Biosimilars; Beyond the Scientific Review

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No applicable conflicts of interest to disclose
Objectives

1. Describe biologic cost trends
2. Review biosimilars background and market penetration in US and abroad
3. Discuss biosimilar manufacturing and approval process
4. Describe biosimilar industry barriers of entry
5. Evaluate biosimilar launch and practice implementation challenges
6. Review potential biosimilar economic impact
Audience Poll

How many have attended a biosimilar presentation before?

Scientific vs. practice content?
Practice Implication

= -P-ractice impact implications
Why Have the Biosimilar Discussion?

- Biosimilars are here
- Payers, patients, providers, other stakeholders may request it
- Others turn to pharmacists as the experts on biosimilars
- Value; lowering cost of care while maintaining quality
- Practice challenges (e.g. education, pt. criteria, inventory, cost & reimbursement)
Background

- Biologics have revolutionized treatment for serious conditions in past 20 years
- Costly biopharmaceuticals

- Similar conflict
  - 30 years ago
  - Synthetic drugs
  - Resolved by generics post patent expiration

- Biosimilars have new characteristics that do not fit previous regulatory frameworks

Background

- Unsustainable and rising healthcare cost calls for **cost containment strategies**
- 3% patients on specialty medications account for >40% of total drug spending

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1970</td>
<td>Biologic products mainly consisted of <strong>vaccines &amp; blood products</strong></td>
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<tr>
<td></td>
<td>&lt;10% pharmaceutical market</td>
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<tr>
<td>1980</td>
<td>Rise of <strong>cloning and gene expression technology</strong></td>
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<td></td>
<td><strong>Biosynthesis</strong> of genetically modified organisms</td>
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<td></td>
<td>Increasingly <strong>complex molecules</strong></td>
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<td></td>
<td>1982 Genentech’s <strong>recombinant human insulin</strong></td>
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<td></td>
<td>1986 First FDA-approved <strong>monoclonal antibody</strong> (muromonab)</td>
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<td>1997 Entry of recombinant monoclonal antibodies for <strong>cancer treatment</strong></td>
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<tr>
<td>2005-2014</td>
<td>Biologics Medicare Part B spend doubled (32%-62%)</td>
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Background

2017  
Over 208 biologic products registered  
>25% of market  
Highest sales growth, doubling from 2006-2016 ($93-200 trillion)

2020  
>50% of market  
Patent expiration of biologics reaching >$20 billion in global annual spend

- Biosimilars expected to assume majority of market share
- Innovator companies pursue biosimilar development

Top pharmaceuticals based on expenditure in hospital setting
- Infliximab
- Pegfilgrastim
- Epoetin alfa

A **biosimilar** is a biologic agent that is NOT chemically identical, but is highly similar, to an approved reference biologic agent, notwithstanding minor differences in clinically inactive components, and with no meaningful differences in efficacy, safety, and purity.

A **reference product** is an approved drug that is compared with new generic or biosimilar version to show bioequivalence of biosimilarity respectively.

A **generic medication** is a drug product that is the same as the brand in terms of:

- Dosage form, strength, route of administration, quality and performance characteristics and intended use.
- Small molecules and agents that undergo **multistep chemical synthesis**

Approval is based on:
- Pharmaceutical equivalence
- Human bioequivalence

**Biogenerics** are a copy of a reference product

- No significant comparative analytical & clinical testing
- Not manufactured under GMP standards
- Targets less- and nonregulated countries and international commerce

GMP = Good Manufacturing Practices

1. Rader, R. *Biosimilars Pipeline Shows Remarkable, Sustained Growth*. Biosimilar Development. March 7th, 2019
First biotech molecules to expire were relatively small

- insulin 5,808 mass units
- filgrastim 18,800 mass units
- erythropoietin 30,400 mass units

Monoclonal antibodies are larger molecules

- Some 150,000 mass units

*Greater molecular heterogeneity

Background

Background – Biosimilar Journey - Europe

2006  First biosimilar introduced

2018*  European Medicines Agency (EMA)
  o 40 biosimilar products in market
  o 15 available in oncology
  o Improved patient care access
  o Reduced cost

* As of May 2018
Regulatory Approval

Public Health Service Act

Biologic Price Competition and Innovation (BPCI) Act [351(k)]

Abbreviated Licensure Pathways for biologics demonstrating “biosimilarity” or “Interchangeability” with FDA-licensed biologics

351(k) Not intended to re-establish proposed product “safety” & “efficacy”

351(k) Demonstrate proposed product is *highly similar* to reference biologic

Manufacturing of Biosimilars

- Reverse-engineered
- Therapeutic proteins
  - Biologic processes
  - Living cellular systems
  - Not stepwise chemical synthesis
- Essentially impossible to produce an identical copy of product
- Even batches of the same reference product that are produced with the use of the same cell line may be dissimilar.

