Adalimumab Biosimilar Tracking

Q1 Readout

Prepared for:

BIOSIMILARS COUNCIL™
A DIVISION OF AAM

April 2, 2024

The Biosimilars Council has partnered with IQVIA to track adalimumab biosimilar launch performance and provide market access insights throughout 2024

Background

After two decades on the US market, Humira began facing biosimilar competition in 2023. Despite potential savings, payers and providers have been reticent to adopt biosimilar competitors. The Biosimilars Council is seeking to monitor adalimumab biosimilar performance and understand the key drivers behind biosimilar uptake.

Key Objectives

1. Track new-to-brand and overall market share for Humira and its biosimilars over time across indications, as well as leverage channel and payer mix to understand the coverage landscape for adalimumab patients
2. Survey access for Humira and its biosimilars, building insight into utilization management, rejection types (NDC block, PA/ST, SP mandate, etc.), and the durability of each rejection type across channels and payers
3. Synthesize findings to understand attrition from written demand to filled Rxs for adalimumab, as well as calculate the opportunity cost of using Humira in place of its more affordable biosimilars to patients and the U.S. health system

Source: US Market Access Strategy Consulting analysis

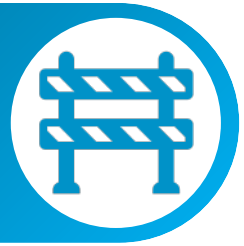
While signs of change are on the horizon, key players in the U.S. healthcare system have slowed biosimilar adoption, risking up to $6B per year

Transitioning patients to biosimilars would bring billions in savings to patients and health plans

Biosimilar uptake is growing but still trails Humira

- **Biosimilar demand has grown rapidly** (4x growth in written Rxs from July – Nov 2023), however, biosimilars accounted for only 1% of adalimumab share in Nov 2023

Big PBMs remain hesitant to adopt biosimilars



- **High volume biosimilars see most fills and favorable coverage at non-big 3 PBMs,** laying out a blueprint for biosimilar success as PBMs remain hesitant to adopt new options

Holding onto Humira comes at an immense cost

- **Switching all adalimumab patients to biosimilars would save up to $6B** for the U.S. health system
- **However, PBMs would lose up to 84% of profit,** explaining limited uptake to date at the largest payers

Trends To Watch

1. Biosimilars may see more favorable payer access in 2024 with Big 3 formularies set to shift
2. Co-branded biosimilars are set to launch*
3. Manufacturer and payer strategy are rapidly changing and will play a large role in the growth of adalimumab biosimilar use

*https://www.cvshealth.com/news/pbm/cvs-caremark-accelerates-biosimilars-adoption-through-formulary-changes.html
**https://www.pharmacytimes.com/view/fda-accepts-supplemental-biologics-license-application-for-hadlima-for-interchangeability-with-humira
Source: US Market Access Strategy Consulting analysis

While the most prescribed biosimilars all launched with a low WAC, biosimilars account for only 1% of adalimumab and ~2% of new starts across indications

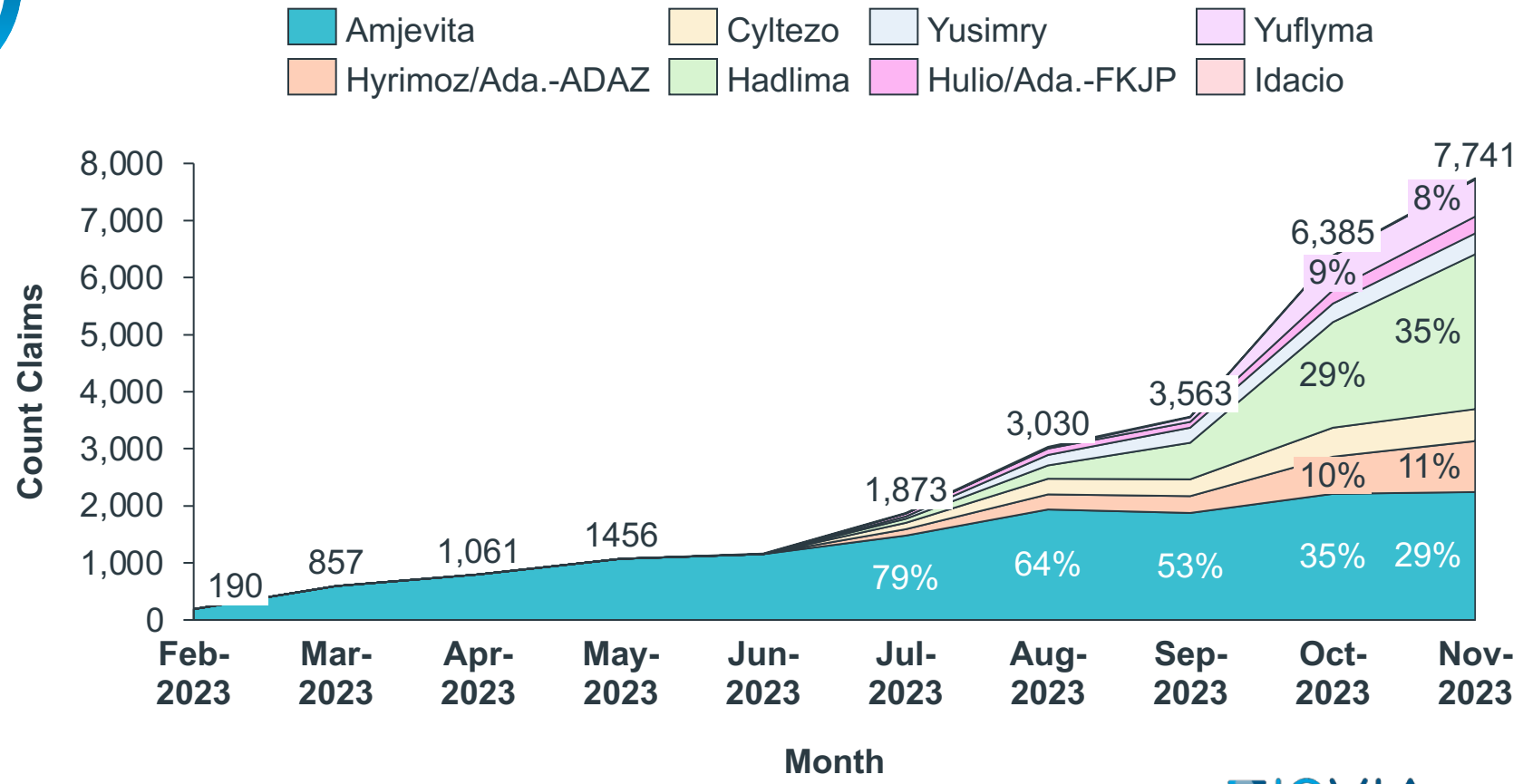
Written Humira prescriptions outnumbered biosimilars by a factor of 46 to 1 in November 2023

