



AAM White Paper

Ensuring the Future of Accessible Medicines in the U.S.

Avoiding Shortages & Ensuring
Competition for America's Patients

aam
Association for Accessible Medicines

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Introduction

For nearly 35 years, the availability of affordable, FDA-approved generic medicines has meant greater access to life-saving treatments for millions of patients. Generics have delivered trillions of dollars in savings for employers, health plans, state and federal governments and, most importantly, patients. And the development of biosimilar medicines and complex generics means the availability of innovative specialty and biologic treatments for patients at lower prices. This is the result of the commitment of generic and biosimilar manufacturers to improving patients' lives through timely access to affordable medications.

Today's generic and biosimilar medicines industry includes a range of diverse companies that have become global leaders both in providing safe and effective FDA-approved medicines and in pioneering new treatment options for patients. Generic competition continues to play a vital role in improving access to pharmaceuticals and driving cost savings to American patients and the health care system. This growth in the generics and biosimilar industry has led to the creation of thousands of new jobs across the country and to better quality of life for millions of people.

But strong headwinds threaten generic and biosimilar competition. Without action to ensure a sustainable, competitive environment for manufacturers of affordable medicines, America's patients will continue to face increasingly high brand drug prices.

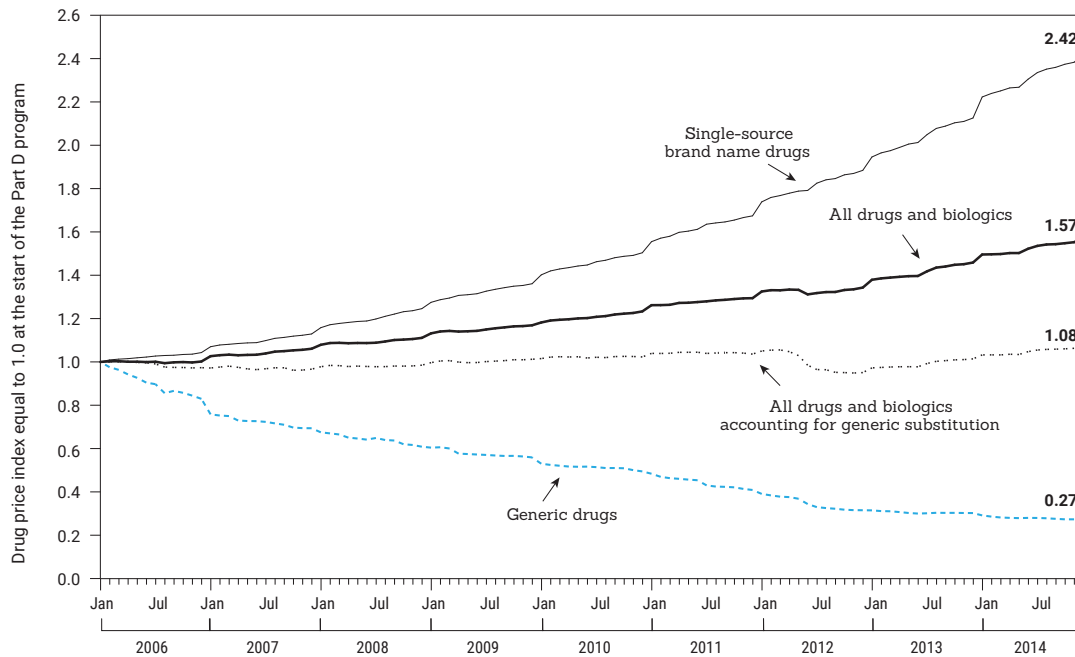
Drug Prices Are Getting Higher – Brand Drugs Are the Culprit

Rising brand drug prices are behind the increase in prescription drug spending and patient costs. In 2016, brand drugs accounted for only 11 percent of prescriptions dispensed, but more than 74 percent of total spending.¹ Conversely, generics made up 89 percent of prescriptions, but only 26 percent of spending. And while brand companies highlight that they are "limiting" year-over-year price increases to less than 10 percent, such price increases are nonetheless many times the rate of inflation and responsible for significant increases in the real cost of brand drugs. These brand drug prices increasingly create significantly larger burdens on patients and payers.

As brand drug prices continue to rise, the health care system faces rising costs. This is seen in the rapid explosion of specialty medicine development. In 2018, expensive specialty medicines used for only 2 to 3 percent of patients are anticipated to account for approximately 50 percent of all spending on prescription drugs,² which accounted for more than \$400 billion in 2017.³

Brand drug manufacturers, payers and providers have sought creative mechanisms to use the savings created by generics to shield consumers from the high prices of brand drugs. Generic substitution automatically provides patients with lower-cost alternatives that are the same as the brand. Unfortunately, recent formulary design trends increasingly subject generic medicines to higher cost sharing to reduce brand drug cost sharing.⁴ Because of high brand drug prices, patients face increasingly higher out-of-pocket costs for all of their medicines.

