Empowering Market Competition To Incent Innovation and Promote Affordability

Biosimilars and Supply Chain Efficiencies

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Innovation and Affordability

Striking the right balance

- Objective of pharmaceutical regulation
  - Encourage Innovation
  - Promote Affordability
- Hatch-Waxman Act of 1984 achieved balance for “small molecule” drugs sold at the pharmacy
  - Innovation encouraged by patent system that provides ***opportunity*** to cover costs of capital ($2.9 billion for drugs and biologics)*
    - R&D expenses ($1.4 billion)*
    - Cost of financing capital over 10 to 15 years
    - Risks developing medicines
  - Affordability encouraged once patents expire, generic medicines enter driving prices for small molecule drugs down

* Tufts University (Joseph A DiMasi); https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub

Generic Medicine's Share of Dispensed Prescriptions

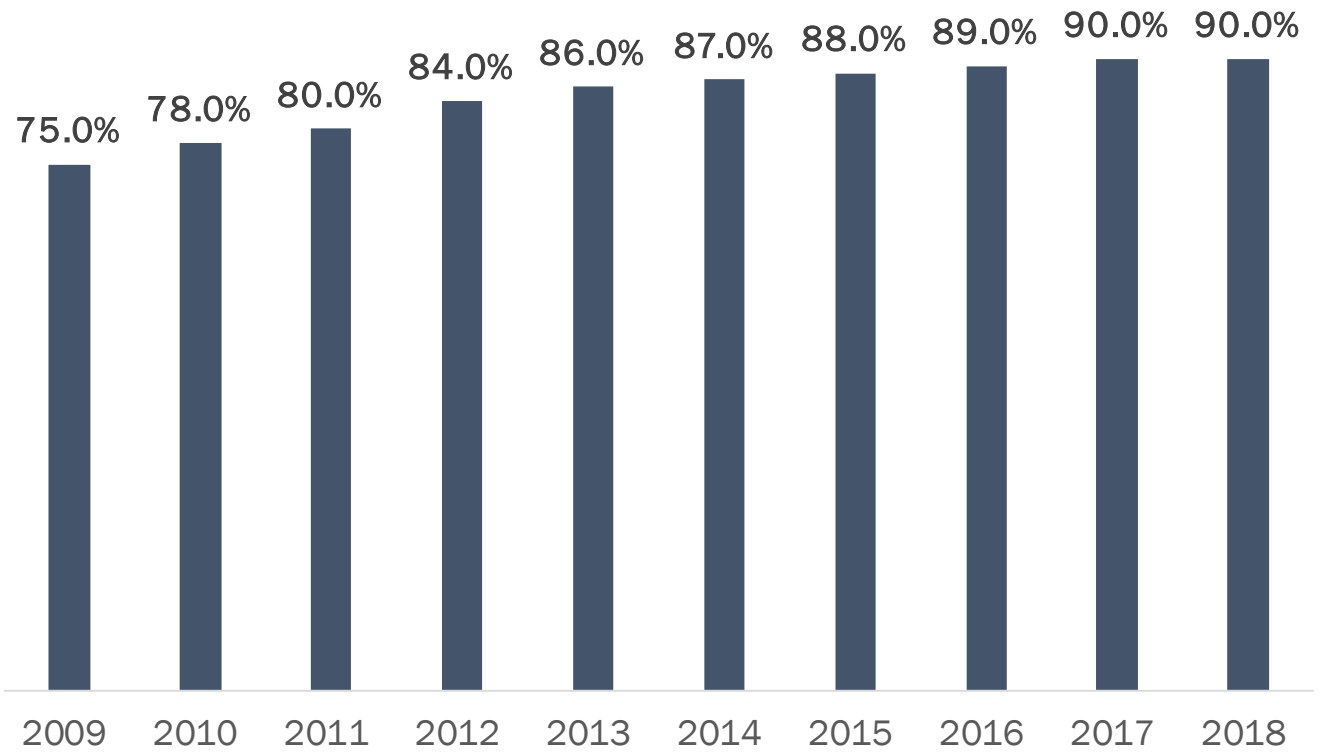
2009 - 2018

- U.S. has highest generic usage rate among the OECD countries
- 95.3 percent of the generic medicines were filled at $20 or less

The Association for Accessible Medicines

- "average member out-of-pocket costs for a 30-day Rx to $11.75, just a 19¢ or 1.6% increase from 2018"

Express Scripts, 2019 Drug Trend Report (https://www.express-scripts.com/corporate/drug-trend-report#2019-in-review)



Source: IQVIA

Generic medicines save health care system $292.6 billion annually

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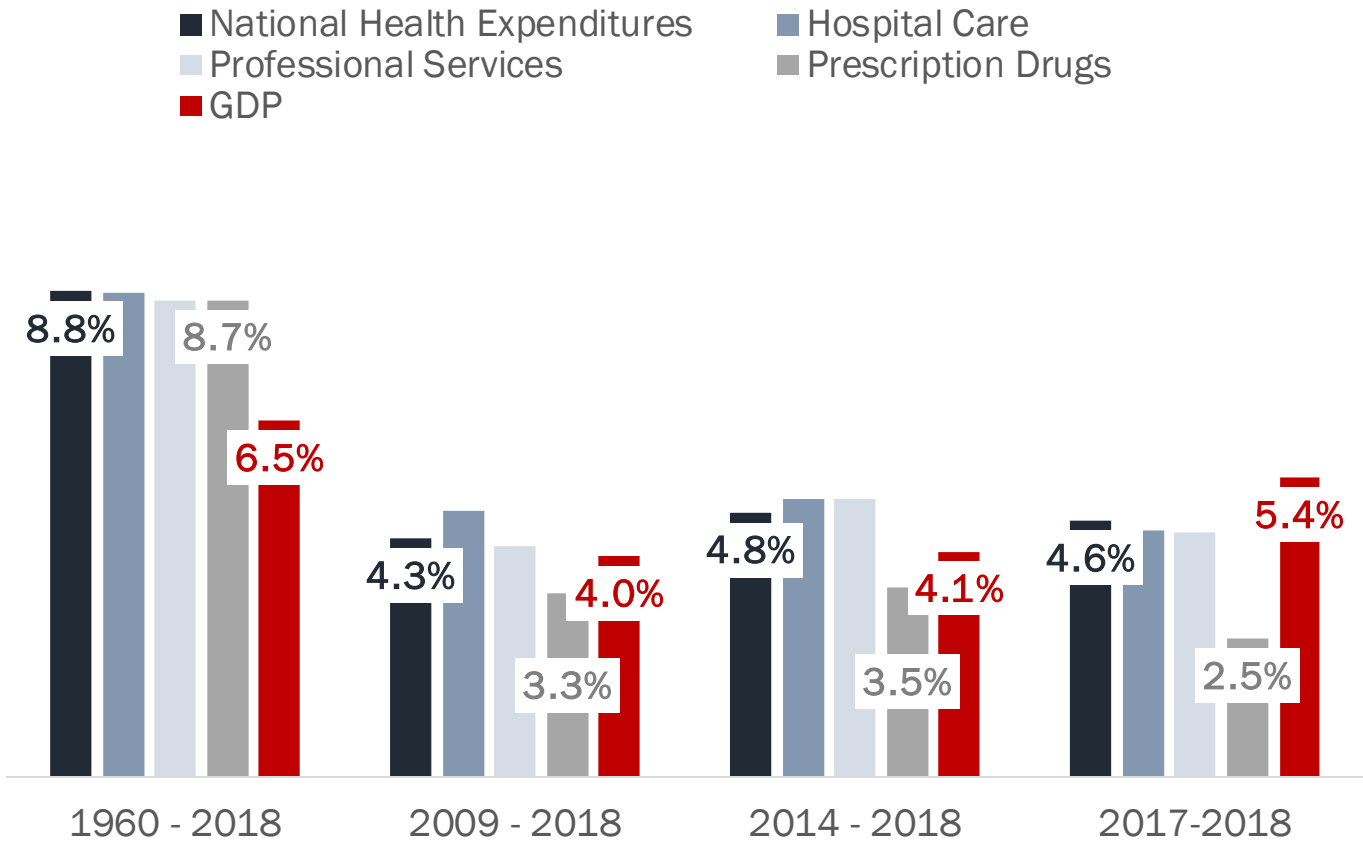
Average Annual Growth in National Health Expenditures & Select Components