Biosimilars MUST have **amino acid** sequences that are the same as those in reference drug but may have **minor differences** due to:

- Post-translational protein modifications (e.g. alterations to C or N terminals)
- Glycosylation (e.g. addition of sugar residues to amino acids bearing amino or hydroxyl groups)
- Formulation (e.g. due to different excipients)

Manufacturing of Biosimilars

Reference medicine  Biosimilar medicine

Address physician leadership first
Biosimilars Approval Process


Provider education
Phase III
Regulatory Approval

Biologic
- Phase III Clinical Trials
- Safety
- Efficacy

Biosimilar
- Analytical Testing
- Molecular Structure
- Biological Function
- Non-clinical Animal Studies
- Toxicology
- Immunogenicity
- Pharmacology
- Pharmacokinetics

Focus

Regulatory Approval

- **Comparability analytical testing not newly introduced** by biosimilars

- Already conducted by reference product manufacturers
  - Changes in manufacturing process
  - Intrinsic variability of batches

- **Comparability criteria changes based on product development state**
  - The further along in the process the more stringent & extensive comparability testing

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Manufacturing of Biosimilars

Molecular Variability “Drift”

- Differences at each step of manufacturing
- Not caused by production error
- Changes are inevitable based on current biologic production process
- Infliximab (37) etanercept (22) adalimumab (20) reported changes to regulator
- Accepted by regulatory entities without new clinical trials
- Product quality data compared before and after change
- Routine continuous analyses on batches compared to historical data

Manufacturing of Biosimilars

Molecular Variability “Drift”

- Manufacturer mandatory comparability plan

- **Biosimilar approval** requires submission of *analytical comparability* and clinical studies that is *much more extensive* and in-depth compared to original producers after production process changes after regulatory approval

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Regulatory Approval

- Alglucosidase Alfa scaled up production resulting in significant glycosylation changes
- FDA concluded that product variations required a new Biologic License Application (BLA) under new product name
- Both products later deemed comparable
- Historically FDA has not requested pre-clinical and clinical studies for comparability purposes
- Analytic characterization will remain backbone of biosimilar development

Immunogenicity

- General immune response (e.g., allergy, anaphylaxis)
- Changes in protein structure increase variation in immunogenicity
  - Incidence rate
  - Severity
- Study endpoints often antibodies (binding, neutralizing), cytokine levels
- FDA recommends a comparative parallel study in treatment naïve patients

Beyond a Tolerability Concern, it is also an efficacy concern

- Neutralizing antibodies can block the effectiveness of drug
- Concerning all biologics, not just biosimilars

Biosimilars Approval Process - Extrapolation

Indication Extrapolation

- Repeat trial across indications **not required**
- May be granted labeling that is identical to reference product
- To date, FDA biosimilar approvals have leaned toward complete or near-complete extrapolation 1. inventory 2. IT 3. safety
- Extrapolation is foundational for cost savings potential of biosimilars
- Strong incentive for biosimilar development
- Extrapolation in the metastatic setting (e.g., trastuzumab) across disease states (e.g., rituximab)

Switching & Interchangeability

**Switching**
- “exchange one medicine for another medicine with the same therapeutic intent”
- “Switching between products presents **no greater safety or efficacy risk** than **continuous treatment with the reference product**”

**Interchangeability**
- If it can demonstrate biosimilarity to the reference product
- If it can be expected to produce the same clinical result as the reference product in any given patient

- No biosimilar has been approved in US as fully interchangeable

Health plans nonetheless moving the needle

1. Davio, K.  Biosimilar Beats Subcutaneous Rituximab on Cost Savings in NHL.  Centers for Biosimilars.  December 5, 2018
Available Data on Switching

**Systematic Search**
- PubMed
- ClinicalTrials.gov

- 8 switching studies biosimilar rituximab and trastuzumab
  - 2 in oncology indications
  - 6 in rheumatoid arthritis
  - 7 had extension study of continued switch element
  - 1 dedicated switching study

**Strengths**
- Randomization
- Blinding

Available Data on Switching

Trastuzumab Biosimilar ABP 980 Study
- Early breast cancer patients (adequately sensitive)
- Randomized, blind switch (n=171)
- Controlled arm remaining on (reference Trastuzumab) (n=554)
- 40 weeks
- End Points
  - Efficacy (event-free survival, overall survival, immunogenicity, safety profile.)

