

PR | CENTER FOR MEDICAL ECONOMICS AND INNOVATION

Empowering Market Competition through Biosimilars

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Newport Beach, California
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Total Annual Savings for Current, 25%, 50%, and 75% Biosimilar Share Scenarios Compared to All-Originator Biologic Baseline

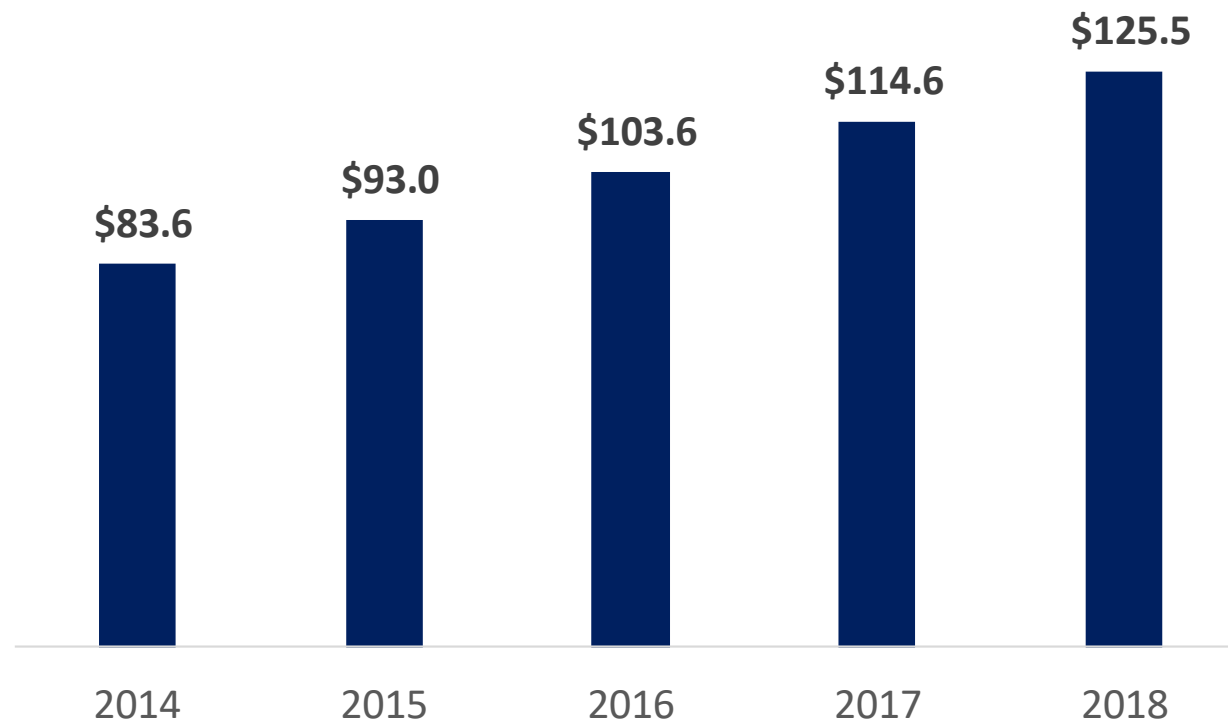
- Biosimilars price discounts expected 30% - 40% off originator biologic
- Forthcoming study estimates possible health care savings from wider adoption of biosimilars.
- Estimates are based on the average sales price (ASP) data that are effective from April 2019 through June 2019 and rolling 12-month volume data through February 2019.
- Methodology: compare potential savings to hypothetical all-originator biologic scenario
- Over 10 years, potential savings of \$24.7 billion, \$48.0 billion, and \$71.7 billion respectively.
- Savings only count the nine biologic drug classes where approved biosimilars already exist.

Drug Class	Originator Biologic	Total Savings (in millions)			
		Current	25% Biosimilar Share	50% Biosimilar Share	75% Biosimilar Share
Infliximab	Remicade	\$79.4	\$318.2	\$636.5	\$954.7
Pegfilgrastim	Neulasta	\$21.8	\$121.9	\$243.8	\$365.7
Filgrastim	Neupogen	\$152.1	\$152.1	\$152.1	\$206.8
Epoetin Alfa	Epogen & Procrit	\$0.5	\$8.4	\$16.9	\$25.3
Bevacizumab	Avastin	\$0.0	\$199.2	\$398.5	\$597.7
Trastuzumab	Herceptin	\$0.0	\$208.0	\$415.9	\$623.9
Rituxumab	Rituxan	\$0.0	\$280.6	\$561.2	\$841.8
Etanercept	Enbrel	\$0.0	\$324.0	\$648.0	\$972.1
Adalimumab	Humira	\$0.0	\$861.1	\$1,722.1	\$2,583.2
GRAND TOTAL		\$253.8	\$2,473.6	\$4,795.0	\$7,171.2

Biosimilars have no “clinically meaningful difference” in safety, purity, and effectiveness relative to its reference originator biologic. Just like generic medicines, the benefits of biosimilars are the substantial price discounts they enable compared to the originator biologic.

