Biosimilars Are Finally Here: So What Happens Now?

sPCMA Business Forum

March 8, 2017

Agenda

- US Biosimilar Launch Experience
- Biosimilar Management Research
- Payer Issues
- Future Considerations

Launch of Biosimilars

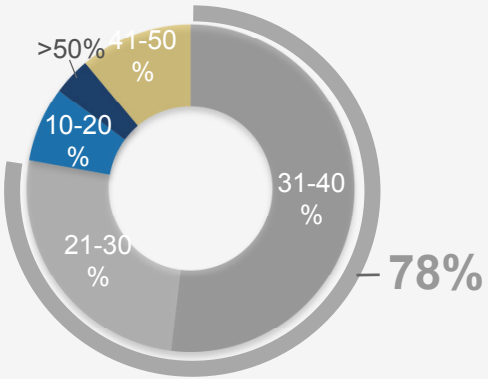
US BIOSIMILAR APPLICATIONS					
Drug	**Sponsor**	**Reference Product**	**Reference Sponsor**	**EU Approval**	**US Status**
Zarxio	Sandoz Inc.	Neupogen	Amgen Inc.	2009	Launched 2015
Inflectra	Celltrion Inc.	Remicade	Janssen Biotech Inc.	2013	Approved 2016
Pegfilgrastim	*Apotex Inc./Intas Pharmaceuticals Ltd.*	*Neulasta*	*Amgen Inc.*		*Accepted December 2014*
Grastofil	*Apotex Inc./Intas Pharmaceuticals Ltd.*	*Neupogen*	*Amgen Inc.*	*2013*	*Accepted February 2015*
Retacrit	*Hospira Inc.*	*Epogen/Procrit*	*Amgen Inc./Janssen Products LP*	*2007*	*Accepted February 2015*
Etanercept	*Sandoz Inc.*	*Enbrel*	*Amgen Inc.*	*2016*	*Accepted October 2015*
Pegfilgrastim	*Sandoz Inc.*	*Neulasta*	*Amgen Inc.*		*Accepted November 2015*
Adalimumab	*Amgen Inc.*	*Humira*	*Abbvie Inc.*		*Accepted January 2016*

Source: EMA, company news releases.

Projections for Zarxio Impact: 2015

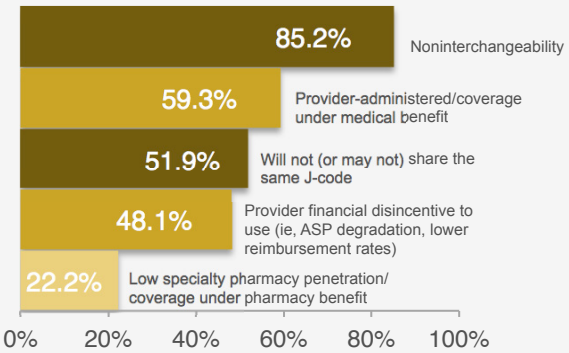
Most indicated discounts of 21-40% would drive action

At what discount off WAC would your organization need to actively work to shift market share to Zarxio (choose the lowest % discount range)?



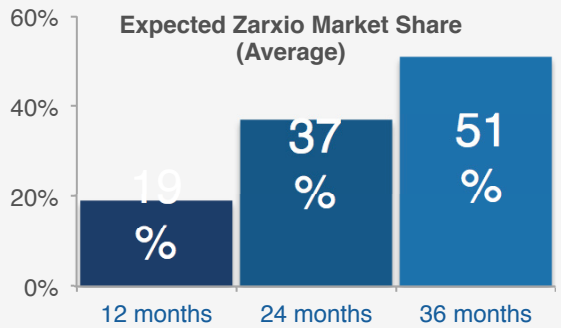
Non interchangeability noted as greatest barrier

Please select the top 3 obstacles you believe would impede the market share growth of Zarxio in your organization.