Results:
Switching did not increase:
- Frequency or severity of adverse events
- Incidence of antidrug antibodies observed
- Disease progression, reoccurrence or death rates was similar in both groups

Limitations
- Short follow-up
- Single switch only

Available Data on Switching

**Rituximab Biosimilar NCT02149121 Study**
- Phase III extension period
- Reference to biosimilar switch
  - EU sourced biosimilar (n=47)
  - US sourced biosimilar (n=62)
  - Remained on reference product (n=64)

**Results:**
Endpoints achieving comparable results among three arms:
- Efficacy
- Pharmacodynamics
- Safety profiles
- Immunogenicity

**Limitations**
- Product source
- Extrapolation to oncology efficacy

Available Data on Switching

- Meta-analysis
  - 58 clinical trials
  - >12,000 patients
  - Included pharmacovigilance data on biosimilars
  - Found no evidence of safety concerns related to switching

Available Data on Switching

- **No significant signs** of switching leading to meaningful clinical **differences**
- Many existing studies only include a **single switch**
- Other studies have significant **design limitations** like no randomization, control arm, power, etc.
- **No pharmacokinetics & pharmacodynamics** assessment during switch period
- **Long-term impact** of switching has **not been fully assessed**
- Existing data **NOT suitable to support interchangeability**
- **Improved study** designs are needed
- Interchangeability expected **later rather than now**

FDA Interchangeability Guidance

- **FDA recognizes** need to evaluate impact of repeated switches
- Recommends at least **3 switches** in study designs with **1 arm remaining unchanged**
- Primary endpoint to assess impact on
  - PD & PK
  - Immunogenicity
  - Safety profile
  - Efficacy (as supportive end point)
- **Sufficiently long** to allow detection of clinically relevant differences
- **Real-world data** contributions
  - More switch cases
  - More switches of same product as more biosimilars of same product become available

Interchangeability – Other Obstacles

- Long elimination half-lives of mAbs (up to 4 weeks) further limitation because an appropriate washout period before switching is often not compatible with the drugs’ dosing schemes in oncology indication.

- Nocebo effect

- Considerations around switching a cancer patient responding to current therapy.
American Society of Clinical Oncology (ASCO) Policy Brief

1. Clinical trails for biosimilars should demonstrate efficacy and safety, including immunogenicity

2. FDA should establish transparent regulatory pathways for biosimilar approval

3. Physician choice in the best interest of patient should not be restricted

4. Approved biosimilars should be subject to careful post-market safety

5. Interchangeability should be established by clinical trials that are adequately designed and performed to support substitution

6. Congress should ensure adequate FDA funding to meet new demands

Approach to Switching

- **Interchangeability** determined at federal level (FDA)

- **Substitution** regulated at state level
  - “dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber”
  - Pharmacist mediated
  - >35 states & Puerto Rico allow
    - If biosimilar is considered interchangeable &
    - Covered under payer’s pharmacy benefit

- Pharmacy & Therapeutics (P&T) Committee substation approval

European Medicines Agency (EMA)

- No additional biosimilar interchangeability classification
- Switching policies governed by individual EU member states
- Long-term differences in efficacy between the switch and control groups
Lot-to-lot differences may result
- Minor modifications in manufacturing
- Processing
- Packaging

Could potentially lead to small risk of differences in
- Immunogenicity
- Adverse effect profiles

Applicable to both reference and biosimilar products


Biologics & Post-Marketing Surveillance

- Pharmacovigilance and reporting is critical
  - Risks and benefits of switching
  - Long term effects

- Continued challenges collecting this data given fragmented nature of US healthcare system

- Challenges with interchangeability and reported safety concerns
  - Product specific identification
  - Half-life overlap

