

A large, blue-tinted photograph of a statue of James Madison, the fourth President of the United States, serves as the background for the top half of the page. The statue is shown from the chest up, facing slightly to the right.

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Price-Fixing Prescription Drugs Will Cost Us in Cures

By Mia Palmieri Heck

Introduction

Prescription drug pricing has been a recent topic of media scrutiny, and is said to be the reason for the high cost of healthcare in the United States. The result has been an encroachment of new legislative and regulatory proposals that either seek to restrict the price of prescription drugs or impose strict new reporting requirements on drug manufacturers. When considering new regulatory oversight, we must examine the impact these policies will have on the biopharmaceutical industry and the future of healthcare in the U.S.

Prescription Drugs, an Overview

The U.S. biopharmaceutical industry is a global leader in the development of new treatments and cures for disease. No other enterprise reinvests more revenue into research and development (R&D), or has made more advances in medical science, including investment made by both the National Institutes of Health (NIH) and all medical research universities combined.¹

However, there are great challenges associated with the business of cures. On average, it takes 10 years to develop a new

prescription medicine, which includes the six to seven year clinical trial process² required for Food and Drug Administration (FDA) approval. Only 12 percent of medicines in the development pipeline will ever reach the market, as the majority of new medicines in development fail. Despite this, scientists turn knowledge gained from failures into research findings, which lead to new breakthroughs in prescription drug treatments and cures.

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“Public policies that include greater regulatory oversight and restrictive pricing for the biopharmaceutical industry will result in less competition for therapies in each medical class over time.”

According to research by Tufts University Center for the Study of Drug Development³ the average cost to develop a new prescription drug is \$2.6 billion dollars, as each drug requires continuous scientific discovery as well as the cost of failed drugs to be accounted for when determining the price of a new FDA-approved medicine.

Along with the challenges of drug discovery comes the ever-changing landscape of the U.S. healthcare system. The implementation of the Affordable Care Act (ACA) brought on a massive expansion of government regulation which affected every part of healthcare delivery, from billing and reimbursement to operations and health insurance benefit design. The result of ACA mandates has been an increase in the cost of care passed on to Americans through health insurance cost sharing practices.

Another cause of the increasing cost of care is the large number of previously uninsured Americans who have recently gained health insurance. Many who gained access to care under the ACA are not the young and healthy that were expected to sign up for health coverage, but are the more sick and costly individuals.

With these changes, drug makers have been effectively targeted as the cause of the high cost of healthcare. While there has been a great deal of media focus on business tactics some pharmaceutical companies have engaged in to create an artificial demand for their product, it is important to remember this practice is made possible by a lack of competition in the market for that drug class.

When companies abuse their monopoly on a certain treatment, their actions should be investigated for criminality as they currently are in the case of both Valeant and Turing Pharmaceuticals.

Apart from these recent incidents, the whole of the biopharmaceutical industry annually reinvests record amounts of money back into research and development in order to drive the discovery of new life-saving medicines. Bad actors exist in every industry, organization and government, and



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enacting new restrictive legislation based on the actions of a few is ill-informed.

Public policies that include greater regulatory oversight and restrictive pricing for the biopharmaceutical industry will likely result in fewer therapeutic options in each drug class over time. When there is competition, the price of a prescription drug is checked by its competitor, and in contrast, where government mandated pricing is in place there will be less incentive to develop, leading to more barriers to access to new innovative medicines. The contribution and commitment pharmaceutical manufacturers make to the science of medical discovery should be encouraged, not penalized with price-fixing and increased government oversight.

Rebates and Discounts Distort the Price of Prescription Drugs

Within the biopharmaceutical industry, the 'price' of a prescription drug is only a starting point for drug manufacturers to negotiate with payers, which include pharmacy benefit manager's (PBMs), employers, health insurers and state and federal agencies. For each market, payers must adhere to a different set of regulatory requirements that each determine the price of a prescription drug. Examples of regulatory variance between the different markets for prescription drugs include:

- The Medicaid Drug Rebate Program statutorily mandates a prescription drug rebate of 23.1 percent for brand and specialty drugs by Section 1927 of the Social Security Act, and often, states will negotiate additional supplemental rebates, sometimes as high as 40 to 60 percent off of the list price.⁴
- For employer and marketplace insurance policies, a multi-tier drug formulary imposes different levels of cost sharing between the patient and the insurer, and often includes a combination of payment requirements such as co-pays, co-insurance and a separate deductible for prescription drugs. Insurers are now using a combination of these cost sharing mechanisms as a strategy to control costs, resulting in an increase in how much each patient will pay for their prescription drugs.