1960 - 2018

- Large generic share helps keep the growth in prescription drug expenditures below overall health expenditures



Source: Calculations based on CMS National Health Expenditure data

There is a systemic health care affordability problem

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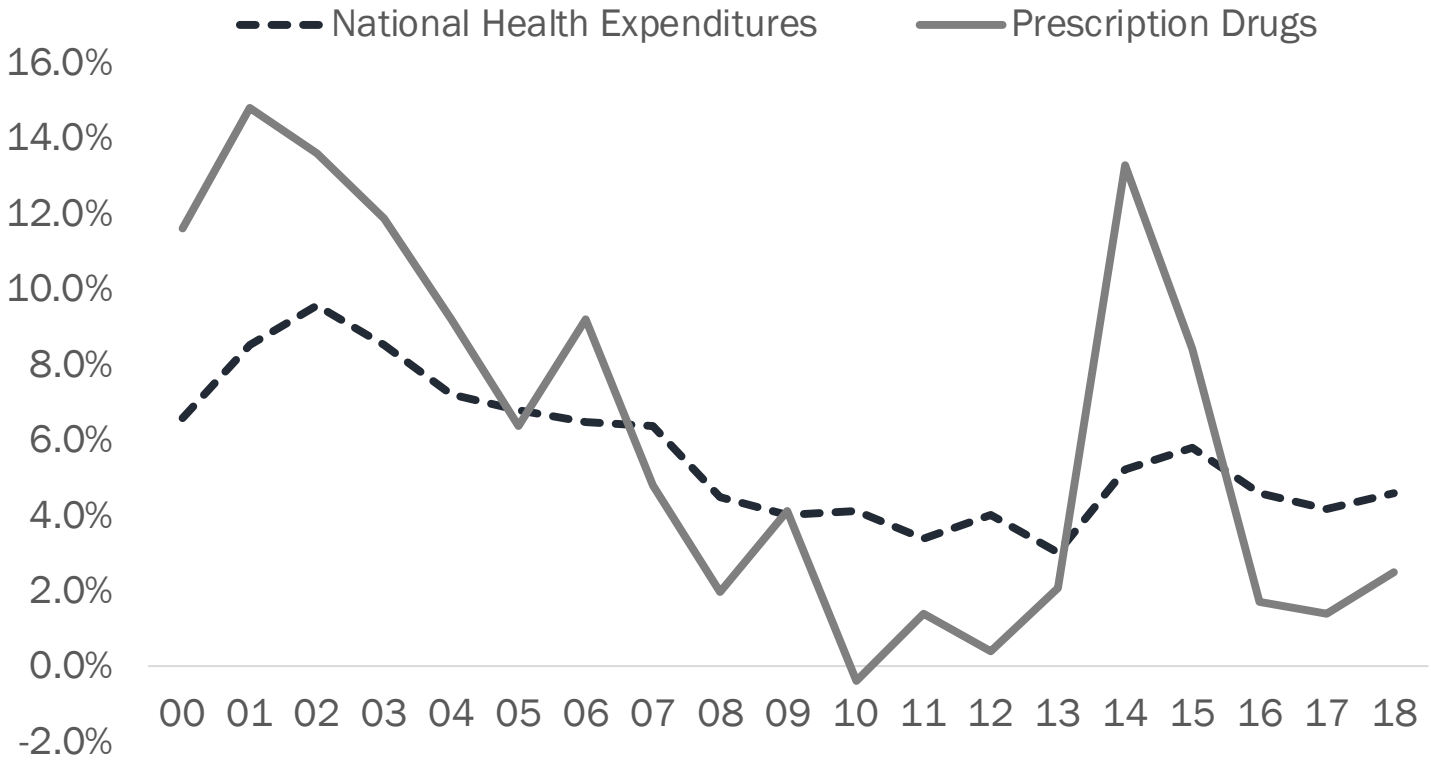
Annual Growth Rates in National Health Expenditures and Select Components

2000 - 2018



Source: CMS National Health Expenditure data

Prescription drug volatility garners attention

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Total Health Expenditures Compared to Out-of-pocket Expenditures

2011 - 2018

	% Change 2011-2018				
	Total	Out-of-pocket	Private Health Insurance	Medicare	Medicaid
NHE	4.49%	**2.76%**	4.88%	4.68%	5.65%
Prescription Drugs	4.16%	**0.43%**	2.92%	7.82%	6.85%
	% Change 2014-2018				
NHE	4.80%	**3.15%**	5.75%	4.94%	4.67%
Prescription Drugs	3.46%	**0.81%**	2.30%	6.04%	5.17%

Source: Author calculations based on CMS National Health Expenditure data

Average prescription drug expenditures under control…the affordability problem is confined to specific high-cost medicines