Uptake is growing but still trails Humira

- Although adalimumab biosimilar uptake is increasing, biosimilars only capture ~2% of new-to-brand prescriptions and have experienced slow rates of switching among established patient

Newly Launched Adalimumab Biosims Written Scripts by Brand

(Rx; All Claims; All Channels; Feb 2023 – Nov 2023)



Source: US Market Access Strategy Consulting analysis

Biosimilars made up only 1% of total purchased adalimumab volume in November 2023, growing at a much slower pace than other recent launches

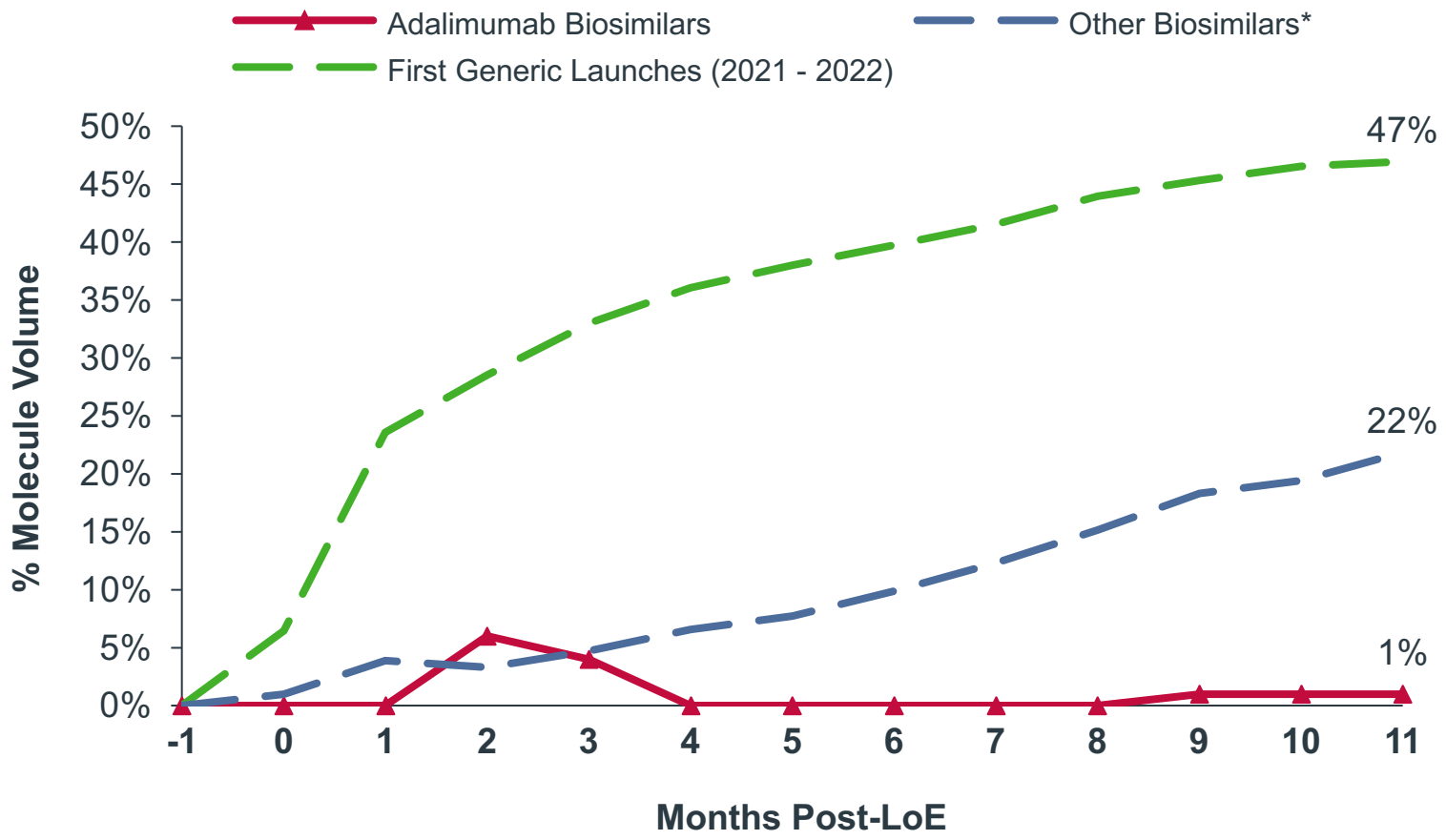
Adalimumab biosimilars have faced more barriers than others, likely due to incentives favoring use of high list price products over lower priced products with lower net cost

