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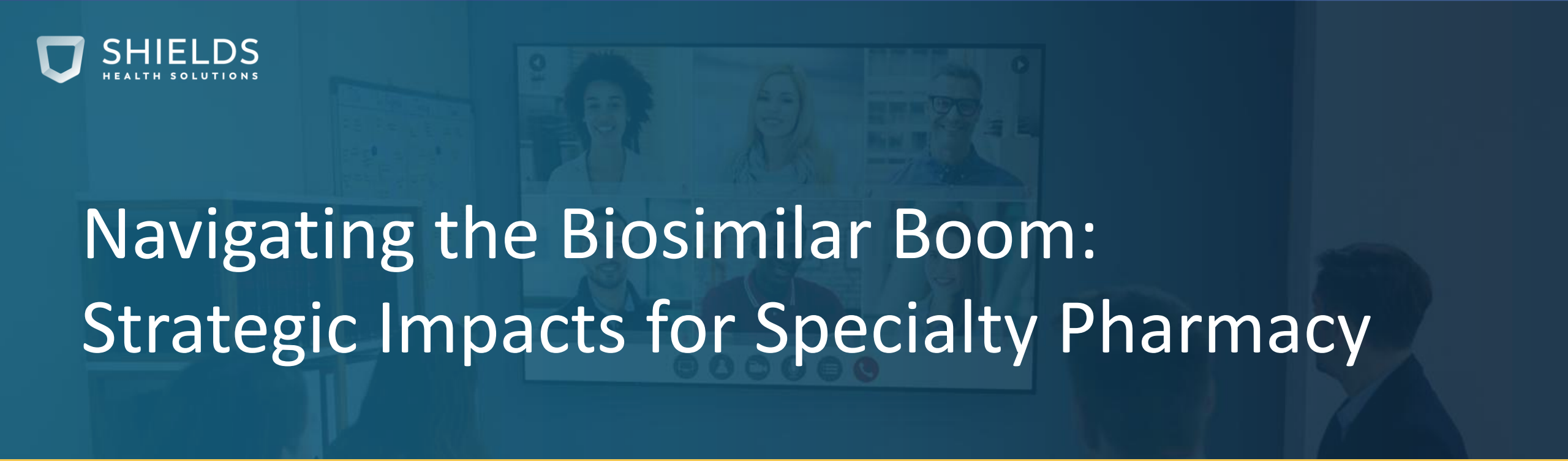

Navigating the Biosimilar Boom: Strategic Impacts for Specialty Pharmacy

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Objectives

01

Describe current biosimilar market trends and projected cost savings associated with biosimilar adoption in specialty therapeutic areas;

02

Discuss the evolving role of specialty pharmacy professionals in supporting biosimilar integration, including patient education, clinical monitoring, and operational workflows;

03

Identify key challenges and opportunities related to biosimilar uptake across medical and pharmacy benefit channels, with emphasis on payer policies, provider engagement, and supply chain considerations;

04

Explain the impact of pharmacy benefit managers (PBMs) on biosimilar access, reimbursement strategies, and formulary management, and how pharmacy teams can align with these dynamics.

Mayo Clinic and Mayo Clinic Health System

Charitable, not-for-profit, academic medical system

MAYO CLINIC

Gartner Healthcare Supply Chain 2025

Masters Class

Ranked Best Hospital and #1

in more specialties than any other hospital in the nation*

$19.7B

revenue
(net and other sources)

73,000

Personnel consisting of physicians, scientists, allied health staff, research associates, fellows, residents and students

22

Hospitals, locations in MN, AZ, FL, WI, IA, London, UAE

Provided essential health care services to more than

1.3M patients

50 states

130 countries

Primary Value - The needs of the patient come first

Mayo Clinic Pharmacy and Specialty Pharmacy

>30 years of specialty pharmacy services

Specialized in rare disease

Largest solid organ transplant program in the nation*

>$800M

revenue
Specialty Pharmacy

MAYO CLINIC

>1,000

Pharmacy personnel consisting of pharmacists, business personnel, technicians, residents and students

340B

DSH, Sole community and rural referral in MN & WI

3 NCCN sites - physician group practice

Pharmacy Benefit Management Services

- Mayo Plan
- Clients
- Integrated formulary across enterprise

Serves the needs of Mayo Clinic patients, employees and plan members

Reflecting on the past decade (2015-2025)

Since the Biologics Price Competition and Innovation Act (BPCIA) created the regulatory pathway in 2010, biosimilars have made significant strides as a growing force in healthcare

Cost Savings

$56.2B saved in an annual biologic market size estimated at $260B (2024) [1]