“Introducing price caps and increased red tape to the process will further complicate the already complex market for prescription drugs.”



In the U.S., states regulate both the health insurance market and Medicaid program, which presents the opportunity for drug manufacturers and payers to negotiate rebates and discounts that are governed by different rules in each of the 50 states.

Prescription Innovation and the Hepatitis C Cure

An example of the impact competition will have on the price of future of pharmaceutical innovations is our experience with the Hepatitis C cure. In December 2013, Gilead Sciences, Inc. released Sovaldi to the U.S. market. A breakthrough therapy, Sovaldi is the first prescription drug cure for Hepatitis C, offering patients a 90 percent success rate. In the initial release, the treatment was priced at \$1,000 per pill, which amounted to \$84,000 for one course of the drug. A year after the first Hepatitis C drug was released, AbbVie Inc. released the second Hepatitis C prescription cure in the U.S. market.

The availability of a second drug in that class allowed pharmacy benefit managers (PBMs) – who negotiate on behalf of payers – to leverage competitive market forces to significantly reduce the final price paid by states, employers and insurance companies. Within one year of the initial release of this breakthrough drug, the average price paid dropped by 46 percent.⁵

Patients who suffer from the Hepatitis C virus will experience severe damage through either the advancement of liver disease, liver cancer and cirrhosis of the liver. Prior to the release of these new breakthrough therapies, Hepatitis C patients would endure a series of costly medical events often resulting in hospitalizations and surgeries ranging from \$59,995⁶ to as much as \$500,000 for a liver transplant.⁷

Biopharmaceutical companies race to bring breakthrough drugs to market, and typically, when one prescription drug is approved by the FDA another medicine to treat the same condition is close behind. In healthcare, unmet needs with no competition result in very high priced procedures, treatments and prescription drugs. The most effective way to combat high cost of care is to create an environment that preserves competition and choice in the market.



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Cost Sharing for Prescription Drugs Has Significantly Increased

Through the design of drug formularies, health insurers determine what consumers will pay for a prescription drug. A prescription drug formulary is a list of approved drugs, which includes both generic, and brand name a health insurer will pay for on behalf of a patient. The implementation of the ACA brought on the use of multiple-tier drug formularies as well as increasing the cost sharing threshold for patients has become a much more common practice for insurers, resulting in patients paying a greater share of the cost of their prescription drugs.