Price Increases for Brand-Name Drugs Are Overwhelming the Effects of Using Lower-Priced Generics



Note: Chain-weighted Fisher price indexes.

Source: MedPAC report to the Congress: Medicare Payment Policy. Status Report on the Medicare Prescription Drug Program (Part D). March 15th, 2017.

Patients Are Better at Taking Generic Medicines

For many patients, not having an affordable generic alternative means the difference between filling a prescription and doing without their medicine. If a patient cannot afford a prescription, he or she will not benefit from it. But half of patients with chronic diseases are estimated not to take their medications as prescribed.⁵ In the United States, non-adherence is considered responsible for approximately 125,000 deaths, at least 10 percent of hospitalizations and a substantial increase in morbidity and mortality annually. In fact, patient non-adherence is estimated to result in between \$100 billion and \$289 billion in annual health care system costs.⁶

Of the various reasons patients do not adhere to a prescribed drug regimen, failure to simply pick up a prescription due to its high price plays a significant role. Expensive brand-name products make up about 20 percent of approved claims but account for about 40 percent of all prescriptions left at the pharmacy counter. Overall, new patient abandonment rates for generic medicines are about two-thirds lower than for branded drugs. Specifically, 20.5 percent of brand-name prescriptions are abandoned, compared to 7.7 percent of generics.⁷ This is a direct result of a competitive market that makes 90 percent of all generic medicines available to the patient for less than \$20.⁸

Generic and Biosimilar Competition Is the Answer to High Brand Prices

Generic and biosimilar medicines are a market-based solution that increases competition and lowers costs for patients. In the last decade, the U.S. health care system has saved \$1.67 trillion due to the availability of low-cost generics.⁹ In 2016 alone, generic medicines generated \$253 billion in savings for patients and taxpayers. Savings for the two largest government health care programs, Medicare and Medicaid, totaled \$77 billion and \$37.9 billion, respectively, in 2016. This means average annual savings of \$1,883 per Medicare enrollee and \$512 per Medicaid enrollee.¹⁰

These generic drug savings accrued even as generic utilization increased – the result of a highly competitive marketplace in which generic drugs are launched at a significant discount to the high-priced brand and then rapidly decline. This trend has been observed in multiple studies from independent analysts and government agencies. The Government Accountability Office (GAO) recently noted that in Medicare Part D generic prices saw 59 percent price deflation between 2010 and 2015.¹¹

And the need, and opportunity, for lower-priced alternatives is particularly acute for patients using high-priced biologic and specialty medicines. This is the most rapidly growing segment of increasing brand-name prescription drug costs in the United States, with more than \$100 billion in annual spending.¹²

To create competition and help bring down prices for patients, Congress created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” (biosimilar) to or “interchangeable” with an FDA-approved biological product,¹³ known as the reference product. Manufacturers must prove that their biosimilar product has no meaningful clinical differences in terms of safety and effectiveness from the reference product. Since the approval of biosimilar medicines can rely, in part, on information attained from the original reference product, thereby diminishing the need for repeating extensive drug clinical trials, they are less costly to develop than brand biologics (although still significantly more costly than small-molecule generic drugs).¹⁴

Consequently, biosimilars offer safe, effective and less-expensive treatment alternatives for patients needing biological therapy. Experts estimate that FDA-approved biosimilars could save as much as \$250 billion over the next 10 years.¹⁵ In addition, they will provide greater access to lifesaving cures for 1.2 million U.S. patients, according to a new analysis. Women, lower-income and elderly patients would particularly benefit from access to biosimilar medicines.¹⁶ In Europe, where biosimilars have been available since 2007, patient access has increased by as much as 100 percent – the result of lower cost, as well as treatment guidelines that reflect the cost effectiveness of biosimilars.¹⁷