Net Spending on Biologic Medicines 2014 - 2018 (in billions)

- Annual average net spending on biologic medicines have grown 10.7 percent a year between 2014 and 2018,
- Biologics are a high-value /high-cost health care treatments
- Biosimilars offer market competition similar to generics



Source: IQVIA

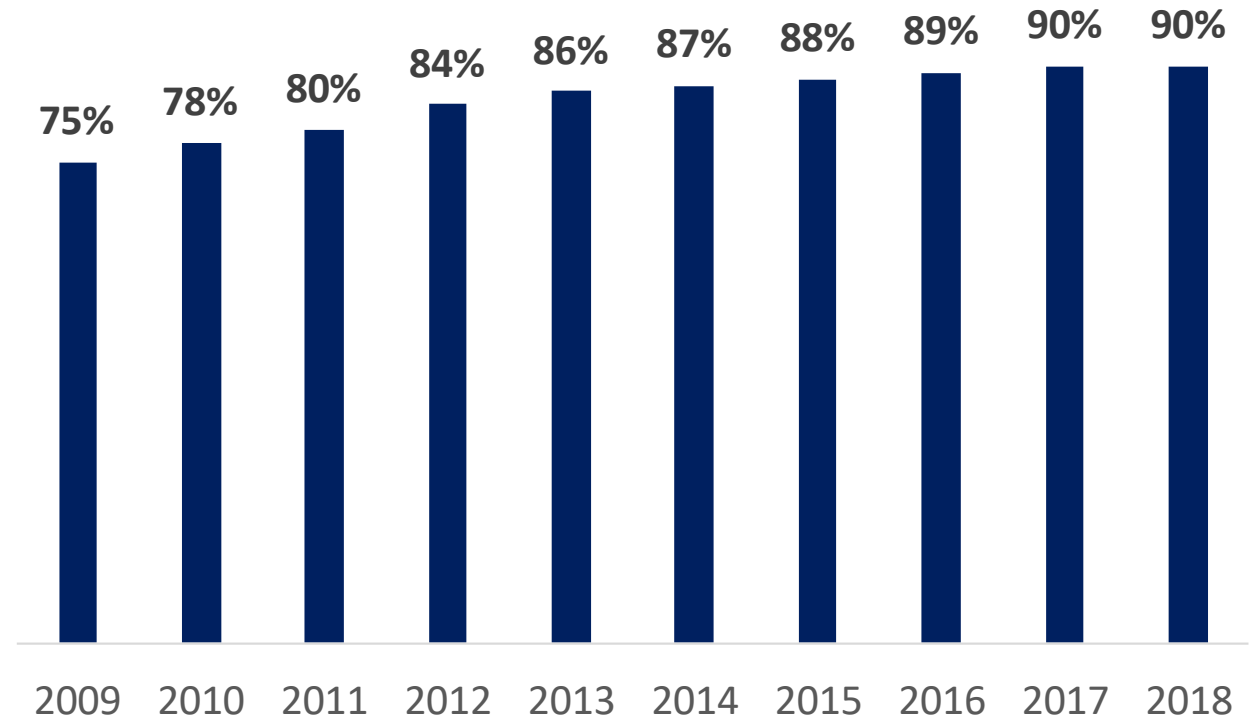
A higher market share for biosimilars, a lower-priced alternative to the originator biologic, will decrease total expenditures on biologics

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
- Save health care system \$292.6 billion

The Association for Accessible Medicines



Source: IQVIA

Biosimilars' low U.S. market share contrasts their large share in the EU, or generics' large share in the U.S.