Uptake is growing but still trails Humira

- **Adalimumab biosimilar uptake has been slow compared to many other recent biologic and specialty LoE events**, likely driven by brand contracting practices and large PBM payer controls
- **Biosimilars accounted for only 1% of total adalimumab volume in November 2023 versus an average of 22%** for recent biosimilars 11 months post-LoE and 86% for emtricitabine/TDF's generic launch

Avg Biosimilar Share of Molecule Volume Indexed to LoE

(NSP; Purchased Volume; Select Specialty Therapies; Nov 2016 – Nov 2023)

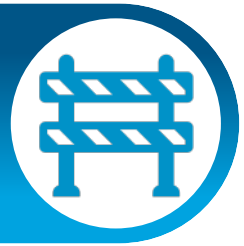


*Biologic LoE average includes rituximab, bevacizumab, trastuzumab, epoetin alfa, pegfilgrastim, and infliximab
Source: US Market Access Strategy Consulting analysis

Uptake for most of the highest volume adalimumab biosimilars has been driven by smaller payers who stand more to gain from a low-cost, no-rebate option

Large PBMs prefer Humira, as its rebates and fees based on high list prices likely makes it a more profitable option than biosimilars

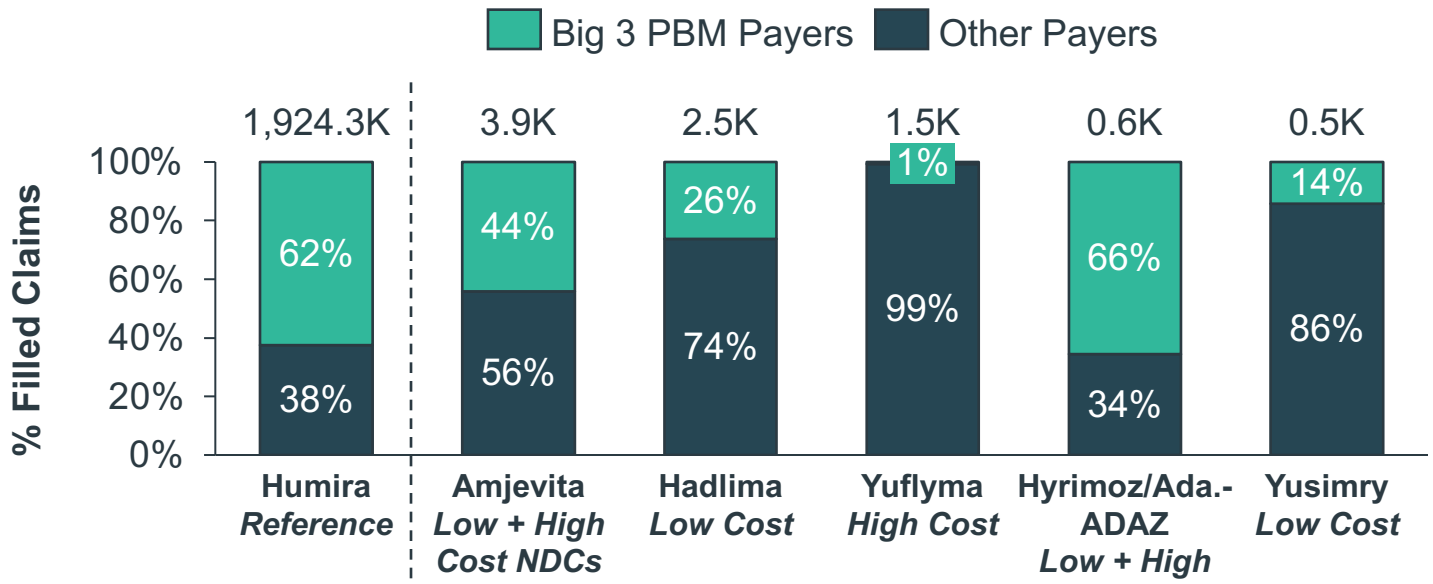
Big PBMs remain hesitant to adopt biosimilars