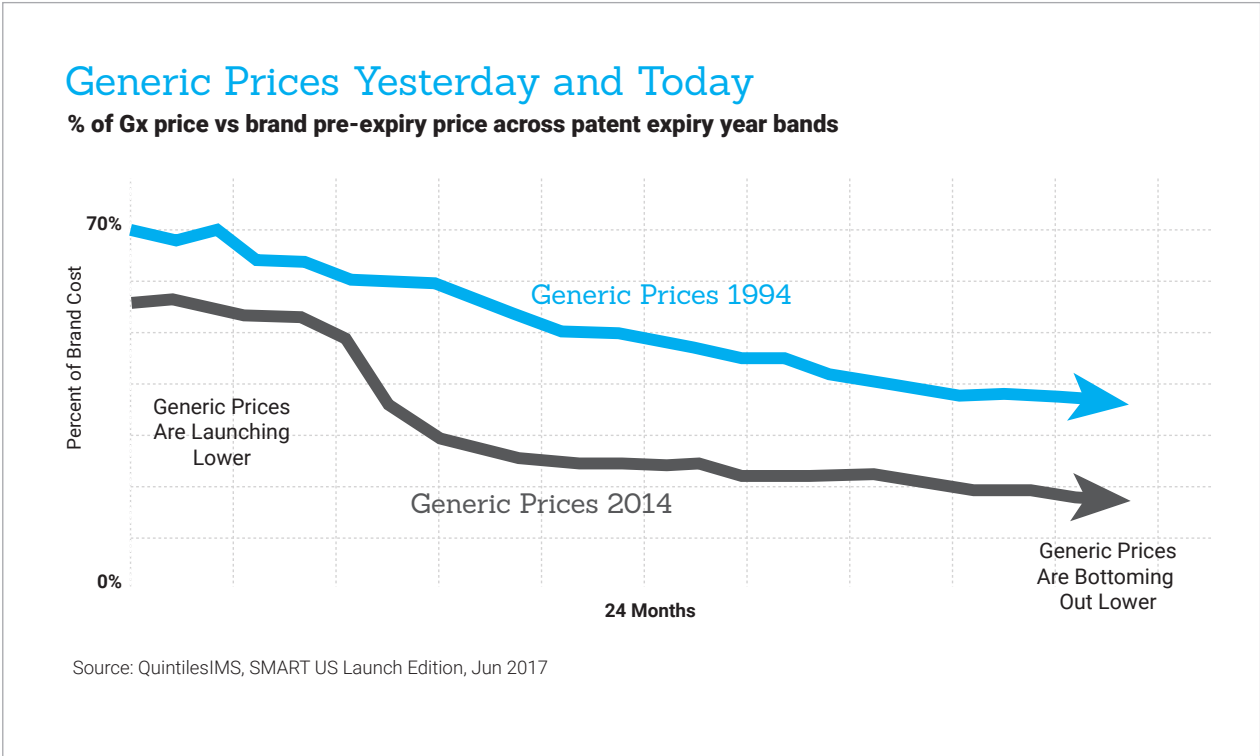
How Competition Creates Savings for Patients

All of this is made possible through a robust system of generic competition. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. Generic medicines can be approved following expiry of the brand's intellectual property or after generic developers establish that the brand patents do not preclude competition.

When the first generic medicine for a brand drug is launched, health payers typically shift patients away from brands for which the payer receives rebates and encourages generic uptake to effectively lower the price of the medicine.¹⁸ Under this system, because they are not providing rebates to payers to lower the cost of their products, generic manufacturers must compete for sales to wholesalers who then sell to payers. Because the products are virtually identical, the primary leverage generic manufacturers have with wholesalers is their ability to lower the price and provide the necessary volume.

Deflationary Pressures Create Savings, but Also Threaten Sustainability

The generic business model has been highly effective at lowering drug costs, exhibiting around 7 percent deflation for existing generic drugs year over year for the last few years.¹⁹ This is a result of manufacturer competition – but also of purchaser consolidation. In 1975, there were more than 200 wholesalers. By 2000, there were fewer than 50. And today, only three large purchasing groups, reflecting wholesaler/pharmacy partnerships, account for more than 90 percent of all generic drug sales.²⁰



This consolidation creates an imbalance compared to a highly fragmented generic drug market with more than 200 generic drug manufacturers,²¹ at times with as many as a dozen manufacturers making any given product. This dynamic allows companies within the supply chain to realize significantly higher margins on generic products, while simultaneously providing patients medicines at extremely low costs. As an example, the top 100 drugs by volume in Medicare Part D last year were sold on average for approximately 10 cents per unit by manufacturers to wholesalers.²² Wholesalers were then able to recognize a 20 percent margin and still deliver those medicines to pharmacies at just 12 cents per unit.²³

The result is striking. Today generic drugs are launching at a greater discount off the price of their branded counterparts, lowering prices at a faster rate and ultimately reaching a lower price point than at any time in the last 20 years. The chart on page 7 provides a breakdown of generic launches over the last 20 years, broken down into five-year intervals. Between 2010 and 2014, generic drugs provided larger discounts to patients and payers at a faster rate than ever before.²⁴

While these trends provide short-term savings to patients and payers, they call into question the market's long-term sustainability. As multiple manufacturers continue to compete for the business of only three purchasers, many previously profitable markets are closed to many manufacturers. This has caused generic manufacturers to reevaluate product portfolios and discontinue certain medicines.

