Your Generics & Biosimilars Industry

Reports and Resources

Biosimilar and generic medicines are a proven solution to lowering drug costs, and the use of these lower-cost medicines saved more than $313 billion in 2019 alone. These medicines often contribute to higher patient adherence and help patients live healthier lives. The reports below highlight the value of generic and biosimilar medicines and the barriers to competition that keep drug prices high for too many Americans.

Roadmaps for Ensuring Patient Access to Generic and Biosimilar Medicines: Safeguarding Sustainable Markets (forthcoming)

Generic and biosimilar medicines challenges include unprecedented rates of price deflation and a growing number of government and payer policies that perversely reward the use of high-cost brands over generic or biosimilar competitors. Left unchecked, these challenges limit patient access to lower-cost medicines and threaten the long-term viability of generic and biosimilar competition. Policymakers must protect the sustainability of generic and biosimilar market competition by securing continued savings from legacy low-cost generic drugs while crafting policies to realize future savings from new generic or biosimilar competition.

Securing Our Access & Savings: 2020 Generic Drug & Biosimilar Savings in the U.S. Report (September 2020)

In 2019, the U.S. health care system saved $313 billion in 2019 from generics and biosimilar drugs, including $96 billion in Medicare savings and $48 billion in savings to Medicaid. At a time when access to reliable, affordable and high-quality prescription medication is more important than ever, generics fill 90% of prescriptions in the United States for only 20% of the cost. This report reinforces the outsized importance of the generics and biosimilars industry in delivering lifesaving medicines to patients.

How to Talk About Drug Prices in a Time of Economic Insecurity (August 2020)

This primer on rising drug costs covers how high launch prices are putting prescription drugs out of reach for millions of patients, particularly at a time of economic insecurity. Monopoly pricing, patent gamesmanship and supply chain dynamics are explained,

along with why competition from more affordable, FDA-approved generics and biosimilars is part of the solution to increasing the amount of savings available to patients each year.

Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain (April 2020)

A closely connected, diverse, high-quality and resilient pharmaceutical supply chain based in the United States and allied countries is the best means to ensure that U.S. patients and the health care system have access to a secure and consistent supply of critical pharmaceuticals. With strategic support from the U.S. government, the economic footprint of the generic drug industry in the U.S. can expand, leading to increased national security, a stronger, more redundant supply chain for key pharmaceuticals and an expanded employment base.

Medicare and Commercial Plans Fail to Get New Generics to Patients: Part D Design Increases Patient Out-of-Pocket Costs (February 2020)

First generics are safe and effective, FDA-approved medicines that are the first competitor to a brand drug and are key drivers in lowering drug costs. But first generics face significant delays in Medicare Part D formulary coverage and are routinely placed on expensive brand drug tiers with higher patient cost-sharing. This report includes recommendations that would restore the competitive balance between high-priced monopoly brand drugs and generic competition.

The Unintended Consequences of the BLOCKING Act (January 2020)

The Hatch-Waxman Act established an important incentive for generic drug manufacturers to challenge brand drug patents and bring lower-cost drugs to market. However, legislation known as the BLOCKING Act would significantly weaken the incentive for generics to challenge brand patients and delay patient access to more-affordable generic medicines. Matrix Global Advisors conducted a study on the unintended consequences of the BLOCKING Act found that discouraging a Paragraph IV challenge would lead to $1.7 billion in lost savings for each generic delayed.

Sidelined: How Seniors Miss Out on Savings Available Through Generic Substitution (January 2020)

Analysis conducted by Avalere Health reveals substantial gaps in generic substitution for seniors participating in Medicare. The analysis found that almost half of Part D plans have substitution rates of 75% or less; expensive brand drugs with generic alternatives do not face robust generic substitution; and generic substitution rates decrease as the

cost of the brand drug increases.

Access Denied: Why New Generics Are Not Reaching America's Seniors (October 2019)

This white paper highlights challenges facing new generic competition, revealing that fewer than half of the first generics approved by FDA since 2016 are commercially available to patients. Policymakers can solve this issue by updating the Part D program to ensure that first generics are covered at launch, saving up to $7 billion over 10 years for the Medicare program and reducing premium and out-of-pocket costs for America's seniors by hundreds of millions of dollars each year.

Failure to Launch: Barriers to Biosimilar Market Adoption (September 2019)

Significant barriers stand in the way of biosimilar adoption, resulting in more than $2.2 billion in potential lost savings since 2015. This report explains that these barriers are a direct result of anti-competitive tactics by brand-name pharmaceutical companies along with inadequate incentives for the use of and insufficient information about biosimilars for patients.

Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients (June 2019)

Patients, taxpayers and the overall health care system are bearing the cost of patent schemes that delay access to biosimilars. In this analysis, AAM's Biosimilars Council found that delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding $7.6 billion in lost savings since 2015.

Medicare Part D Generic Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs (February 2019)

The Medicare Part D program has offered prescription drug coverage through private plans that actively manage prescription drug benefits through the creation of formulary tiers and cost-sharing. In 2019, CMS proposed restricting plans' ability to place generic drugs on non-generic tiers. In this analysis, Avalere estimates the implications of CMS' potential new requirement on beneficiary cost-sharing, plan liabilities and the implications for plans' share of total costs for beneficiaries.

Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D (July 2018)

HHS released a study finding that the Medicare program, through its Part D plans, spent almost $9 billion on brand-name prescriptions drugs when lower-cost, therapeutically equivalent generics were available. If these prescriptions were instead dispensed as generics, the Part D program and its beneficiaries could have saved almost $3 billion.

Ensuring the Future of Accessible Medicines in the U.S.: Avoiding Shortages & Ensuring Competition for America's Patients (February 2018)

Generic and biosimilar competition continues to play a vital role in improving access to pharmaceuticals and driving cost savings to America's patients and the health care system. This growth in the generics and biosimilars industry has led to the creation of thousands of new jobs across the country and to a better quality of life for millions of people. But strong headwinds threaten this competition and America's patients will continue to face increasingly high brand drug prices without action to ensure a sustainable, competitive environment for manufacturers of affordable medicines. This paper recommends a series of solutions to avoid potential shortages and ensure competition drives costs lower for patients.

Penalizing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages (September 2017)

In 2017, Bates White analysis found that the Medicaid Generics Penalty is likely to reduce competition in generic drug markets, lead to fewer companies competing in the market and increase the likelihood of shortages.

Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines (August 2017)

Biosimilar medicines are a solution that provide greater access to these advanced therapies for patients. An analysis by Avalere Health for the Biosimilars Council shows that 1.2 million U.S. patients could gain access to biologics by 2025 as a result of biosimilars availability.