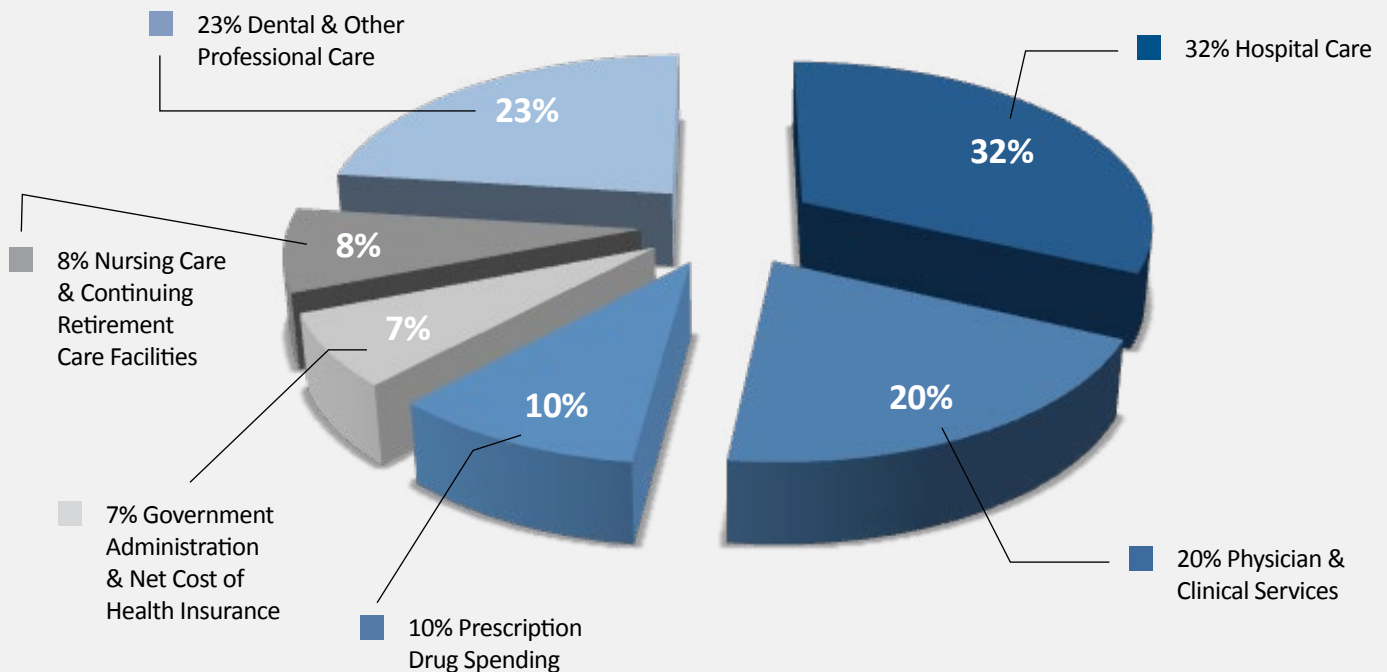
Multi-tier formularies often include four to five tiers, with inexpensive generic prescription medicines assigned to the lower tiers, and the new innovative and more expensive medicines on the upper tiers.

Gone are the days when patients simply had a flat co-pay to cover the entire cost of their prescriptions. Depending on which tier insurers place medicines on the formulary, there are now varying levels of cost and cost sharing. In addition, many insurers have accelerated the trend toward shifting the costs of prescription drugs onto patients through high priced coinsurance and including a separate deductible for prescription drugs.

For patients, a separate deductible for prescription drugs means out-of-pocket spending for doctors and hospital visits will not go toward paying for prescriptions. In addition, many health plans require patients be responsible for a coinsurance amount, which means patients will pay a percentage of the list price of a prescription drug. Because these cost sharing practices have become much more common, and are often poorly explained, many consumers are unaware of cost implications when choosing their health plans which is cause for concern and surprise when filling prescriptions at their local pharmacy, reinforcing the notion prescription drugs are overpriced.

- On average, 17 percent of cost sharing for prescription drugs is passed on to patients, as opposed to 4 percent of the cost of hospitalization.⁸
- Despite the increase in patient responsibility to pay for their medicines, spending on prescription drugs in the United States is just 10 percent. That is the same percentage spent on prescription medications in 1960 and is projected to be this percentage ten years from now.⁹ (See Figure 1)
- Specialty medicines, which treat complex conditions and are usually higher-priced medicines, are generally used by less than 5 percent of U.S. patients—typically those with severe or rare conditions.¹⁰
- Generic drugs make up 89 percent of prescriptions filled in the U.S.¹¹

Figure 1 Healthcare Spending in the United States



Price-Fixing Prescription Drugs Is Not the Answer

Increased national discourse on the drug pricing issue has resulted in a call for greater transparency and regulatory restrictions on drug manufacturers at both the federal and state level. While the proposed policies vary, each centers on increasing regulation and reporting requirements on the cost and development of prescription drugs.

The first proposal calls for increased price transparency for prescription drugs, however requires drug manufacturers to disclose proprietary information about drug development to regulators, not the public. This approach will not bring down the cost of prescription drugs. Vermont was the first state to enact a law requiring increased regulatory oversight with prescription drug pricing.¹²

While Vermont's legislation was intended to increase transparency in determining the price of a prescription drug, it may have the unintended consequence of driving up costs associated with R&D of new prescription medicines. Not only will revealing pricing among competitors (which was previously unreported) remove competitive market forces that would have led to an increase in discounts and rebates, it will also require accounting for specifics of R&D as a new level of compliance for drug manufacturers.

