



# Social Media Toolkit

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## Dear Champion of Accessible Medicines,

We are excited for your support in sharing the work of the Association of Accessible Medicines and The Biosimilars Council in social media channels. Whether you are a Tweeter newbie or guru, we hope you find this toolkit helpful.

## Social Media Impact

Using Facebook, Twitter, and other social platforms are vital tools for:

- Engaging elected officials, government agencies, business allies, patient groups, and other stakeholders.
- Increasing awareness about your patient story, your business, the industry and the importance of generic drugs.
- Thanking political and media champions and highlight their positive public statements about generic drugs and other important issues to our industry and patients.
- Sharing news and enlisting support from friends in your network.

## ENGAGING YOUR MEMBER OF CONGRESS

As a voter, your opinion matters to your Member of Congress. Elected officials work for their constituents. As an American, your advice and counsel matter concerning the issues that impact your business, patient care, medical costs and ultimately – your quality of life.

It is essential to develop a strong, multi-faceted relationship with your elected officials. The first step is for them to hear from you. You can start this process by looking for active campaigns on our website and by clicking on the “TAKE ACTION” button on [accessiblemeds.org](http://accessiblemeds.org).

Here are three simple ways to build a relationship with your Member of Congress:

- Tag them in a Facebook post or Tweet
- Share an active AAM campaign and use our #hashtag
- Send an email through our TAKE ACTION button on [accessiblemeds.org](http://accessiblemeds.org)



# 2017 CONGRESSIONAL CALENDAR

115<sup>th</sup> Congress, First Session

## January

M	T	W	TH	F
2	3	4	5	6
9	10	11	12	13
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30	31			

## February

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## March

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## April

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## May

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## June

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## July

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31				

## August

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## September

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## October

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## November

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## December

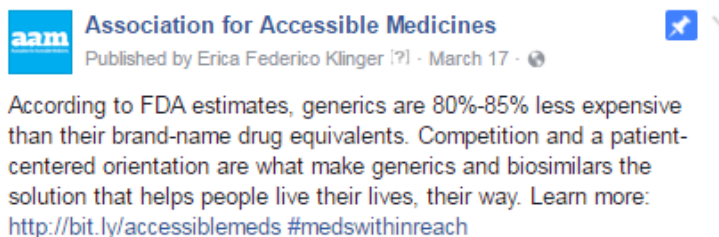
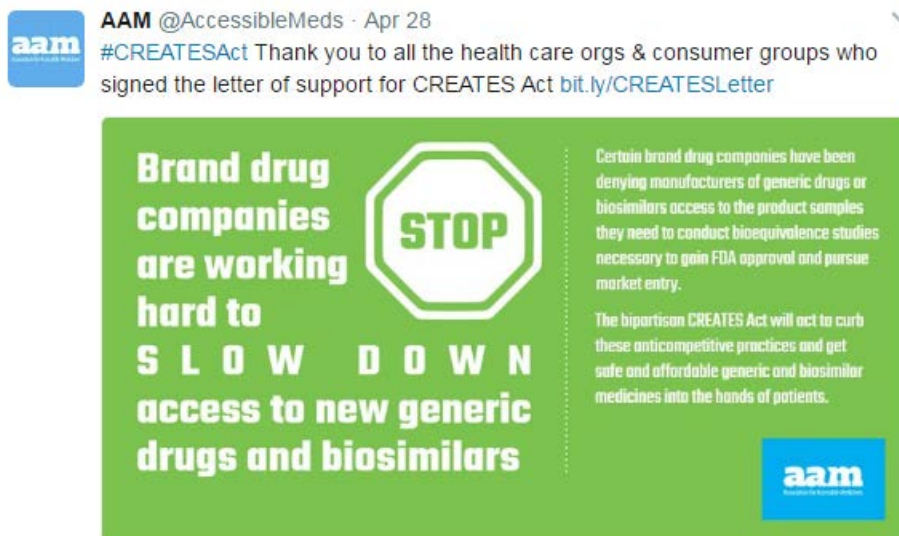
M	T	W	TH	F
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25	26	27	28	29

■ Senate in Session

■ House in Session

## ENGAGING ON SOCIAL MEDIA

Social media, including platforms like Facebook and Twitter, is an excellent way to thank lawmakers and highlight positive public statements about generic drugs, and other important issues that impact Americans.



## Pro Tips

1. Follow and like the Twitter and Facebook accounts of your elected representatives.
2. Follow reporters who write about health care and prescription drugs. That improves the likelihood that your social media posts are viewed by journalists who need to understand your business and our industry.
3. The more you build up your personal/professional social media network, the further AAM's reach grows.
4. Use visuals; photos and charts attract more attention than text alone.
5. Post "in the moment" or as close as possible; social media moves fast.
6. Be interesting/authentic but not harsh.
7. Proofread before posting; if you have multiple accounts, double-check that you're signed into the right one.

