
How to Talk to Voters About the High Cost of Medicines...
...and Ways to Lower Them
aam
Association for Accessible Medicines

High Drug Costs, Inflation, and Voters

With record high inflation, voters are concerned about the rising costs of goods – including life-saving medicines. Patients and their families face difficult choices when confronted with the ever-increasing costs of brand-name drugs. **An estimated 18 million Americans cannot pay for needed drugs, per a Gallup survey.**[1] Seniors with Medicare coverage are experiencing higher drug costs due to anticompetitive tactics that limit access to lower cost, FDA-approved generics and biosimilars. Voters want action and are paying attention to what candidates have to say on the issue.

Unleashing the Potential of Generics and Biosimilars Will Save Patients Money

What you need to know:

- Generic and biosimilar medicines account for 9 out of every 10 prescriptions dispensed in the United States each year, but only 18% of all spending on prescription drugs spending.[2]
- But further savings are possible by addressing anticompetitive tactics from brand-name pharmaceutical companies and the role middlemen often play in denying patient access to lower cost generics and biosimilars.

1 Gallup, "In U.S., an Estimated 18 Million Can't Pay for Needed Drugs," https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx

2 Association for Accessible Medicines 2022 U.S. Generic and Biosimilar Medicines Savings Report https://accessiblemeds.org/resources/reports/2022-savings-report

Defining Generic and Biosimilar Medicines

What is a Generic Drug?

Generic medicines are FDA-approved alternatives to brand-name drugs. Generics contain the same active ingredients, in the same strength, as the brand-name drug, and meet the same FDA quality and effectiveness standards as the brand product.

What is a Biosimilar?

A biosimilar is a lower-cost versions of costly biologic medicine and is approved by FDA as highly similar to and with no clinically meaningful difference from an existing FDA-approved reference product.

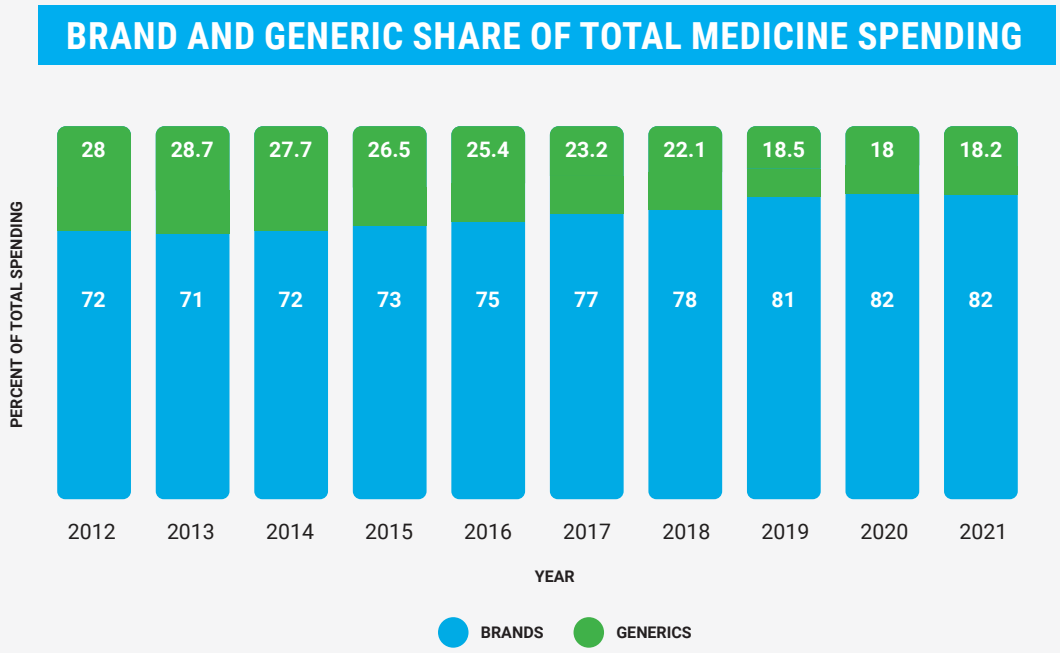
Are generics and biosimilars the same as brand-name drugs?