- Pharmacovigilance evidence support


Barriers of Entry – “Patent Dance”

- Infringement litigation to delay marketing of biosimilar

- Affecting most biosimilars and delaying by months to years

- Several product patents
  - Primary patent on molecule and manufacturing
  - Formulations
  - Delivery systems
  - Absorption
  - Other patents may extend exclusivity for years

Barriers of Entry – “Patent Dance”

- Time-consuming process
- Questionable intent of US patent law
  - Adalimumab lost initial exclusivity period in 2016
  - The earliest biosimilar Adalimumab can appear in US is 2023
  - Additional patent layers may still extend further*
- Reference manufacturer may settle biosimilar patent litigation
  - Avoiding legal costs
  - Allowing biosimilar faster market penetration/revenue
  - In exchange for royalties
  - Likely to inflate biosimilars’ price

*Legislation

*Three adalimumab FDA approved programs by June 2019
2. Editorial. Factors Influencing the Economics of Biosimilars in the US. Journal of Medical Economics. Vol 20, No 12, 1268-1271. 2017
Barriers of Entry – “Rebate Trap”

Health Plan grants reference drug preferred status

May include

Greater manufacturer/PBM rebates

Exchange

+ Exclusive arrangements to reduce competition

May include

Product bundling

- Contracting and rebating practices

- Placing biosimilars on preferred tier may conflict with competing existing rebate arrangements

Barriers of Entry – Payment Policies

- Innovator rebates to lock up payers in multi-year contracts right on the eve of biosimilar entry
- Payers’ incurred resources to organize switch
- Originator manufacturer produces biosimilar of competitor and offers single contract
- Multi-million dollar reductions for large health plans
- Payer-practice formularies misalignment: no economies of scale for volume discounts

Barriers of Entry – “Rebate Trap”

- Rebates generally not designed to be shared with patients in the form of lower out-of-pocket cost
- Reimbursement reform that tackles these rebate incentives is in its infancy
- Advocacy work

- Performance in a world w/o rebates?

Barriers of Entry – Reimbursement

- Medicare, Medicaid and commercial payers have all **approached biosimilar reimbursement differently**

- Front and center with provider **margin declines**

- **New reimbursement models**

- **Cuts from payer** and government agencies

- Beginning January 2018 CMS codes each biosimilar separately with reimbursement on its own ASP (and %age of reference)

- **CMS Pass-through**

Barriers of Entry – Reimbursement

- Biosimilar lower net revenue relative to reference product
  
  \[
  \text{ASP (acquisition cost)} \times \text{mark-up (4-6+ factor)} = \$\text{Charge}
  \]
  
  \[
  \text{Reimbursement} = \%\$\text{Charge}
  \]

- Multi-million net revenue impact for some drugs

- Financial impact education
  - e.g., budgeting
  - e.g., lowest cost-of-care provider

Barriers of Entry – Education

- Significant knowledge gaps in key stakeholders
- Overall effect on healthcare cost dependent on (provider, payer, and patient) understanding of safety and efficacy

2013 survey prior to launch of first infliximab biosimilar

13% of gastroenterologist were very or totally confident with safety and efficacy compared to 47% after 2 years of experience with product

2. Editorial. Factors Influencing the Economics of Biosimilars in the US. Journal of Medical Economics. Vol 20, No 12, 1268-1271. 2017
Barriers of Entry – Education

Other USA Surveys (2013-2016)

30% oncologists perceive biosimilars **less safe** than reference counterpart due to **abbreviated regulatory** pathway

12% only indicate comfort with **extrapolation**

70% thought a manufacturer-specific **suffix** should be added to biosimilar name

- Significant knowledge gaps in key stakeholders

2. Editorial. Factors Influencing the Economics of Biosimilars in the US. Journal of Medical Economics. Vol 20, No 12, 1268-1271. 2017
1. “Managing Oncology Drug Cost” Live Poll. Advisory Board. 6/13/2019

What is the biggest barrier to using biosimilars at your cancer program? Select one.