- **Small payers not aligned with big 3 PBMs have been the first to grant favorable access to most biosimilars,** as their low cost makes them a more appealing value proposition for small payers rather than large PBMs who favor rebate dollars
- Payer mix analyses reveal that uptake for most low-cost biosimilars is being supported by access pathways at small payers rather than at big 3 PBMs, who continue to encourage Humira use

Top 5 by Filled Volume Adalimumab Biosimilar Payer Mix

(Commercial/HIX; Jan 2023 – Nov 2023)



Insights

- ***Most high volume biosimilars see uptake driven by small payers,*** *who stand more to gain from low-cost, no rebate formulations*
- ***The value of biosimilar rebates and fees based on high list prices may never match Humira's for large payers****, driving their resistance to adopt their use*

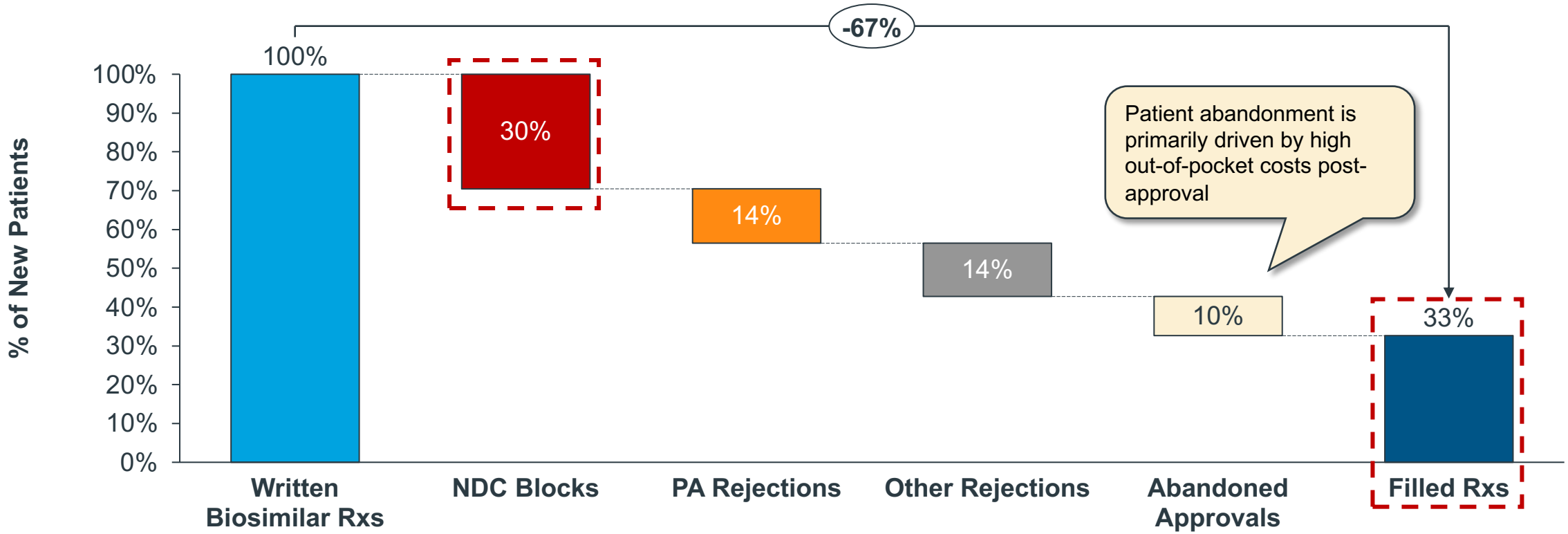
Source: US Market Access Strategy Consulting analysis

Access at big 3 payers remains a barrier for most biosimilar patients, while brands contracting with smaller payers have seen early access wins

Only 1 in 3 patients prescribed an adalimumab biosimilar manage to fill in the 30 days following their first attempt

Adalimumab Biosimilar Patient Attrition Flow

(New Patient Attempts; All Channels; Feb 2023 – Oct 2023; 30D LF)



Source: US Market Access Strategy Consulting analysis; IQVIA LAAD 3.0

Maintaining patients on Humira comes at a cost of up to ~$6B per year for patients and employers compared to a full transition to adalimumab biosimilars