## AAM on Social Media

1. "Like" the Facebook page of the Association for Accessible Medicines (<https://www.facebook.com/accessiblemeds/>). That way you'll get the latest news from AAM and you can share with your network. We are also on [YouTube](#), [LinkedIn](#) and [Instagram](#).
2. *Follow @AccessibleMeds on Twitter.* You will see all AAM's latest Tweets, and can re-tweet ("RT") them to your followers.
3. *Follow @BiosimsCouncil on Twitter.* You will see all AAM's latest Tweets, and can re-tweet ("RT") them to your followers.
4. Like and follow your Members of Congress' Twitter and Facebook accounts.
5. Follow reporters who write about health care and prescription drugs. That improves the likelihood that your social media posts are viewed by journalists who need your help to understand the impact of policy decisions on patient lives.
6. Posts with images and video perform best. We urge you to use the resources on our website and share patient stories, infographics and videos to help educate lawmakers.

## Other Twitter Accounts to Know

@A4Affordability Americans for Affordable Products  
@AMGN\_PR Amgen  
@AmJNurs American Journal of Nursing  
@Alnylam Alnyam  
@ARIADPharm Ariad  
@BayerUS Bayer US  
@biogen Biogen  
@BioPharmaReport Biopharma Reporter  
@biosimilars101 Biosimilars 101  
@FDAMedWatch US FDA MedWatch  
@GileadSciences Gilead  
@GoodRx GoodRx  
@hcldr Healthcare Leadership  
@HHSgov U.S. Dept. of Health and Human Services  
@INFIPharma Infinity Pharma  
@ironwoodpharma Ironwood  
@JNJInnovation J&J Innovation  
@JanssenUS Janssen  
@JoinAPPA American Pharmacy Purchasing Alliance  
@NHCouncil National Health Council  
@Novartis Novartis  
@NovartisScience Novartis Science  
@NovartisCancer Novartis Cancer  
@patientaccess Alliance for Patient Access  
@PharmaVOICE Pharma Voice  
@RxDrugCoalition Coalition for Affordable Prescription Drugs  
@P4AD\_ Patients for Affordable Drugs  
@PBOAssoc Pharma and Biopharma Outsourcing Association  
@SunPharma\_Live Sun Pharma  
@VertexPharma Vertex



## Using Twitter Tags

The @ sign is used to call out usernames in Tweets: "Hello @twitter!" People will use your @username to mention you in Tweets, send you a message or link to your profile.

The # sign indicates a hashtag, a word or phrase (with no spaces) immediately preceded by the # symbol. When you click or tap on a hashtag, you'll see other Tweets containing the same keyword or topic.

#medswithinreach

#RxSolutions

#generics

#biosimilars

#biotech

#GenericDrugs

#HealthCareReform

#rxprices

#drugcosts

Note that #pharma is the hashtag to signal posts having to do with our industry, whereas @PhRMA is the user tag for PhRMA.



## Suggested Tweets

Generic competition is a proven way to contain the cost of medicine. What policymakers can do now: <http://www.rxsolutions.us>

We support @AccessibleMeds commitment to more generic competition and lower drug spending!

Generic drugs saved [state] billions of dollars each year (Image: state savings map)

We support @AccessibleMeds 5 policy solutions to lower drug costs at [rxsolutions.us](http://rxsolutions.us)

Generic prices overall go down. One-size fits all "solutions" to high drug prices put generic savings at risk.

Generic #rx save (state) taxpayers and patients billions of dollars each year, strengthening public programs like Medicare and Medicaid (Image: state Medicare and Medicaid savings)

#generic medicines saved (state) \$(state savings)! Support smart policies to protect and expand these savings.

Generic drugs provide real solutions for real people, find out more at <http://accessiblemeds.org> #medswithinreach

Generic drugs save Americans over \$ billion a week, find out more at <http://accessiblemeds.org> #drugcosts

Brand drug prices go up...and generic prices go down, find out more at <http://accessiblemeds.org> #drugcosts



## Suggested Facebook Posts

I support the Association for Accessible Medicines who is working to ensure that patients have access to affordable prescription drugs. [www.accessiblemeds.org](http://www.accessiblemeds.org)

Did you know that generic drugs saved the US #healthcare system \$1.46 trillion over the past decade? Find out how much your state saved, and what we need to do together to keep medication prices competitive: [www.rxsolutions.us](http://www.rxsolutions.us)

Generic drugs are 89%+ of all US #prescriptions. See why generic drugs are important for keeping our #healthcare system costs low at [www.rxsolutions.us](http://www.rxsolutions.us)

Generic drugs save all of us, and our #healthcare system, real money. But there are thousands of generic drug applications waiting for review by #FDA. This is a missed opportunity. See why: [www.rxsolutions.us](http://www.rxsolutions.us)

If you care about the millions of patients whose health and lives have been improved and saved through access to generic medicines, your voice is urgently needed. You can make the Association for Accessible Medicines a more powerful source of pro-competition, market-based and patient-centered solutions. Find out how at [www.accessiblemeds.org](http://www.accessiblemeds.org)

## ASSOCIATION FOR ACCESSIBLE MEDICINES COMMUNICATIONS

The Association's new identity elevates what our work is truly about— getting more medicine to more people who need it. The generic and biosimilar medicines industry is one of the nation's great healthcare success stories, and we want to continue to shine a light on how critical competition from generics and biosimilars is to lowering the cost of medicines so that Americans and our health system can afford them.