Rapid uptake expected

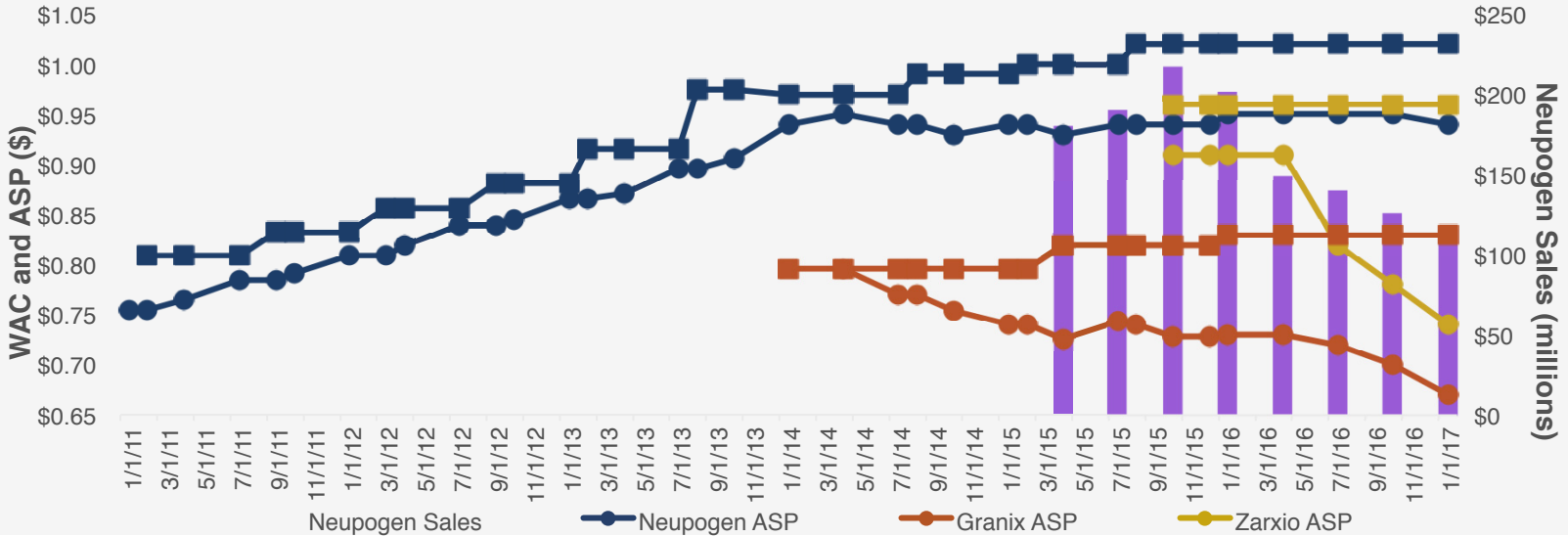
Estimate the Zarxio % of CSF market share penetration in your plan in 12 months, 24 months, and 36 months.



Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

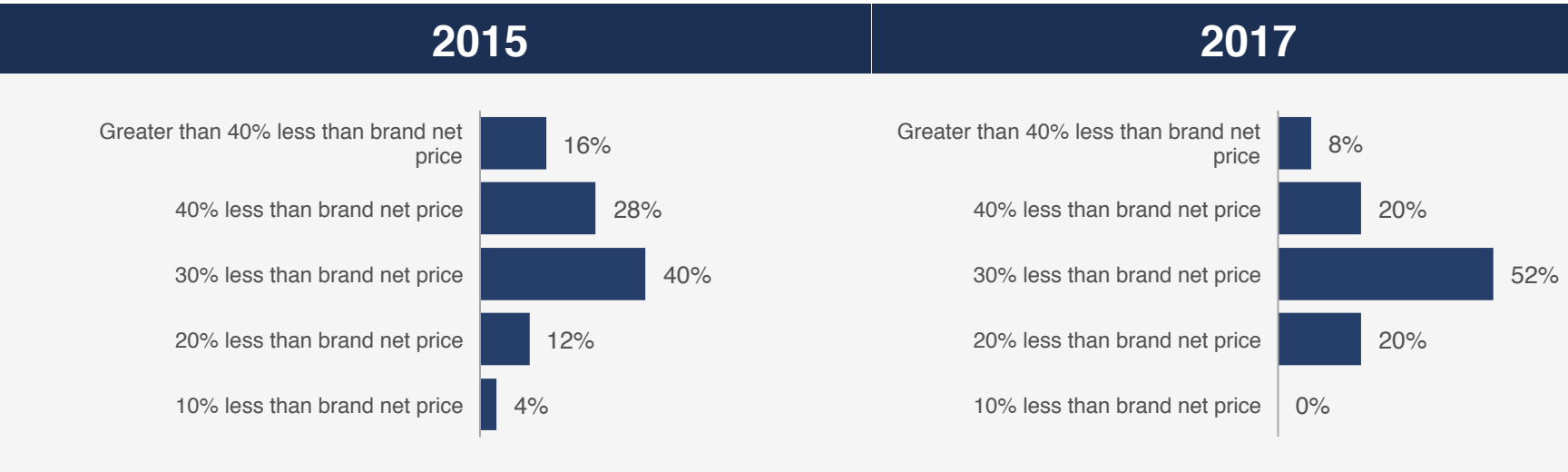
Zarxio's Launch Has Directly Impacted the ASP and WAC of Both Neupogen and Granix, Also Causing a Decrease in Neupogen Sales

Neupogen, Granix, and Zarxio ASP and WAC, Neupogen Quarterly Sales



Sources: ReimbursementCodes accessed February 2017, Evaluate Pharma accessed February 2017. Novartis, Amgen, Teva.

Payer Trends in Biosimilar Management – Discounts



Q2. What biosimilar price difference from the comparable brand's net price would significantly change your product preference and access?