Increased Patient Access

Reducing costs expands access to treatments previously constrained by price

Market Competition

Biosimilars foster a competitive landscape that curbs price escalation

Regulatory Maturation

Zarxio®, the 1st biosimilar approved

Focus has shifted from regulatory approval processes to sustainability

Stakeholder Education & Acceptance

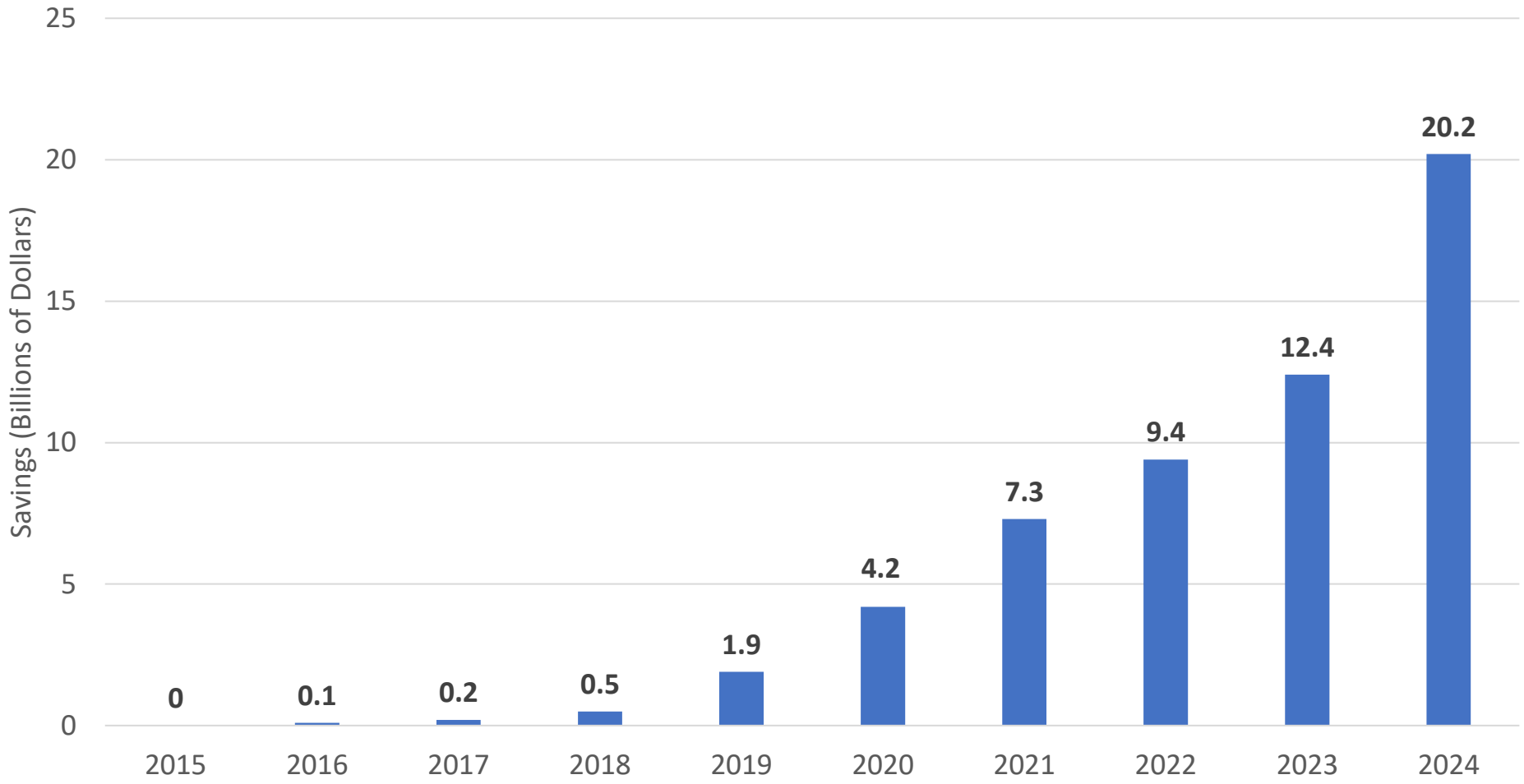
FDA campaigns and real-world evidence have increased confidence and trust in biosimilars

Influence

Set a precedence for balancing innovation and affordability

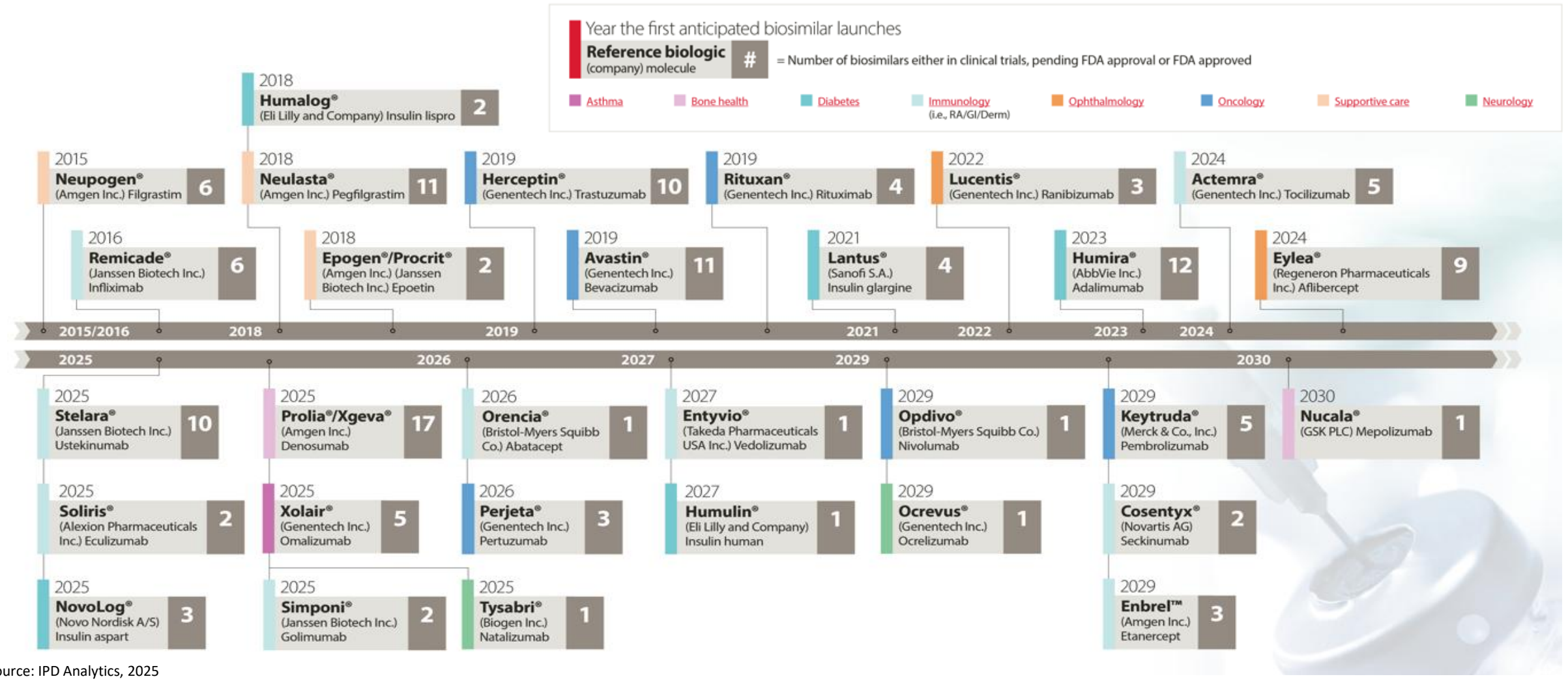
1: Association for Accessible Medicines. (2024, December 21). 2024 Savings Report | Association for Accessible Medicines. https://accessiblemeds.org/resources/blog/2024-savings-report/

Biosimilars Generated $20.2 Billion in Savings in 2024



Source: IQVIA National Prescription Audit, December 2024; IQVIA Institute, June 2025.

