Value in Innovation Forum

The Value in Innovation Forum is made possible through funding from Amgen.
The Formulary is the KEY

- List of drugs that insurance will pay for

So...

If an expensive medicine is not on formulary

No one will take it
Best Rebate (+ fees) Offer is WINNER

Rebate =

\[ \text{List Price} \times \% \text{ Discount} \times \# \text{ Scripts filled} \]

1) List price of the drug *
2) % Discount promised
3) # Scripts filled (Market share) *

An Increase In Any One Of These Variables
Better Chance At Preferred Placement
MANUFACTURERS COMPETE FOR THE PREFERRED SPOT...

What Is The Effect Of Competition On Drug Prices?

BUILDING A HOUSE
WINNER= Lowest Bidder

SELLING A HOUSE
WINNER= Highest Bidder

• PBMs receive rebates/fees based on a % of the list price of the medicine.
• These price concessions can be over 50% of the list price.
• This creates a perverse incentive for HIGHER PRICED MEDICINES, not lower, because the HIGHER PRICED MEDICINE can provide the larger rebate /fee package.
What about the...
Biosimilars Forum for Patients

Christine Simmon
Executive Director, Biosimilars Council
SVP, Policy & Strategic Alliances, Association for Accessible Medicines
JAMA on the Rebate “Wall”

Coverage of Biosimilars, U.S. Health Plans, 2019

- Reference product preferred over biosimilar: 53%
- Parity coverage: 33%
- Biosimilar preferred over reference product: 14%

In US physician dispensed drugs US ASP price decline linearly at 9% per year

% change in ASP

Quarters since biosimilar launch

Source: Redbook; CMS; Bernstein analysis
Biologics Price Competition and Innovation (BPCI) Act:
The biosimilars pathway 10 years later

Sarah Yim, M.D.
Director
Office of Therapeutic Biologics and Biosimilars
OND/CDER/FDA
**Key Definitions from the BPCI Act**

**Reference Product**
A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared.

**Biosimilar Product**
A biosimilar is a biological product that is highly similar and has no clinically meaningful differences from an existing FDA-approved reference product.

**Interchangeable Product**
- Is a biosimilar
- Expected to produce the same clinical result as the reference product (RP) in any given patient
- Switching between the proposed product and the RP does not ↑safety risks or ↓effectiveness compared to using the RP without switching
Standards for Interchangeable Biosimilar Products

- If determined to meet the defined standards, an interchangeable biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, subject to state laws.

- The additional information in an interchangeable application is intended to address the potential impact of immune reactions in the scenario of pharmacy-level substitution, because developing antibodies against the biologic product can sometimes cause loss of effectiveness or allergic reactions.
Why can’t a biologic be copied exactly?

The problem is not because of the copi-er, but the thing to be copied. So what are we trying to copy?
Cells can make exact copies of the protein, but after the protein is made, other add-ons and changes may occur

- Result: Millions of slightly different versions of the same protein or antibody per dose or batch

- Both reference products and biosimilars contain these variations

- Reference products try to keep a consistent mix of variants within a certain range, over time

- Biosimilars try to match the patterns and variations of the reference product
Q: Why can’t a biologic be copied exactly?

A: It’s not one thing, but a mix of versions of one thing, and it is never exactly the same.

(Exception: small proteins that are short strings of amino acids may be produced in one version and copied exactly)
### Biosimilars Approved by FDA in 2019

- **Ontruzant** (trastuzumab-dttb) - **Ruxience** (rituximab-pvvr)
- **Trazimera** (trastuzumab-qyyp) - **Hadlima** (adalimumab-bwwd)
- **Eticovo** (etanercept-ykro) - **Ziextenzo** (pegfilgrastim-bmez)
- **Kanjinti** (trastuzumab-anans) - **Abrilada** (adalimumab-afzb)
- **Zirabev** (bevacizumab-bvzr) - **Avsola** (infliximab-axxq)

### Biosimilars Approved by FDA in 2018

- **Retacrit** (epoetin alfa-epbx) - **Udenyca** (pegfilgrastim-cbqv)
- **Fulphila** (pegfilgrastim-jmdb) - **Truxima** (rituximab-abbs)
- **Nivestym** (filgrastim-aafi) - **Herzuma** (trastuzumab-pkrb)
- **Hyrimoz** (adalimumab-adaz)

### Biosimilars Approved by FDA in 2017

- **Renflexis** (infliximab-abda) - **Ogivri** (trastuzumab-dkst)
- **Cyltezo** (adalimumab-adbm) - **Ixifi** (infliximab-qbtx)
- **Mvasi** (Bevacizumab-awwb)