Generic and biosimilar medicines are lower cost, FDA-approved alternatives to brand-name drugs. Generics contain the same active ingredients, in the same strength, as the brand reference drug. Biosimilars are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product.

Patients Save More With Generics

Generics and Biosimilars Account for 18.2% Of Total Medicine Spending

GENERICS AND BIOSIMILARS ARE 91% OF ALL PRESCRIPTIONS



Source: IQVIA, National Sales Perspectives, Dec 2021.

Problems Causing the High Cost of Medicines – and How to Solve Them

Problem:
"Rebate traps" occur when middlemen, such as Pharmacy Benefit Managers (PBMs), prefer high-cost brand drugs with high rebates over lower cost generics and biosimilars. Sometimes patient access is blocked to lower-cost medicines causing patients to pay more in out-of-pocket costs for the brand-name drug.

Solution:
Ensure coverage of lower-cost medicines. Policymakers must address the challenge of "rebate traps" that prevent greater generic or biosimilar adoption. Generic and biosimilar medicines are the proven solution to the burden of expensive brand-name drugs by successfully expanding access and reducing costs for patients and taxpayers.

Problem:
Brand biologic drugs account for less than 3% of prescription in the U.S. but now account for more than half of all spending on prescription drugs. Reimbursement and coverage policies often discourage the use of biosimilars.

Solution:
Increase patient access. Public and private payers must properly align provider incentives to encourage greater use of lower cost biosimilars.

Problem:
In the Medicaid program, generic manufacturers are paying millions in additional rebate penalties due to minor fluctuations in the average manufacturer price – even if a generic manufacturer did not increase the price of the drug.

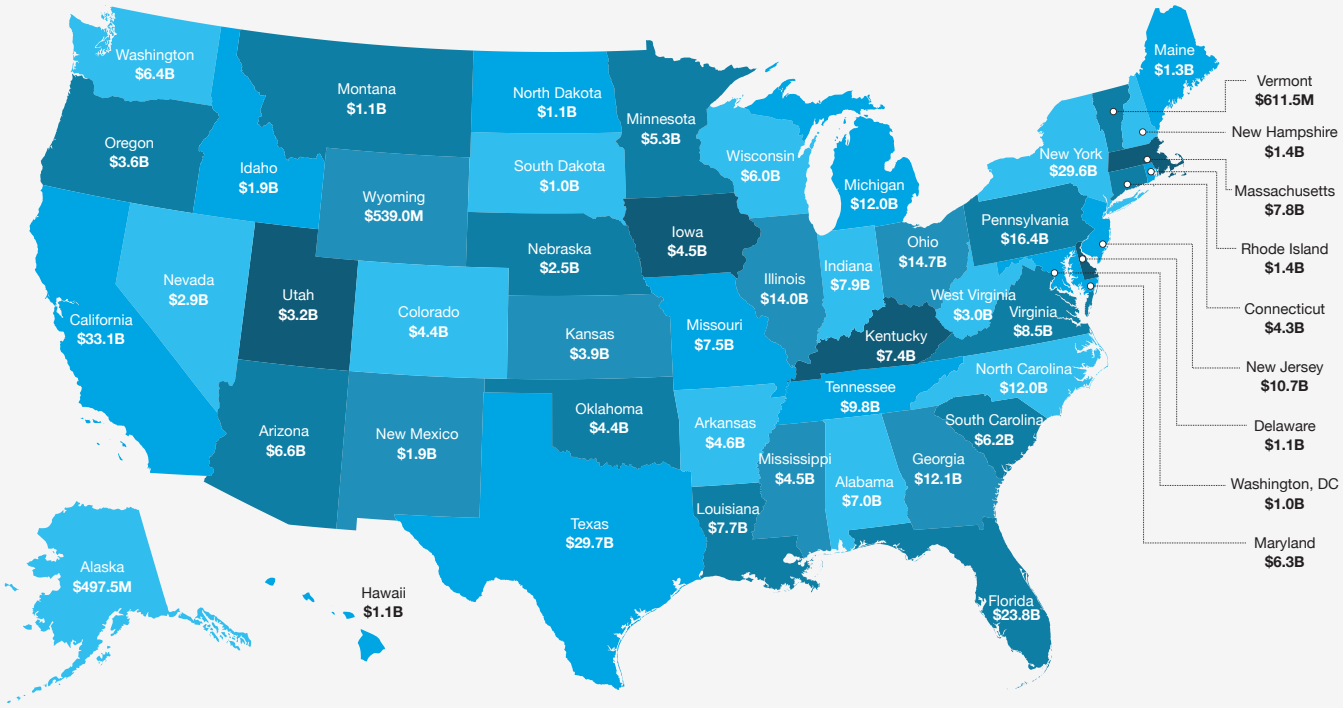
Solution:
Mitigate the impact of rebate penalties on generic medicines. This would reduce the risk of drug shortages and benefit patients through sustainable access to low-cost generics.