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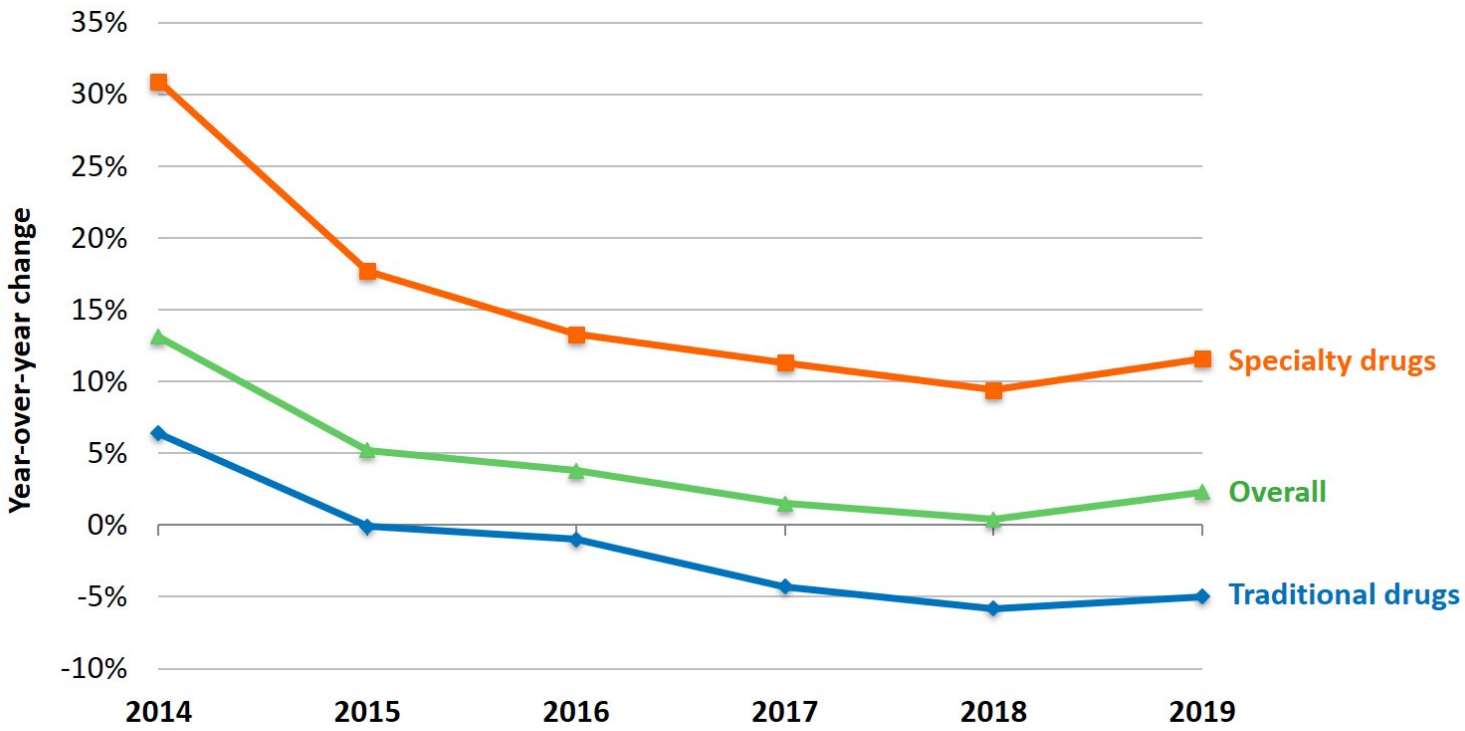
Express Scripts, Change in Net Drug Spending, Commercial Payers

2014 to 2019



Source: Drug Channels Institute analysis of *Express Scripts Drug Trend Report*, various years. Figures include the effect of rebates.

Published on *Drug Channels* (www.DrugChannels.net) on February 25, 2020.

DRUG CHANNELS INSTITUTE

Specialty drugs (i.e. biologics) driving drug spend

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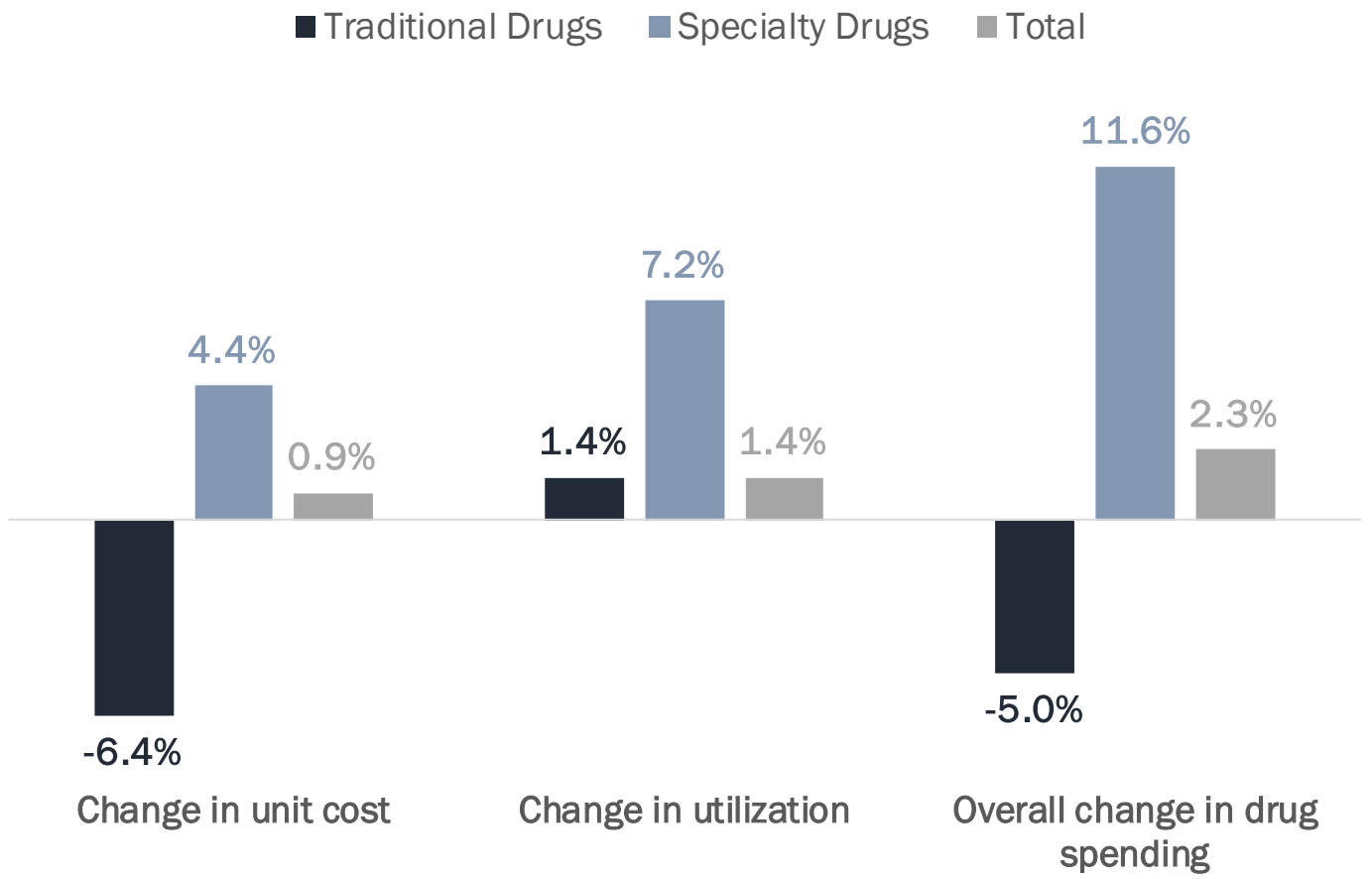
Express Scripts, Components of Change in Net Drug Spending, Traditional vs. Specialty

2019



Source: Drug Channels Institute

Specialty drugs (i.e. biologics) driving drug spend

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Net U.S. Spending on Medicines: Biologics and Non-biologics
(in billions)

- Biologic Medicines Driving Growth in Drug Expenditures

	2017	2018	Change 2017-18
Non-biologics	$214.59	$218.50	$3.91
Biologics	$114.60	$125.50	$10.90
Net Spending	**$329.19**	**$344.00**	**$14.81**

