



## Your Generics and Biosimilars Industry

Statement of Chester "Chip" Davis, Jr.  
Senate Health, Education, Labor and Pensions Committee  
The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay  
October 17, 2017

### Introduction

Chairman Alexander, Ranking Member Murray and members of the Committee, thank you for the invitation to testify today. I am Chip Davis, President and CEO of the Association for Accessible Medicines (AAM). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities, and manufacture more than 61 billion doses in the United States every year. AAM's core mission is to improve the lives of patients by advancing timely access to affordable generic and biosimilar medications.

I commend you for convening today's hearing to examine the critical challenge of high and rising drug prices.

Generic medicines represent greater than 89% of all prescriptions dispensed in the U.S., but only 26% of expenditures on prescription drugs, saving patients and payers nearly \$5 billion every week.<sup>1</sup> Our industry is proud to be able to deliver these savings to the healthcare system.

It is sobering to consider what America's patients would face if there were no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics don't just deliver the most medicine at the lowest cost and greatest savings; generics cushion the significant impact dealt to patients and the healthcare system by high brand name drug prices every day.

Put another way, the availability of low-cost generics offsets the impact of high brand drug prices. Whereas prices for FDA-approved generic medicines are currently declining by over 7% year-over-year, prices for brand drugs, especially biologics and specialty medicines, are increasing at an unsustainable rate. From 2007 to 2016, brand specialty medicines grew to occupy almost 43% of spending. These

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<sup>1</sup> \$253 billion total savings in 2016, equivalent to approximately \$5 billion every week. AAM 2017 Generic Drug Access & Savings in the U.S., <http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.



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products treat less than 3% of the population, and can often cost patients thousands of dollars per treatment.

To illustrate this fact, consider that in the past twelve months, prescriptions of brand drugs have decreased by 7%, but their revenue has climbed by 5%. This is a direct result of price increases. By contrast, generic prescriptions increased by 2%, but revenue declined by 13%.<sup>2</sup>

Consider the costs that patients would face in the absence of these levels of generic competition. Last year, use of generic medicines saved \$253 billion. It has produced \$1.67 trillion in savings over the last ten years. This has produced meaningful and sustained patient access. Without generic medicines, spending on cholesterol drugs would be more than 3.5 times higher, diabetes drugs almost 3 times higher, and spending on breast cancer drugs 8 times higher.<sup>3</sup>

However, the sustainability of a competitive generic market and the availability of generic medicines for patients, uninterrupted by shortages, is in jeopardy. In 1984, Congress enacted the Hatch-Waxman Act which represents a model of successful, bipartisan public policy. Over its more than thirty-year history, the Act has produced a thriving and constantly-changing marketplace by balancing innovation in drug development and accelerating the availability of lower cost generic alternatives. This has important effects on the public health, allowing patients to live longer, healthier lives.

This balance is now threatened by three factors:

- changing and increasingly challenging market and reimbursement frameworks,
- the abuse of laws and regulations by bad actors, and
- a failure of policy to account for the unique challenges facing generic and biosimilar medicines.

In fact, while brand drug innovation has benefited from a series of subsequent laws establishing incentives and development tools, the generic and biosimilar marketplace and patient access has not received an equivalent level of attention. That neglect, combined with current market and

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<sup>2</sup> Morgan Stanley: Major Pharma Rx Chart / North America, September 2017.

<https://ny.matrix.ms.com/eqr/article/webapp/89cddeb4-96d6-11e7-8a10-ce4c0a51e87f?t=1506097268%3A3184%3A22035%3Avmias1106666&m=1&ch=autob#>

<sup>3</sup> AAM 2017 Generic Drug Access & Savings in the U.S., <http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.



anticompetitive realities, reinforces why this hearing – and the FDA’s recent public hearing and the FTC’s upcoming public meeting on the same issue – are so important.

Congress must act to support generic and biosimilar competition and supply to ensure continued access for patients. It can do so by:

1. Repealing the misguided Medicaid penalty on generic drugs,
2. Preventing brand abuses designed to block generic and biosimilar competition by passing the bipartisan CREATES Act, and
3. Ensuring that biosimilar medicines have a level and competitive playing field in Medicare.