Problem:
Abuses in the patent system prolong a brand-name drug's monopoly and thwarts timely patient access to lower cost medicines. The initial patent term is 20 years. However, brand drug companies often file late-stage patents to extend patent protections and increase the barriers to competition.

Solution:
Strengthen patent law to ensure only true innovation is rewarded and anticompetitive tactics are eliminated. Policymakers must focus on removing anticompetitive patent and market barriers to competition to bring lower-priced biosimilar and generic competition to market as early as possible for America's patients.

Generic Drug Savings Across the Country

2021 Savings by State



Source: IQVIA, National Sales Perspectives, Dec 2020.

FAQs

What is the Association for Accessible Medicines?

The Association for Accessible Medicines (AAM) and its Biosimilars Council are the nation's leading trade association for the manufacturers and distributors of FDA-approved generic and biosimilar medicines.

Generics and biosimilars help more people live healthier and longer. AAM works to make generic and biosimilar medicines more accessible to more people who need them. AAM improves access to safe, quality and effective medicines.

AAM's members provide more than 52,000 jobs at nearly 150 facilities in the United States and manufacture more than 60 billion doses of medicines every year.

What can be done to strengthen the U.S. supply of generic medicines?

Policies can ensure a stable and sustainable market and price for U.S.-made medicines, including harnessing the purchase power of the federal government.

Policymakers can incentivize additional U.S.-based manufacturing – including grants and tax credits – in order to ensure a more diversified and resilient supply chain.

I've heard that medicines and their ingredients are often made abroad. Should patients in the U.S. be concerned?

FDA oversees the manufacturing of medicines for the U.S. market and ensures that – regardless of where the medicine is made and sourced from – the same stringent standards for safety and efficacy are adhered to. The FDA is the gold standard for safety and its officials declare the U.S. drug supply is the safest that it has ever been.[3]

Can biosimilars help lower drug prices and increase patient access?

The most expensive prescription drugs on the market are brand-name biologics. Biologics comprise more complex molecules than standard small-molecule drugs and are more complicated to manufacture. Although biologics are roughly 2% of prescriptions filled in the United States, these expensive brand-name biologic medicines, like the heavily advertised Humira and Trulicity, are responsible for nearly half of all spending on drugs in this country. Currently, the FDA has approved 39 biosimilars in the U.S., accounting for 364 million days of patient therapy and $13.3 billion in savings since 2015.