### Our Brand Promise

Our brand promise conveys what we stand for and how that's distinct in the market. It provides an internal north star, guiding all our words and actions as we bring AAM to life across all touchpoints and audiences.

#### ***The Ripple Effect***

We're driven by the belief that access to safe, quality, effective medicine has a tremendous impact on a person's life and the world around them.

Generics and biosimilars help more people in more places live healthier lives. And when a person has the foundation of health, they have a foundation for life. They're able to do more, be more and reach their potential; and our society, economy and country are stronger for it.

We work to drive down the costs of existing drugs and the development of new ones so people can afford the medicines they need.

We work to get safe, effective and more affordable medicines out of the labs and into the hands of the people that they'll benefit.

We work to increase competition, so payers and patients have a choice in the marketplace.

We work to improve people's lives, improving the world in turn.

Include a link to [accessiblemeds.org](https://accessiblemeds.org) or [biosimilarscouncil.org](https://biosimilarscouncil.org) on your website or in your email communications.

## Talking About the Association for Accessible Medicines

### ENHANCING PATIENT ACCESS: Making it easier for more people to get the medicine they need

Our priority is increasing access to generic and biosimilar medicine so Americans can put their health and their lives within reach.

#### Our Goals:

- Streamline and expedite FDA approvals
- Expand the use of generic prescription medicine in every community
- Promote the growth of a vibrant new biosimilars market
- Incentivize innovation and R&D investment to improve treatments and enhance access

### EXPANDING MARKET ACCESS: Increasing competition to promote a vibrant marketplace.

AAM promotes more competition by lowering barriers to entry for manufacturers. We expose and combat anti-competitive abuses by some brand drug companies.

#### Our Goals:

- Advance policies that recognize that generic & brand drug business models are not the same & the market dynamics differ
- Promote an IP framework that puts an end to "ever-greening" and other patent strategies that stifle competition
- Prevent harmful "one-size-fits-all" policy approaches that don't recognize the distinction between generics and brands
- Stop the abuse of REMS patient safety regulations by some brand drug manufacturers that block generic competition

### EXPANDING MARKET ACCESS: Educating all stakeholders to help inform critical policy decisions.

AAM is a trusted partner and established authority. We provide accurate, timely data to educate policymakers, the media, and others, and we work to prevent misinformation and confusion leading to harmful public policy.

#### Our Goals:

- Educate about the differences between branded and generic business models
- Commission research that shows the economic and social benefit of generic medicines and increased competition
- Highlight the distinction between "off patent" and "generic" designations (e.g., Daraprim® is not a generic), which has led to inaccurate conclusions about generic price increases
- Steer debate away from "percentages" and instead focus attention on real dollar impact in pricing conversations
- Work with third party organizations and advocacy groups to help educate their constituents

## Talking About the Industry

### HELPING PATIENTS

- Generic and biosimilar medicines make it easier & more affordable for patients to live healthier lives.
- Generics provide the same quality, the same active ingredients and the same safety standards as branded drugs - but at lower prices.
- More generic alternatives means greater choice and more safe, effective treatment options for patients.
- For the most vulnerable patient groups, including those with low income, senior citizens, and patients with multiple chronic diseases, generics reduce out-of-pocket costs.
- These meaningful cost savings can translate into improved quality of life and greater financial security for those who need it most.

### STRENGTHENING OUR ECONOMY AND OUR SOCIETY

- Generic drugs have a profound positive impact on the U.S. economy: Today, generics make up 89% of all prescriptions dispensed in the U.S. but only 27% of total spending on medicine.
- Over the last decade, 2006 to 2015, generics have saved the U.S. healthcare system \$1.46 trillion dollars - \$227 billion in 2015 alone (\$4 billion every week.)
- According to the FDA, on average generics are 80-85% less expensive than their brand drug equivalents, and unlike specialty medications, the generic market overall experiences price deflation year over year.
- Generic prices under Medicare Part D fell 59% from Q1 2010 to Q2 2015, according to the GAO.

### INCREASING COMPETITION AND EXPANDING ACCESS

- The generic industry has a fundamentally different economic model than patent-protected brands
- "One size fits all" policies risk stifling, rather than encouraging competition. For generics, it's not cost of doing business, it's cost of going out of business
- Applying percentage, not real dollar limits to price fluctuations, will significantly decrease generic competition.