### Generic Drug Markets are Fundamentally Different than Brands

First, it is important to provide context about the generic marketplace. Not only is the FDA approval process different for generics and brand name drugs, but their respective markets and the path by which they reach patients diverge significantly, with important policy implications.

The 1984 Drug Price Competition and Patent Term Restoration Act, commonly referred to as the “Hatch-Waxman” Act, created an abbreviated pathway for generic drugs. This allows manufacturers to rely upon the existing clinical data of the brand product and demonstrate to FDA that their product is the same as the reference product.

Hatch-Waxman also provided numerous lucrative incentives for brand name drug companies, including extensions of patent terms, regulatory exclusivities that guarantee market monopolies regardless of the intellectual property status, and a clear litigation pathway for asserting intellectual property claims against generic manufacturers.

### Differences in Supply Chain

The balance created by Hatch-Waxman also created a new and different market for generic drugs – separate from brand drugs – that has supported growth in generic utilization and its attendant savings for patients. Although brand manufacturers often criticize pharmacy benefit managers (PBMs) and health plan formulary and rebate practices, the supply chain and pricing models they criticize do not represent the vast majority of prescription drugs distributed in this country. The 89% of prescriptions filled by generic medicines are subject to a different set of economic incentives and arrangements –



the result of multiple manufacturers marketing identical products and competing exclusively on price, in a commodity-style market.

When brand manufacturers leverage the pricing power granted by their patents and regulatory exclusivities, PBMs, distributors, and payors rely on formulary management and rebating agreements to control costs.

However, upon generic entry, payors typically shift away from rebate models of reimbursement and rely on distribution channels to effectively lower the price of the medicine. Rather than providing rebates to lower the cost, generic manufacturers must compete for sales to wholesalers. Because the products are virtually identical, the primary leverage manufacturers have is their ability to lower the price and provide the necessary volume. With over 200 generic manufacturers recognized by FDA, competition is fierce and prices decline rapidly. The wholesalers, often in collaborative purchasing agreements with pharmacies across the country, then distribute generic medicines to various retail pharmacies. Generic manufacturers may have to compete even further by negotiating separate payments to pharmacies to stock their product.

The different business model leads to a different type of business planning by generic and biosimilar manufacturers. As part of this, the decisions by which generic and biosimilar manufacturers select which products to develop can take into account multiple variables. Considerations include the complexity in reverse engineering the original product, the state of the intellectual property claimed by the brand manufacturer over the product, the size of the patient population served, the number of likely competitors for that product, the product development and manufacturing capabilities and costs.

Generic drug reimbursement is also different. Rather than relying on per-transaction rebates, PBMs and insurers typically establish a "Maximum Allowable Cost" (MAC) list that sets a specific reimbursement rate for the product, regardless of the generic product cost to the pharmacy. These MAC lists create additional incentives for pharmacies to maximize their dispensing margins by finding the lowest cost source for generic products.

The result is a business model that differs significantly from the brand business model. While brand companies typically market a small number of high margin products, many generic manufacturers market hundreds of products with varying levels of profitability or loss.



## Supply Chain Pressures on Generics

These differences in the generic and brand marketplaces create vastly different incentives for the various manufacturers, wholesalers, distributors, pharmacy benefit managers (PBMs), insurers, and retail pharmacies that make up the supply chain. To put it simply, virtually all other actors in the supply chain enjoy significant financial benefits from the manufacture of generic medicines.

This phenomenon was most recently examined by a group of researchers at the USC Leonard D. Schaeffer Center for Health Policy & Economics. That analysis, “The Flow of Money Through the Pharmaceutical Distribution System,” identified two items relevant to today’s hearing:

- First, for every sale of a brand name drug to a patient, the brand manufacturer captures approximately 76% of that revenue. Comparatively, generic manufacturers keep only half of that percentage. Moreover, generic manufacturers cannot rely on capturing the total volume within the market as the brands do, and therefore individual generic manufacturers are forced to rely on much smaller revenue streams. To put it simply, brand drugs capture a higher percentage of the spend of a higher value market.
- Second, the supply chain captures significantly more of the revenue spent on generic medicines than on brand name drugs. For every \$100 spent on dispensing generic medicines in this country, approximately \$65 goes to the distribution and reimbursement of those products by the members of the supply chain. PBMs make nearly three times as much on generics as they do on brands. Wholesalers make about eight times more. Pharmacies make over 10 times more for every \$100 on generics than brands.<sup>4</sup>

While the analysis demonstrates a series of strong incentives to drive patients to generic medicines, supply chain consolidation may jeopardize that success.

