERATIONS AND ACTIONS

In addition to the changes discussed above, State and Federal governments have been busy enacting a variety of legislative initiatives geared to simplifying the existing pricing models. These include:

[38] Pachman, Eric. 46brooklyn Research LLP. "Inside the Wild Universe of Prescription Drug Prices." October 4, 2018.

Federal Initiatives - Prohibition of "Gag" Clauses

On October 10, 2018 President Trump signed two pieces of legislation – one for Medicare and Medicare Advantage participants and one for the commercial health insurance market – both of which prohibit imposition of "gag" orders in the pharmaceutical industry. Such contractual provisions negotiated by PBMs, prohibited pharmacists from telling patients if they could save money by simply paying cash instead of their health plan's deductible or copayment. A number of state legislatures have passed similar legislation. As reported in Kaiser Health News, Medicare Part D patients overpaid $135 million in 2013 in situations where simply paying cash would have been less costly than their health plan's deductible.[39] A number of states have enacted similar legislation this year.

Proposed Repeal of Safe Harbor, Imposition of a New Fiduciary Standard

The federal government has also discussed solutions such as repealing the safe harbor against kickbacks which could adversely affect the payment of rebates and, as noted above, possibly imposing fiduciary standards on the industry as a means of reducing costs. Given the Department of Labor's refusal to defend a similar, previously adopted broad fiduciary rule for defined contribution pension providers, however, it is unlikely this will be one of the first measures adopted for the pharmaceutical industry.

Proposed Price Controls

In October 2018, President Trump announced a demonstration initiative that would restrict Medicare Part B reimbursement in "half the country" for physician administered prescriptions to an average of costs for similar services in other countries. The estimated savings to Medicare and patients is $17.2 billion over five years.[40] This proposal carries obvious negative implications for both the pharmaceutical industry in the U.S. which, as noted above, is the world's leader in research and innovation, and the patients who benefit from such innovation. In fact, many of the medicines are not even available to patients in the countries listed for comparative pricing.

State Based Initiatives

States have also been busy in attempting to regulate the prescription drug industry. In addition to state based actions to prohibit gag clauses, states have enacted a number of other pharmacy related laws to reduce costs to patients. Among others, the topics included: licensure or registration of PBMs; disclosure of their aggregate rebates and the amounts paid to the PBM by

[39] Jaffe, Susan. Kaiser Health News. No more Secrets: Congress Bans Pharmacist "Gag" Orders on Prescription Drugs. October 10, 2018.
[40] US New and World Report. "The Latest: Trump Says Proposal Will Lower US Drug Prices." Washington, DC. October 25, 2018.

Managed Care Organizations; and a law that prohibits PBMs from retaining rebates or spread pricing in excess of what was paid to the pharmacist.[41]

Online Auction of PBM Services – The New Jersey Initiative

One of the more innovative approaches was implemented by the state of New Jersey for its 750,000 employees, retirees and their dependents which has been projected to save $1.6 billion or 18% of their expected drug costs over the three-year period ending in 2020. Their approach was to conduct a state-of-the-art, online auction for their PBM services by vendors deemed to be qualified. Among the qualifications is a requirement that the successful bidder accept "best in class" contract terms as defined by the state. One of the features that makes this approach unique is the fact that participants will realize these savings without having to suffer any benefit reductions or increases in cost-sharing requirements. As reported by *America's Agenda*:

> *The advanced technology platform included a price adjudication engine comparable to those used by the PBMs, but deployed it to apply standardized pricing assumptions, prescription drug classifications, definitions, price lists, and drug price data sources to all the PBM proposals. Applying this methodology and best-in-class PBM contract terms required by the state, the price adjudication engine was able to generate "apples to apples" comparisons of diverse and complex PBM bids, calculate the real dollar costs of each PBM proposal over the 3-year contract term, and produce rankings of the anonymous PBM bids, viewable online by the competing PBMs and the State PBM Selection Committee after each bidding round.*[42]

This same innovative technology will be utilized to audit the performance of the PBM electronically in real time, something that has not been done for the previous PBM.

> *"Adoption and execution of this technology-enabled strategy is a major paradigm shift for elected state leaders and public worker unions," says Mark Blum, executive director of America's Agenda, the non-profit health care coalition and think tank that proposed the new strategy and has worked closely with New Jersey public employee unions and elected officials to carry it out.*[43]*"*

When originally proposed, then governor Chris Christie rejected this high-tech auction. After New Jersey Senate President Steve Sweeney spearheaded extensive negotiations he introduced legislation that was backed by New Jersey's public sector unions, led by the New Jersey Education Association (NJEA), to enable expedited procurement procedures, the contract was awarded to Truveris, Inc. to conduct the online auction and ultimately to Optum Rx as the winning PBM. Savings to the citizens of New Jersey are estimated at approximately $30 million per month, with even greater savings projected in subsequent years.[44]

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[41] Sullivan, Thomas. Policy and Medicine. Pharmacy Benefit Managers: States Put Middlemen on the Run Passing Multiple Laws In 2018.

[42] Blum, Mark. America's Agenda. "Bucking the National Trend, NJ Captures $1.6 Billion in Prescription Drug Savings Without Cutting Benefits or Shifting Costs to Public Employees. July 11, 2017.