Proposals calling for increased reporting requirements (i.e., transparency of specific R&D spending) will not only significantly compromise fundamental business interests of drug manufacturers, these measures will do nothing to benefit consumer access to prescription drugs. Policy makers who wish to continue the development pipeline of breakthrough pharmaceutical innovations should enact common sense payment reforms that incentivize drug manufacturers and insurers to work together to create an opportunity for patients to access the medicines they need based on the value a medicine brings to market. When payment is tied to the effectiveness of a prescription drug, therapy or surgery, greater value and efficiency for patients and our healthcare system will result.



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Do Not Enact the Veterans Affairs (VA) Model

Another policy proposal often cited as a way to bring down costs is to give state agencies the same authority the U.S. Department of Veterans Affairs (VA) has to negotiate mandated price caps for their Medicaid program. This approach is riddled with misinformation and is also misguided. Here are the facts:

- Veterans are a protected population who receive lower priced prescription drugs in honor of their service to our

country. Expanding these protections will jeopardize the low-to-no co-pays they pay for the medicines they need.

- If states pay the same price for prescription drugs as the VA does, there will be fewer dollars for reinvestment in R&D which will result in significantly reduced incentives to develop new pharmaceutical innovations.
- If investors see less return-on-investment in the biopharmaceutical industry, fewer will continue to reinvest revenues into the development of tomorrow's medical discoveries.

Government-mandated limits on what is paid for prescription drugs, whether through price caps or mandates on drug pricing, may result in a reduction in patient access to new and innovative therapies. Countries that price-fix the cost of drugs hurt their citizens, as evidenced by centrally planned systems such as the National Institute for Healthcare and Excellence (NICE) in the United Kingdom, where on average it takes nine years¹³ for new drugs to reach patients, and cancer survival rates are significantly lower.

This is also true of the three jurisdictional agencies¹⁴ required to approve what medicines are available in Canada. Creating any additional state or federal oversight of the biopharmaceutical industry imposes more bureaucratic red tape between doctors and patients, while also slowing the rate of medical advancements that will be produced in the future.

In addition, the challenges that plague the VA system are foreshadowing of what greater government oversight will bear if increased regulation is introduced into state and federal health laws. Stanford University Researchers¹⁶ have shown findings on the restrictive nature of the VA formulary. Their comparison of prescriptions available to veterans and Medicare beneficiaries showed veterans only have access to one-third the medicines Medicare provides to seniors. If lawmakers mandate low cost prescription drugs, they can ensure patients will have reduced access to both new prescription medications and a reduction in the development of new breakthrough medicines over time.

“Instead of mandating an increase in regulation and oversight on an already heavily regulated industry, lawmakers should explore opportunities for policy reforms to payment reimbursement prescriptions and other therapies.”



Payment Reform and Increased Competition Will Bring Down the Price of Prescription Drugs

As previously noted, drug companies race to bring a new drug to market. Where there is an absence of options for treatment, there will often be high cost healthcare. Instead of mandating an increase in regulation and oversight on an already heavily regulated industry, lawmakers should explore opportunities for policy reforms to payment reimbursement for prescriptions and other therapies.

When considering how much prescription drugs cost, state leaders should consider:

- How effective the therapy is in the prevention of expensive surgery and hospitalization.

- What the effect will be in managing the cost of care for a person or population that suffers from expensive chronic disease such as heart disease or diabetes.
- How prescription drugs bring value by reducing downstream healthcare cost savings.

With the use of value-based contracting for prescription drugs, payers can tie the way we pay for drugs to specific health data that show the effectiveness of a treatment in preventing future surgery or costly hospitalization.

Paying for performance and other strategies that show value for the effectiveness of prescription medications will require some modernization of our healthcare system. To develop payment reimbursement based on value or performance models, tracking of indicators in digital and electronic health records must be improved. A flexible pricing system will allow drug

manufacturers and insurers to work together to design payment schedules according to the effectiveness of a treatment.