Biosimilars full pipeline



Source: IPD Analytics, 2025

Biosimilars – Provider Administered Space

- FDA has approved 70 biosimilars
  - 42 launched biosimilars
  - 18 biosimilars approved in 2024
    - 8 new biosimilars for 4 novel reference products marketed in 2025
      - Ustekinumab
      - Aflibercept
      - Eculizumab
      - Denosumab
  - 17 reference products
    - Oncology
    - Immunology
    - Ophthalmology
    - Diabetes

Setting	Total Biosimilar Expenditure		
	2022	2023	2024
Clinic	$5.6 Billion	$4.9 Billion	$5.3 Billion
Non-Federal Hospital	$1.2 Billion	$1.0 Billion	$1.1 Billion

Provider Administered Biosimilars Expenditures: Hospital

	2024 Expenditures Reference and Biosimilar	Percent Biosimilar Market Share 2024	Percent Biosimilar Market Share 2023
Adalimumab	$238,428,810	7.1%	0.91%
Bevacizumab	$227,670,078	77.0%	79.5%
Filgrastim	$107,238,839	67.2%	59.2%
Epoetin alfa	$224,528,866	59.4%	53.7%
Infliximab	$260,923,559	48.8%	46.0%
Pegfilgrastim	$303,082,988	40.0%	32.1%
Rituximab	$452,083,020	72.6%	69.9%
Tocilizumab	$151,263,365	2.83%	n/a
Trastuzumab	$98,327,729	74%	72.0%

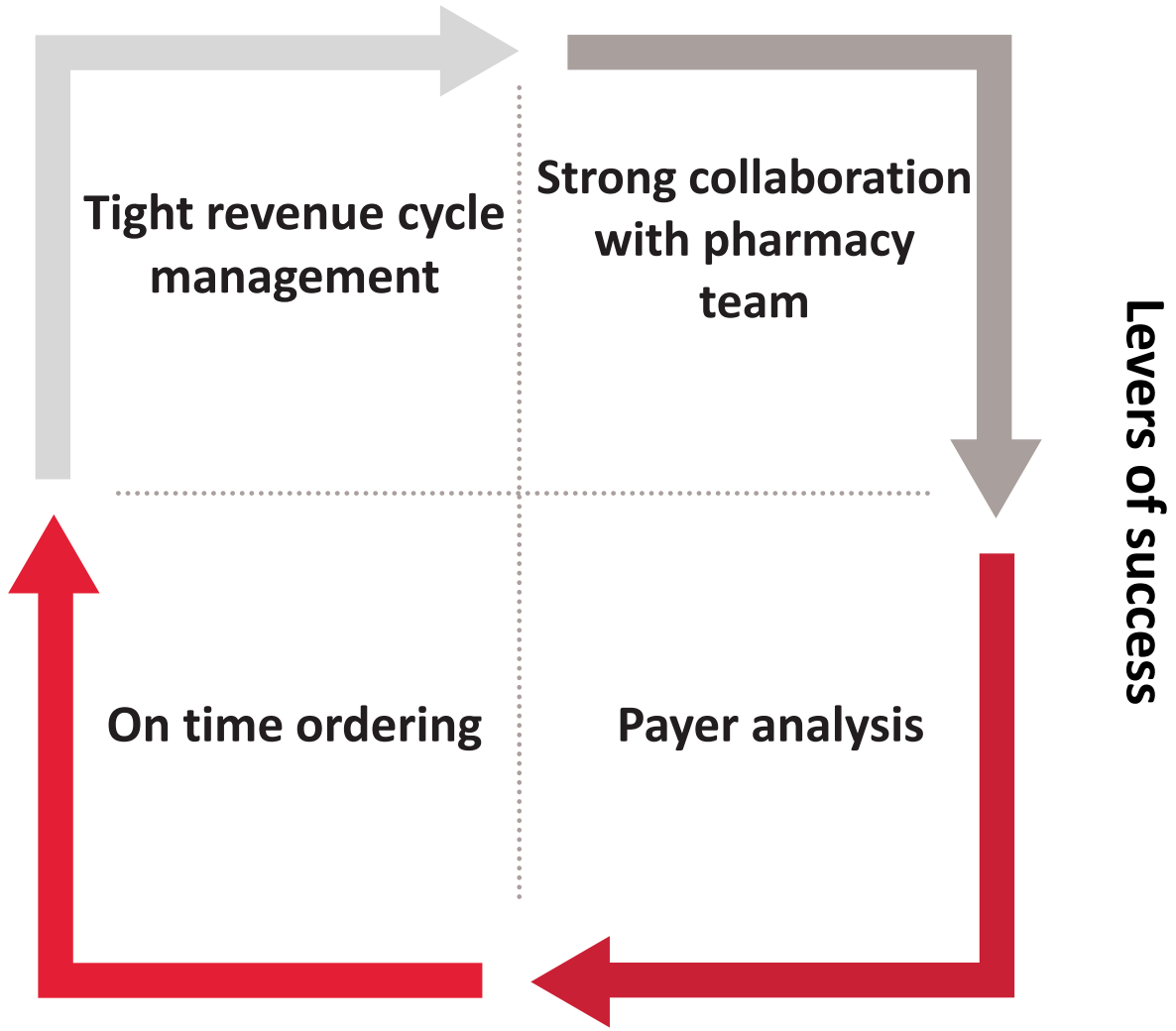
Provider Administered Biosimilars Expenditures: Clinic