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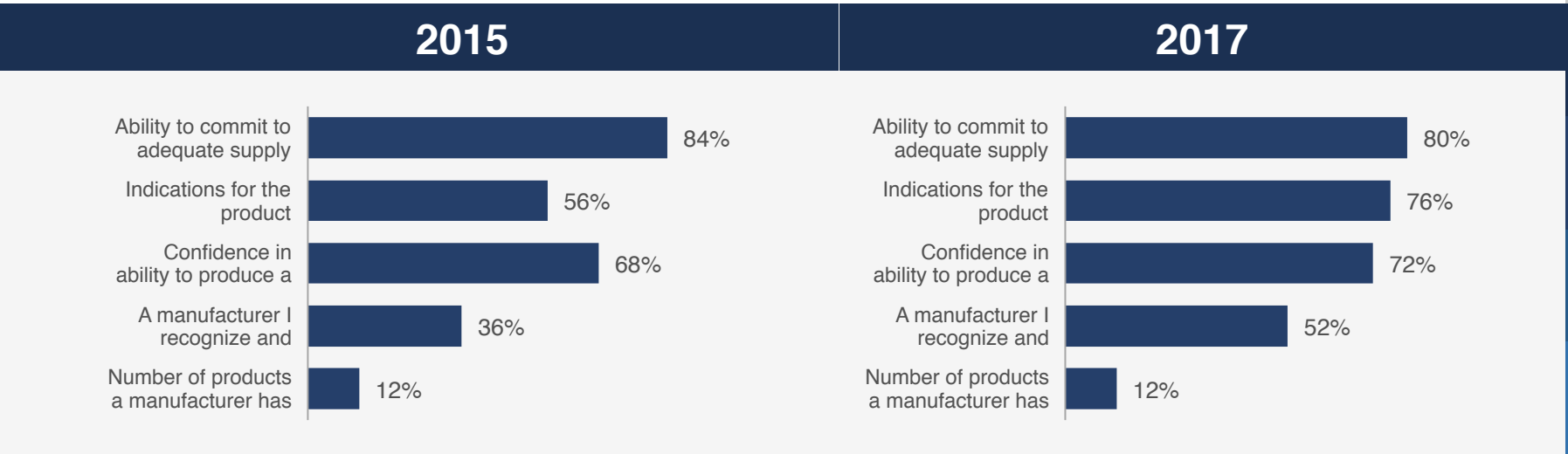
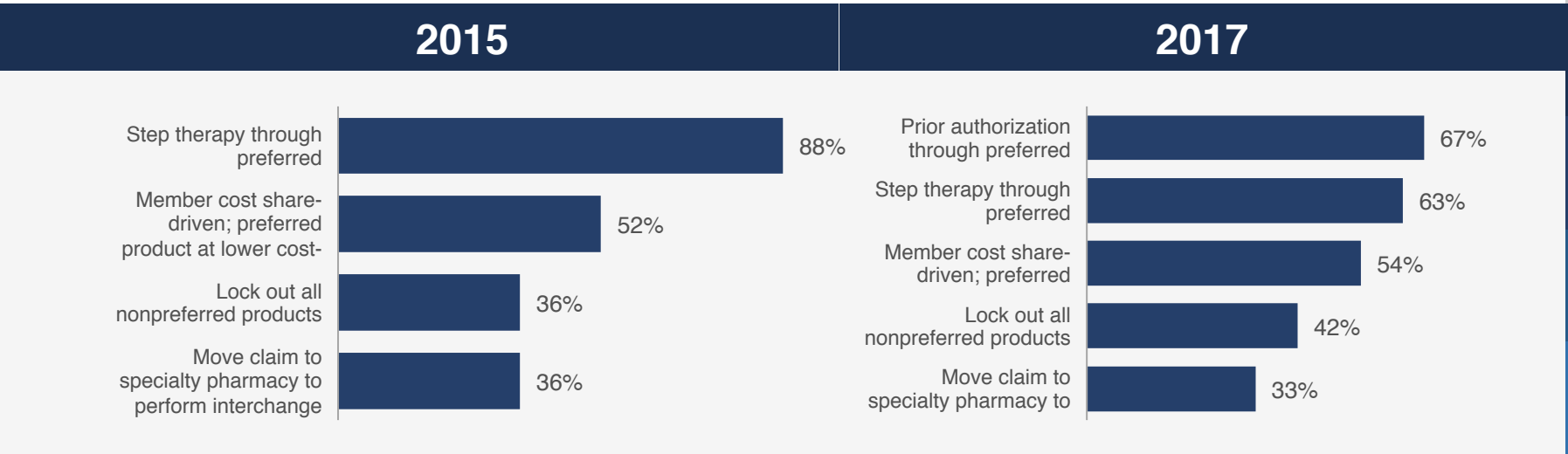
Payer Trends in Biosimilar Management: Non-price Considerations



Q3.What considerations, outside of price, would you explore when selecting biosimilar partners? (Select all that apply.)

Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Pharmacy Management

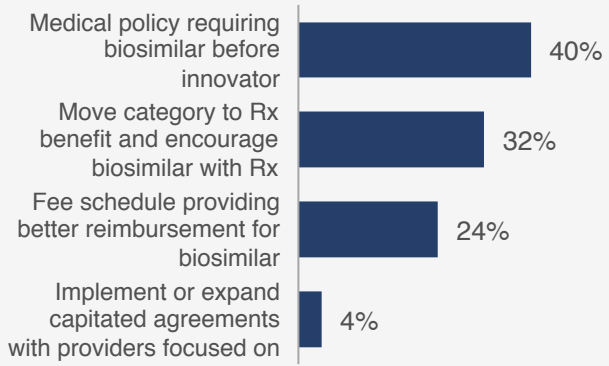


Q5. Assuming your plan prefers a biosimilar in a category, what mechanism(s) would you use to encourage the biosimilar? (Select all that apply)