Ultimately, generic and biosimilar manufacturers need certainty that they can reliably enter new markets without artificial barriers to entry from anticompetitive practices and that the markets they are participating in will not be excessively burdened by new regulations that make low-margin products unprofitable.

Therefore, continued savings from biosimilar and generic medicines depends on two primary considerations:

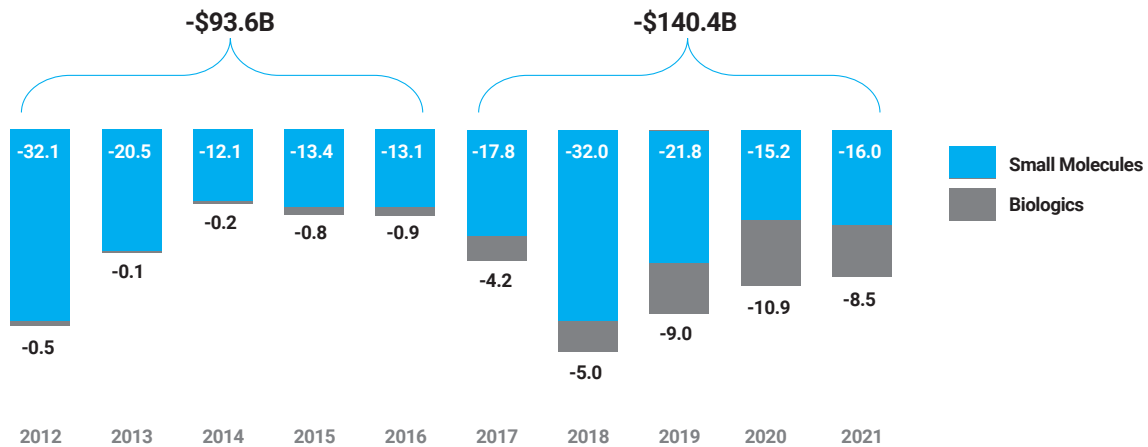
1. Ensuring that there are no artificial barriers to launching a new generic or biosimilar competitor, and
2. Preventing the erosion and potential unsustainability of existing generic markets.

Challenges to Market Entry Even as Patent Expiries Create Opportunity (Getting In)

Accordingly, the next five years present a significant opportunity for new generic and biosimilar entries and robust competition. In a 2017 report, IQvia, formerly IMS Quintiles, noted that the total number of patent expiries is expected to be 50 percent higher in the next five years. This could represent at least \$140 billion in lower brand drug spending – significantly more than came off-patent in the past five years.²⁵

Potential Savings From Loss of Brand Exclusivity

\$U.S. Billion



Source: QuintilesIMS Market Prognosis, National Sales Perspectives, QuintilesIMS Institute, Mar 2017.

However, whether America’s patients will see these savings remains unclear. Future competition is threatened by a series of challenges. These include:

- Gaming FDA regulations to delay generic entry
- Abusive patent behaviors
- Lack of clarity on FDA’s treatment of complex generics
- A slanted playing field that favors brand drugs in Medicare

Gaming FDA Regulations to Delay Generic Entry

Last year, FDA Commissioner Scott Gottlieb, M.D., criticized the “shenanigans” used by certain brand drug companies to delay generic competition.²⁶ One high-profile example of this “gamesmanship” is the now years-long effort by Celgene to delay generic competition to its best-selling drug Revlimid. In 2014, the Federal Trade Commission filed an amicus brief intervening in long-running litigation in which Mylan, N.V. sought access to samples needed for testing to develop a generic competitor to Revlimid.²⁷

This occurs when brand companies, using a Risk Evaluation and Mitigation System (REMS) or their own voluntary “safety” program as a rationale, refuse to sell samples of their products to generic and biosimilar companies so that they can conduct the requisite bioequivalence and other testing for applications to FDA. To date, FDA has received more than 150 complaints of specific challenges to obtaining samples.²⁸

This is a lucrative undertaking. Revlimid represented the seventh-highest amount of drug spending in Medicare Part D in 2015 – more than \$2 billion alone through the Medicare program.²⁹ And while it delays generic competition, Celgene continues to profit. The price of Revlimid increased almost 20 percent in 2017 alone – to almost \$19,000 for a 28-count bottle, and it represents roughly two-thirds of Celgene’s entire revenue.³⁰

A 2014 study concluded that REMS abuse costs the U.S. health care system \$5.4 billion annually – \$960 million of which is directly borne by patients.³¹ Given the increasing reliance on higher-priced biologics, the use of these tactics to block competition to biosimilars is likely to be even greater in the years to come.