Volumes and Market Share Biologic Drugs with Approved Biosimilar Competitors

12-month Volume Data through February 2019

- Ran 4 scenarios based on the total sales of each drug class over the past 12-months
- 9 drug classes have approved biosimilar competitor
- 7 biosimilars had market sales as of February 2019, competing in 4 drug classes

Drug Class	Originator Biologic	Biosimilars	Unit Volumes 3/2018 – 2/2019	Market Share
Infliximab	Remicade		6,905,827	93.8%
		Inflectra	389,148	5.3%
		Renflexis	70,375	1.0%
Pegfilgrastim	Neulasta		1,120,412	95.5%
		Fulphila	25,965	2.2%
		Udenyca*	26,436	2.3%
Filgrastim	Neupogen		660,323	44.8%
		Zarxio	808,281	54.9%
		Nivestym	4,012	0.3%
Epoetin Alfa	Epogen & Procrit		8,621,211	95.5%
		Retacrit	127,784	1.5%
Bevacizumab	Avastin		1,779,490	100.0%
Trastuzumab	Herceptin		2,507,961	100.0%
Rituxumab	Rituxan		2,227,270	100.0%
Etanercept	Enbrel		1,080,208	100.0%
Adalimumab	Humira		1,368,606	100.0%

* Udenyca volumes are annualized from the units sold data from 1/2019 – 2/2019.

“A recent study from March 2018, comparing global data spanning over 20 years, shows that when patients switch from reference product to biosimilar, there were no meaningful differences in safety or efficacy.”

Carioto J and Mirchandani H (2018) “Barriers and potential paths for biosimilars in the United States” *Milliman*, November.

Prices: Originator Biologic Compared to Biosimilar Competitors

- Medicare pays the administering facility a 6 percent markup over the price of the originator biologic regardless of the actual medicine used

	Reimbursement Rates (ASP + 6%)	
	Medicare/Medicaid	Commercial
Infliximab		
Remicade (10 mg)	\$71.83	\$71.83
Weighted Avg Biosimilar	\$55.09	\$54.09
Inflextra	\$54.34	\$53.29
Renflexis	\$59.27	\$58.51
Pegfilgrastim		
Neulasta (6 mg)	\$4,655	\$4,655
Weighted Avg Biosimilar	\$4,251	\$4,227
Fulphila	\$4,201	\$4,174
Udenyca	\$4,300	\$4,279
Filgrastim		
Neupogen (1 mcg)	\$1.00	\$1.00
Weighted Avg Biosimilar	\$0.64	\$0.61
Zarxio	\$0.64	\$0.61
Nivestym	\$0.73	\$0.72
Epoetin Alfa		
Epogen (& Procrit) (1,000 units)	\$11.73	\$11.73
Retacrit	\$11.36	\$11.34
Bevacizumab		
Avastin (10 mg)	\$81.22	\$81.22
Mvasi (25.8% Discount)	\$60.26	\$59.01
Trastuzumab		
Herceptin (10 mg)	\$10.70	\$10.70
Biosimilar (25.8% Discount)	\$7.94	\$7.78
Rituxumab		
Rituxan (10 mg)	\$952	\$952
Biosimilar (25.8% Discount)	\$706	\$692
Etanercept		
Enbrel	\$1,067	\$1,067
Biosimilar (50.0% Discount)	\$533	\$533
Adalimumab		
Humira	\$2,237	\$2,237
Biosimilar (50.0% Discount)	\$1,119	\$1,119

Biosimilar Market Share Compared to Biosimilar Discount*

- Biosimilars that obtain more than 50 percent of the market (e.g. Zarxio) and sell around a 40 percent discount to the originator biologic will create substantial savings for the health care system