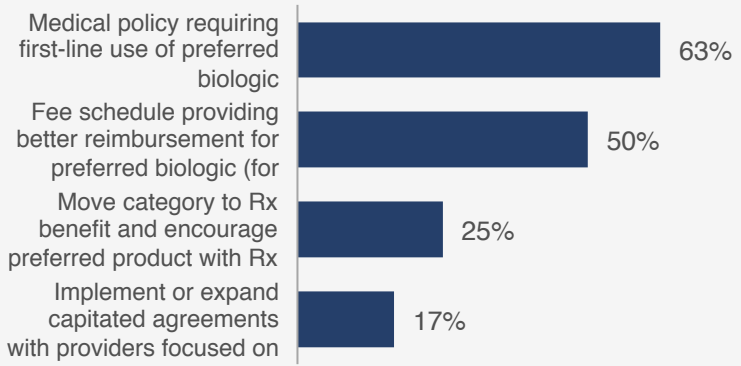
Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Medical Management

2015



2017

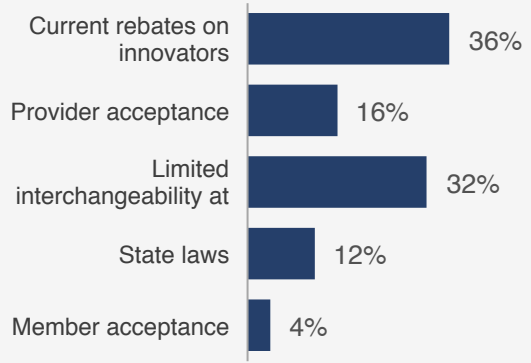


Q6. What mechanism(s) would you use to encourage biosimilar use on the medical benefit?

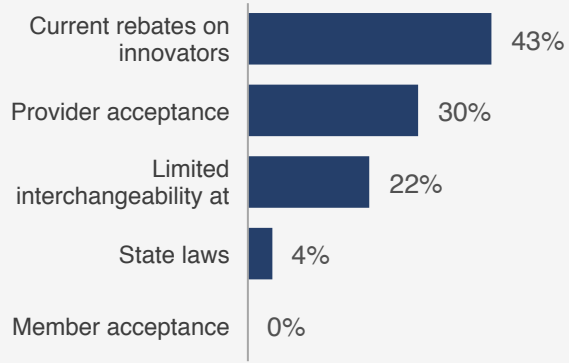
Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Barriers

2015



2017

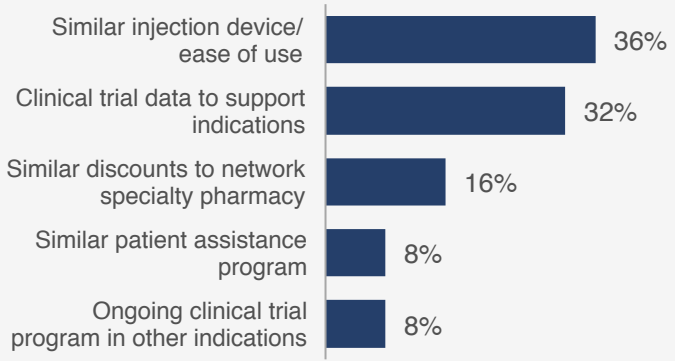


Q7. What do you consider to be the biggest barrier to biosimilar adoption in your market?

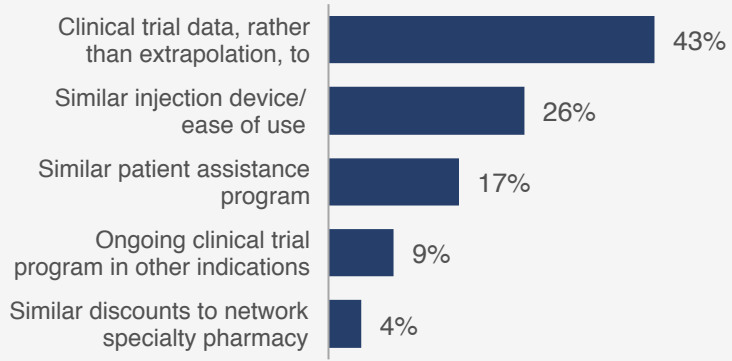
Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Product Factors

2015



2017

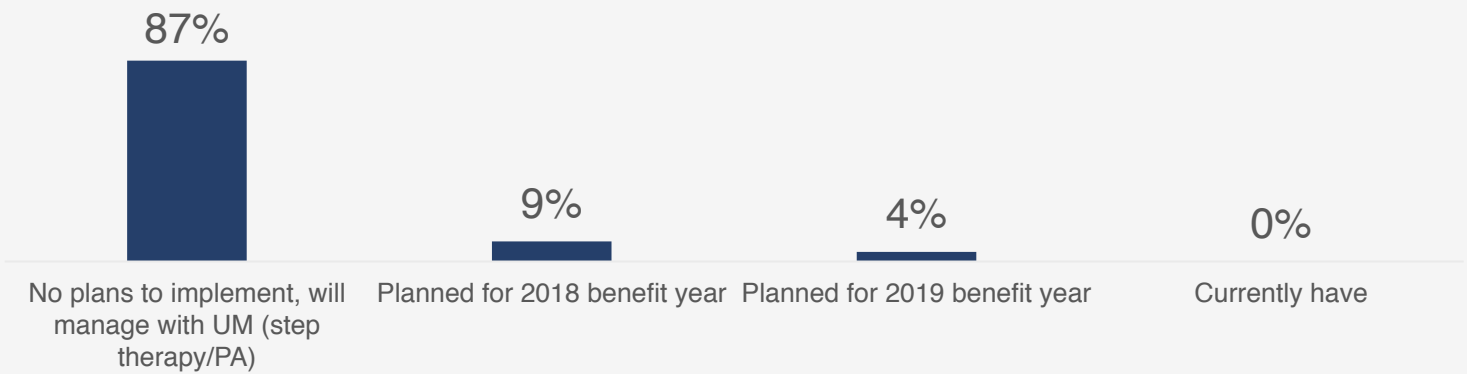


Q8. Aside from price, what other factor is most important for a biosimilar to have?

Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Benefit Design

Most respondents do not have a separate, distinct tier for biosimilars and do not intend to implement one in the near future

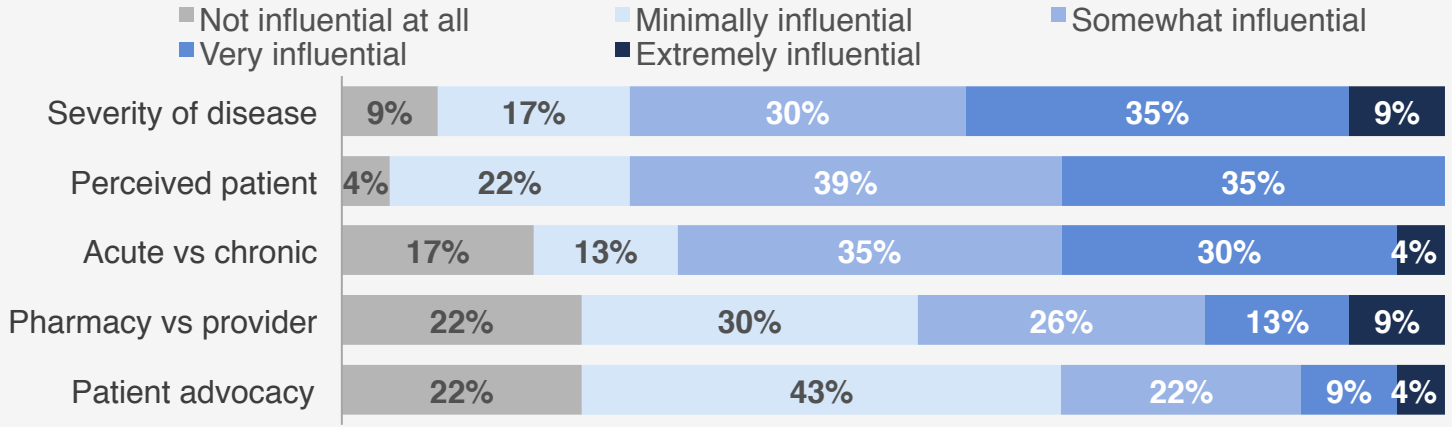


Q9. Do you have a distinct cost-sharing tier for biosimilars that differs from your current specialty tier?

Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Payer Trends in Biosimilar Management: Switching Considerations

Severity of disease state, and patient "fragility" were the most influential factors in not requiring a patient to change product



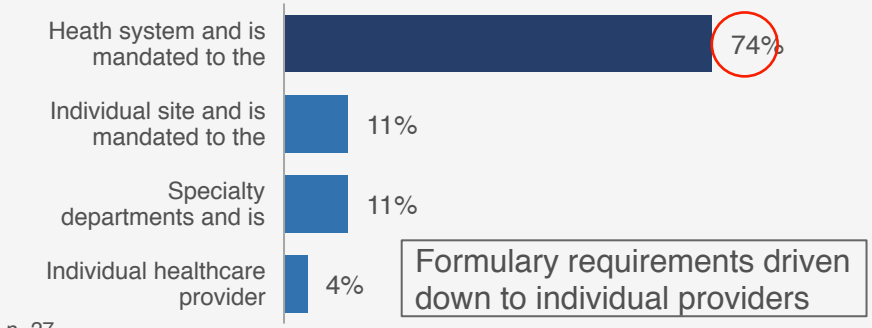
Q10. Were your organization to consider preferring a biosimilar over the originator, how influential would the following be in determining if you would encourage switching among existing patients?

Proprietary research; n=25 market access decision makers from national and regional carriers, state Medicaid, PBMs, and IDSs, representing 130 million medical lives and 140 million pharmacy lives.

Health System Biosimilar Management: Formulary Management

Product Management

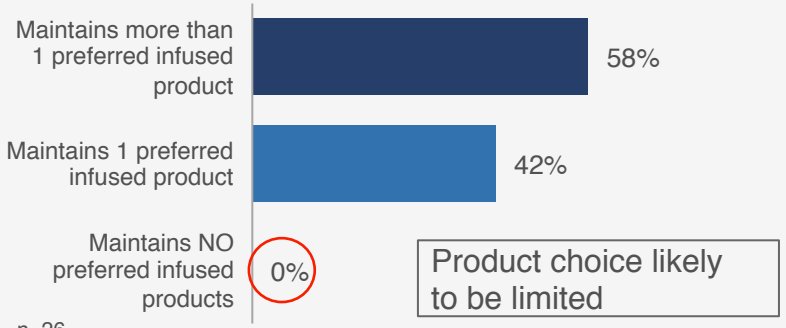
At what organizational level of the health system is product selection managed for infused medications with clinically similar products (eg, intravenous immunoglobulin)?



n=27.