3 Michael Kopcha, Ph.D., R.Ph., director of CDER Office of Pharmaceutical Quality https:// www.fda.gov/drugs/news-events-human-drugs/cder-conversation-assuring-drug-qualityaround-globe

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Biosimilars Council
A division of the Association for Accessible Medicines
biosimilarscouncil.org

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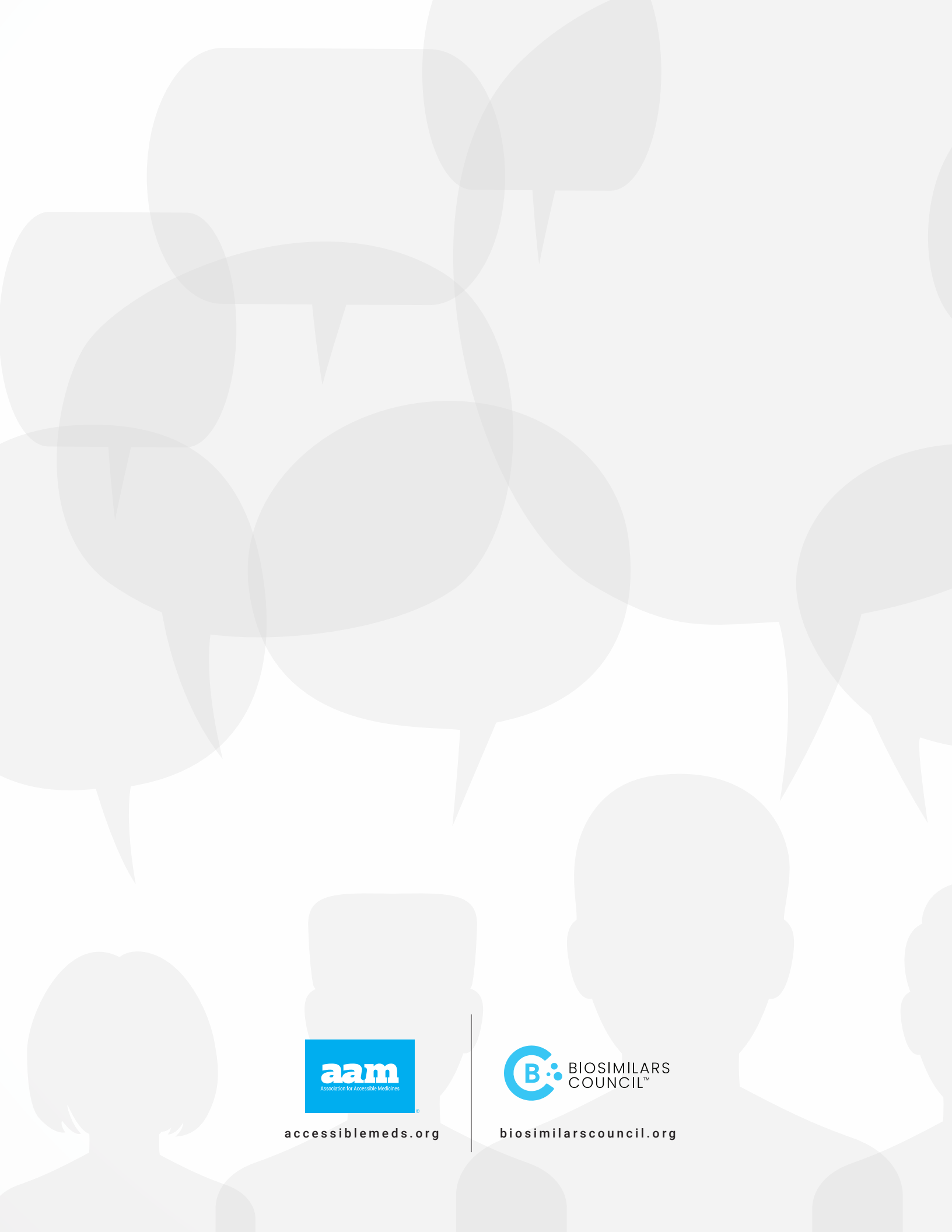
To learn more about ways to make medicine more accessible to patients in your state, go to accessiblemeds.org/2022voterguide.



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