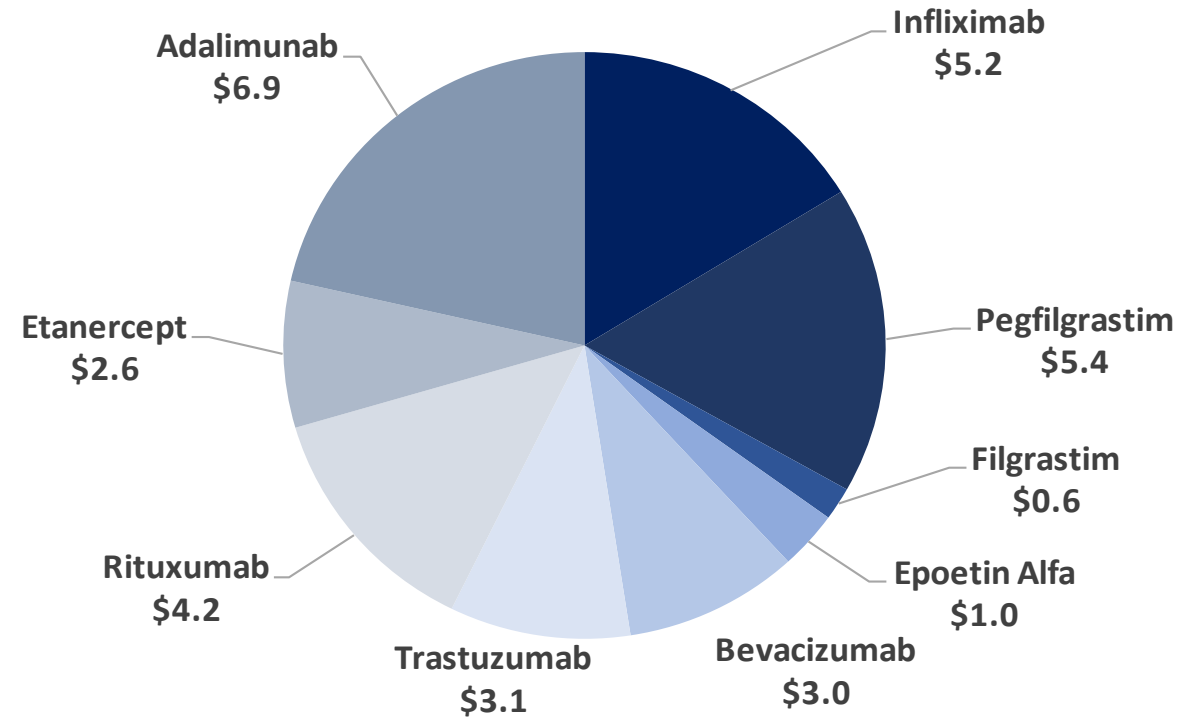
	Biosimilar Market share	Price Discount
Infliximab		
Inflectra	5.3%	-25.8%
Renflexis	1.0%	-18.5%
Pegfilgrastim		
Fulphila	2.2%	-10.3%
Udencya**	2.3%	-8.1%
Filgrastim		
Zarxio	54.9%	-38.3%
Nivestym	0.3%	-28.0%
Epoetin Alpha		
Retacrit	1.5%	-3.4%

* Price discounts are estimated based on the average sales prices (ASP) effective April 1, 2019 through June 30, 2019. Market share is based on units sold based on IQVIA data.

** Udencya volumes are annualized from the units sold data from 1/2019 – 2/2019.

Total Expenditures by Drug Class
based on ASP Effective 4-2019 and
12 Month Rolling Average of Units
Sold through February 2019

- Current total expenditures on biologic medicines in 9 drug classes estimated based on the current prices and total units (adjusted into dosages).
- Current savings defined as the gap between the current and baseline scenarios.
- Annualized total costs on 9 biologic drug classes is \$32.1 billion.
 - Based on the current ASP rates and actual 12-month sales through February 2019



Total Annual Expenditures on Biologic Medicines: All Originator Biologic Baseline Compared to Current, 25%, 50%, and 75% Biosimilar Share

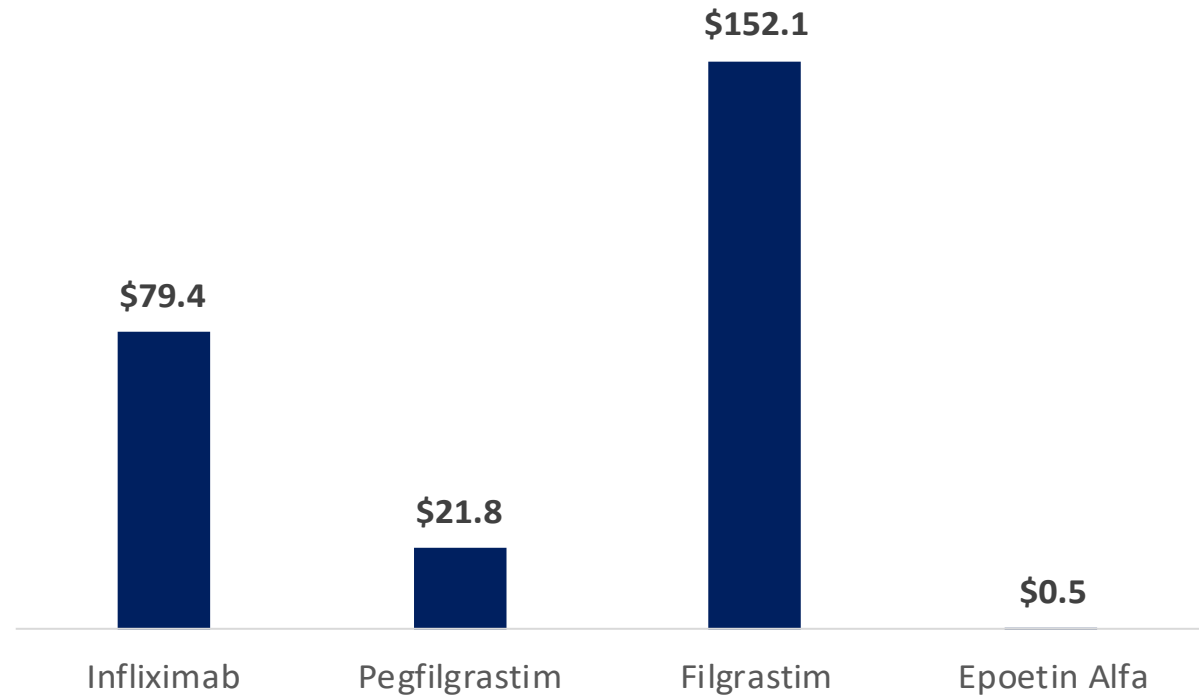
- Savings are compared to the baseline scenario
- The biosimilars competing against Neupogen (Filgrastim drug class) have 55.2 percent of the market