	2024 Expenditures Reference and Biosimilar	Percent Biosimilar Market Share 2024	Percent Biosimilar Market Share 2023
Adalimumab	$1,428,730,462	3.7%	0.25%
Bevacizumab	$1,702,282,409	82.9%	78.2%
Filgrastim	$159,641,090	71.8%	68.6%
Epoetin alfa	$404,633,850	22.2%	20.2%
Infliximab	$1,984,188,896	42.3%	44.9%
Pegfilgrastim	$1,551,130,379	60.3%	35.0%
Rituximab	$1,908,547,416	57.8%	53.5%
Tocilizumab	$856,641,848	0.75%	n/a
Trastuzumab	$957,916,211	75.2%	71.1%

Barriers turned to optimization in Oncology

Economic barriers:
Reimbursement polices & pricing dynamics

Non-economic barriers:
Provider & patient awareness, inventory management & benefit investigation processes



Value-based care model

Therapeutic Substitution makes it easy

- Within a US health system, the P&T committee may declare drugs therapeutically equivalent
  - Therapeutically equivalent – same therapeutic or pharmacologic class expected to have similar outcomes or adverse effects
- Gives pharmacy the permission to change out drugs based on predefined protocols
- Allows the institution to select a preferred product
- Pharmacy is authorized to interchange to the preferred product without provider consent when a nonpreferred product is ordered
- Need to check state laws and state pharmacy rules

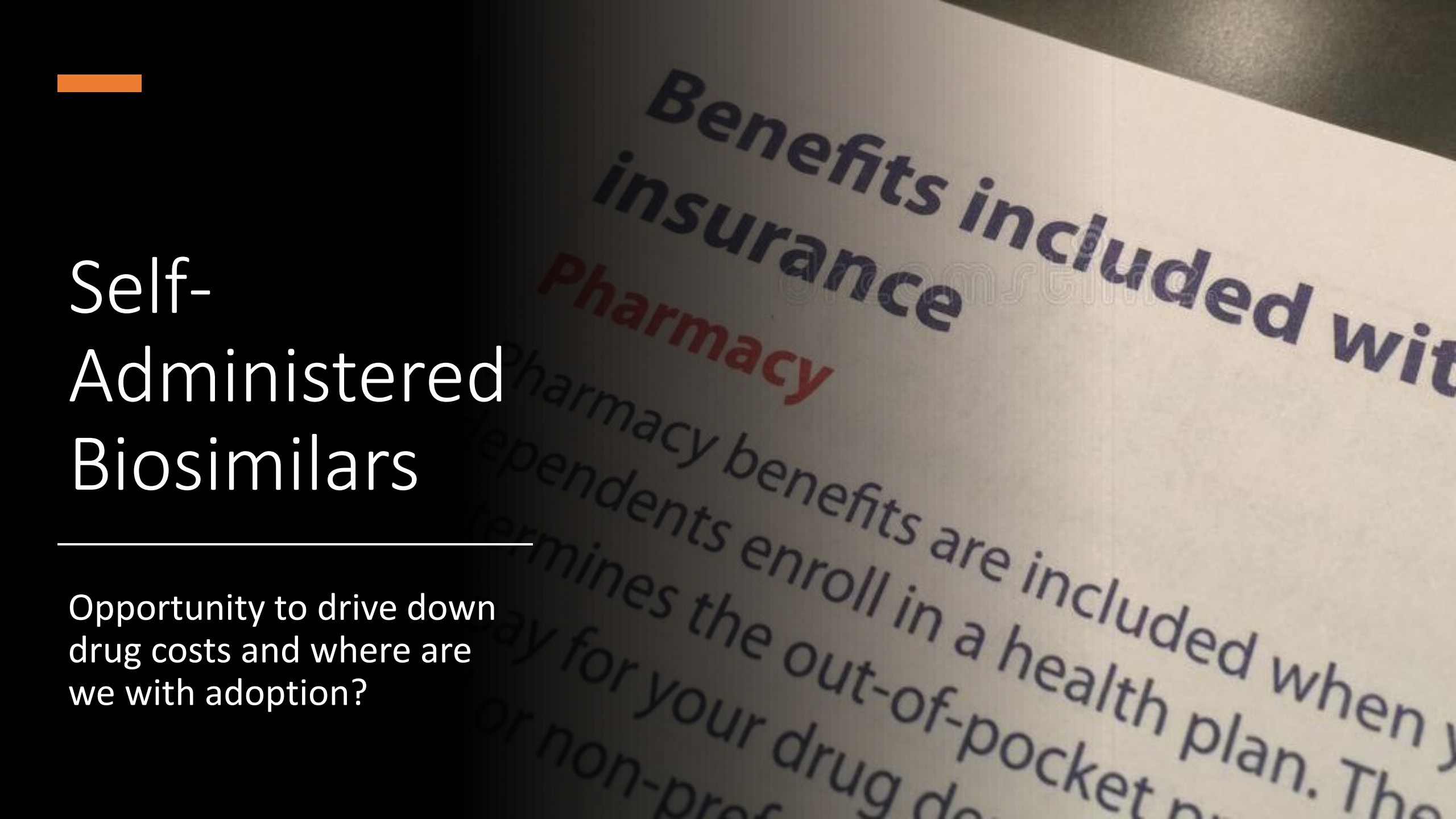
Cuellar S, et al. *Am J Health Syst Pharm*. 2019;76(21):1725-1738.

What can we learn from the hospital experience?

- Biosimilars are safe and effective
- Economics are not always favorable for the provider
  - What happens to patient support
  - Can we sustain high-touch pharmacy services in a low-cost environment?
- Payers can be a barrier
  - Preference for high-rebates
  - Administrative burden
  - Diverse product preferences lead to swollen pharmacy inventory
- Patients are unlikely to experience direct financial benefit

Self-Administered Biosimilars

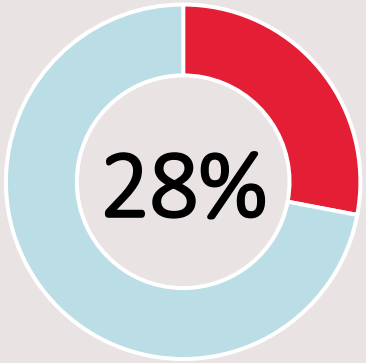
Opportunity to drive down drug costs and where are we with adoption?