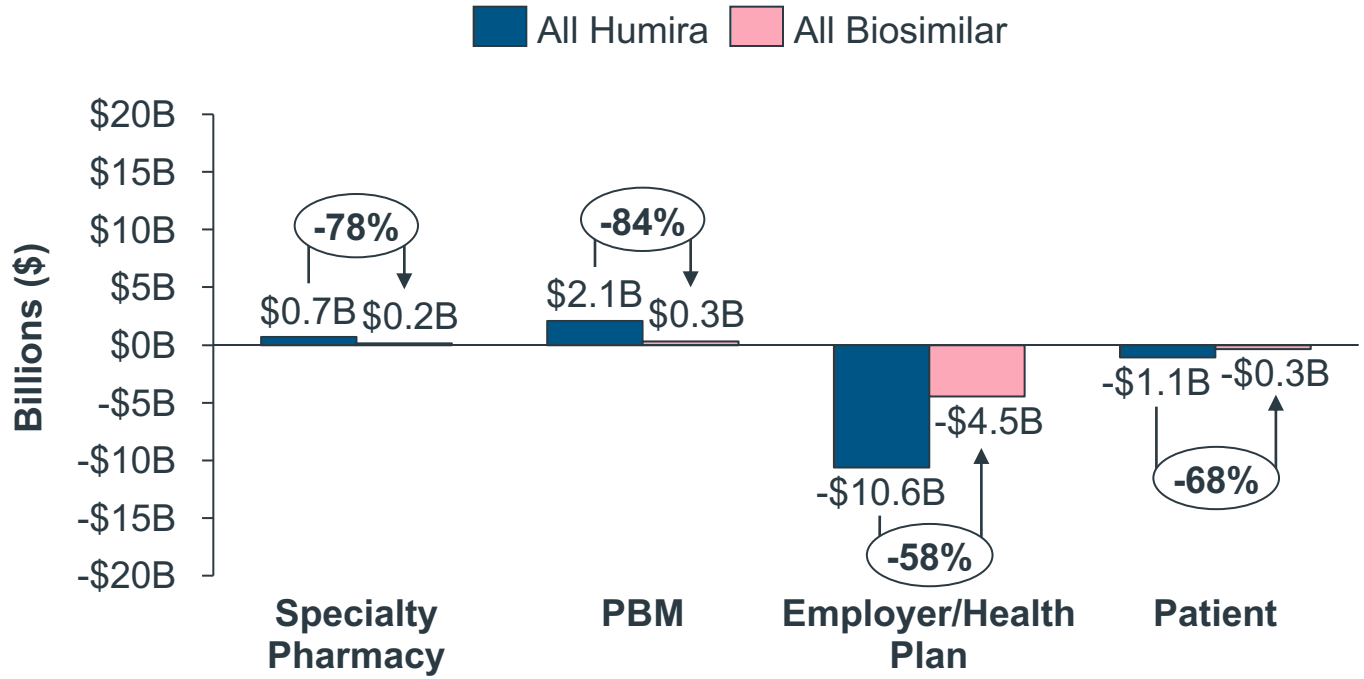
Transitioning patients to biosimilars would result in lower profits under traditional PBM and SP business models

Holding onto Humira comes at an immense cost

- **Switching to low cost biosimilars would reduce both the direct cost** liability of coverage and copays ***and*** **associated admin fees** for employers and patients
- **A transition to biosimilars would disrupt the traditional PBM profit model,** as they would take in less in rebates and WAC-based fees
  - This may lead to shifts in PBM strategy to maintain profitability, e.g. co-branding

Projected Net Profit Differential from Humira to Biosimilar Transition

(Various sources; Sales estimates from IQVIA NSP and AbbVie financial statements)*



Key Drivers	*Lower costs, margins*	*Lower costs; reduced fee revenue*	*Lower drug costs*	*Lower copays*

*Humira gross and net sales sourced from IQVIA NSP and AbbVie financial figures for 2023; revenue and costs by stakeholder sourced from various reports, NADAC data, and LAAD claims data; Assumes biosimilar WAC of $995

Source: US Market Access Strategy Consulting analysis;

Continued Humira use cost patients, employers, and health plans up to ~$700M each month since the launch of biosimilars in increased drug costs and fees