Drug Class	Originator Biologic	All Originator Biologic Baseline	Annual Expenditures (in millions)			
			Current	25% Biosimilar Share	50% Biosimilar Share	75% Biosimilar Share
Infliximab	Remicade	\$5,290	\$5,211	\$4,972	\$4,654	\$4,336
Pegfilgrastim	Neulasta	\$5,460	\$5,438	\$5,338	\$5,216	\$5,094
Filgrastim*	Neupogen	\$736	\$584	\$584	\$584	\$529
Epoetin Alfa	Epogen & Procrit	\$1,027	\$1,026	\$1,018	\$1,010	\$1,001
Bevacizumab	Avastin	\$3,010	\$3,010	\$2,811	\$2,611	\$2,412
Trastuzumab	Herceptin	\$3,120	\$3,120	\$2,912	\$2,704	\$2,496
Rituxumab	Rituxan	\$4,241	\$4,241	\$3,960	\$3,680	\$3,399
Etanercept	Enbrel	\$2,592	\$2,592	\$2,268	\$1,944	\$1,620
Adalimumab	Humira	\$6,889	\$6,889	\$6,027	\$5,166	\$4,305
GRAND TOTAL		\$32,364	\$32,110	\$29,891	\$27,569	\$25,193

* 25 percent and 50 percent scenarios are not applied

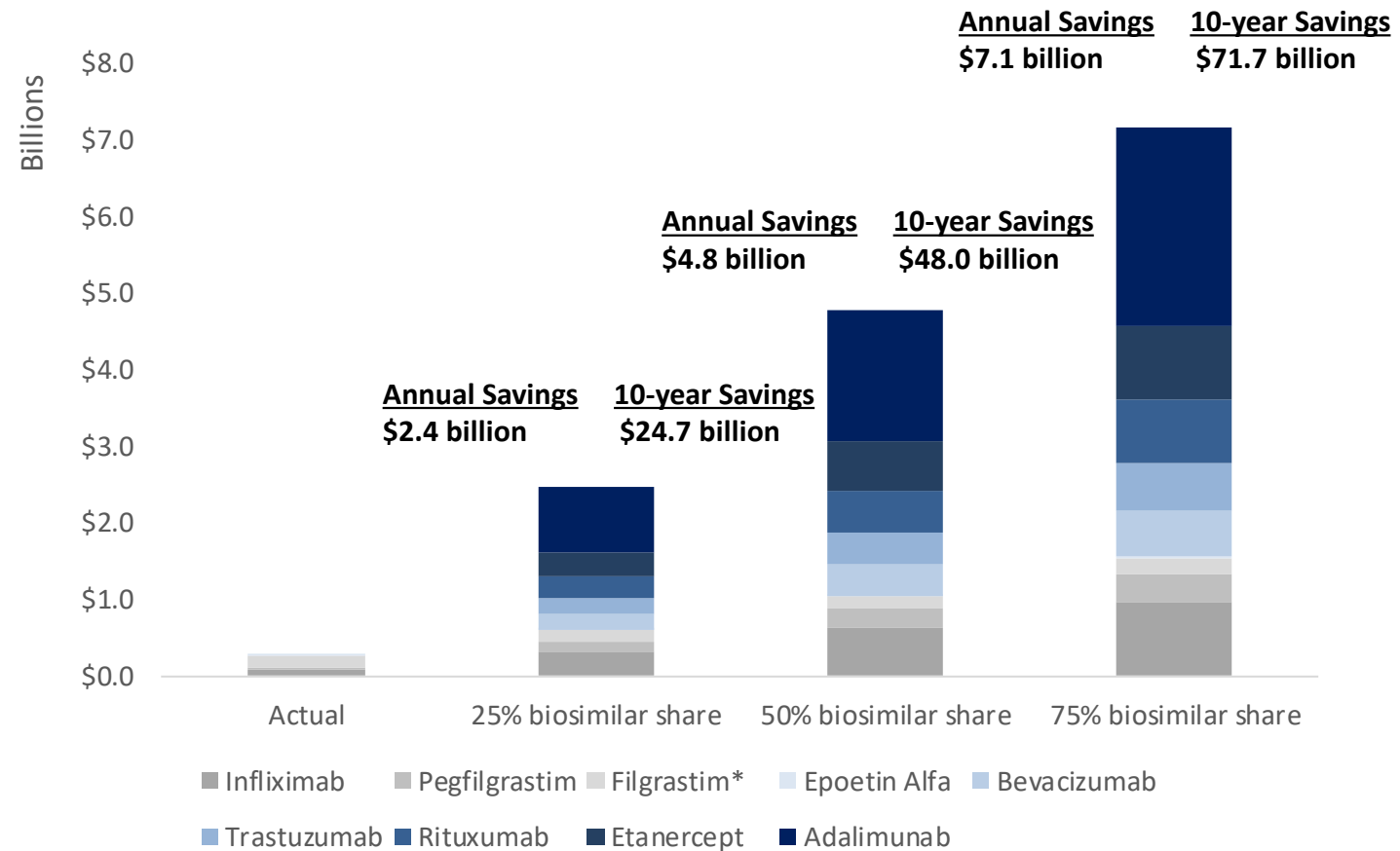
Current Biosimilar Savings by Drug Class

- Filgrastim biosimilars generate the largest dollar savings due to Zarxio (a biosimilar) surpassing Neupogen (the originator biologic).
- Infliximab biosimilars generate the next largest savings



**Total Annual Savings on Biologic Medicines Relative to the Baseline
Current, 25%, 50%, and 75%
Biosimilar Share Scenarios**

- Current savings exist, but pale in comparison to the potential savings indicated by current price discounts.



* 25 percent and 50 percent scenarios are not applied

Total Annual Savings on Biologic Medicines Relative to Current Expenditures

25% Biosimilar Share, 50% Biosimilar Share, and 75% Biosimilar Share Scenarios