Access Management

Which of the following best describes the access management strategy of your health system/care facility/specialty departments?



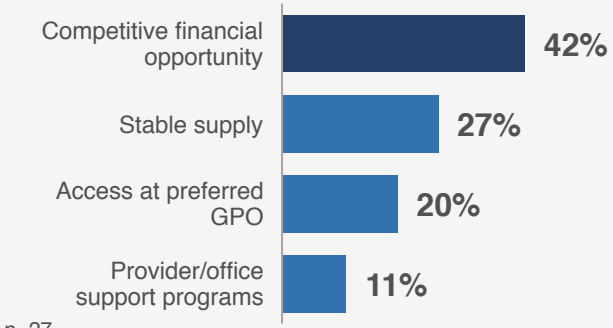
n=26.

Many of the health systems in the survey owned both specialty pharmacies and health plans, meaning that formulary decisions could spill outside the system into broader populations and self-administered products.

Health System Biosimilar Management: Adoption Factors

Biosimilar Adoption

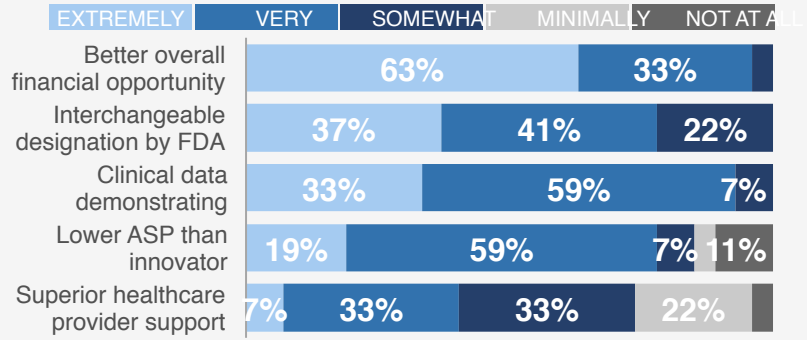
How important, relatively, will each of the following be to your organization's adoption of a particular biosimilar-infused product, aside from clinical factors (safety/efficacy)?



n=27.

Influence Factors

How influential will each of the following factors be in encouraging your organization to make a biosimilar preferred over the innovator brand?



n=27.

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Payer Issues: Maximizing Cost Savings

Discounting Example: Remsima (infliximab)
Distributed by Orion Pharma under license from Celltrion

	Discount	Volume Share
Norway	69% (March 2015)	90% (July 2015)
Denmark	70% (June 2015)	69% (July 2015)

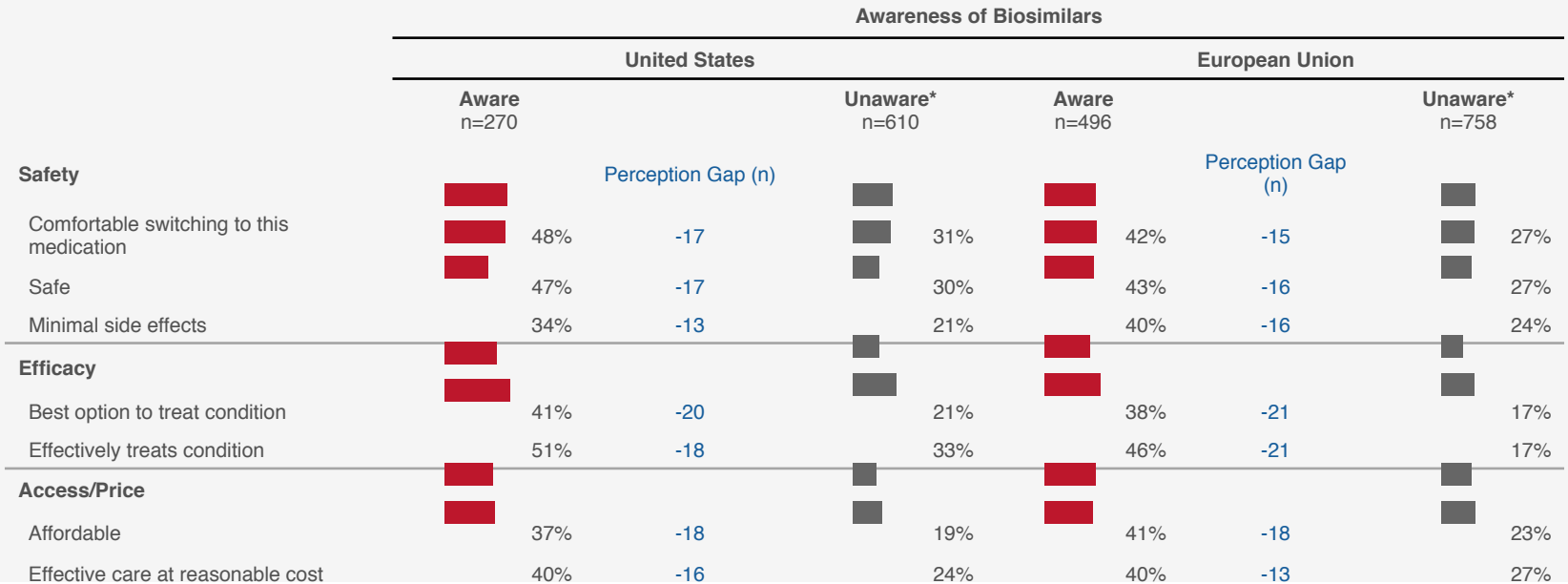
Who will be the US version of

Similar discounts have also been offered in Finland

Payer Issues: Patient Acceptance

Where patients were aware of biosimilars, gaps in perception existed, with the largest related to efficacy and safety.