Compared to the fragmented generic drug market, consolidation in the wholesale market and contractual arrangements between pharmacy chains and the wholesalers have left generic

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<sup>4</sup> Sood, et al., “The Flow of Money Through the Pharmaceutical Distribution System.” June 2017.  
[http://healthpolicy.usc.edu/documents/USC%20Schaeffer\\_Flow%20of%20Money\\_2017.pdf](http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf)



manufacturers with only a small number of purchasers. The result is a market where three purchasers account for over 90% of all wholesale revenue.<sup>5</sup>

As these purchasers move more and more towards single-source contracts for generic drugs, it creates a dynamic where it is possible that no more than three generic manufacturers may be able to successfully market any given product. This dynamic risks future competitive success in the generic market as generic drug manufacturers may be forced to maximize economies of scale and consolidate themselves.

### Cost Pressures for Patients

Patients thrive because of generic medicines, both in terms of health outcomes and financial savings. For insured patients, over 90% of generic prescriptions are filled for \$20 or less out-of-pocket. That is in comparison to just 39% for brands at that price.<sup>6</sup>

Data shows that patients are far less likely to fill a prescription for a high-priced brand drug. In fact, brand name drugs make up 20% of approved claims but account for 40% of all abandoned claims for new patients. Moreover, new patient abandonment rates for generics are three times lower than for branded products.<sup>7</sup> Patient abandonment has a serious effect on patient health – leading to hospitalizations, deaths and extensive health system costs.

This is not to say that the market functions perfectly in providing patients with the lowest cost possible. Many generic medicines are subject to significant markups after they leave the generic manufacturer. As an example, amoxicillin/ potassium clavulanate, commonly referred to by its branded name Augmentin and used for the treatment of infections, is sold by the generic manufacturer for pennies per pill. However, by the time a patient picks it up at the pharmacy counter, it may have a cash price as high as \$60 for 20 pills, or \$20 for a fill for patients with commercial insurance.<sup>8</sup>

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<sup>5</sup> Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.

<sup>6</sup> AAM 2017 Generic Drug Access & Savings in the U.S., <http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.

<sup>7</sup> *Id.*

<sup>8</sup> Data on manufacturer sales from CMS Average Manufacturer Price (AMP) data. Typical pharmacy prices from GoodRx.com.



It is clear the significant benefits for patients of reliable access to affordable generic medicines are at risk. Notwithstanding the economic principle that more suppliers of a good or service creates lower prices for consumers, it is unclear that the new imbalance between 200 generic competitors and a handful of purchasers is sustainable. Some industry analysts have already begun to forecast consolidation among generic manufacturers.

An unfortunate yet foreseeable consequence of fewer generic manufacturers is a significantly increased risk of drug shortages. Evidence suggests that generic drugs are particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.<sup>9</sup> Such shortages have a serious effect on patient care. Responding to a series of drug shortages in 2011, Dr. 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 to sit on waiting lists for vital drugs.”<sup>10</sup>

### The Importance of Recognizing Differences in Policymaking

It is critical that policymakers take steps to ensure the continued supply of affordable FDA-approved generic medicines. Failure to do so threatens a stable supply of generic medicines.

Congress recently created a new inflation-based penalty in the Medicaid program for generics as part of the Bipartisan Budget Act of 2015. The legislation inappropriately applied a tool crafted for the brand drug market to generic markets, essentially conflating what transpires in a monopolized market with what occurs in a commoditized market with multiple competitors. Under the legislation, generic manufacturers are now subject to additional rebates for products *even in the absence of changes in the actual price* of the product. This is a direct result of a flawed application of a brand drug scheme that fails to recognize the significant volatility in generic prices.