Poll Results (single answer required):

- Reimbursement: 33%
- Provider reluctance: 31%
- Patient reluctance: 1%
- Operational changes required to adopt: 28%
- Other: 6%
Barriers of Entry – Others

- Active prevention of originator drug sale to biosimilar company in clinically sufficient quantities to enable comparative clinical testing
  - Legislation

- Lack of regulatory policy

- Provider and patient economics

- Volatile market (innovator before/after launch counter strategy)
  - Innovator lowering price below biosimilar

- Innovator products add new value; OnPro, Rituximab hyaluronidase; Trastuzumab hyaluronidase-OYSK
  1. infusion operations
  2. revenue impact

Barriers of Entry – Others

- Pharmaceutical companies dropping biosimilar development programs
  - Pfizer – 5 (confirmed Jan 2019)
  - Momenta – 5 (late 2018)
  - Merck – 1

Biosimilars – Current State of Affairs

- 20 biosimilars FDA approved in US*
  - Less than half in the market
  - Less than 2% of total US biologics market

- 40 biosimilars for sale in EU**
  - Covering nearly 70% of all biologic therapies

- International biosimilar sales
  - 87% spend in EU
  - 2% send in US

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* As of June 2019  **As of April 2019
Biosimilar Journey

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

<table>
<thead>
<tr>
<th>PRODUCT (PROPER NAME)</th>
<th>PROPRIETARY NAME</th>
<th>DATE OF LICENSURE (mo/day/yr)</th>
<th>DATE OF FIRST LICENSURE (mo/day/yr)</th>
<th>REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)</th>
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Purple Book
Reference to identify 351(k)-licensed products and respective biosimilarity and interchangeability status

FDA Biosimilar Support Efforts

**Biosimilar Action Plan**

- More efficient review process
- Encourage greater biosimilars uptake
  - Education to clinicians and patients
  - Biosimilar efficacy and safety
  - Address misconceptions that foster reluctance to prescribe or use
- >60 biosimilar development programs to 31 different reference products*
  - Prompting need for creation of new “office”

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*FDA pipeline as of July 2018
FDA-approved biosimilars are safe, effective options for patients.

Biological products, including biosimilars, are used to treat a wide variety of life-threatening and life-altering diseases. A biosimilar approved by FDA meets rigorous standards and has no clinically meaningful differences from the FDA-approved reference product in terms of safety and effectiveness for its approved use. The availability of FDA-approved biosimilars in the U.S. means that patients may have access to more medications at a potentially lower price.

Visit www.FDA.gov/biosimilars to learn more.

Have questions about biosimilars?

- Are they safe?
- Are they effective?
- How are they developed?
- Do they meet FDA’s rigorous standards for approval?

FDA has developed new resources for health care providers to answer your questions about biosimilar products. Learn key terms, how biosimilars are developed and approved and FDA’s role in these processes, and about the data and information required to demonstrate biosimilarity.

Visit www.FDA.gov/biosimilars to learn more.
Biosimilars Financial Impact in the US

The New York Times

F.D.A. Commissioner Scott Gottlieb, Who Fought Teenage Vaping, Resigns

CMS allowed Medicare Advantage (MA) plans to utilize step therapy to negotiate drug prices (August 2018)

UnitedHealthcare first to publically announce several biosimilars as preferred treatment (effective January 2019)
  - infliximab-dyyb
  - Infliximab-abda
  - Epoetin Alfa-epbx
  *Excluding* pegfilgrastim-cbqv effective July 1st 2019

Requires a product to be used first before patient moves to another therapy

“Fail first” approach

DiGrande, S. UnitedHealthcare Names 3 Biosimilars Preferred Treatment in 2019 MA Plans. Centers for Biosimilars. October 17, 2018
Payer Policy

- Neupogen formulary exclusion
  - UnitedHealthcare*
  - CVS Caremark
  - Veterans Affairs

* Prior to July 1st 2019

2. Editorial. Factors Influencing the Economics of Biosimilars in the US. Journal of Medical Economics. Vol 20, No 12, 1268-1271. 2017
Increasing number of providers working in Accountable Care Organizations (ACOs) and “narrow networks”

- UPMC/Highmark - Allegheny Health System/Kaiser
- Self-insured Employee Health Plans

CMS Value-based Oncology Models

- Disproportionally greater elderly population in oncology

- Cost mitigation strategies
  - Incentivizing high-quantity (not necessarily high-quantity services)
  - Payment increasingly tied to performance

- Oncology Care Model (OCM) (launched June 2016)
  - Voluntary, two-sided risk model
  - Better care coordination
  - Quality metrics and practice reforms
  - Lower cost than traditional Medicare FFS
  - 192 practices & 14 commercial plans participating
  - Drug budget management