Gaps in Perceptions About Biosimilars Among Patients Aware and Those Unaware of Biosimilars*



*Unaware="never heard of biosimilar" in response to the question, "Which of the following types of medications have you heard of before today?"

Payer Issues: Patient Acceptance

Despite a longer time in the market, and greater uptake, perceptions are not widely different between the United States and Europe. Indicates need for more education.

Gaps in Perceptions About Biosimilars vs Biologic Therapies Among Patients Aware of Biosimilars

	Perceptions					
	United States			European Union		
	Biologics n=258	Perception Gap (n)	Biosimilars n=258	Biologics n=439	Perception Gap (n)	Biosimilars n=439
Safety						
Comfortable switching to this medication	53%	-5	48%	51%	-9	42%
Safe	52%	-5	47%	52%	-9	43%
Minimal side effects	40%	-7	33%	39%	0	39%
Efficacy						
Best option to treat condition	60%	-19	41%	50%	-13	37%
Effectively treats condition	66%	-16	50%	53%	-7	46%
Access/Price						
Affordable	37%	+1	38%	34%	+7	41%
Effective care at reasonable cost	38%	+3	41%	35%	+5	40%

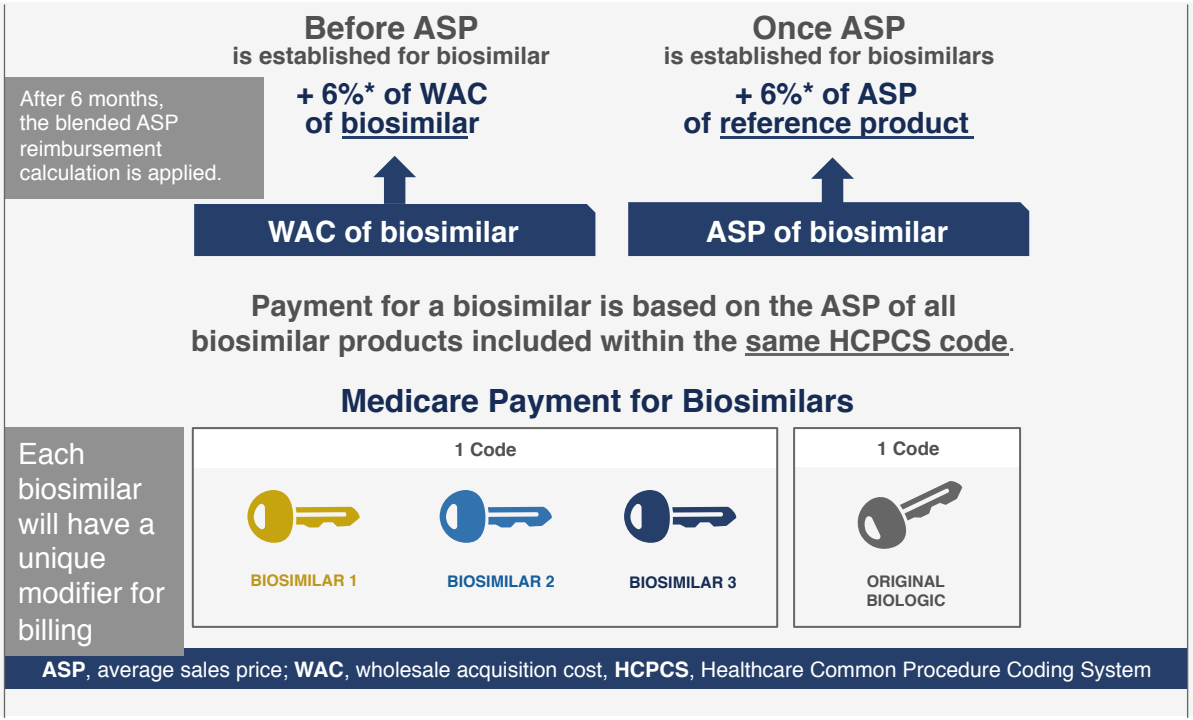
Payer Issues: Perverse Incentives in Reimbursement

Challenges

A blended rate does not incentivize the use of lower cost agents.

A blended rate allows the possibility that an individual company can decrease overall ASP by providing significant discounts.

The opportunity cost for a sponsor will be based on whether it can drive market share, most likely by offering a low price, creating a race to the bottom.



*The current federal spending sequester requires all Medicare government payments be reduced by 2%.
Source. CMS. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016. October 2015.