As a result, manufacturers of affordable generic medicines are now paying millions of dollars in “penalties” on products that have not been subject to a price increase. In many instances, changes in customer mix from one quarter to another have triggered penalties solely due to purchasers getting

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<sup>9</sup> Stromberg, C. (May 2014). Drug Shortages, Pricing, and Regulatory Activity. National Bureau of Economics Working Paper. <http://www.nber.org/chapters/c13102.pdf>

<sup>10</sup> Gottlieb, Scott. “Drug Shortages: Why they happen and what they mean” Testimony before the Senate Finance Committee. December 2011. <https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf>



lower discounts on smaller volume orders – a normal occurrence in a competitive market. These changes do not necessarily reflect any new price being set by the manufacturer, but may merely reflect new purchasing patterns.

These unpredictable, onerous penalties on often low-margin medicines creates significant risk for manufacturers that would consider entering these markets, and makes it more challenging for manufacturers to continue participating in those 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.”<sup>11</sup> 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 generic medicines.”<sup>12</sup>

Accordingly, we urge Congress to repeal this penalty.

### Barriers to entry

AAM and its members strongly support innovation. The generic and biosimilar marketplaces rely on the existence of a vibrant brand medicine industry. Fortunately, innovation continues to flourish. FDA has already approved more new molecular entities this year than it did in all of 2016. This is good news for all of us.

But the balance between innovation and access requires a clear opportunity for FDA-approved generic or biosimilar entry. Without that competition, there can be no savings for patients or taxpayers. Unfortunately, many brand medicine companies have responded to the threat of competition by deploying new and controversial ways to extend their high monopoly prices.

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<sup>11</sup> Manning and Selck, “Penalizing Generic Drugs with the CPI Rebate will Reduce Competition and Increase the Likelihood of Drug Shortages,” September 2017. <https://www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf>

<sup>12</sup> *Id.*





## Challenges to Intellectual Property Law

Recently, one company went so far as to pay a Native American tribe to rent its tribal sovereign immunity by taking ownership of certain brand name drug patents facing a challenge. Allergan, Plc (Allergan), a Dublin, Ireland-based drug company, transferred the patent rights to its blockbuster drug Restasis® to the St. Regis Mohawk tribe in a blatant effort to shield those patents from an administrative review process established by Congress in 2011 and block generic competition.

The deal stands to be a profitable one for Allergan. Restasis® generated \$1.4 billion in 2016 sales.<sup>13</sup> For less than 0.1% of the drug's annual sales, Allergan's deal could delay patient access to affordable generic drugs for six more years. This is a supply chain failure that Congress should prevent.

According to press reports, Allergan provided an initial payment of \$13.75 million to the St. Regis Mohawk Tribe and \$15 million in annual licensing fees. Every day Allergan delays competition, the company takes in over \$4 million in revenue due to the lack of generic competition. Allergan will recoup this licensing fee in around four days.

Allergan's transfer of its patents to the St. Regis Mohawk Tribe is an end-run around the legal process established by Congress to challenge questionable patents. If Congress wants to ensure that Americans have access to affordable prescription drugs, it must address schemes like Allergan's to delay generic competition by renting sovereign immunity. The action by Allergan to ensure that patients and payors do not benefit from timely generic competition to Restasis® is an alarming example of the steps that brand name drug companies will take to put profits above the public interest. But it is by no means the only such example. Congress should outlaw these practices and strengthen the IPR system.

## Barriers to Generic and Biosimilar Development

As this Committee is aware, many generic and biosimilar manufacturers face significant challenges obtaining the samples needed for generic or biosimilar development. This is a result of the misuse of systems designed to ensure the safety of medicines by certain brand drug companies focused on delaying or prevent competition. Such delays created by misuse, abuse or regulatory failure deserve

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<sup>13</sup> Allergan plc, Annual Report (Form 10-K), at 59 (February 2017) ([link](#))



Congressional attention. In short, if generic and biosimilar development is frustrated, they will never enter the supply chain.

FDA Commissioner Gottlieb has highlighted the abuse of FDA-mandated restricted distribution systems and restricted distribution systems that brand companies create on their own, without any mandate from FDA, to delay or completely prevent generic competition.

This occurs when brand companies, using a Risk Evaluation and Mitigation System (REMS) or their own voluntary “safety” program as an excuse, refuse to sell samples of their products to generic and biosimilar companies so that they can conduct the requisite bioequivalence and other testing. AAM members that have sought to purchase brand products from wholesalers in the supply chain are often informed that the wholesalers’ contracts prohibit the sale of the brand product for generic studies. To date, FDA has received more than 150 complaints of specific challenges to obtaining samples.