#### Five policy priorities:

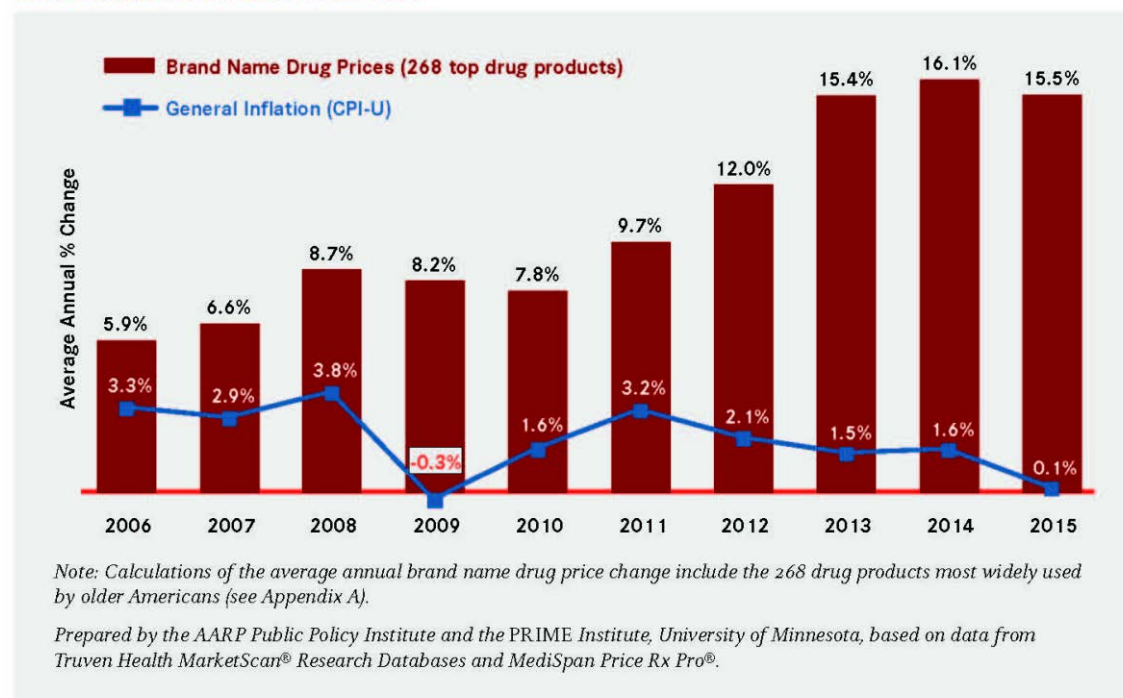
- Streamline the FDA approval process
- Pass the CREATES Act and fix REMS abuses
- Repeal the generic drug penalty in Medicaid
- Increase generic utilization by the low income subsidy population of the Medicare Part D program
- Foster an IP framework that balances innovation with the need for cost-saving competition.

## RESOURCES

The following are some public online resources on third party pricing trends:

### AARP

#### AVERAGE ANNUAL BRAND NAME DRUG PRICES CONTINUE TO GROW SUBSTANTIALLY FASTER THAN GENERAL INFLATION IN 2015



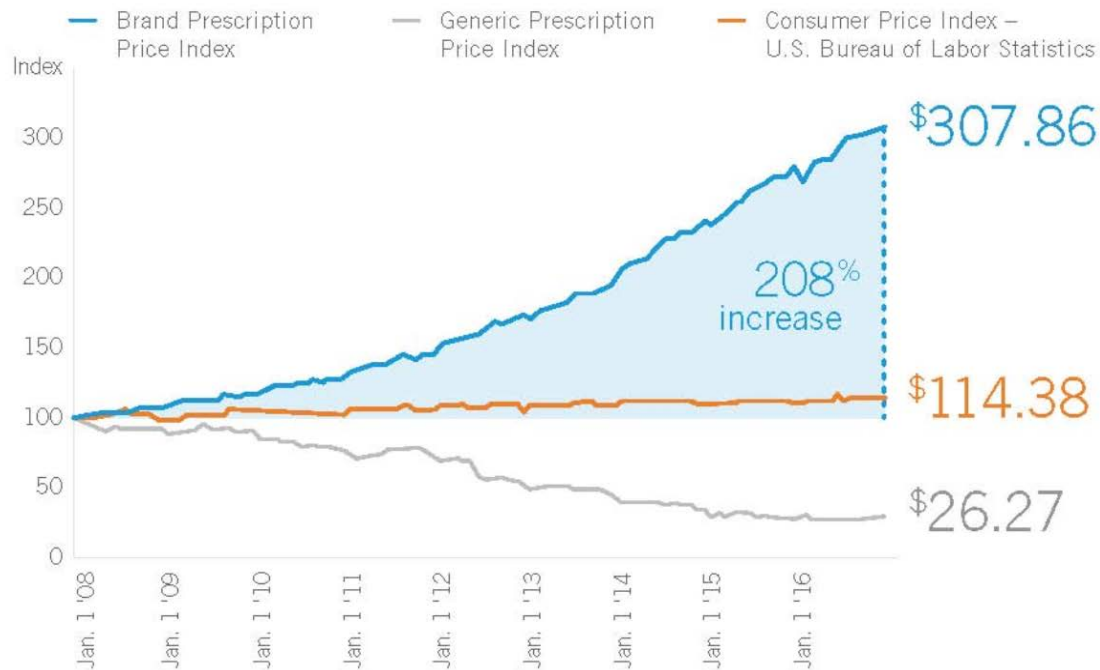
A new AARP study showed that branded pharmaceutical prices soared by 15.5% in the past year and notes that the average annual cost for one brand name drug used on a chronic basis now exceeds \$5,800. In contrast, **AARP's similar study of generic medicines found that generic prices for 280 widely used drugs dropped by 4%, with some medicines dropping by as much as 30%.** The earlier AARP study on generics identified brand and specialty drugs as key drivers of growing costs while noting that generic drug costs continue to decline. **That report also showed that an average senior with three prescriptions who used a generic alternative stood to save as much as \$850 per year.**