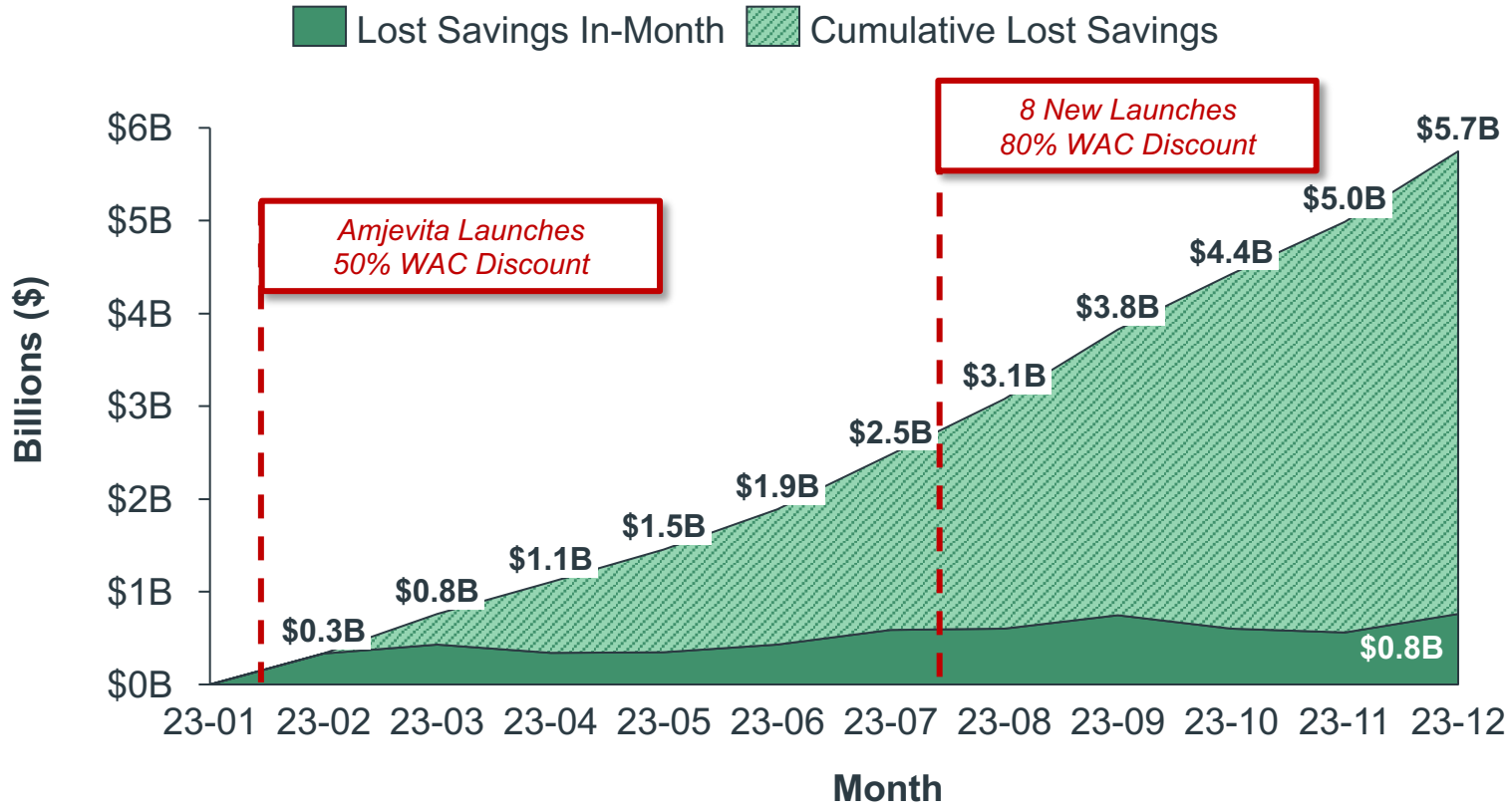
The expected lost savings from Humira use is expected to grow in 2024 with continued use

Holding onto Humira comes at an immense cost

- **Each Humira Rx comes with an extra cost upwards of $1,300** compared to a low price (~$1,000 WAC) adalimumab biosimilar
- **Continued Humira use has created nearly $6B in lost savings** over the course of the first 11 months since the launch of Humira biosimilars, which could be realized by moving more patients onto biosimilars

Projected Lost Savings from Continued Humira Use by Month

(Various sources; Sales estimates from IQVIA NSP and AbbVie financial statements)*



*Assumes low-cost biosimilar WAC of $995 **Humira net sales sourced from AbbVie annual financial report for 2023; 50% discount biosimilar net price inferred from Amgen financial statements for Amjevita; net price calculations for low cost biosimilars sourced from various reports, NADAC data, and LAAD claims data

Source: US Market Access Strategy Consulting analysis;

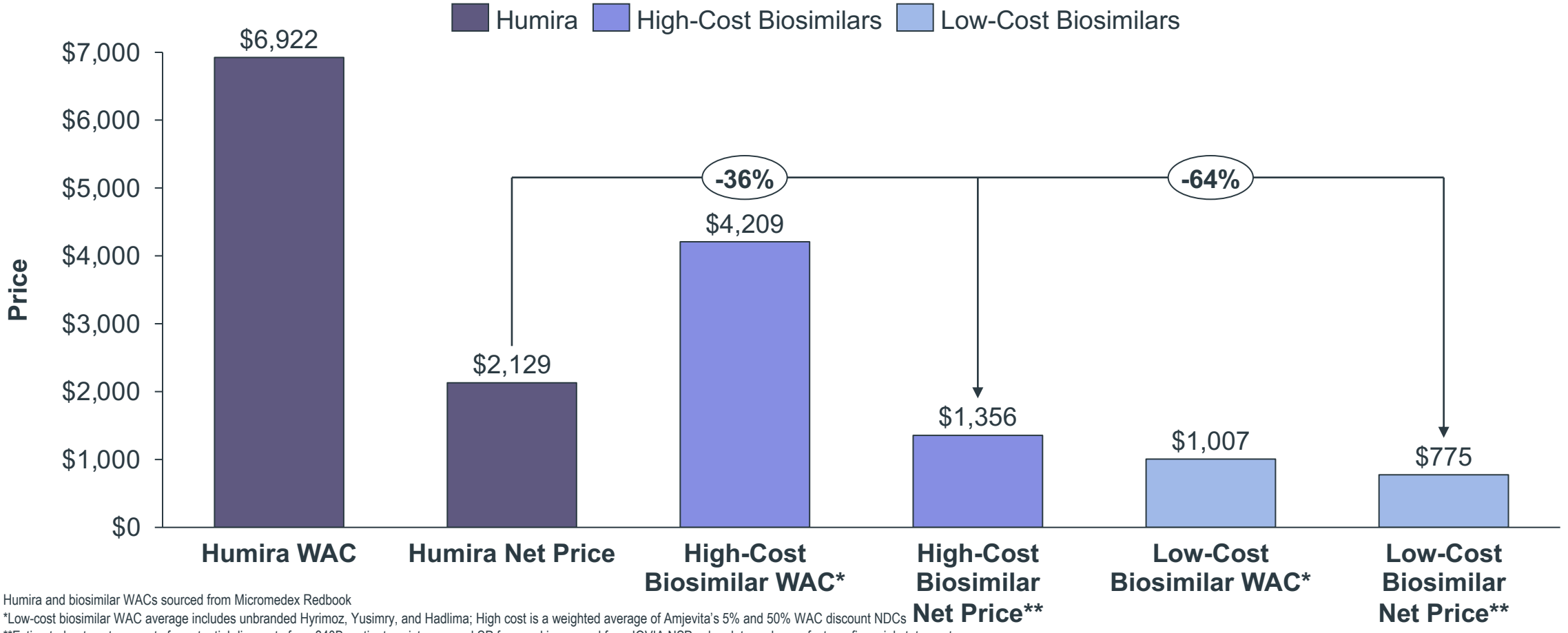
Humira remains a costlier option than biosimilars for health plans even after rebates, with a net price of ~$2.1K compared to <$1K for some biosimilars