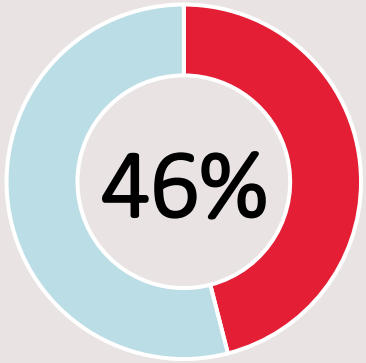
Sustainability

Biosimilars have demonstrated notable **cost-savings potential**, which is a proven **key indicator of sustainability**

Adalimumab biosimilars



Current market share[1]



Predicted market share by the end of 2025[1]

Current dynamics

- Uptake varies widely across molecules, ranging from 8%-82% three years post launch – slower for self-administered
- Reimbursement and incentive alignment can greatly improve viability
- Lack of interchangeability makes conversion operationally onerous
- Navigating payer preference for rebates versus upfront discounts and limitations on plan changes impact flexibility

1: IPD Analytics database. Financial Forecasting & Rebate Analysis. Market & Financial Insights. Accessed December 15, 2024. .

Success Factors in Specialty Pharmacy

- Interchangeability is crucial
  - State laws vary on substitution and communication requirements
- Differences in health plan coverage
  - Challenging to stock all NDCs
  - Hard to identify payer preferred product at prescribing
- $Zero patient copay is very common with copay cards
  - No incentive for patients to change

[State regulations for biosimilar interchangeability]

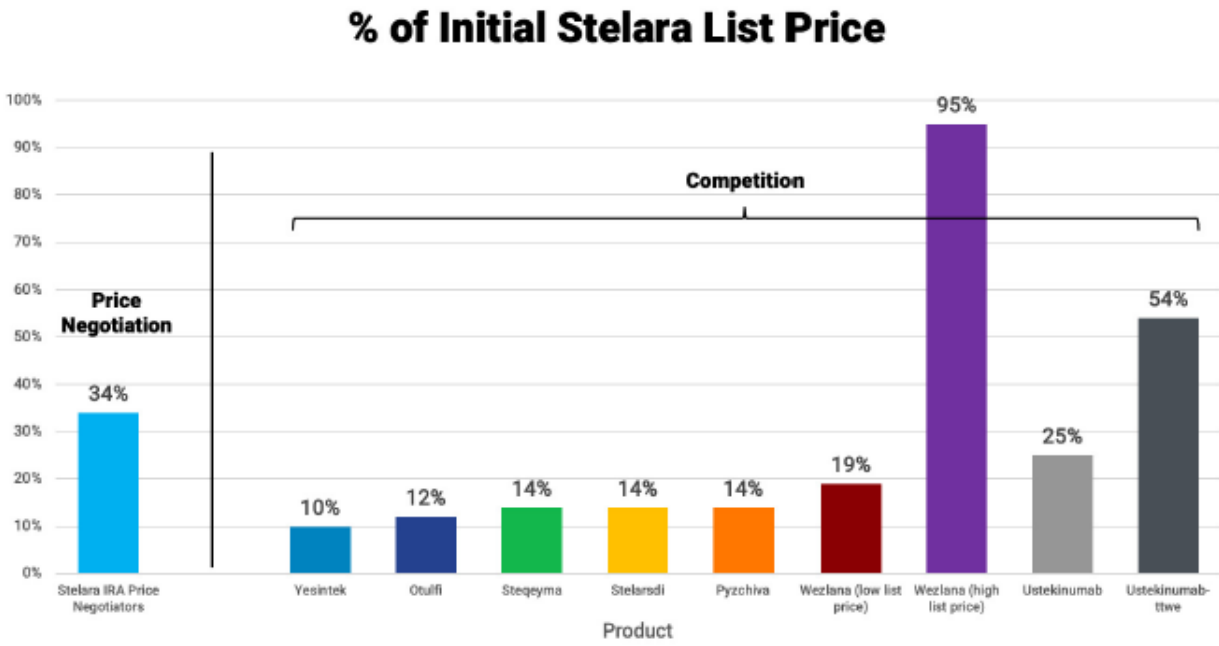
Operational Challenges for Specialty Pharmacy

Variability of patient assistance programs	Co-pay cap could be lower leading to out-of-pocket exposure Consider preferencing products with higher caps
Impact of copay maximizers – differences in how max out of pocket is affected depending on product/coverage	
Additional patient touchpoints around patient education	
Risks for “nocebo” effect	Position product with a positive light
Margin and cash flow improvements with lower cost of goods	Do margins support high-touch pharmacy services?