December 14, 2016 AAM Press Release

## Express Scripts

### EXPRESS SCRIPTS PRESCRIPTION PRICE INDEX

2016

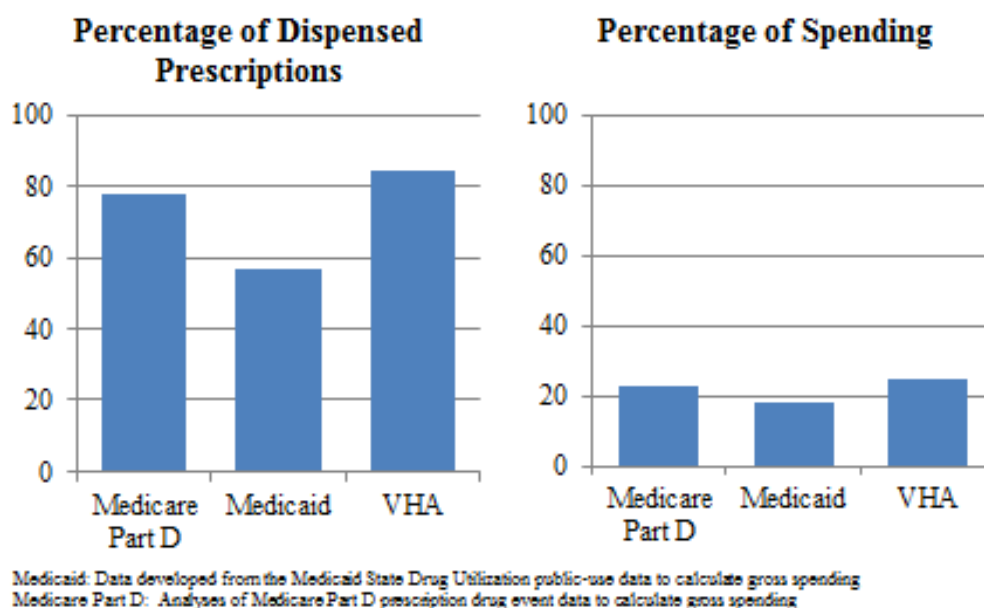


While news reports focus on a few outliers, payers should remain confident that, on the whole, generic medications continue to deliver significant cost savings. **Encouraging use of generics over more-expensive brand alternatives, when clinically appropriate, keeps costs down and helps patients adhere to their prescribed therapy. From the base price of \$100.00 set in January 2008, in December 2016, prices for the most commonly used generic medications decreased to \$26.27 (in 2008 dollars), and prices for the most commonly used brand medications increased to \$307.86 (in 2008 dollars).**

Express Scripts 2016 Commercial Drug Trend Report

U.S. Department of Health & Human Services

## Utilization and Spending for Generic Drugs in 2014, by Program



**Generic drugs account for the majority of dispensed prescriptions, but a relatively small percentage of spending.**

- In the Medicare Part D program, generics increased from 52.8 percent of filled prescriptions in 2007 to 77.5 percent in 2014. As a percentage of gross spending, generics increased from 18.5 percent to 23.0 percent over the same period.
- In 2014 in the Medicaid program, generic drugs represented the majority of drugs used, almost 57 percent of units. However, generics represented only 18.3 percent of gross spending and 32.4 percent of net spending.
- In 2014 in the VHA, generic drugs represented approximately 84 percent of the outpatient 30-day equivalent prescription fills and 25 percent of the prescription drug spending.

Report to Congress:

PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS

December 7, 2016

Department of Health and Human Services

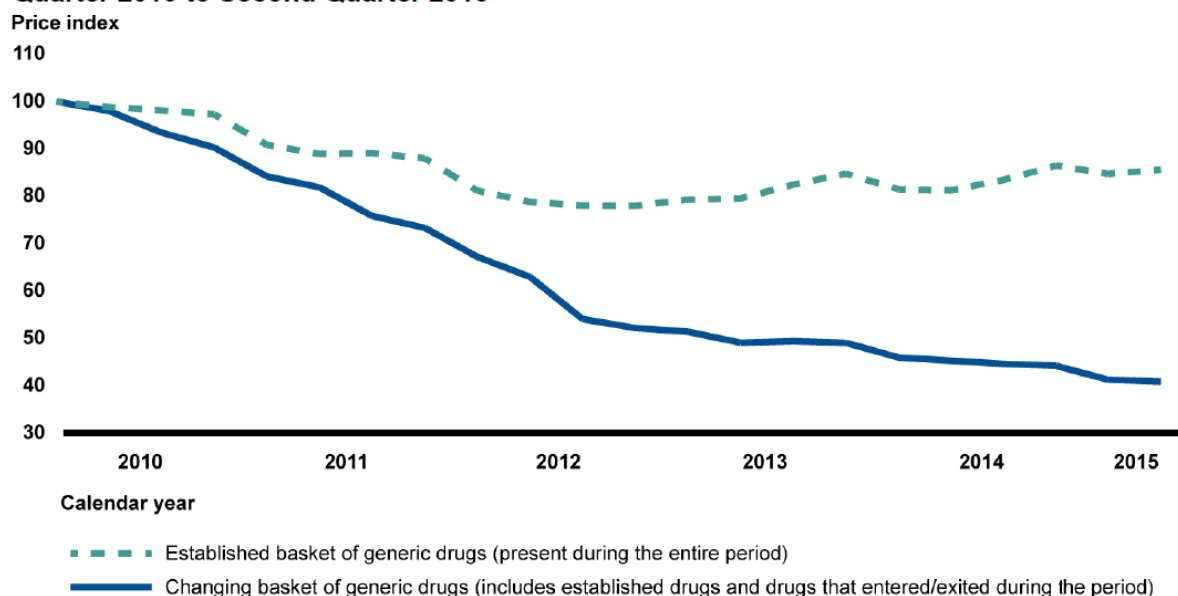
Prepared by:

Office of the Assistant Secretary for Planning and Evaluation (ASPE)



## U.S. Government Accountability Office

### Medicare Part D Generic Drug Price Trends for All Generics and Established Generics, First Quarter 2010 to Second Quarter 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

**Generic drug prices declined overall under Medicare Part D—the voluntary outpatient prescription drug program administered by the Centers for Medicare & Medicaid Services within the Department of Health and Human Services (HHS)—since 2010. Specifically, generic drug prices fell 59 percent from the first quarter of 2010 through the second quarter of 2015.** This decline reflects a changing basket of 2,378 unique generic drugs, including those that came into or exited the market during this period. GAO also analyzed an established basket of 1,441 generic drugs that were present during the entire period of analysis. Unlike the larger changing basket of drugs, prices of established generics decreased moderately and then increased slightly (see figure). The steeper price decrease for the changing basket of generic drugs is at least partially attributable to more rapid price declines among new generic drugs as they enter the market.

Report to Congress:

GENERIC DRUGS UNDER MEDICARE

Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases

August 2016

## Rx Solutions Campaign (Print Ad)

24 | POLITICO | WEDNESDAY, SEPTEMBER 21, 2016



Name: Lawmakers Date: Fall, 2016  
 Address: United States Congress

**R<sub>x</sub>** We understand concerns about the cost of medicines. That is why the Generic Pharmaceutical Association (GPhA) is advancing policy prescriptions to increase competition and make safe, effective and affordable generic drugs and biosimilar medicines more accessible for all Americans.

GPhA is advocating a five point plan:

1. Promote timely access to quality, affordable generic drugs that meet high standards of a streamlined development and approval process
2. Create policies that recognize the different economic dynamics of the brand and generic markets
3. Ensure an intellectual property framework that balances the need for innovation and robust generic competition
4. Stop some brand drug companies from blocking or delaying generic drug development
5. Increase utilization of affordable generics across all patient populations

Approve a regulatory pathway to remove duplicative international drug approval processes

Repeal the generic drug penalty in Medicaid

Maintain IPR patent review and put an end to "Evergreening"

Pass the CREATES Act in the Senate and FAST Generics Act in the House

Increase generic utilization among Medicare LIS population

Visit [www.accessiblemeds.org](http://www.accessiblemeds.org) for more information

The Biosimilars Council  
 A Division of the Association for Accessible Medicines

aam  
 Association for Accessible Medicines

## Issue Fact Sheets



### Patients Lose When Brand Drug Manufacturers Game the Generic Drug Approval Process

More Americans are growing anxious about the rising cost of health care and their access to affordable medicines. They're looking for answers from our leaders in Washington. And while there may not be one single answer, we must acknowledge the problems we are facing and the players in the industry that are contributing to them.

More and more, brand pharmaceutical companies are exploiting a broken system by stifling competition and denying Americans access to affordable generic prescription drugs to the tune of \$5.4 billion a year in lost savings, with a government price tag of \$1.8 billion.

The Food and Drug Administration (FDA) considers generic drug alternatives to brand name drugs through an Abbreviated New Drug Application (ANDA). Safety protocols known as Risk Evaluation Mitigation Strategies (REMS) accompany certain brand drugs and are designed to ensure the distribution of these drugs follows certain FDA safety procedures. These systems are well intentioned and designed to have patients' best interest at heart, yet gaping loopholes in the process are having the opposite effect.

Here's how it works: when a generic or biosimilar drug maker is interested in bringing a competitive medicine to the marketplace, the generic drug company must first acquire the most basic component of the process: purchasing samples from the branded drug company. The catch is, as the FDA has reported, generic companies are often simply unable to acquire the samples essential to testing and meeting requirements necessary to developing an application for a generic drug. More troubling, some brand manufacturers are now using similar mechanisms, of their own making, to block generic and biosimilar drug developers from obtaining necessary samples without any FDA mandate.

The reason for this is simple: some branded drug companies are using every means possible to thwart lower cost alternatives from entering the market. This is a major problem, especially considering that nearly 9 of every 10 of the 12 million prescriptions taken each day is a generic. And despite their near universal usage, generics accounts for a mere 28 percent of the amount spent on prescriptions.

The bottom line is that generic drugs are saving the American health care system \$5 billion per week, yet the current system is limiting patient access to these savings. That's a lot of money being left on the table.