And although the FDA has taken steps to limit these kinds of abuses,³² these steps continue to fall short of fixing the problem. It is critical that Congress pass the CREATES Act, a bipartisan solution to rein in such abusive efforts to delay generic and biosimilar competition. In the absence of strong penalties for failing to make samples available to generic developers under the same terms as any other willing purchaser, such unlawful behavior is likely to continue – costing patients and taxpayers alike.

Abusing the Patent System to Extend High-Priced Monopolies

As noted, policymakers have sought to strike a balance between innovation and competition by allowing for timely generic competition. But the patent and regulatory systems are increasingly being gamed as a means of unfairly prolonging a brand drug’s monopoly and delaying patient access to more affordable, FDA-approved generic and biosimilar medicines. Recent research shows the pharmaceutical industry is manipulating this well-intentioned system in an effort to maintain or obtain patent protection for advances or changes that are not innovative or novel.³³

- At least 74 percent of the new patents in the FDA’s records were associated with existing drugs on the market.³⁴
- Of the roughly 100 best-selling drugs, almost 80 percent obtained a patent that extended the monopoly period beyond the duration of the initially granted patent.³⁵

In 2016, one of the principal initial patents on the world’s best-selling drug, AbbVie’s Humira, expired. But before that patent expired, AbbVie filed more than 100 late-stage patents in an effort to delay biosimilar competition,³⁶ even though the Biologics Price Competition and Innovation Act (BPCIA) gives brand biologic drug manufacturers a 12-year market exclusivity period for their products to ensure a return on investment for new medicines – longer than anywhere else in the world. As a result, the last Humira patent won’t expire until 2034.

By establishing a patent thicket around Humira, AbbVie uses the patent system to protect annual revenues of more than \$18 billion on its blockbuster drug. Meanwhile, the company continues to take annual price increases of almost 10 percent, claiming that it “will continue to act responsibly with respect to drug pricing.”³⁷ But this annual increase is roughly four times the annual inflation rate – and when applied to a drug with a list price of \$38,000, it costs patients and taxpayers dearly.

In another high-profile and widely criticized case, Allergan entered into an agreement to rent the sovereign immunity of a Native American tribe in a blatant effort to block competition by attempting to circumvent the congressionally established inter partes review (IPR) process at the U.S. Patent and Trade Office. In his decision finding the patents to be invalid, U.S. District Court Judge William Bryson said, “The Court has serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed.”³⁸

These creative practices are intended to unfairly prolong a brand drug’s monopoly and delay patient access to more affordable, FDA-approved generic and biosimilar medicines. They run counter to Congress’s stated goal of bringing lower-cost generic alternatives to market at the earliest possible date under the law – causing patients to suffer from high monopoly prices for brand-name drugs and biologics for far longer than Congress intended.

FDA’s Lack of Clarity Delaying Complex Generics

As the generic market becomes more challenging, and older generics are increasingly commoditized, new generic entries become increasingly important to the sustainability of the industry so it can deliver affordable medicines to patients. And as medicines have grown in complexity and innovation in recent years, “complex generics” are in need of greater regulatory attention. These are products that may have a complex active ingredient, formulary or delivery mechanism, or are a drug-device combination.

Complex generics include products to treat cancer, metered dose inhalers to treat asthma and products designed for other challenging diseases. However, the scientific challenges of complex generics development are sometimes compounded by a lack of regulatory clarity from FDA.

Commissioner Gottlieb has taken a number of key steps to improve the review and approval of complex generics³⁹ and prioritize new generic applications through the Drug Competition Action Plan. This includes expediting the review of generic drug applications in markets where there are fewer than three approved generic versions of a given product.⁴⁰ While these steps are important, a recent GAO report highlighted the agency’s lack of clarity and timeliness in working with manufacturers seeking to develop complex generics – particularly with respect to the development and updating of product-specific guidance documents.⁴¹

These products may also benefit from other provisions included as part of the reauthorization of the Generic Drug User Fee Act, including the Competitive Generic Therapies’ provision that provides for greater interaction between the developer and the agency.⁴² Ultimately, the ability of generics to benefit from lower-cost versions of complex medicines will depend on FDA’s ability to support continued generic innovation.

Ensuring a Level Playing Field for Competitive Biosimilar Medicines

As previously noted, Humira, a treatment for rheumatoid arthritis, presently has a price of more than \$38,000 per year.⁴³ In January, its manufacturer raised the price by 9.7 percent, and forecast sales of \$21 billion by 2020.⁴⁴ Like other products that are subject to anticompetitive abuse, it represents a large share of its company's overall revenues – roughly two-thirds of the manufacturer's 2017 revenue.