These abusive practices are directly counter to Congressional intent reflected in both Hatch-Waxman, which seeks to create generic competition as soon as brand monopoly protection has expired, and the Food and Drug Administration Amendments Act, which specifically prohibited the use of REMS to delay generic competition.

FDA has taken steps to limit these kinds of abuses. In 2014, FDA released a draft guidance that attempted to assist prospective generic and biosimilar applicants in their efforts to acquire the samples necessary to conduct bioequivalence testing. Under the guidance, FDA reviews bioequivalence protocols. Following its review and identification of any required changes, FDA sends a letter to the brand sponsor indicating that the proposed testing contains safety protections that provide the same level of patient-protection as those in the applicable brand’s safety protocol and that FDA will not consider it a violation of the law for the brand sponsor to provide samples to the designated potential generic or biosimilar applicant. Although well-intentioned, the draft guidance has failed to solve the problem and patients wait in vain for FDA-approved generic and biosimilar versions of these medicines.

Generic applicants are also challenged by brand companies’ refusal to negotiate in good faith the creation and implementation of a single-shared REMS system (SSRS). Under current law, if a brand drug is subject to a REMS that contains Elements To Assure Safe Use (ETASU), generic versions cannot be approved unless they are subject to a SSRS to implement the ETASU elements. Moreover, the Federal Food Drug and Cosmetic Act provides that a generic drug must utilize a shared system along with the brand drug unless FDA waives this requirement for one of the reasons set forth in the



statute. In other words, the brand and generic must agree on how to implement the existing safety protocol jointly, unless FDA says otherwise.

The creation of a shared system should be relatively straightforward and simple—generic applicants merely join the existing safety system. Fundamentally, this is the business of generic manufacturers: taking a sole-source product and making it a multi-source product. However, brand companies regularly use a variety of tactics to systematically delay and extend the brand/generic negotiations. This refusal to engage in good faith negotiations can delay the approval of the generic product and force consumers to pay more to fill their prescriptions.

This abuse injures competition. Commissioner Gottlieb recently testified that:

brand companies often have an incentive to refuse to agree to a single, shared system REMS. By prolonging the negotiations over a single, shared system REMS, they further delay generic drug approval and competition. We see prolonged negotiations and inability to agree on the terms of a single, shared system REMS regularly.<sup>14</sup>

AAM applauds Commissioner Gottlieb's leadership to develop a "Drug Competition Action Plan" to address regulatory issues that are impeding competition, including abuse of restricted distribution and REMS systems. However, AAM is concerned that FDA's enforcement authorities as provided in FDAAA will not be adequate to fully stem the brand abuses that have become so widespread in recent years. For instance, the civil monetary penalties available under FDA's enforcement authority pale in comparison to the revenue available by impeding generic entry. Center for Drug Evaluation and Research (CDER) Director Dr. Janet Woodcock noted that "fines and everything might simply be considered a cost of doing business because there's so much at stake in delaying generic competition."<sup>15</sup> Also, FDA's authority to address the brand abuses using voluntarily imposed restricted distribution system are highly limited.

Brand manufacturers who have recognized the incentives created by REMS-related delays have developed novel distribution schemes that mimic these programs even when the FDA has not recognized any inherent safety risk with the handling or use of the medicine. According to a recent

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<sup>14</sup> Gottlieb, Scott. "Antitrust Concerns and The FDA Approval Process," Testimony before the House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, July 2017.

<https://www.fda.gov/NewsEvents/Testimony/ucm568869.htm>

<sup>15</sup> Testimony of Dr. Janet Woodcock at "Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs." Senate Committee on Health, Education, Labor and Pensions, January 2016.