Changing the way we pay for prescription drugs, and all treatments and services in healthcare is one targeted approach to address drug pricing without imposing new stagnating state and federal regulations. Currently, some outcome based payment models are being piloted by payers, and should be closely evaluated before enacting centralized control of prescription drug development.

For years the healthcare industry has relied on the fee-for-service model for payment reimbursement, in which each service and treatment is reimbursed at a fixed amount regardless of effectiveness or health outcome. This volume-driven service model has set pricing for doctor's visits, clinical care, surgeries and the cost of hospitalization (quite inaccurately) for decades.

However, modernizing this system will encourage the development of healthcare that will show the true value of care, including the effectiveness of a prescription drug. Introducing payment reform centered on the effectiveness of a prescription treatment will require a significant shift in the way people think about the healthcare in the U.S. Some of the needed changes include:

- Interoperability of electronic health records; systems will need to 'talk' to each other.
- Developing comprehensive health indicators that will accurately measure the effectiveness of a prescription drug or treatment for each class of care.
- Privacy measures will need to be put in place, along with protocols to protect patient information between healthcare providers.

Innovations in payment reimbursement will require a commitment from all state and federal agencies, healthcare providers, insurers and drug manufacturers. This approach will allow for modernization of healthcare payment reimbursement in the U.S. and put the focus of care on meeting quality standards that are tied to payment.



“Developing comprehensive health indicators that will accurately measure the effectiveness of a prescription drug or treatment for each class of care”

New Medicines Will Play a Critical Role in Controlling Future Healthcare Costs

As more prescription innovations are realized their role in the way we manage disease will improve both quality of life and life expectancy for patients.

- The National Bureau of Economic Research on the Medicare Part D program showed this in a study, where researchers determined hospitalizations decreased 8 percent when the patient has prescription drug coverage.¹⁷
- A recent study by the Manhattan Institute shows the prescription drug benefit to patients and the healthcare industry is monetized at \$4 trillion dollars¹⁸ in cost savings and less healthcare utilization over time.
- Adherence to prescription drugs is also a key component in projecting future healthcare costs. Patients who have very high co-pays or deductibles for their prescription medications have difficulty adhering to the prescribed dosage of their prescription drugs over the long term.
- The IMS Institute for Healthcare Informatics recently reported the U.S. healthcare system could save \$213 billion annually, if medicines were used properly.¹⁹ New medicines will save money and increase life expectancy and quality of life over the long term.

“Free-market incentives for the discovery of more life-saving medications are what the U.S. needs to bring down the cost of both prescription drugs and the cost of healthcare over the long term.”

“As more prescription innovations are realized their role in the way we manage disease will improve both quality of life and life expectancy for patients.”



Conclusion

Free-market incentives for the discovery of more life-saving medications are what the U.S. needs to bring down the cost of both prescription drugs and the cost of healthcare over the long term. Increased drug development and a competitive marketplace will encourage the opportunity for more breakthrough therapies, and keep the price of prescription drugs within reach. While media scrutiny of bad actors has rightfully brought the discussion of prescription drug pricing to elected officials, it is critical to remember proposed policies that over-regulate private sector investment in pharmaceuticals will discourage continued reinvestment in research and development resulting in less prescription drug cures in the future.

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ABOUT THE AUTHOR

Mia Palmieri Heck joined ALEC in August 2015. As the Health and Human Services Task Force Director, Mia leads the nationwide effort to promote free-market, pro-patient healthcare reforms at the state level. In her immediate past position she served as an executive at a Texas-based child and family services provider where she led the strategic planning and program development efforts for the agency.

From serving at the US Department of Health and Human Services in the Administration of George W. Bush, to her work contributing to the design of community based models of care for at-risk populations, Mia’s experience shows her early and lifetime commitment to advancing free-market principles in the spheres of health and human services.

A proud Texan, Mia holds a Bachelor of Arts in Government from the University of Texas at Austin; she then later earned a Healthcare MBA from George Washington University in Washington, DC.

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