Congress has the ability to fix this problem and foster more competition in the prescription drug market by passing two initiatives that are currently circulating on Capitol Hill. The FAST Act which has been proposed in the House and the CREATES Act in the Senate are viable reforms that could prevent the current anti-competitive business practices that are increasing costs in the American health care system and impeding patient access to more affordable generic drugs. Any fix considered by Congress must ensure that generic and biosimilar drug makers aren't inappropriately stymied by brand drug makers from bringing more safe, effective, lower-cost alternative medicines to market—either by brands misusing FDA safety programs or placing artificial restrictions on access to their products.

Now, more than ever, Americans are looking to Washington for answers to problems in our health care system. It's time to start showing them some results. The Generic Pharmaceutical Association is now proposing 5 concrete policy prescriptions, including this one - curbing the abuses of REMS and REMS-like programs - that policymakers can enact today to spur competition and bring treatments within reach for more Americans.





As published in *National Journal* September 15, 2016

**National Journal**

## Expanding Patient Access by Preserving Drug Patent Challenges

In so many drug cost conversations, two truths are constant; competition from generics and biosimilars lowers the cost of medicines; and, brand drug companies have proven time and again they will do anything they can to preserve their market monopolies at the expense of patients seeking access to affordable medicines.

One of the more complex ways that brand drug companies can hinder competition is by taking advantage of the patent process. Instances of brand company “evergreening,” making minor changes to a product and pursuing a new patent with its requisite protection from competition are commonplace. When this results in more revenue for the protected brand products, patients lose out. Sometimes, these patent extension efforts lead to “weak” patents that the U.S. Patent and Trademark Office can invalidate if the “innovation” is not found to merit additional patent protection.

Congress approved a process to address these scenarios that allows generic and biosimilar manufacturers to challenge these weaker patents through a process called inter partes review (IPR). Successful IPR challenges are more efficient than the usual patent challenge procedures because they happen outside of the court system—and they are working.

It may not surprise some to learn that brand drug makers want to exempt pharmaceuticals from IPR and are asking Congress to make changes to a process that currently helps expedite patient access to more affordable generic drugs. The IPR process is allowed across many industries and a proposed pharmaceutical “carve out” would single out generic and biosimilar manufacturers.

The fact is, brands want to block IPR challenges because they promote generic and biosimilar competition.

Misguided efforts to exempt pharmaceuticals from the IPR process could be costly, and should be worrisome to anyone interested in holding down health costs. Exempting generic and biosimilar manufacturers from using the IPR process adds an estimated \$1.3 billion in increased government spending on medicines.

Brands argue that IPR is abused and that third party investors such as hedge funds are manipulating the system. Distortion of the patent

system by hedge fund managers should be prevented. But, in order to address isolated cases of these abuses, brand drug companies endorse the drastic measure of removing pharmaceutical patents from the IPR process altogether, which also conveniently shelters them from legitimate competition.

Eliminating bad actors from patent challenge processes is important but so is preserving legal avenues for generics and biosimilars to reach patients as quickly as possible. Some brand drug companies would assert that IPR disrupts the balance between competition and innovation that Hatch-Waxman and BPCIA establishes. In fact, the opposite is true. IPR is working in favor of patient access by expediting a path to invalidating weaker patents, promoting generic and biosimilar competition.

It's time for Congress to look for new ways to break down the barriers preventing patient access to affordable medicines. The Generic Pharmaceutical Association (GPhA) is proposing five policy prescriptions to boost drug competition and expand patient access to affordable medicines. Preserving legal avenues for patent challenges, such as IPR, is one such way to ensure that our nation's intellectual property framework balances innovation and competition while accelerating patient access to affordable medicines.

Nearly 9 of every 10 of the 12 million prescriptions taken each day is a generic. And despite their near universal usage, generics account for a mere 28 percent of the amount spent on prescriptions.

The bottom line is that generic drugs are saving the American healthcare system \$5 billion per week, yet more can be done to expand patient access and grow these savings.

As policymakers evaluate their options, it is important to ensure that proposals do not have a chilling effect on competition and spur the market entry of more affordable medicines.

Generics and biosimilars create hundreds of billions of dollars in annual savings for our healthcare system, ensuring access to safe and effective medicines to millions who would otherwise go without. This is a foundation to build upon – not to inhibit or put at risk.



## A Single Development Pathway Can Improve Patient Access to Generic Drugs

It's time for the U.S. to remove an unnecessary roadblock to competition for generic prescription drugs. Regulators on both sides of the Atlantic are often doing the same job at the same time, causing unnecessary costs and delays in bringing affordable generics to the marketplace.

The Food and Drug Administration (FDA) and its European regulatory counterparts work tirelessly to ensure that generic drugs meet the same strict standards for purity, quality, strength, and stability as their branded counterparts. Improving regulatory coordination can avoid unnecessary duplication of product development, regulatory review, and approval efforts; as well as help alleviate significant delays in getting safe, effective and more affordable medicines to patients.

We need a joint regulatory strategy where generic drug guidances and guidelines are coordinated and adopted by both the E.U. and the U.S. regulatory authorities. Thus, generic drug manufacturers can follow a single development pathway leading to greater consumer access to affordable generic medicines.