In many ways, it and other biologics are clearly ripe for competition from less-expensive biosimilars in the Medicare program. However, reimbursement policies being established now will have a significant impact on the development of the market for biosimilars.

Since the introduction of the first biosimilar in 2015, CMS, FDA, Congress and other policymakers have made a number of critical policy decisions that biosimilar manufacturers will rely on in planning their portfolios. Fortunately since that time there have been a number of positive developments, in particular establishing independent coding and reimbursement in outpatient settings and putting biosimilars on equal footing with their brand counterparts in Medicare Part D.

Nonetheless policymakers will need to closely monitor the progress of the biosimilars market as it continues to mature to effectively maximize competition and incentivize biosimilar development. Biosimilar developers will need to be able to rely on consistent reimbursement and formulary placement to justify significant development costs. For that reason, policies should ensure that new biosimilars are able to quickly be added to formularies and to compete directly on price with their brand counterparts.

Challenges to Generic Sustainability (Staying In)

Once a generic manufacturer has successfully navigated both the FDA approval process and patent thickets, there remain significant challenges to ensuring sustainable levels of competition and supply, particularly for older, established generic medicines. This is highlighted in the persistent and pronounced generic drug price deflation over the last few years. Since 2008, generic drugs have seen approximately 7 to 8 percent price deflation year over year.⁴⁵ These low prices been highlighted by wholesalers and other observers over the past year.

These market challenges are further compounded by short-sighted policies that place additional regulatory burdens on generic manufacturers already squeezed by their market, as described below.

"Downward pressure on generic prices could challenge future profits for wholesalers and retailers."

**McKinsey & Company
(January 2018)⁴⁶**

"We now expect full year pharma segment profit to decline to low double digits versus the prior year. This is primarily due to the previously mentioned generic market pricing."

**Cardinal CFO Michael
Kaufmann (May 2017)⁴⁷**

"We have yet to see generic deflation ease from its current high single digits (-7 percent to -9 percent) where it's been for about three quarters now."

**AmerisourceBergen CFO
Tim Guttman (August 2017)⁴⁸**

The Medicaid Generics Penalty Harms Functioning Generic Markets

As part of the Bipartisan Budget Act of 2015, Congress mandated that generic manufacturers pay additional penalties in the Medicaid Drug Rebate Program when the price of a generic product rose faster than inflation. However, the methodology used to calculate this penalty was directly imported from the formula used for branded pharmaceuticals, which sees consistent, sustained price growth.⁴⁹

Because the generic market functions differently, this methodology does not adequately account for the fact that low-cost generics may have highly volatile prices directly related to the purchasing volume at any given time, and that this volatility often amounts to a change in price to no more than a few cents per dose. This is why generic manufacturers are now subject to millions of dollars in additional rebates for products even in the absence of changes in the actual price of the product. These changes do not necessarily reflect any new price being set by the manufacturer, but may merely reflect new purchasing patterns. This is a direct result of a flawed methodology. These penalties are often unpredictable for the generic manufacturer and significant in relation to the overall revenue of many low-cost products.

These unpredictable, onerous penalties create significant risk for manufacturers, and make it more challenging for manufacturers to continue participating in certain markets. A recent analysis concluded that the penalty would “increase uncertainty, reduce revenues, encourage manufacturers to exit the market, and discourage the entry of new manufacturers. The predictable effect of discouraging entry into competitive markets is that product availability will be hampered: shortages will be more likely, and the market forces that lead prices to fall will be dampened.”⁵⁰ Ironically, the analysis also concluded that the penalty “will not only have little effect on generic prices, but it will also have the unanticipated and unintended consequence of increasing the likelihood of shortages for potentially life-saving generic medicines.”⁵¹ Accordingly, Congress should repeal this penalty or modify it to create more predictability for generic manufacturers.