Source: IQVIA

Nearly 75 percent of the increase in total net spending on medicines was spent on biologic medicines

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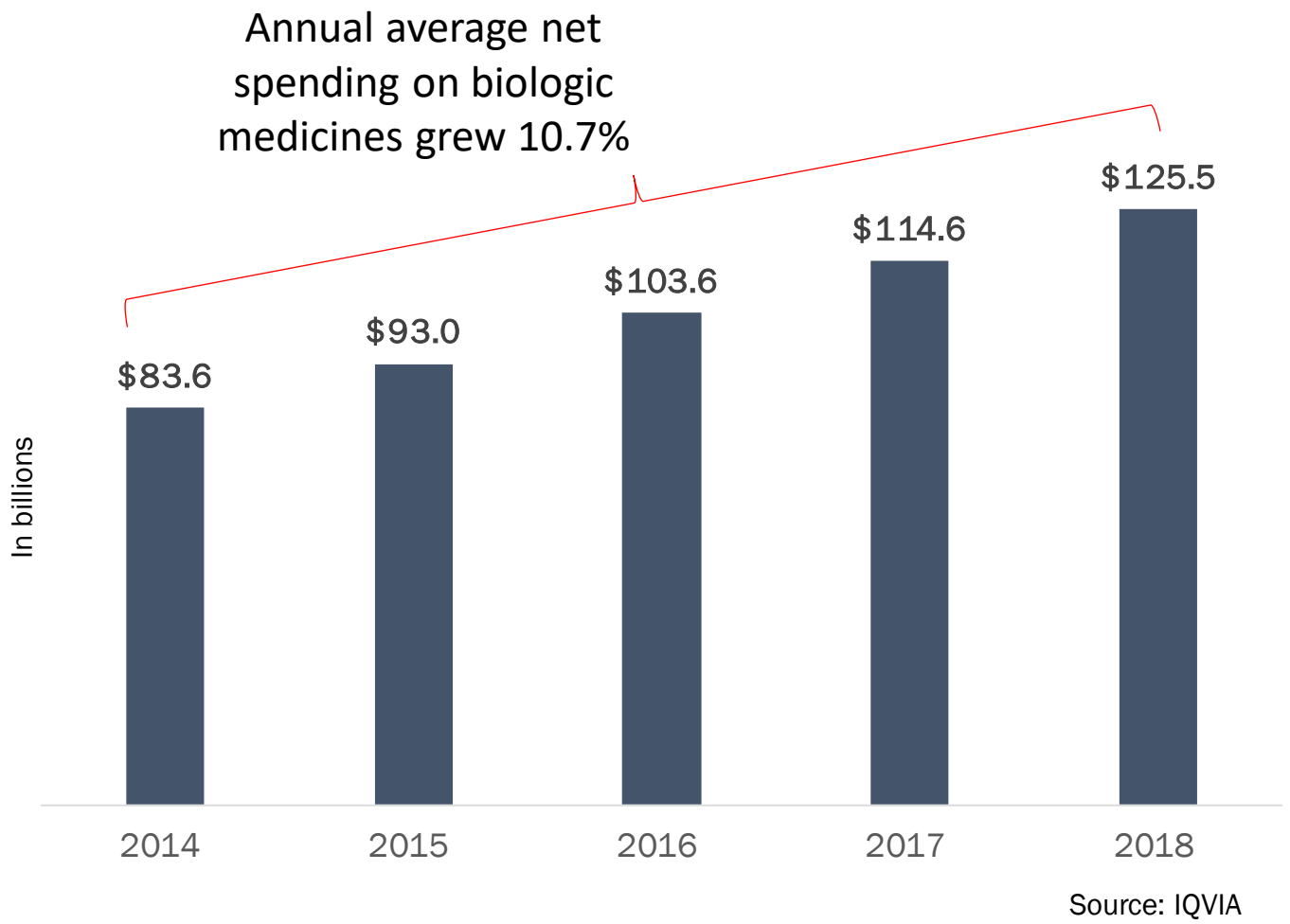
Net Spending on Biologic Medicines 2014 - 2018

(in billions)

- Biosimilars are high-value health care treatments that create competition similar to generics

- "Biosimilar spending has doubled since 2017 but still represents under 2% of the total U.S. biologics market in 2018."

IQVIA "Medicine Use and Spending in the U.S." May 2019



Source: IQVIA

A higher market share for biosimilars will decrease total expenditures on biologics

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Reforms Should Remove Anti-Competitive Obstacles

- Regulatory hurdles and market distortions
  - Decrease affordability
  - Impose excessive costs on patients

- Reforms that address unaffordability without jeopardizing innovation
  - Remove obstacles to biosimilars by incenting use of lower-cost options
  - Fix supply chain inefficiencies

Competition removes obstacles diminishing affordability without jeopardizing innovation

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Innovation versus Affordability

- The right balance is lacking in the biologics market

- Strong market for high value originators – innovation has been a success, but the competitive part of the market, biosimilars, is lagging in the U.S.

- In the EU:
  - Legal framework established in 2003
  - 64 biosimilars approved through February 2020*

- In the U.S.
  - Legal framework established in 2009 (Biologics Price Competition and Innovation Act, BPCIA)
  - 28 biosimilars approved through July 9, 2020**
  - 17 marketed
  - 1 with more than 50% market share

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* http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe

** https://biosimilarsrr.com/us-biosimilar-filings/

The Biosimilar Market in the EU

- Biosimilars market share exceeds 50% for a majority of countries across multiple drug classes

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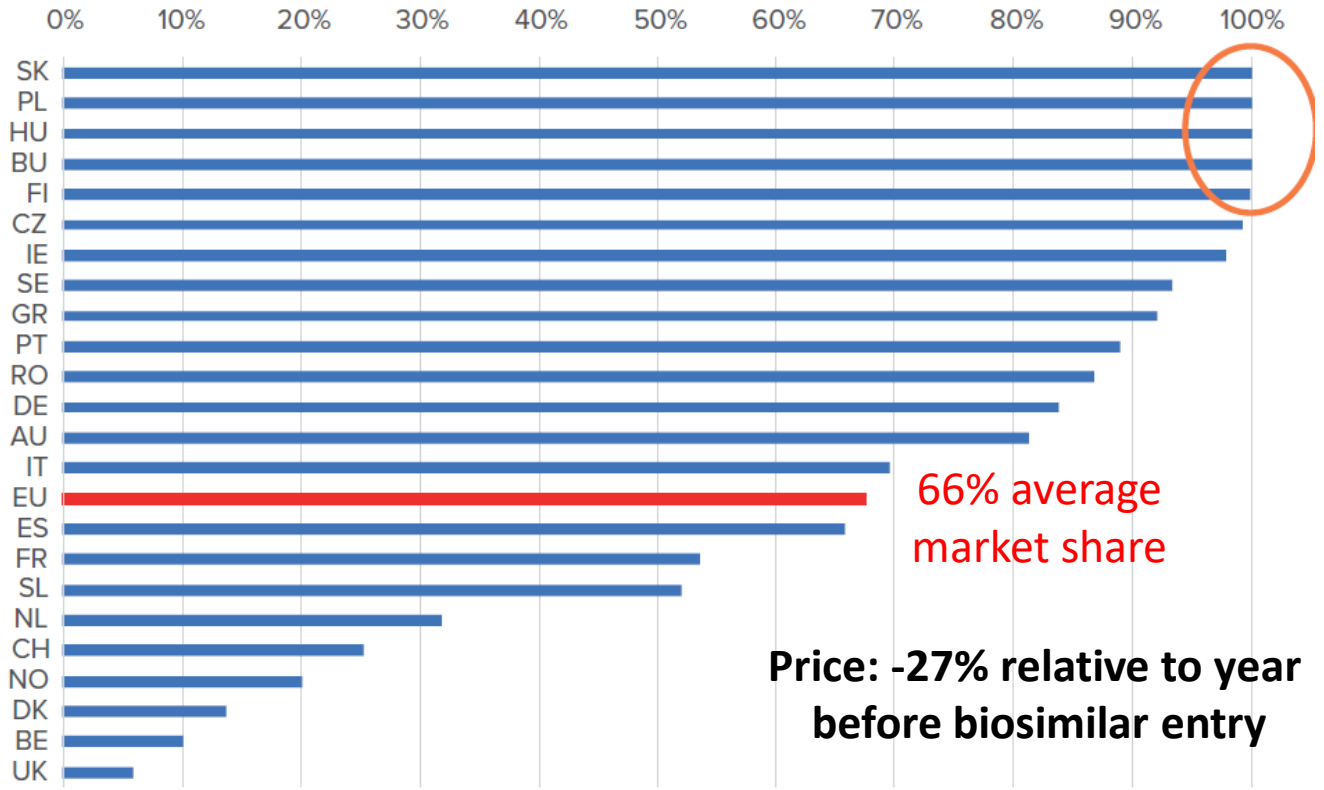