Stelara Biosimilar Price War

PBM-Affiliated Private Labels Are Reshaping the Market

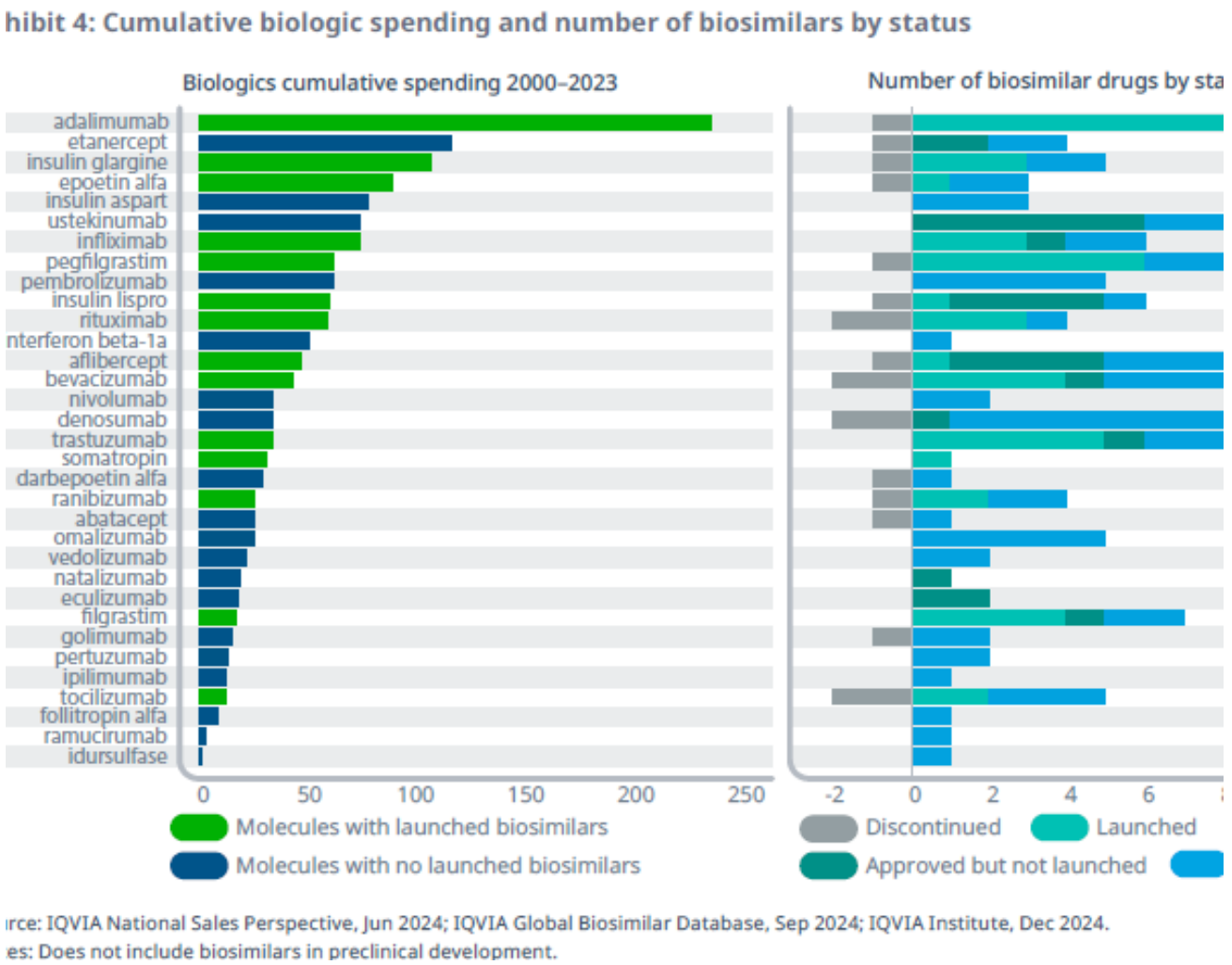
- 2025 launch: nine interchangeable ustekinumab biosimilars plus J&J's unbranded Ustekinumab
  - list-price discounts range from 5 % to 90 %
- Private-label strategies driving formulary control and rebates:
  - CVS Caremark via Cordavis (Cordavis Pyzchiva + Sandoz; 86–90 % off)
  - Express Scripts via Quallent (unbranded PL at 46 % off; two biosimilars at 86–90 % off)
  - Optum Rx via Nuvaila (exclusive low/high-price Wezlana; Stelara tiered in Select)
- Competitive dynamics: vertical integration enables financial gamesmanship — even as the IRA sets a Maximum Fair Price 66 % below 2023 list for 2026



Source: Drug Channels. Drug Channels Institute Research. April 2025.

Biosimilar Void

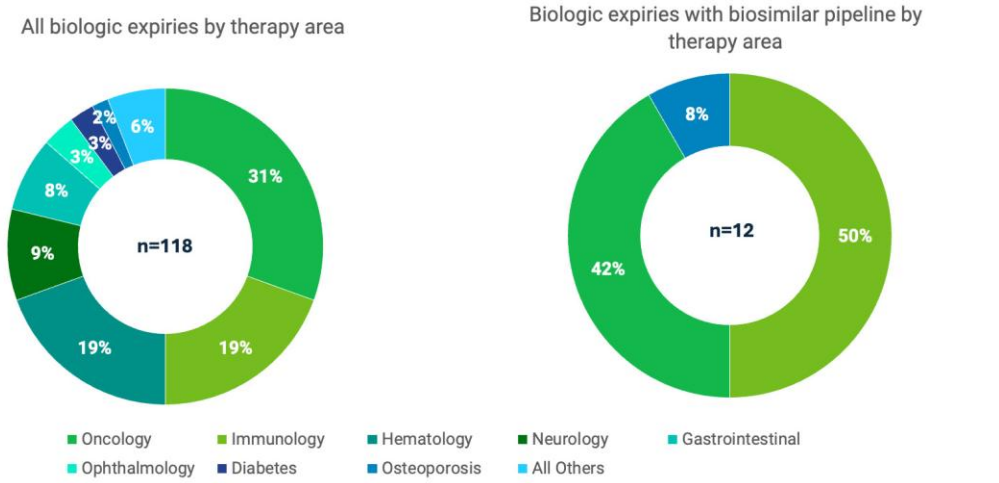
- Only 10% of the 118 biologics with pending patent expiration have a biosimilar in the pipeline
- 14 originator products face competition
- Biosimilar development is concentrated in a small number of molecules with high sales