As U.S. and E.U. negotiators continue to hammer out the details of a trade deal in the Trans-Atlantic Trade and Investment Partnership (TTIP), this single development pathway for generics would be a clear winner for American consumers. Drugs that have already undergone strict regulatory review and approval processes, including clinical trials where

appropriate (for example in the more complex products), in either Europe or the U.S. shouldn't need to hit the roadblock of another lengthy, costly and unnecessary approval process. Instead, these safe and proven medicines should be made readily available to patients in both regions, each who face the harsh economic realities of purchasing prescription drugs.

Congress should urge the U.S. Trade Representative to forcefully argue to include a mandate in TTIP requiring the FDA and its European regulatory counterparts to advance a single development regulatory pathway for generic medicines. A successful single development pathway for generic medicines would foster competition and lead to more affordable medicines for the American people.

Generic drugs are nearly 9 of every 10 prescriptions dispensed each day but a mere 28 percent of the amount spent on prescriptions. Generics are saving the American healthcare system \$5 billion per week. Yet the current system can do more to expand patient access to these important medicines.

Now, more than ever, Americans are looking to Washington for answers to problems in our healthcare system. The Generic Pharmaceutical Association is proposing five concrete policy prescriptions, including this one—creating a single pathway for the approval of generic drugs—that policymakers can enact today to spur competition, expand access and increase savings for millions of Americans.





## One Size Does Not Fit All: Repeal the Medicaid Penalty on Generic Drugs

We understand concerns about the cost of prescription medicines. Nearly all policymakers, stakeholders, patients, and others agree that the solution to runaway brand drug prices is to increase generic drug competition.

Without generics, medicine spending in our nation's public programs would nearly double. In fact, a new Government Accountability Office (GAO) report shows that generics in Medicare Part D fell 59% from 2010 to 2015.

Congress historically has recognized the unique contributions generic and brand drugs contribute to the U.S. health care system. Unfortunately, a new penalty on generic drugs in Medicare could put patient access and savings at risk.

This penalty will add significant hurdles to generic drug investment and development, making it more challenging for patients to access generics as an FDA-approved alternative to more expensive brand medications—the exact opposite of what both patients and payors need right now.

The new Medicaid rebate penalty fails to reflect the very clear differences in the brand and generic business models. One such difference is that generic drug makers operate under a high volume and low margin business model—this is one reason that generics are able to be sold at a fraction of the brand price.

Part of the challenge inherent in this business model is that generic manufacturers are much more sensitive to changes in material costs and supply fluctuations than most brand

manufacturers. For example, where a brand drug selling for \$1,000 per pill gets penalized for raising its price \$100, the same penalty would be triggered on a 10 cent generic product if the price rose 1 cent. This can have a major impact on manufacturers of low-cost products.

Applying a brand Medicaid rebate to generic products can constrict generic drug development and puts some of our nation's most vulnerable patients in a position where they have fewer generic options, raising costs for patients and payors, increasing state budgets, and adding more of a burden on taxpayers.

The Medicaid rebate penalty on generic drugs is harmful for Medicaid and its beneficiaries, bad for taxpayers, and should be immediately repealed.

GPhA welcomes the opportunity to work with policymakers to identify a smarter way forward that brings about more savings and does more to curb unsavory business practices that delay generics from reaching the people who need them.

The Generic Pharmaceutical Association (GPhA) is proposing five policy prescriptions to boost drug competition and expand patient access to affordable medicines. Repealing the generic drug Medicaid rebate penalty is one way to ensure that millions of Americans can continue to rely on timely access to safe, effective, and more affordable generic drugs.



## Lowering the Cost of Prescription Drugs for Low Income Seniors

The federal government is the nation's largest health care purchaser and generic drugs are an essential part of the success and sustainability of public programs such as Medicare.

By all accounts, the Medicare Part D program has enabled access to more affordable generic drugs for millions of seniors. Generics in these programs expand access to medicines and keep patient and program costs low.

In fact, without generic drugs, prescription drug spending in Medicare would nearly double. And, a new Government Accountability Office report shows that prices for generic drugs in Medicare Part D fell 59 percent from the first quarter of 2010 to the second quarter of 2015.

There are still opportunities to improve access to generics, particularly for seniors in the Medicare Part D low income subsidy (LIS) program. LIS beneficiaries, which include some of the most vulnerable patients in the program, represent only 8 percent of all Medicare Part D enrollees but they account for 20 percent of all program prescriptions and 40 percent of all Part D spending. Most would assume seniors in this category utilize high-quality generic drugs whenever possible. But this is not the case.

Nearly nine in ten (88 percent) of prescriptions dispensed in the U.S. are generic drugs but the LIS program has historically lagged behind national rates. That means there

is an opportunity for millions of the neediest seniors to be spending less money on their medicines and the program could be saving more money, too. In fact, the Congressional Budget Office estimates changing the LIS co-pay structure to incentivize the use of more generics would save \$18.8 billion over 10 years.

It is time for Congress to approve legislation to modify the Medicare Part D program to encourage the use of generic medicines in the LIS population. Now, more than ever, Americans are looking to Washington for answers to problems in our health care system. It's time to start showing them some results.

The Generic Pharmaceutical Association is proposing five concrete policy prescriptions, including this one—encouraging access to generics for LIS beneficiaries—that policymakers can enact today to spur competition and bring more safe, effective and affordable generic drugs within reach for millions of Americans.