IQVIA, "The Impact of Biosimilar Competition in Europe" September 2018

Robust market share in EU illustrates possibilities of biosimilar competition

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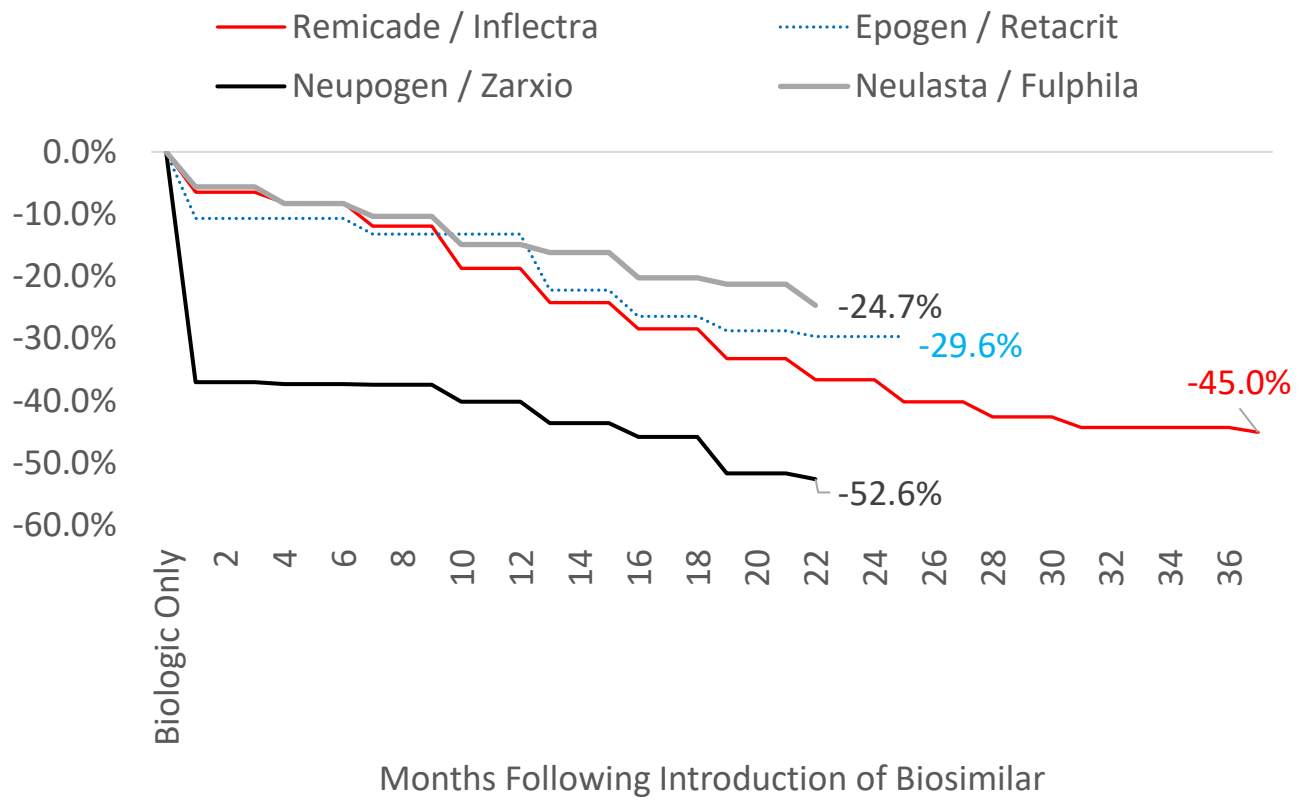
Biosimilar Prices Relative to Originator*

(Relative to price prior to biosimilar launch)

- Biosimilars Sell At a Steep Discount Relative to pre-Competition Prices



* Only evaluates biosimilars available for at least 12 months

Source: FDB MedKnowledge

Biosimilar prices in U.S. are significantly lower than originator prices prior to biosimilar entry