Payer Issues: “Shadow Regulators”

A BIOWORLD SPECIAL REPORT

BIOSIMILARS: U.S. MARKET OPPORTUNITIES AND CRITICAL STRATEGIES 2016

THOMSON REUTERS

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DRUG COVERAGE IN PART D DONUT HOLE

	2017	2020
For a reference biologic		
Patient	40%	25%
Plan	10%	25%
Manufacturer Discount	50%	50%
For a biosimilar		
Patient	51%	25%
Plan	49%	75%

Source: Avalere Health

one payment code while all its biosimilars are lumped together with another code. (See *BioWorld Today*, July 21, 2015, and Nov. 3, 2015.)

By setting the Medicare payment for each biosimilar on the average sales price and market share of all the biosimilars within a single code, the opportunity cost for a sponsor will be based on whether it can drive market share, most likely by offering a low price, creating “a race to the bottom,” Pfenex Inc. CEO Bert Liang told *BioWorld Today*.

In that situation, many drugmakers would find it more profitable to focus on developing novel drugs rather than biosimilars. “It’s going to be a challenge for some players out there,” said Liang, who also serves as chairman of the Biosimilars Council, a division of the Generic Pharmaceutical Association.

“SHADOW REGULATORS”

Biosimilar reimbursement is not just a CMS issue. All payers, especially PBMs, are becoming “shadow regulators” by dictating which drugs are used in the market, David Fox, a partner at Hogan Lovells LLP, told *BioWorld Today*. Their policies could make or break the emerging market, depending on how they’re structured.

PBMs contract with pharmacies, administer Medicare Part D plans, negotiate the actual drug prices – as opposed to the publicized “list price” – with manufacturers, and determine which drugs make it to payers’ formularies and where those drugs are placed in that scheme.

With three PBMs comprising nearly 80 percent of the market, they exercise power as great as any regulator and often have more prescribing input than a doctor, determining which drug a patient gets and how much that drug will cost the patient out of pocket. In short, they will be the market gatekeepers for biosimilars. //

– *BioWorld Today*, April 28, 2016

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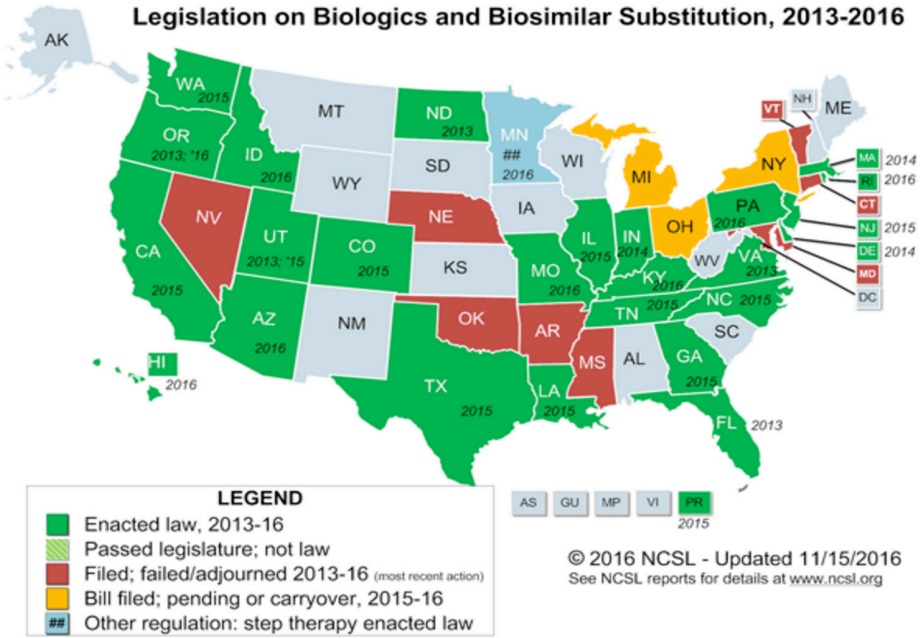
Payer Issues: Interchangeability and State Actions

Just under 30 states have or are in the process of enacting regulations pertaining to biosimilar interchangeability.



Typical provisions

- HCP notification
- Patient notification
- Record keeping requirements
- “Cost less” requirement

National Conference of State Legislators. http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx. November 15, 2016. Accessed March 6, 2017.

Payer Issues: Pricing and Contracting

Rebate/discount contracts with brands
- Manufacturer terms
- Innovator value

Rebate guarantees
- Biosimilar impact on downstream clients
- Downstream client terms with rebate aggregator

Network rates
- Same for biosimilar and innovator?

Provider implications
- ASP/reimbursement
- Purchase point

Patient impact
- Differential cost sharing to incent use?
- Equivalent availability of manufacturer copay support?

Future Biosimilars: Oncology

Likelihood of prescribing oncology biosimilars

Average answers based on 1-5 rating (n=16 payers)

Likelihood: Low Medium High

KEY INSIGHTS

- Due to spiraling cost for cancer drugs, oncologists are likely to be quick to accept the use of biosimilars in their naive patients, but opinions are likely to differ with switching existing patients
- On the one hand, they already have biosimilar experience with EPOs, and the anti-TNFs have caused no concerns (in terms of long-term safety or immunogenicity)
- Nevertheless, as cancer is a life-threatening condition, many will resist switching patients for fear of jeopardizing prognoses - also recognizing that, with shorter treatment cycles in cancer, originator-treated patients will soon be replaced by new incident patients initiated on biosimilar

Questions and Contact

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