- Relative to current expenditures, the currently approved biosimilars would generate \$2.2 billion, \$4.5 billion, and \$6.9 billion in annual savings if the obtained 25%, 50%, and 75% market share, respectively

Drug Class	Originator Biologic	Biosimilar Savings Relative to Actual (millions)		
		25% biosimilar share	50% biosimilar share	75% biosimilar share
Infliximab	Remicade	\$238.8	\$557.1	\$875.3
Pegfilgrastim	Neulasta	\$100.1	\$222.0	\$343.9
Filgrastim*	Neupogen	\$0.0	\$0.0	\$54.7
Epoetin Alfa	Epogen & Procrit	\$8.0	\$16.4	\$24.8
Bevacizumab	Avastin	\$199.2	\$398.5	\$597.7
Trastuzumab	Herceptin	\$208.0	\$415.9	\$623.9
Rituxumab	Rituxan	\$280.6	\$561.2	\$841.8
Etanercept	Enbrel	\$324.0	\$648.0	\$972.1
Adalimumab	Humira	\$861.1	\$1,722.1	\$2,583.2
GRAND TOTAL		\$2,219.8	\$4,541.2	\$6,917.4

Policy Implications

Large potential savings makes identifying barriers a top priority

- **Market Practices**

- **“Buy-and-bill” process:** typically ASP plus a percentage mark-up often causes providers to lose money by prescribing a biosimilar medicine
- **Fail-first, or step therapy:** Work in reverse for biosimilars -- patients can only use the less expensive biosimilar if they first failed on the more expensive biologic, biasing the market against less expensive biosimilars.
- **Anti-competitive contracting practices:** For example, linking rebates on pre-established minimum volume-thresholds; or, connecting biologic sales with other medical devices.

- **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