State-Based Burdens Create Disproportionate Regulatory Burdens for Generics

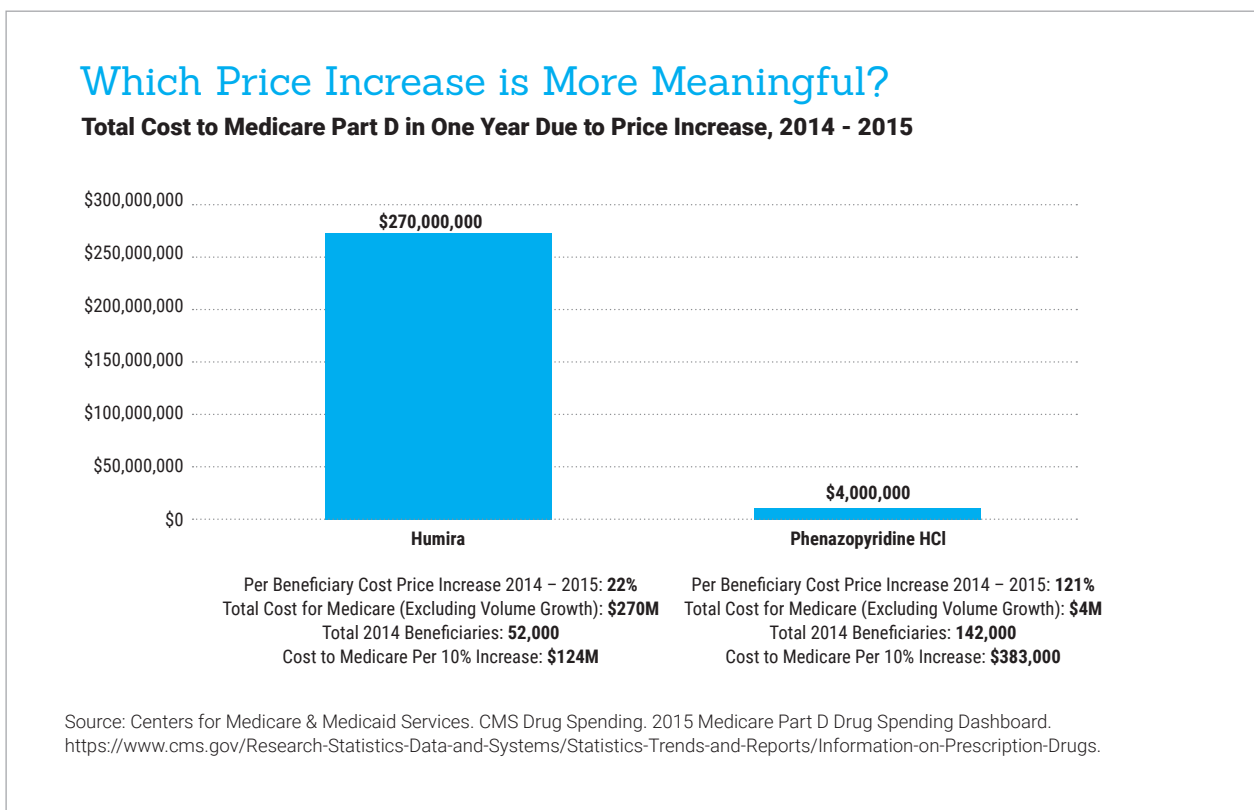
The federal government does not have exclusive domain over misguided policies harmful to generic markets. Numerous state legislatures have enacted or considered legislation aimed at regulating the prices of generic drugs without considering significant differences between branded and generic businesses.

To date, these proposals have largely been referred to as attempts to create “price transparency” for pharmaceuticals or prohibit “price gouging” by generic drug manufacturers. Both approaches are similarly flawed in that they fail to account for the regular price variability that has always existed in the generics market. Each approach creates additional costs for generic manufacturers exclusively related to the normal course of business that has created significant savings for patients and payers.

Many of these proposals seek to create “thresholds” for various pricing metrics of generics drugs that when reached create some form of new requirement for the manufacturer.⁵² The requirements may be a report to a local health department,⁵³ or may mandate the manufacturer lower the sales price or pay additional penalties to the state in excess of the thresholds.⁵⁴ Some proposals lack clear standards and impose reporting burdens on manufacturers whenever there is an ambiguously defined “unconscionable” change in the cost of a product.⁵⁵ Some state attorneys general have also sought the authority to bring legal action against manufacturers whenever these unclear pricing thresholds are met.⁵⁶

Such proposals fail to account for the commoditized nature of generic medicines. Wholesalers regularly negotiate new pricing for competitive generic products with manufacturers, with bulk purchase prices showing a great deal of variability as represented by percentages. However, generic manufacturers are solely responsible for the reporting, and ultimately have no insight into how those prices ultimately affect patient out-of-pocket costs or acquisition costs for the state. The enforcement mechanisms, whether they be manufacturer reporting or onerous litigation with the state’s attorney general, place additional cost on manufacturers solely for operating within competitive markets.

Moreover, such proposals fail to reflect the fact that brand drugs, not generics, drive costs. As previously noted, a review of the 100 most-utilized generic drugs in the Medicare program reveals that an average 30 day-fill is sold by the manufacturer for only \$5.94 and by the wholesaler for a 20 percent markup.⁵⁷ By any measure, generic drugs are not responsible for high prescription drug prices. State lawmakers who ignore this fact – who instead focus on percentage changes rather than prices – miss out on the true cost driver, high brand drug prices.