study,<sup>16</sup> 74 drugs are subject to restricted access programs (i.e., drugs that are either subject to REMS or self-imposed restricted distribution programs) with total sales of \$22.7 billion in 2016. Of these, 41 drugs are restricted by REMS programs, with \$11.5 billion in sales in 2016. The remaining 33 drugs are restricted by the brands in a voluntarily imposed non-REMS program, with \$11.2 billion in sales in 2016. And a 2014 study concluded that REMS abuse costs the U.S. healthcare system \$5.4 billion annually.<sup>17</sup> Consumers bear \$960 million of that cost while Medicare and Medicaid incur \$1.8 billion; private insurers bear the remaining \$2.4 billion.<sup>18</sup> This estimate is conservative “and should not be construed as the entirety of the lost savings from REMS misuse, either currently or going forward.”<sup>19</sup> AAM and its members are committed to ensuring that all Americans have access to safe, effective and affordable medicines and believe that FDA’s REMS programs can and do serve a compelling public good – namely, the safe distribution and use of certain pharmaceuticals that have a higher risk profile. We do not support any policies that would jeopardize patient safety. Any suggestion to the contrary is simply an effort to distract us from the real issue we need to focus on: addressing the use of REMS or non-FDA mandated restrictions on drug supply that are designed to block lower cost generics and biosimilars from coming to market. By refusing to sell their product for research purposes, or restricting its sale to a named patient, brand manufacturers can distort the supply chain to limit competition.

To address this problem once and for all, Congress must pass the CREATES Act, bipartisan legislation introduced by Senators Leahy, Grassley, Klobuchar and Lee, to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.

The cost of failure is significant, and will only encourage anti-competitive practices to grow. In the absence of Congressional action, AAM members today must consider the difficulty involved in obtaining branded drugs when determining which generic development programs to pursue. Where access to brand drugs is subject to restricted access programs, some AAM members have determined that generic development was not feasible and decided against initiating these development programs.

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<sup>16</sup> Alex Brill, REMS and Restricted Distribution Programs: An Estimate of the Market (June 2017), *available at* [http://www.gphaonline.org/media/cms/Alex\\_Brill\\_REMS\\_Study\\_June\\_2017.pdf](http://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf).

<sup>17</sup> Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, at 5 (2014), *available at* [http://www.gphaonline.org/media/cms/REMS\\_Studyfinal\\_July2014.pdf](http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*



This means that patients and taxpayers lose out on opportunities for affordable access to life-saving medicines and our nation's health care system leaves savings on the table.

### Biosimilar Medicines are Critical to Future Savings

Nowhere is the need for lower-priced alternatives, and the challenges facing them, more real than among high-priced biologic medicines. Biologics, many of which are specialty medicines, are the most rapidly growing segment of increasing brand-name prescription drug costs in the United States, with more than \$100 billion in annual spending. And the role of biologic drugs in the health care system is expanding – while only 2 percent of America's patients use biologics, they account for about 40 percent of prescription drug spending in the United States.<sup>20</sup>

These products are often life-saving therapies for serious illnesses, but they come at steep expense to patients, taxpayers and insurers. Many biologics cost tens of thousands of dollars per year per patient – some more than \$200,000.

To help bring down prices for patients, Congress designed and approved the Biologics Price Competition and Innovation Act (BPCIA) in 2010 – creating an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” (biosimilar) to or “interchangeable” with an FDA-approved biological product. The BPCIA also gave brand biologic drug manufacturers a 12-year market exclusivity period for their products to ensure a return on investment for new medicines. This period is longer than anywhere else in the world that has a similar abbreviated pathway for biosimilars.

Biosimilar medicines represent a key step forward in reducing high drug prices. They are safe, effective and affordable versions of costly brand biologics. By the year 2025, over 70% of drug approvals are expected to be biological products.<sup>21</sup> Experts estimate that FDA-approved biosimilars could save between \$44 billion and \$250 billion over the next 10 years.<sup>22</sup> In doing so, they will mean 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.

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<sup>20</sup> Medicine Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021, April 2017.

<sup>21</sup> U.S. Pharmacist, “Biosimilars: Current Approvals and Pipeline Agents,” October 2016 ([link](#)).

<sup>22</sup> AAM, “Generic Drug Access & Savings in the U.S.,” June 2017 ([link](#)).



Today, there are 38 biosimilars approved for use in the European Union, but only 7 in the United States. However, more than 66 biosimilar programs are under FDA review for development of 20 different biologic products. The ability of biosimilars to fulfill their potential is threatened by market abuses and policy challenges.