The stark price difference underscores the potential impact of a switch to biosimilars

'Price' represents price for a one month's supply of therapy

Humira and Biosimilar Gross and Estimated Net Price Comparison

(2023 WACs; Net Price for Humira sourced from AbbVie financial statements; Biosimilar net price estimated)



Humira and biosimilar WACs sourced from Micromedex Redbook

*Low-cost biosimilar WAC average includes unbranded Hyrimoz, Yusimry, and Hadlima; High cost is a weighted average of Amjevita's 5% and 50% WAC discount NDCs

**Estimated net cost accounts for potential discounts from 340B, patient assistance, and SP fees and is sourced from IQVIA NSP sales data and manufacturer financial statements

Source: US Market Access Strategy Consulting analysis;

Lower product reimbursement for biosimilars would primarily impact high volume, PBM-integrated SPs

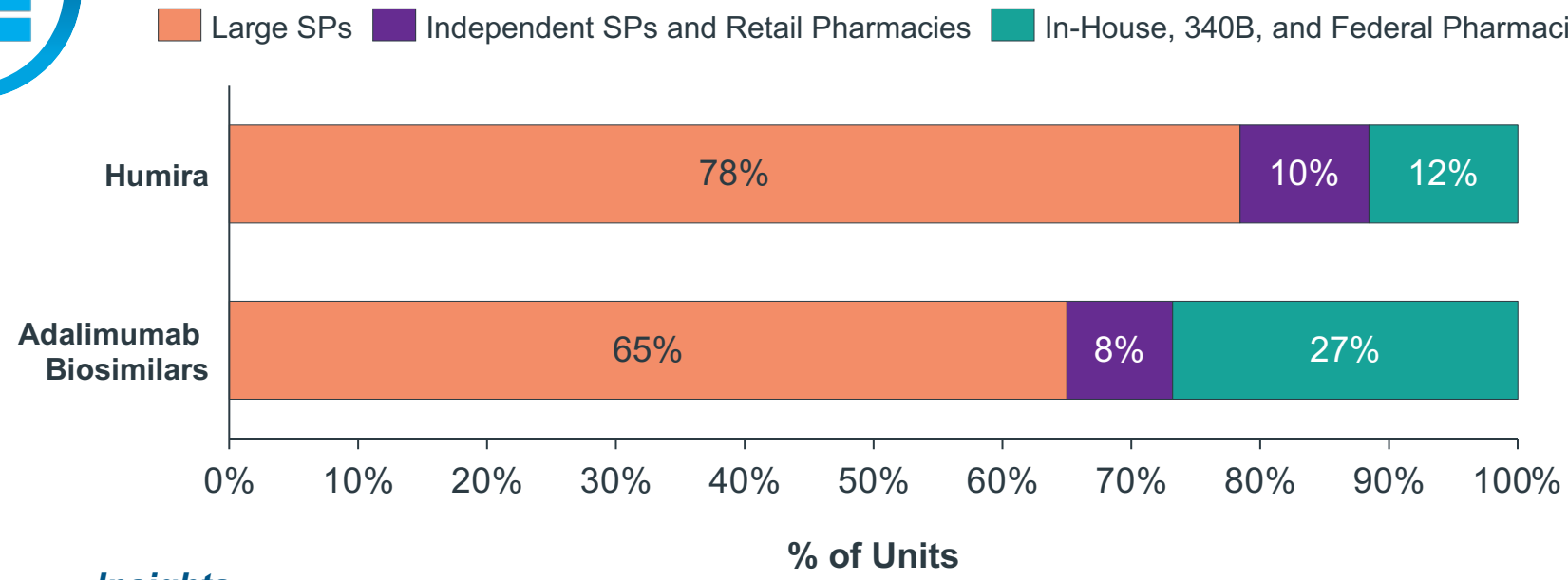
Independent pharmacies may benefit from lower acquisition costs for biosimilars

Holding onto Humira comes at an immense cost

- Nearly ~80% of Humira volume is dispensed by large specialty pharmacies
- Most lost revenue from Humira biosimilars would be realized at PBM-affiliated SPs