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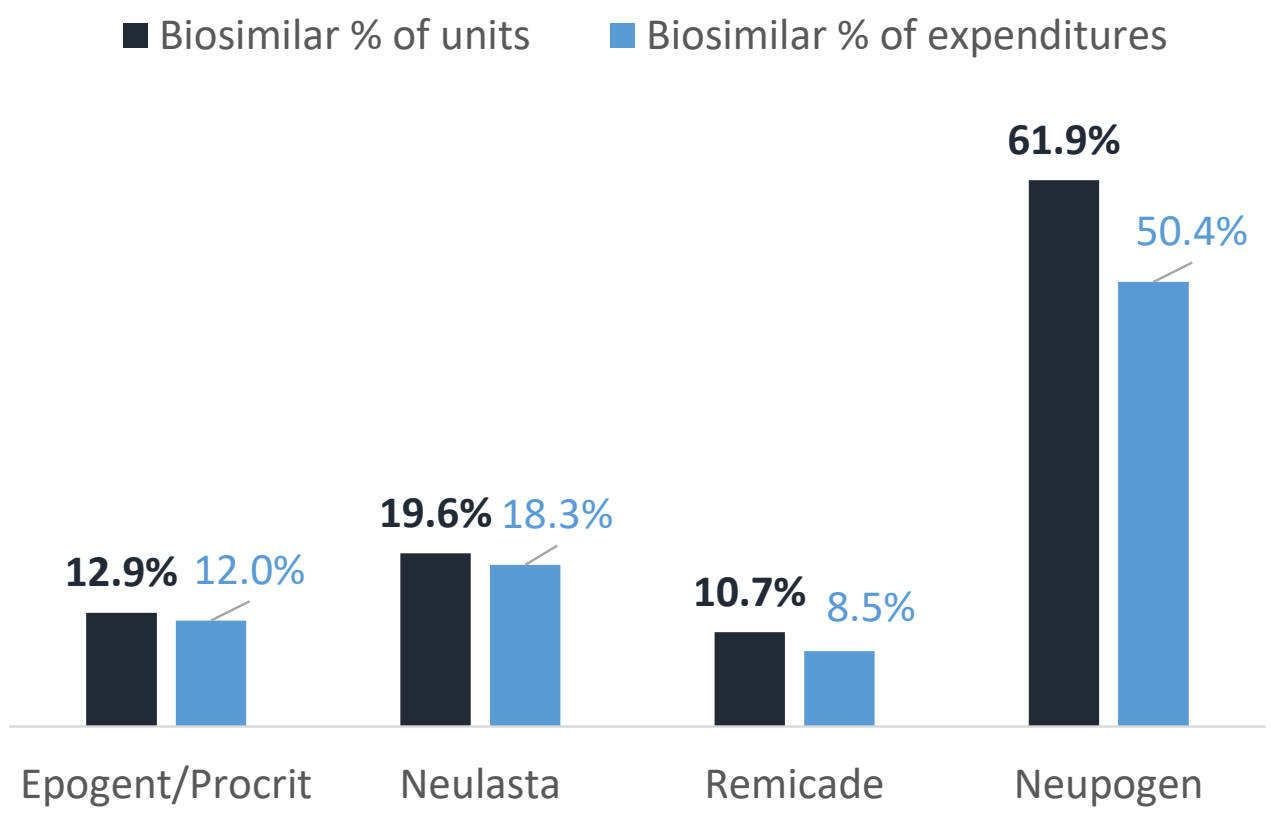
Biosimilar Share of Market 2019*

- Except for Zarxio, Biosimilars Still Comprise less than one-fifth of the Market



* Only evaluates biosimilars available for at least 12 months

Source: IQVIA data

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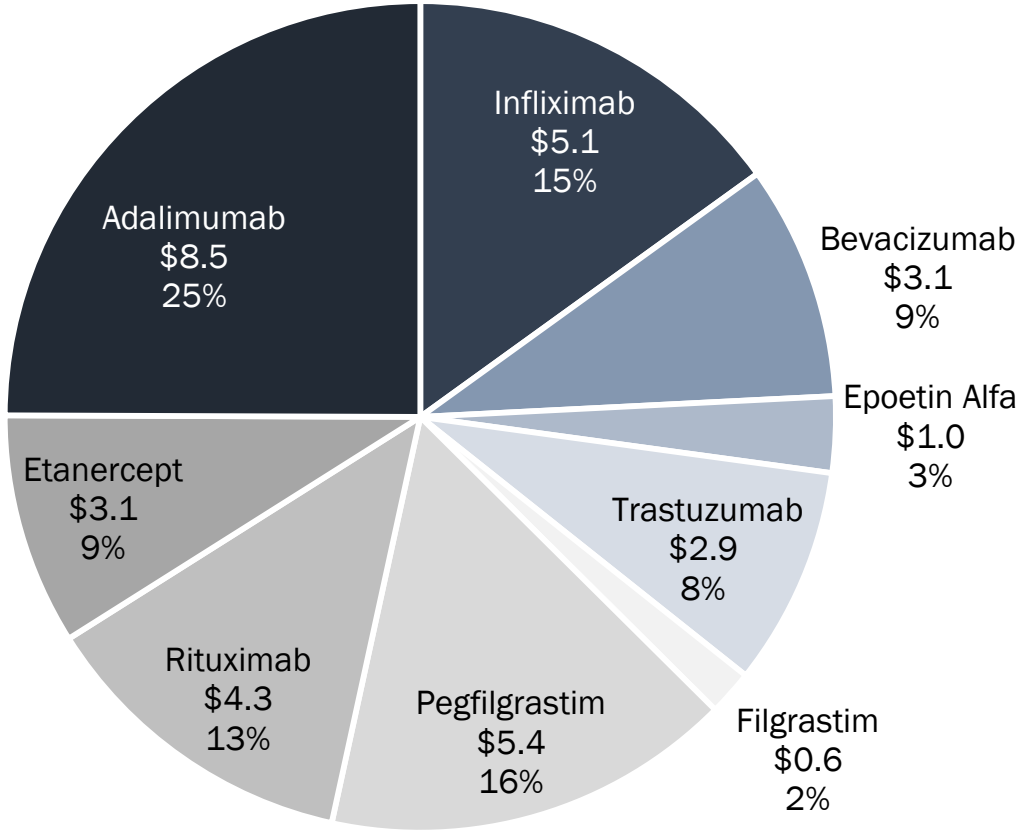
Total Expenditures by Drug Class 2019

- Total Expenditures: $34.1 billion

- Average 2019 national average sales price (ASP) data effective and 12-month volume data



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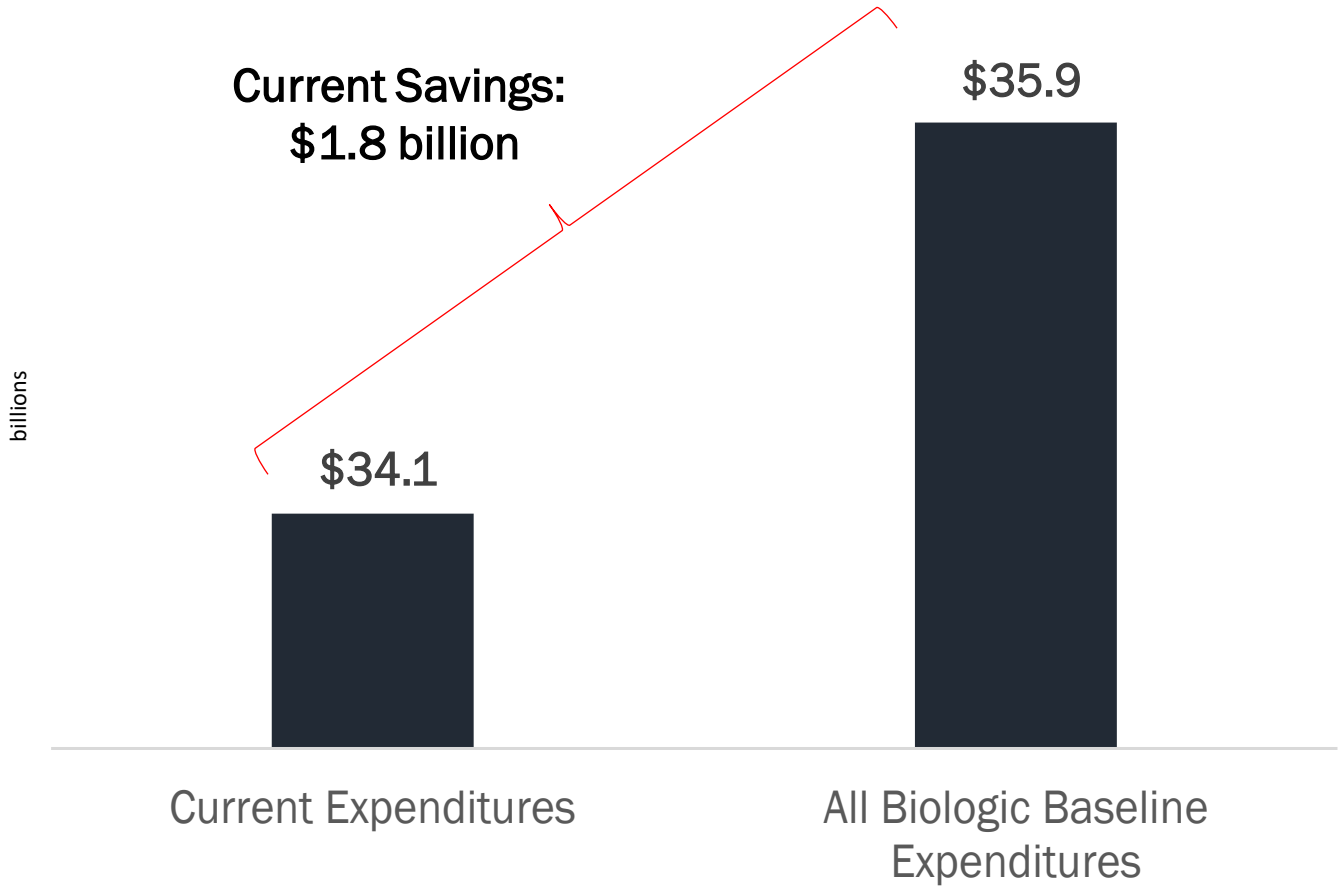
Source: Pacific Research Institute