Biosimilars Economic Impact in the US

- Biosimilars expected to enter market at **15-30% discount** from reference

- Discount variation: manufacturer **quality**, manufacturer **location** and ability for continuous **supply**, availability of programs (e.g. **free drug assistance**), managed care contracting order of entry*, number of implementations

- Driving further price competition once in market
  - Multiple biosimilars/reference
  - Major discounts may take **up to a decade**

*Speaker opinion  **As of June 2019
Biosimilars Economic Impact in the EU

- Europe has achieved mean price discount ranging from 15-40%
  - 39% in France
  - 55% in Germany
  - Highest number of approved biosimilars worldwide

Biosimilars Economic Impact in the US

- **Medicare Drug-Specific Cost**
  - Bevacizumab $1.1 billion in 2014 to treat 215,000 patients
  - Rituximab cost $1.5 billion in 2014 to treat 68,000 patients
  - 23 reported Rituximab biosimilars in preparation worldwide

- **Patent Expiration:**
  - Cetuximab – 2014
  - Rituximab - 2016
  - Bevacizumab - 2019
  - Trastuzumab - 2019
  - “heavy dent in oncology cost curve”

Biosimilars Economic Impact in the US

- Too little experience available to assess biosimilars effect on rising biologic spend
  - Regulation/approval process/pricing assumptions/interchangeability/payer action/patent litigation/education, etc.

- RAND Corporation predicted a cumulative biosimilar saving of $44.2 billion from 2014-2024

- Express Scripts estimated $250 billion in savings by 2024
  - Infliximab and filgrastim accounting for $22 billion
Biosimilars Financial Impact in the US

Top Opportunities for Cost Savings
(Percentage of respondents that ranked opportunity in top 3)

63%  Clinical standardization
62%  Drugs
28%  Supplies
24%  Capital expenses (e.g., radiation and imaging equipment)
22%  Non-clinical staff (e.g., financial advocates, billing and coding specialists)

Top Threats to Future Cancer Program Growth
(Percentage of respondents that ranked threat in top 5)

68%  Cost of drugs and/or new treatment modalities
47%  Physician alignment around services and program goals
46%  Changes in healthcare coverage
44%  Cuts to fee-for-service reimbursement
43%  Shifting reimbursement from fee for service to value-based care
35%  Marketplace competition

Summary

- Population growth
- Population aging with increased life expectancy
- Multiple health conditions
- Growing number of biologics
- Improved side effect profiles
- Earlier treatment initiation
- Use of multiple lines of therapy
- Long-term use in newly considered chronic conditions
- Increasing drug cost

Summary

Biosimilars
- Similar to reference product
- $100-200 million development cost
- 8-10 years in development
- Interchangeability challenges
- 20-30% discounts

Generics
- Identical to reference product
- $1-5 million development cost
- 3-5 years in development
- Interchangeability guaranteed
- 80-90% discounts

Summary

- Biologics have **revolutionized** treatment for serious conditions in past 20 years
- Biosimilars have new characteristics that **do not fit previous generic regulatory frameworks**
- Biologic Price Competition and Innovation (BPCI) Act [351(k)] in 2010
- Highly similar to reference with **minor differences** in inactive components that lead to no clinically meaningful differences in **efficacy, safety, purity**.
- Biosimilar product development **does not intend** to re-establish safety and efficacy, but biosimilarity
- Inevitable lot-to-lot biologic and biosimilar product variation which is **closely monitored**
Summary

- Pharmacovigilance is critical (e.g., immunogenicity)

- **Available switching studies** are limited to support full interchangeability

- High barriers of entry remain (e.g., patent disputes, payer policies, education)

- Internationally the US has seen slower biosimilar adoption rates

- As more biologic patent expirations come to end, more marketplace competition is expected to bend the cost curve

- Increasing number of biosimilar guidelines and adoption of products worldwide

- Uniquely positioned to perform in value-based arrangements
Summary

- Sustainability of health care financing remains a key public concern
- Biosimilars bring a promising value proposition
- Realization of that value requires biosimilars to be utilized
- As pharmacists we are uniquely positioned to evaluate the growing body of clinical evidence to promote safe and effective use of biosimilars
Questions?