Humira and Biosimilar Pharmacy Type Mix

(WSP Sales Units; Humira; 2022-2023)



Insights

- *Transitioning to biosimilars is unlikely to have a large negative impact on retail and independent pharmacy business*
- *Despite lower revenue, biosimilars are likely to be appealing for small pharmacies due to their low upfront cost and high reimbursement rates*

Source: US Market Access Strategy Consulting analysis;

Low-cost biosimilars are cheaper for independent pharmacies to acquire and can bring favorable reimbursement rates relative to Humira

PBM contracting strategy rewards integrated specialty pharmacies

Holding onto Humira comes at an immense cost

- Most lost revenue from Humira biosimilars would be realized at **PBM-affiliated SPs**
- **Independent pharmacies see favorable reimbursement for biosimilars** relative to Humira, which may make them appealing despite lower total profit

Humira and Hadlima Estimated Reimbursement by Pharmacy Type

(NADAC used for acquisition cost; LAAD Rx data for pharmacy identification and reimbursement; Humira and Hadlima; 2022-2023)

	Humira Est. Avg. Acquisition Cost**: $6,240	***Hadlima*** Est. Avg. Acquisition Cost**: $1,040
Large Mail SP	***+10%/$593 Margin*** Est. Average Reimbursement** of $6,833	***+3%/$183 Margin*** Est. Average Reimbursement** of $1,066
Independent SP And Retail Pharmacies	***+2%/$26 Margin*** Est. Average Reimbursement** of $6,423	***+10%/$107 Margin*** Est. Average Reimbursement** of $1,147

*Humira gross and net sales sourced from IQVIA NSP and gross-to-net sales library for 2022; revenue and costs by stakeholder sourced from various reports, NADAC data, and LAAD claims data; Assumes biosimilar WAC of $995

**Humira 2022 average acquisition cost sourced from NADAC. Acquisiton cost estimated for Hadlima due to limited data availability. Cost may be inflated as chain pharmacies do not participate in NADAC reporting. Reimbursement pulled from average reimbursement fields in LAAD with outliers >2x WAC removed

Source: US Market Access Strategy Consulting analysis;

Patients and employers are the clear winners from a transition to adalimumab biosimilars, while PBMs may lose profit under a traditional strategy

***Projected* Impact from Biosimilar Transition on Key Managed Care Stakeholders**

Stakeholder	Net Impact from Biosimilar Transition	Pros	Cons	Takeaway
Specialty Pharmacy	  **90% Profit Loss**	• Lower drug costs • Lower DIR fees	• Lower drug reimbursement	**Cost savings ↑** **Profits ↓**
PBM	  **87% Profit Loss**	• Lower reimbursement • Lower fees to SPs	• No rebates • Lower revenue from WAC-based fees	**Cost savings ↑** **Profits ↓**
Employer/ Health Plan	  **80% Costs Saved**	• Lower drug costs • Lower PBM admin fees	• None of note	**Cost savings ↑↑**
Patient	  **76% Costs Saved**	• Lower copays • Less pressure on plan premiums	• None of note	**Cost savings ↑↑**

Note: Humira gross and net sales sourced from IQVIA NSP and gross-to-net sales library for 2022; revenue and costs by stakeholder sourced from various reports, NADAC data, and LAAD claims data; Assumes biosimilar WAC of $995
Source: US Market Access Strategy Consulting analysis;

Appendix

IQVIA assessed all approved adalimumab biosimilars alongside Humira to understand their current impact and future trajectory in the U.S. market

Biosimilars have differentiated themselves based on price, interchangeability, concentration, and citrate use

Product	Manufacturer	Launch	Interchangeable	Concentration	Citrate Free	Discount
Amjevita	Amgen	Jan 31, 2023	No	Low (50MG)	Yes	-5%, -50%
Idacio	Fresenius Kabi	July 1, 2023	No	Low (50MG)	Yes	-5%
Adalimumab-AACF	Fresenius Kabi	Dec 1, 2023	No	Low (50MG)	Yes	-87%
Hadlima	Samsung	July 1, 2023	No	Low (50MG) + High (100MG)	No (low) + Yes (High)	-85%
Cyltezo	BI	July 1, 2023	Yes	Low (50MG)	Yes	-5%, -7%,-80%
Adalimumab-ADBM	BI	October 2, 2023	Yes	Low (50MG)	Yes	-81%
Yusimry	Coherus	July 1, 2023	No	Low (50MG)	Yes	-85%
Hyrimoz	Sandoz	July 1, 2023	No	Low (50MG) + High (100MG)	No (low) + Yes (High)	-5%
Adalimumab-ADAZ	Sandoz	July 1, 2023	No	Low (50MG) + High (100MG)	No (low) + Yes (High)	-81%
Yuflyma	Celltrion	July 1, 2023	Applied	High (100MG)	Yes	-5%
Hulio	Viatris/Biocon	July 1, 2023	No	Low (50MG)	Yes	-5%
Adalimumab-FKJP	Viatris/Biocon	July 1, 2023	No	Low (50MG)	Yes	-85%
Abrilada	Pfizer	Jan 1, 2024	Yes	Low (50MG)	Yes	-5%, -60%

Source: US Market Access Strategy Consulting Thought Leadership