Current Expenditures Compared to Baseline 2019

- Baseline relative to prices of originator prior to biosimilar entry
- Current Savings Exist, But Smaller than Potential
- Savings defined as the gap between the current and baseline scenarios
- 2019 savings of $1.8 billion (include price reductions in originator prices)



Source: Pacific Research Institute

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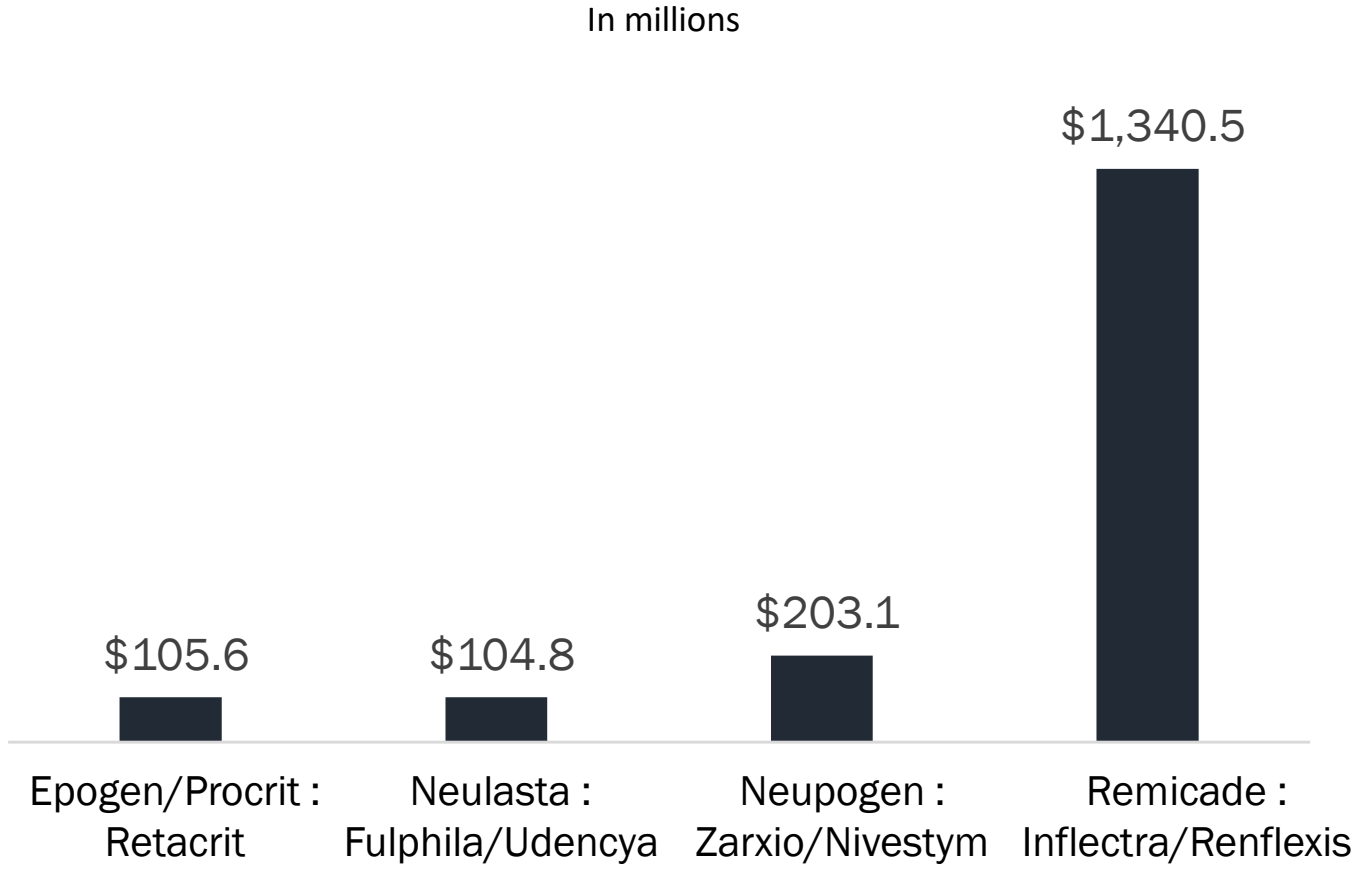
Current Expenditures Compared to Baseline 2019
(by Drug Class)

- 9 drug classes have approved biosimilar competitor
- Competition has grown to 7 drug classes