Few Biologics Losing Patent Expiration have a Biosimilar in Development

Biologic Expiries 2025–2034 and Biosimilar Pipeline by Therapy Area

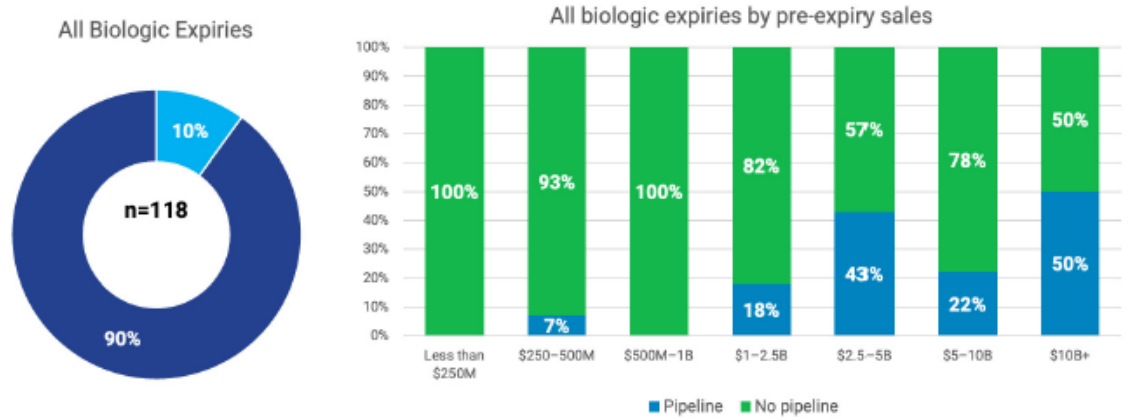
The Image Below Shows That Biosimilar Pipeline Development Is Limited to a Few Specific Therapy Areas — With the Rest Stuck in the Void



Source: IQVIA Institute for Human Data Science. February 2025. Assessing the Biosimilar Void in in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. Available from iqviainstitute.org.

High-Value Biologics Are More Likely to Have Biosimilars in Development as There Is Greater Potential for Revenue

Share of Biologics With Biosimilars in Development by Pre-Expiry Sales, Expiries 2025–2034



Source: IQVIA Institute for Human Data Science. February 2025. Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. Available from iqviainstitute.org.

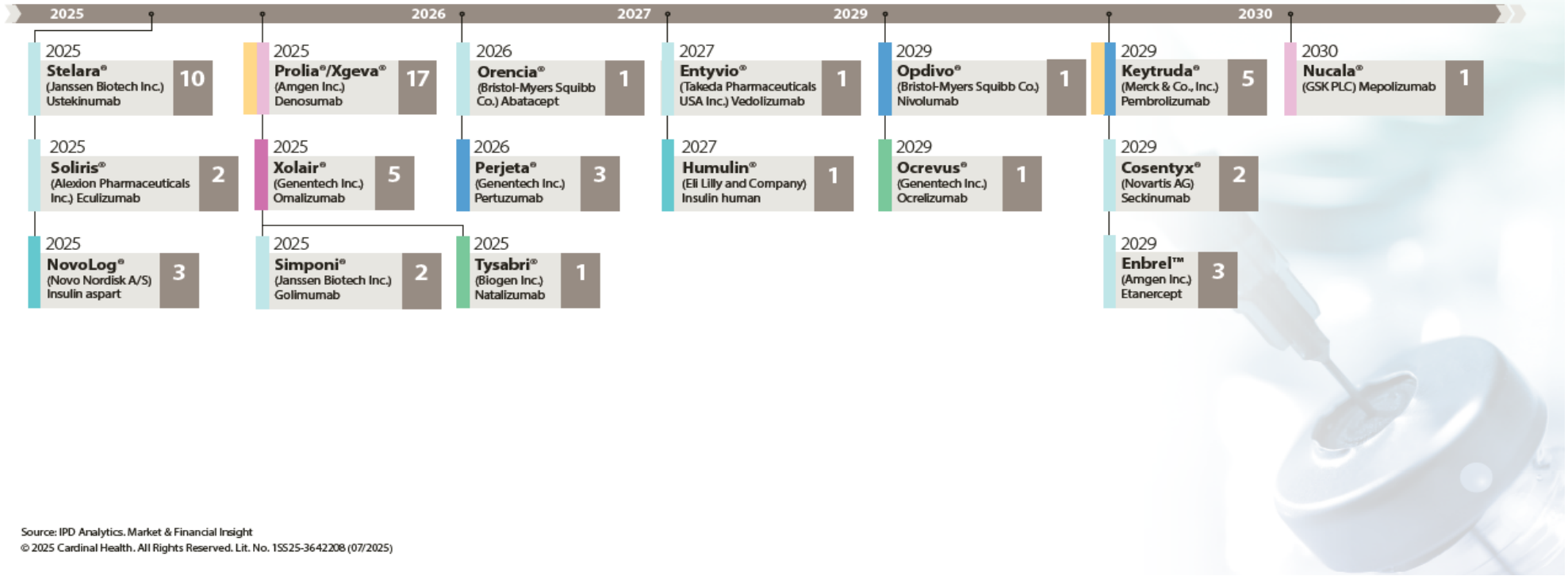
Biosimilars pipeline

CardinalHealth™

Year the first anticipated biosimilar launches

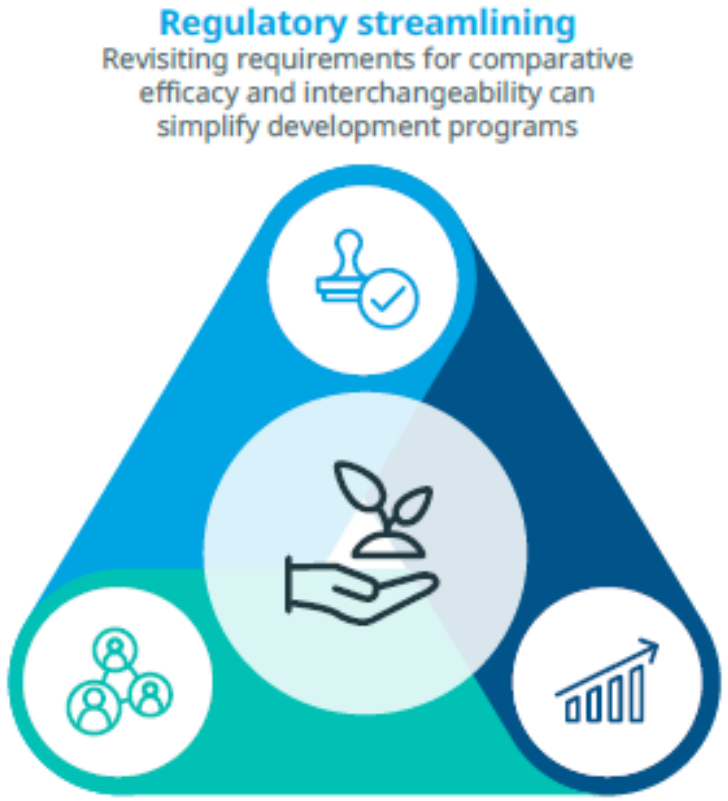
Reference biologic (company) molecule | # = Number of biosimilars either in clinical trials, pending FDA approval or FDA approved

