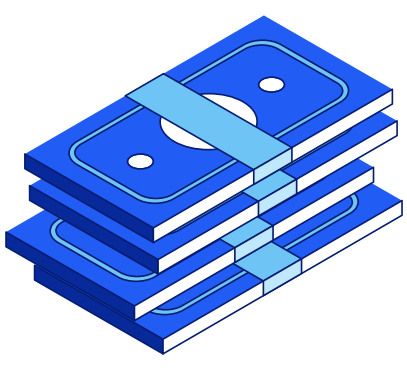
Hatch-Waxman at 40

Historic legislation that brought down prescription drugs costs – but does it have a future?

What is Hatch-Waxman?

Officially dubbed The Drug Price Competition and Patent Restoration Act of 1984, this bipartisan legislation was negotiated by Rep. Henry Waxman and Sen. Orrin Hatch.

- Established the legal and economic foundation for today's generic pharmaceutical industry
- Streamlined approval of generic medicines
- Served as the model for biosimilar legislation



Savings in 2022

$408

Billion

Generics and biosimilars expanded access and reduced spending, saving patients, employers and taxpayers billions.

10-Year Savings

$2.9

Trillion

The U.S. healthcare system has saved nearly $3 trillion over the past decade due to the availability of low-cost generics and biosimilars.[1]

90.3%

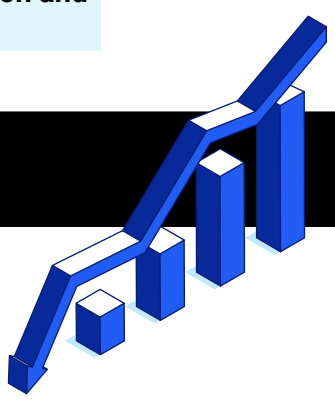
Percentage of prescriptions that were generics

17.5%

Percentage of total spending from generic medicines

The U.S. leads the world in pharmaceutical innovation and adoption of lower-cost generic drugs.[1]

Today, those savings are at risk.



Unchecked Price Deflation Causes Drug Shortages

$6.4 billion lower

Change in value of generic sales since 2017

According to the IQVIA Institute:

- Shortages are overwhelmingly found in generic drugs, particularly sterile injectables;
- Shortages are increasingly in multi-source generic markets; and
- Shortages are centered in low-cost products below $1 and $5.

Too-low pricing can cause market exits and create conditions ripe for a shortage.

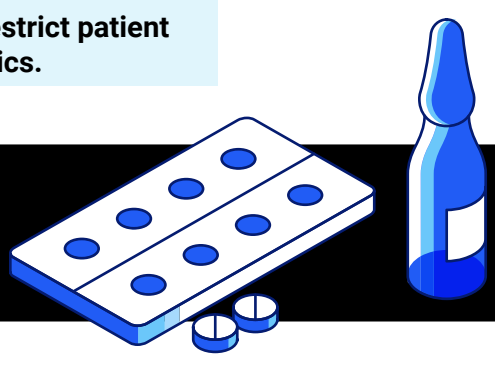
PBMs Delay Adoption of New Generics

1,000+ days

How long it takes before first generics are covered on more than half of Medicare Part D formularies

These delays and lack of coverage restrict patient access to lower-cost generics.

Other worrying factors for generics and biosimilars:



PBMs Block Biosimilar Adoption

52% written prescriptions **vs** **31%** filled prescriptions

Lower prices and abusive contract terms lead to increased fragility in manufacturing of low-cost medicines.

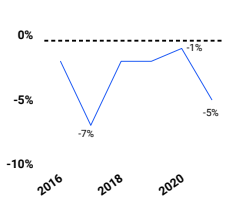
Market Consolidation

Generic purchasing is dominated by consolidated group purchasing organizations (GPOs) and wholesale purchasing consortium

Strong forces pressure generics sustainability

Price Deflation

US Generics Net Price Growth



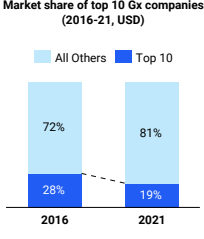
Powerful buyers

Market Share Wholesale Distributors 2012 VS 2022

	2012	2022
Amerisource Bergen (Cencora)	24%	32%
Cardinal Health	29%	28%
McKesson	34%	36%
Other	13%	4%
Total Share	100%	100%
Total Distribution Revenue ($bn)	$318	$646

Fragmentation

Market share of top 10 Gx companies (2016-21, USD)



Notes: Generic companies with sales over $10mn used to calculate crowding; Developed countries defined as US, EU4 + UK and Japan. Excluded TAs=hospital solutions, Kanpo and Chinese, imaging agents, Diagnostics, vaccines, non-therapeutic agents
Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS MAT Q4 2021; Rx only; Innovation insights; IQVIA Institute General US Medicines Spending Outlook 2018-2023

Lower prices and abusive contract terms lead to increased fragility in manufacturing of low-cost medicines.

What's slowing down generics and biosimilars?

Delayed Entry / Patent Thickets

Ongoing patent litigation and large patent estates on brand drugs frequently delay generic and biosimilar medicines from coming to market. Although, the original compound patent on Humira® expired in 2016, AbbVie obtained over 160 patents on the product which do not expire until 2037.

What can be done to give patients more access to generics and biosimilars?

Medicaid Generic Drug Inflation Program

Congress should amend the Medicaid inflation penalty to limit such rebates to single-source generics with average annual costs exceeding $100 per patient.

340B

Policymakers should amend the 340B program to provide that generics be available at the Average Manufacturer Price (AMP), ensuring providers continue to have access to generics at a low price while increasing the payment rate for generic manufacturers.

State Drug Pricing Initiatives

Stop laws that create costly new reporting burdens for generic manufacturers.

Ensure Timely Access to Generic and Biosimilar Medicines

Congress should ensure that companies can enter into pro-competitive, pro-patient patent settlement agreements that expedite generic and biosimilar entry. Patent settlements have led to generic drugs being introduced, on average, 81 months prior to patent expiry.

Address IRA Uncertainty

Congress should protect generic and biosimilar competition by expanding the time for generic and biosimilar entry, preventing brand gamesmanship that delays generic/biosimilar entry, permitting generics to receive a pause in the negotiation process and providing greater clarity for the price-setting process.

Ensure Rapid Adoption

Policymakers should ensure rapid coverage of lower-cost generics and biosimilars and remove PBM incentives in Medicare and the commercial market for use of higher list price brand drugs with high rebates and fees.

It's time to make generics and biosimilars a top priority.

Generic and biosimilar medicines are the backbone of accessible care for America's patients. Policymakers have a unique opportunity to preserve and enhance generic and biosimilar competition and sustainability, safeguarding and stabilizing not only future savings, but future care.

LEARN MORE ABOUT GENERICS AT **ACCESSIBLEMEDS.ORG**
LEARN MORE ABOUT BIOSIMILARS AT **BIOSIMILARSCOUNCIL.ORG**