### Biosimilars Approved by FDA in 2016

- **Inflectra** (infliximab-dyyb) - **Amjevita** (adalimumab-atto)
- **Erelzi** (etanercept-szzs)

### Biosimilars Approved by FDA in 2015

- **Zarxio** (filgrastim-sndz)

**Highlighted = currently marketed**

### Reference Product

<table>
<thead>
<tr>
<th>Reference Product</th>
<th>Approved = 26</th>
<th>Marketed = 17</th>
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<tr>
<td><strong>Herceptin</strong></td>
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<td><strong>Avastin</strong></td>
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<td><strong>Epogen</strong></td>
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Biosimilars Action Plan (BAP)

1. Improving the efficiency of the biosimilar and interchangeable product development and approval process

2. Maximizing scientific and regulatory clarity for the biosimilar product development community

3. Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors

4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition
Improving the efficiency of the biosimilar and interchangeable product development and approval process

- Finalize Biosimilar-specific multidisciplinary review templates
- Publish product-specific recommendations for comparing proposed biosimilars and their reference products
Maximizing scientific and regulatory clarity for the biosimilar product development community

- Enhanced Purple Book
  - Continue enhancements and data updates
- Continue work on Biological Product Regulatory Modernization
Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors

- Continue development of new healthcare professional and stakeholder educational material in multiple media
- Updating FDA websites
- Continue direct outreach and education
- Expand staff involved in outreach and education
Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition

• FDA-FTC Joint workshop 3/9/20

• FDA-FTC Joint Statement 2/3/20
  - Described goals of the collaboration to advance competition in the biologic marketplace

• FDA Guidance 2/20
  - Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers

• CREATES (Creating and Restoring Equal Access To Equivalent Samples) Act 12/19
  - For products with REMS ETASU, developers obtain a Covered Product Authorization (CPA) letter from FDA
COVID-19 and FDA’s Work

• COVID-19 related submissions are voluminous and take priority
• The same review areas handling new drug and biologic submissions also handle biosimilar submissions
• Divisions involved in biosimilar work are receiving COVID-19 submissions
• Staff in low-COVID-19 areas are helping in high COVID-19 areas
• Non-COVID work is continuing based on remaining resources, and a prioritization approach
Resources

Visit:

• [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars) for access to all the education materials and information about biosimilar and interchangeable products.

• [https://purplebooksearch.fda.gov/](https://purplebooksearch.fda.gov/) The Purple Book: Database of Licensed Biological Products for information on biological products, including if products are biosimilar to a reference product.

• [www.fda.gov/drugsatfda](http://www.fda.gov/drugsatfda) ([Drugs@FDA](http://www.fda.gov/drugsatfda)) for information on all FDA approved drug products, including labeling and review information.

Back up
What are Biosimilars?

- Biosimilars are FDA-approved, biologic medications that are compared to another medication – the original biologic (also called a reference product).

- Biosimilars are made with the same types of natural sources as the original biologic they were compared to – and provide the same treatment benefits.
Biosimilarity vs Interchangeable Biosimilarity

- Interchangeable biological products are not yet available in the United States
- Interchangeable products are pharmacy substitutable without intervention of the prescribing health care provider, subject to state laws.
- Different statutory criteria reflect the different scientific considerations for biologic products that may be administered more than once
- Business considerations also may influence applicants’ decisions about which type of licensure to seek.
Biosimilars may provide patients with **more access** to important treatments.
Amgen Biosimilars: Global Policy Presentation

Experience That Can’t Be Replicated

Advancing policies that support innovation and competition to promote a robust and sustainable marketplace with biosimilars
Amgen is developing biosimilar products in key therapeutic categories

Biosimilar Pipeline
Therapeutic Areas

- Oncology
- Hematology
- Chronic Inflammatory Diseases

Amgen Biosimilars Program
10 Medicines in Portfolio
Elements crucial to fostering a robust and sustainable marketplace with biosimilars over the long term

- Stakeholder confidence requires scientifically appropriate regulatory standards
- A marketplace that encourages competition allows for meaningful savings and long-term sustainability
- Scientifically accurate educational outreach supports market success
- A successful marketplace requires a foundation of intellectual property
Thank you
For more information:

Visit www.AmgenBiosimilars.com
Engage with us on Twitter @AmgenBiosim
Connect with me on LinkedIn
Value in Innovation Forum

Please send suggested topics for future briefings to Jen.Childress@NationalForum.org

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