Asthma | Bone health | Diabetes | Immunology (i.e., RA/GI/Derm) | Ophthalmology | Oncology | Supportive care | Neurology | Urology



Source: IPD Analytics. Market & Financial Insight

Potential Solutions to Achieve Sustainable Biosimilar Competition



Regulatory streamlining
Revisiting requirements for comparative efficacy and interchangeability can simplify development programs

Collaboration
Ensuring collaboration among stakeholders both in the U.S. and globally can reduce burdens on biosimilar companies

Improving market conditions
Ensuring biosimilar uptake through incentives and education can improve biosimilar market potential

Source: IQVIA Institute, Dec 2024.

FDA Efforts Boosting Biosimilar Adoption

- In action
  - Removing requirements for clinical efficacy trials
- Proposed
  - Make all biosimilars interchangeable at approval by removing the designation
- Under Consideration
  - Reduce regulatory barriers and fees for biosimilar application

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FDA Allows First Biosimilar Without Clinical Efficacy Trials

September 10, 2025
By Briana Contreras

News Article

The FDA's groundbreaking decision to waive clinical efficacy studies for a monoclonal antibody biosimilar revolutionizes drug approval, reducing costs and enhancing patient access.

The FDA granted its first-ever acceptance to waive clinical efficacy studies (CES) for a monoclonal antibody biosimilar earlier this month, marking a major shift that could lower drug costs, speed up approvals and broaden access to affordable treatments worldwide.

For years, CESs have been a required step when approving biosimilars. According to Sarfaraz K. Niazi, a professor at the University of Illinois at Chicago, he said in a news release, these studies are expensive and time-consuming and typically can cost hundreds of millions of dollars while rarely uncovering meaningful differences from the reference product.

Which of the following statements is true?

A. Few of commercial payers prefer biosimilars

B. Interchangeability of biosimilar with reference product allows all biosimilars to be substituted at the point-of-sale

C. Prive label biosimilars have accelerated biosimilar adoption

D. Rebate models drive biosimilar savings to the patient

Which of the following statements is true?

A. Most biologics have a biosimilar competitor in the pipeline

B. Majority of payers have a MAC strategy in place for the biosimilars

C. Market share of biosimilars have not changed for payers with a biosimilar preferred strategy due to provider pushbacks

D. FDA is exploring options to increase biosimilar availability and uptake

A look into the next decade…

Key priorities

Increase market adoption

Education is required to improve confidence and trust for providers and patients as well as clarifying the interchangeability designation

Expand the pipeline

118 biologics are expected to lose patient protection over the next decade; only 10% have biosimilars in the pipeline, which equates to a $234B opportunity

Market viability

Align incentives for all stakeholders with policy support

The foundation is built

Biosimilars have proven their worth and have not unleashed their full impact. The foundation has been built setting the stage for a boom in the next decade.

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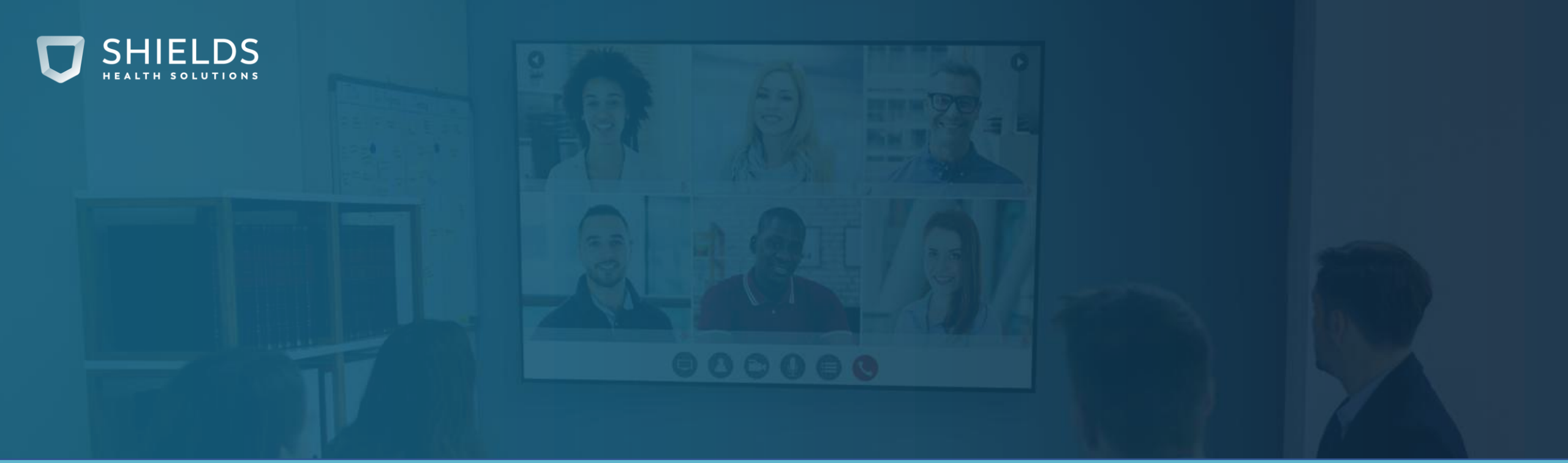

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