While many of these ideas have been suggested as ways to curb excessive spending growth in the branded space, they unfortunately place a substantially larger and costlier burden on generic manufacturers due to the larger size of generic portfolios and the regular variation within the markets.

Federal Programs Do Not Adequately Incentivize Generic Utilization

In addition to misguided policies that create additional burdens on generic manufacturers, federal payers also need to examine whether patients are provided adequate incentives to use lower-cost therapies when available. For instance, policymakers should consider use of generic medicines among the Low-Income Subsidy (LIS) population within Medicare Part D. According to the nonpartisan Medicare Payment Advisory Commission (MedPAC), significant savings in prescription drug spending in the LIS program could be achieved by improved generic utilization.⁵⁸ The Congressional Budget Office has estimated that the proposal could save the federal government \$18.3 billion over 10 years,⁵⁹ while ensuring that these beneficiaries continue to have access to high-quality prescription drugs.

Patients within the LIS program pay statutorily established copays for branded and generic drugs. In 2018 the branded copay will be \$8.35 while the generic copay will be \$3.35.⁶⁰ In comparison to commercial insurance plans, this is not a significant difference in patient out-of-pocket.⁶¹ Accordingly, the LIS population has historically maintained a lower generic utilization rate than the rest of Part D.

In order to better align this program with the rest of the market, Congress should approve legislation directing the Centers for Medicare and Medicaid Services to modify the Medicare Part D LIS copayment structure to encourage the use of generic medicines by these beneficiaries. This policy would build on the cost and access successes that both private and public purchasers have achieved as they have moved to incentivize utilization of generic drugs, while assuring beneficiary access to life-saving medications.

Risk of Generic Drug Shortages for Older Generic Drug Markets

As brand drug prices continue to rise, low-cost generic and biosimilar manufacturers face new challenges – first in overcoming barriers to get to market with new competitive products and, second, in maintaining profitability for older products. This uncertain environment for generic and biosimilar medicines imperils manufacturers' continued ability to deliver value.

For example, market uncertainty forces generic manufacturers to reconsider production of lower-margin, often older, medicines in order to ensure their continued corporate sustainability. And the consolidation of purchasers means that other manufacturers never have a chance to launch a competitive product due to the limited contracting opportunities. An unfortunate yet foreseeable consequence of these dynamics is a significantly increased risk of drug shortages for patients and challenges to the ability of medical providers to optimize patient care.

Evidence suggests that generic drugs are particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.⁶² This is directly related to the economic forces at play in generic markets. Hypercompetitive markets prevent generic manufacturers from raising prices to reflect changing demand for products. This results in a dynamic landscape where manufacturers regularly enter and exit markets as conditions change. However, these dynamics can create strain on the supply chain, and may leave providers without sufficient supply to meet medical need for patients. For instance, sterile injectable drugs, which have significant complexities to them due to their manufacturing processes, and therefore have limited suppliers with these capabilities, have experienced shortages in the past.

In 2011, now-FDA Commissioner Scott Gottlieb testified before Congress that many such shortages were a direct result of low reimbursement for older, low-margin products and that “many hospitals are being forced to ration key medicines and patients must sit on waiting lists for vital drugs.”⁶³ These shortages can directly affect patients and the ability of medical providers to optimize patient care.⁶⁴ They cause physicians to delay therapy or resort to less than optimal therapies in order to preserve supply, ultimately deciding patient care based on cost rather than standard medical practice. When shortages create these kinds of difficult environments, patients directly suffer from reduced access to proven, effective treatments. The likelihood of such shortages will only increase as generic companies discontinue unprofitable medicines – and as fewer generic companies manufacture certain products – in response to purchaser consolidation and increasing government-imposed burdens.

Conclusion

Patient health and well-being depends on the uninterrupted availability of lower-cost generic and biosimilar medicines. Moreover, as patients live longer the importance of a robust and sustainable generic and biosimilar medicines industry becomes only that much more important. Policymakers must act quickly to ensure continued saving and market-based competition, as well as prevent shortages, for future availability of affordable medicines. This requires:

- Enactment of the CREATES Act to prevent regulatory shenanigans;
- Scrutiny of patent gamesmanship to ensure that generics and biosimilars are able to launch at the earliest possible date;
- Continued regulatory attention to the review and approval of complex generics;
- Placement of biosimilar medicines on a level competitive playing field;
- Repeal or modification of the Medicaid Generics Penalty to prevent unintended harms;
- Focusing state drug pricing efforts on high-priced brand drugs that drive costs; and
- Increasing use of cost-saving generics for low-income patients in Medicare.

Altogether, these will ensure that generic and biosimilar medicines can enter new markets and that such markets are sustainable for the long-term.

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