Source: Pacific Research Institute

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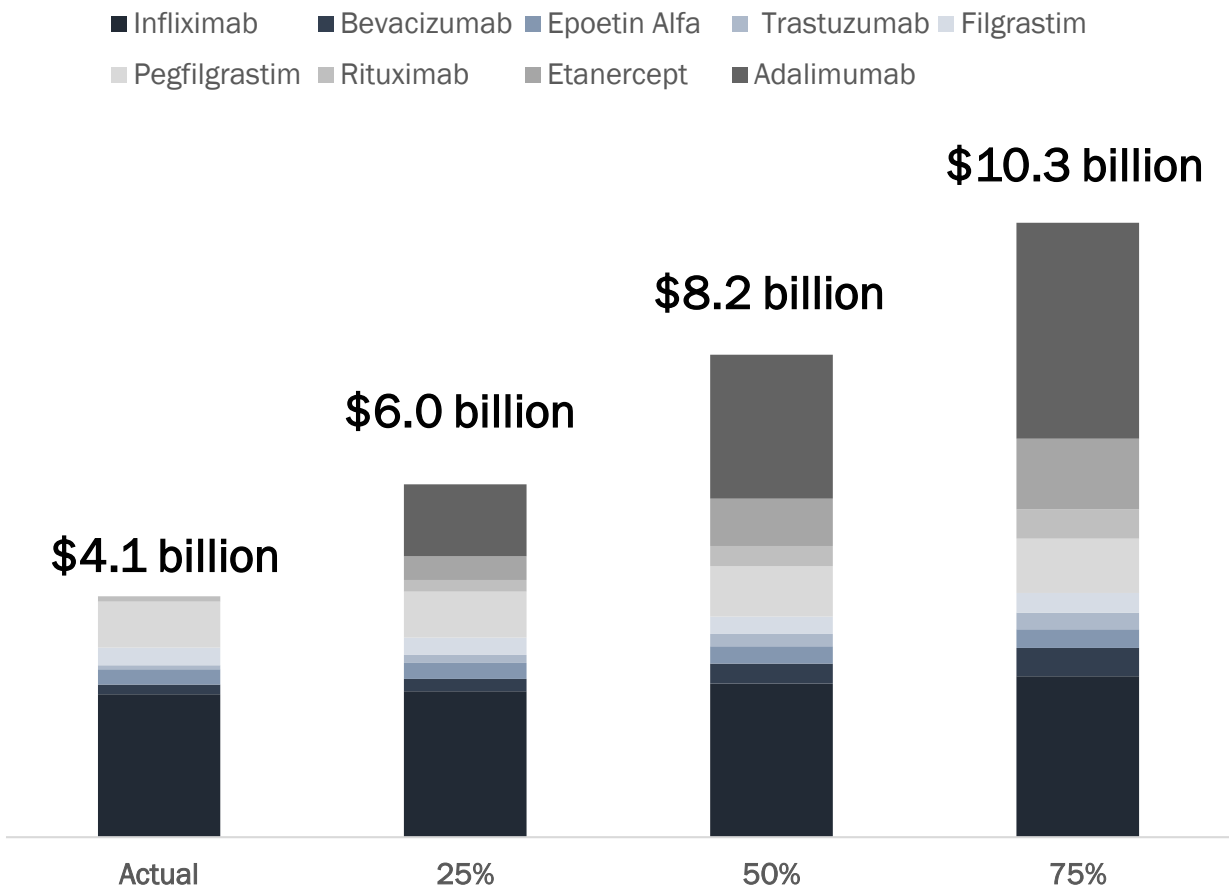
Total Potential Biosimilar Savings 2020f
(by Drug Class)

- Ran 3 scenarios based on the total sales of each drug class over the past 12-months
- Savings Relative to All-Biologics Baseline



Source: Pacific Research Institute

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Potential Biosimilar Savings
(by State)

- If biosimilars obtained 75% market share, then savings will benefit every state

Compared to Baseline

California	$734.0 million
North Carolina	$356.7 million
Wyoming	$ 8.7 million

	Biosimilar Market Share		
	75%	50%	25%
Alabama	$156.0	$124.2	$92.8
Alaska	$17.4	$13.7	$10.1
Arizona	$252.2	$190.3	$128.6
Arkansas	$103.9	$78.6	$53.3
California	$734.0	$579.9	$431.7
Colorado	$176.7	$138.5	$100.0
Connecticut	$116.2	$96.2	$76.2
Delaware	$26.4	$23.0	$19.5
District of Columbia	$22.3	$19.0	$15.8
Florida	$727.9	$563.0	$399.8
Georgia	$227.1	$185.9	$146.1
Hawaii	$39.3	$29.1	$18.8
Idaho	$45.1	$36.7	$28.3
Illinois	$326.6	$267.7	$210.2
Indiana	$167.1	$133.6	$101.0
Iowa	$104.5	$82.7	$60.6
Kansas	$80.8	$68.8	$55.9
Kentucky	$137.1	$107.5	$78.6
Louisiana	$143.7	$110.5	$78.4
Maine	$61.0	$47.9	$34.8
Maryland	$210.1	$167.5	$125.7
Massachusetts	$305.4	$234.1	$163.2
Michigan	$257.0	$214.3	$171.9
Minnesota	$177.0	$148.4	$122.8
Mississippi	$106.1	$78.5	$51.3
Missouri	$205.9	$166.3	$128.5

	Biosimilar Market Share		
	75%	50%	25%
Montana	$37.9	$29.8	$21.6
Nebraska	$78.3	$62.6	$47.6
Nevada	$81.7	$61.3	$41.0
New Hampshire	$44.1	$37.0	$29.8
New Jersey	$192.8	$168.0	$143.1
New Mexico	$68.0	$50.5	$33.0
New York	$652.0	$513.5	$378.9
North Carolina	$356.7	$283.4	$210.5
North Dakota	$52.1	$40.6	$28.7
Ohio	$369.9	$296.7	$226.5
Oklahoma	$88.4	$70.6	$53.3
Oregon	$298.2	$219.1	$139.3
Pennsylvania	$583.2	$447.5	$315.3
Rhode Island	$30.2	$25.6	$20.8
South Carolina	$128.0	$106.0	$84.0
South Dakota	$56.6	$42.1	$27.4
Tennessee	$301.1	$228.6	$157.4
Texas	$602.8	$486.6	$368.6
Utah	$193.7	$138.7	$84.2
Vermont	$32.2	$24.4	$16.6
Virginia	$256.7	$202.3	$147.8
Washington	$195.7	$161.0	$127.6
West Virginia	$60.4	$45.2	$30.6
Wisconsin	$438.3	$319.9	$202.7
Wyoming	$8.7	$7.4	$6.0
Total State Savings	***$10,135***	***$7,974***	***$5,847***

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Source: Pacific Research Institute

Reform Implications

Biosimilars with > 50% market share (e.g. Zarxio) and sell > 40% discount to the originator biologic can create substantial savings for the health care system

- **Market Practices**
  - **Fail-first, or step therapy**: Work in reverse for biosimilars -- use less expensive biosimilar if first failed on more expensive biologic.
  - **Anti-competitive contracting practices**: Rebates connected to pre-established min. volumes; biologic sales connected to other medical devices.

- **Promote Shared Savings**
  - **Preferred Biosimilar Formulary Tier**: Based on price discounts provide scaled co-pay and co-insurance discounts for biosimilars (relative to an average originator price over time)
  - **"Buy-and-bill" process**: typically ASP plus a percentage mark-up often causes providers to lose money by prescribing a biosimilar medicine
  - **Star rating**: Insurers should benefit with respect to Medicare Advantage rating system by gaining an additional start for encouraging biosimilar use
  - **Out of pocket cap**: Medicare Part D patients should not face unlimited exposure to drug costs

Reform Implications

- **Regulatory Inefficiencies**
  - **Interchangeability designation**: Currently there is uncertainty regarding how the interchangeable designation will be applied. The designation should refer to enabling pharmacists to substitute generic or biosimilar versions without the intervention of the prescribing healthcare provider only. Including interchangeability designation for biosimilars in other situations is beyond the intended scope and definition (BPCIA and FDA requirements).

  - **Promote education**: Efficacy of biosimilars in terms of safety and efficacy