[43] Ibid.

[44] Ibid.

Senator Sweeney was quoted as having remarked about the process - "*We are rooting out PBM profiteering at the expense of New Jersey taxpayers and public employees*." NJEA President Wendell Steinhauser echoed Senator Sweeney's comments, noting "*Without the technology-enabled auction, that $1.6 billion in savings would have shown up simply as extra profits for private companies at the expense of our members and other taxpayers*." [45]

CONCLUSION

The drug supply chain is comprised of numerous parties or "links," ostensibly to facilitate the delivery of products designed to do everything from making one's life more comfortable, easing suffering and providing immediate relief to acute symptoms, to managing chronic conditions and extending our lives. Whether the "links" involve the manufacture, distribution, or dispensing of the products themselves, or are more engaged behind the scenes in contracting, facilitation, administration, or the creation of drug formularies and/or provider networks, they all provide a valuable service in this complicated industry. As with any enterprise, along with their respective responsibilities comes an expectation of reasonable compensation for their work.

For the variety of reasons set forth above, the questions of what is considered to be reasonable and who makes that determination have become so complex that change - either voluntary, by bringing those directly engaged together, or mandatory, being imposed by government legislators and regulators - appears imminent. What is abundantly clear, however, is that, just as no one "link" is responsible for the "Rube Goldberg" design of today's system, any change will affect every other component, requiring a thoughtful solution rather than one which is simply politically expedient.

As the focus on prescription drug costs continues to intensify, the pressure to identify alternative models will also continue to rachet up. Innovation, such as the technology-enabled auction initiated by the joint efforts of the state of New Jersey, America's Agenda and Truveris, Inc., offer valuable lessons for those interested in reining in some of the abuses of the current system.

For the members of the supply chain who have utilized the current model of opaque contracting and pricing to maximize their profitability, it is time to work with the others to explore alternatives that provide policy makers, regulators, patients and the payers who stand in their shoes with sufficient clarity of the supply chain process and their impact on prices to comprehend whether the value of the products and services rendered are commensurate with the payments they currently command and properly evaluate the market basis for pricing in the future.

[45] Ibid.

Glossary: Common Terms and Acronyms

Term	Definition
Average Actual Cost (AAC)	An estimate of the retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices.
Average Manufacturer Price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law.
Average Sales Price (ASP)	A calculation of the weighted average of the manufacturers' sales price for a drug for all purchasers, net of sales adjustment. This price is defined by federal law.
Average Wholesale Price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank.
Dispensing Fee	The amount reimbursed to a pharmacy to cover the charge for professional services and overhead costs.
EBITDA	Earnings before interest, taxes, depreciation and amortization.[46]
Estimated Acquisition Cost (EAC)	An estimate of a price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid Agency.
Federal Upper Limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies.

[46] Grant, Charley. *The Wall Street Journal* "Hidden Profits in the Drug Supply Chain." February 24, 2018.

Health Savings Accounts (HSAs)	Health Savings Accounts (HSAs) were created in 2003 so that individuals covered by high-deductible health plans could receive tax-preferred treatment of money saved for medical expenses. Generally, an adult who is covered by a high-deductible health plan (and has no other first-dollar coverage) may establish an HSA.[47]
Maximum Allowable Cost (MAC)	A price ceiling, similar to the FUL, established at the state level.
Multiemployer Plan	An employee benefit plan which is the product of collective bargaining whereby contributions to a trust fund are negotiated between at least one union and more than one employer. Often mistakenly referenced as "union," or "Taft-Hartley" plans, since the enactment of the Labor Management Act of 1947 (aka the "Taft-Hartley Act") these plans must be maintained by equal representation of labor and management on the Boards of Trustees. Furthermore, while rare, there are some single employer plans which are operated pursuant to the joint labor-management structure, which have only one set of contributing parties; hence the appropriate term is "*multiemployer*."
National Average Drug Acquisition Cost (NADAC)	A government survey of pharmacy purchase prices, the National Average Drug Acquisition Cost (NADAC). The analysis encompasses over 500 dosages and formulations.
National Drug Code (NDC)	An eleven-digit code used by Medicaid to identify a drug based on its manufacturer, strength and package size.

[47] U.S. Department of the Treasury. Resource Center. December 1, 2015

Spread Pricing	The difference between the amount Pharmacy Benefit Managers (PBMs) pay pharmacies for a drug and the amount they charge their clients[48]. When a managed care organization (or for that matter, any payer) enters into a traditional "spread" contract with its pharmacy benefit manager the PBM graduates from being a claims adjudicator for generic drugs to actually setting the price for individual generic claims.[49]
Usual and Customary (U&C)	The average cash price paid at a retail pharmacy.
Wholesale Acquisition Cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law.

[48] Langreth, Robert; Ingold, David; and Gu, Jackie. https://www.bloomberg.com/graphics/2018-drug-spread-pricing/. "The Secret Drug Pricing System Middlemen Use to Rake in Millions." September 11, 2018, p.1.

[49] Pachman, Eric. 46brooklyn. "Inside the Wild Universe of Prescription Drug Markups." October 4, 2018, p.8.