### **Anticompetitive Threats to Biosimilar Availability**

As discussed above, while the abuse of restricted distribution programs continues to impede generic development, the problem of access to samples is likely to be even more acute for biosimilar development. Biosimilars are more complex and difficult to develop than traditional generic drugs. Their development requires multiple lots of the brand product produced over time. If access to the variability that is inherent in brand lot development of biologics is denied, the development of the biosimilar will be greatly delayed and patients will be held hostage to higher prices and fewer options. Plus, unlike with small molecule generic drugs, the development of biosimilars is more likely to involve clinical trials requiring even more samples of the reference product. Restricted access to samples at any point during the clinical trial could cause a study to fail. This further highlights the importance of Congressional action on the CREATES Act.

And it now appears that brand manufacturers of biologic drugs are misusing their negotiating leverage to insist on contract terms that effectively block use of biosimilar alternatives by physicians. In a recent lawsuit, one branded company has alleged that another company that manufactures Remicade has misused its negotiating power to force PBMs and purchasers to block access to a biosimilar product. Such actions could threaten the ability of biosimilars to deliver on the promise of savings for patients.

Finally, it is critical to reiterate that biosimilars are just as safe and effective as their reference product. While we understand that physicians must remain directly involved in their patients' treatment, it is also important to recognize that some have sought to create uncertainty around the efficacy and pharmacovigilance standards of biosimilars in comparison to their reference products. These messages are in direct contradiction with the standards established in the BPCIA, and enforced by the FDA. Differentiation between biosimilars and their reference products risks undermining the important provider education that is already being done by FDA. It is also directly in contradiction to the medical evidence found in Europe and other advanced countries that have more experience with biosimilars, and have seen no measurable clinical differences between biosimilars and their reference products.



## Policy Barrier to Biosimilar Adoption

Biosimilars present a significant opportunity for patient and program savings in the Medicare Part D program. However current law creates barriers to biosimilar access for patients in Part D, who may be forced onto higher priced biologics.

Because of the structure of Medicare Part D, the 50% discount required of brand biologics is counted towards a patient's out of pocket costs – but competing biosimilars are barred from providing such a discount. This creates a perverse incentive for health plans and patients to use a higher-priced brand biologic – moving patients through the coverage gap and into catastrophic coverage faster and with lower out-of-pocket costs compared to a lower-cost biosimilar.

This approach creates substantial barriers for biosimilar manufacturers, as it may be effectively impossible to ever offer sufficient discounts to be included on Part D formularies. The resulting imbalance severely undermines the market potential for biosimilar competition. Ultimately, patients, payers, and Medicare all pay more for brand biologics than they would if the Coverage Gap Discount program were amended to include biosimilars.

Congress should amend the Part D coverage gap discount program to classify biosimilars as “applicable drugs” in the Coverage Gap Discount Program. This change would allow biosimilar manufacturers to pay the 50 percent discounts paid by their brand competitors, and participate on a level playing field to compete for placement on the Part D plan's formulary. It would reduce both patient out-of-pocket costs and save at least \$1 billion over the next ten years for the Medicare Part D program.

Additionally, in Part B CMS has chosen to create a coding and reimbursement structure that deeply disincentivizes development of biosimilars. Under current CMS policy, all biosimilars are grouped into an average reimbursement rate, separate from their reference brand product. This allows the brand to maintain control over its reimbursement rate, and allows the company to provide physicians with consistent reimbursement, free from price competition. Meanwhile, the biosimilar products would be forced to compete on price with one-another, despite only ever being compared to the reference product rather than each other.

This policy could significantly limit biosimilar adoption in outpatient settings, which would create a significant barrier to entry for any potential biosimilar competitors. To better incentivize competition in settings reimbursed by Part B, CMS should change this policy to grant individual codes and payment



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rates to non-interchangeable biosimilars. This would create a market much more conducive to price competition.

### **Conclusion**

AAM and its members commend the Committee for holding today's hearing addressing the challenge of high drug prices through the lens of the pharmaceutical supply chain. Generic and biosimilar medicines are a critical part of the solution for patients and America's health care system. But they are under threat from market imbalances, policies that fail to distinguish their business model from brand drugs, and anti-competitive behavior by other supply chain actors. AAM stands ready to work with you to ensure uninterrupted access to affordable therapies for patients and taxpayers.