The Promise of Biosimilars

Workshop Report

Strategies to reduce drug spend, improve healthcare access, and achieve better value

October 20, 2022

DFWBGH Biosimilars Workshop

The Promise of Biosimilars: Strategies to reduce drug spend, improve healthcare access, and achieve better value

October 20, 2022

Participants:

17 Benefits Specialists from 10 DFWBGH Employers:

- 7-Eleven, Inc
- BNSF
- City of Fort Worth
- City of Plano
- DART
- Fluor, Inc.
- Frisco ISD
- Greyhound Lines, Inc.
- Team Car Care/Jiffy Lube

Speaker: Alex Jung, Benefits Consultant

Key Discussion Issues:

- Understanding the value of Biosimilars
- Understanding the difference between Biologics & Biosimilars
- Biosimilars pipeline
- Breaking down barriers to adoption
- Ensuring availability on formulary
- Role of Precision Medicine
- Offsetting the impact of rebates

Making the Case for Biosimilars

- Prescription drugs account for nearly 25% of employers' total healthcare costs, which are expected to climb 6.5% in 2023, according to a recent Aon report.
- One of the biggest drivers is expensive biologics that make up just 2% of prescriptions, but account for 40% of employers' total drug spend.
- **Enter Biosimilars**, which are lower-cost, FDA-approved biologic drugs, as safe and effective as branded biologics, to treat a range of high-cost conditions, including cancer, arthritis, Crohn's disease, kidney disease, eye disease, and others.
- However, many employers have limited understanding of biosimilars and their important role in effective treatment for high-cost conditions and in pharmacy cost control.

Pharma Overview

Generic

- Can be administered in any modality (most commonly oral solid "pills"

Brand

- Can be administered in any modality (most commonly oral solid "pills"
- Patent protected and can be extended into new diseases

Administration

- Oral solid "pills"
- Oral gel "pills"
- Oral liquid (e.g., Rx cough syrups)
- Liquid subcutaneous under the skin (a small dose shot)
- Liquid injectable in the vein (antibiotic or vaccine)
- Liquid infusible in the vein (chemotherapy)

Brand

Non-Specialty

- High BP, cholesterol, diabetes
- Example biosimilar is Semglee which replaces Lantus

Specialty

- MS, RA, HepC, HIV Oncology
- Example biosimilar is Inflectra which replaces Remicade

How are Generics Different from Biosimilars?

Parameters	Generics	Biosimilars
Characteristics	Small molecules. Low molecular weight and complexity	Complex macromolecules. High molecular weight, complex 3-D structure
Manufacturing	> Type of production: Chemical synthesis, simple microbial fermentations or simple analytical process > Not very sensitive to production process changes > Reproducibility easy to establish > Very low manufacturing cost	> Type of production: Genetically modifies cell lines, fermentation and purification complex procedures, or complex analytical methods > Reproducibility difficult to establish relative to generics; however, less difficult compared with originators > Sensitive to production process changes and manufacturing changes > High manufacturing cost
Clinical Studies	Limited clinical activities, often only Phase I trials	Only Phase I & III trials required excluding Phase II studies, however, pharmacovigilance and periodic safety updates after launch are needed.
# of Patients	20-50 Patients	~ 500 Patients
Time to Market	2-3 Years	7-8 Years
Development Costs	US: $2-3 Million	US: $100-$300 Million
Success Probability	90-99%	50%
Regulatory Process Requirements	> To be approved as a generic, a drug must have the same active ingredient, strength, dosage form, and route of administration as the reference drug; furthermore, it needs to demonstrate bioequivalence with the reference medicinal product through appropriate bioavailability studies > Automatic substitution allowed > Abbreviated registration procedures in EU and US	Biologics Price Competition and Innovation Act, 2009 in the US > II dimensions of approval: biosimilarity and interchangeability > Market exclusivity for reference product - 12 years > Market exclusivity for first biosimilar product – 12-14 months > Interchangeable product can be substituted without authorization from health care providers > Regulatory pathway defined in the EU (BLA), not yet in the US > No automatic substitution intended > Needs to demonstrate “comparability

Biologics vs. Biosimilars

- **Biologic drugs** are large, complex proteins made from living cells through highly complex manufacturing processes. Unlike generic drugs, which are copies of chemical drugs, a biosimilar is a copy of a biologic medicine that is similar, but not identical, to the original medicine.

- Not all Biosimilars are specialty drugs. The FDA approved the first interchangeable biosimilar insulin product, for Type 1 diabetes & Type 2 diabetes mellitus.
  - **Semglee** (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for) its reference product **Lantus** (insulin glargine), a long-acting insulin analog.
  - **Semglee** is the first interchangeable biosimilar product approved in the U.S. for the treatment of diabetes.

Biologics vs. Biosimilars *(continued)*

- **Interchangeability** is defined by statute in the United States to mean that the product may be substituted for the reference product without the intervention of the physician who prescribed the reference product. The legal standard for interchangeability is an additional standard beyond demonstration of biosimilarity.

- According to guidance issued by the FDA in May 2019, in order for a biological product to be deemed interchangeable, the information submitted must be sufficient to show that:

  - The biological product is biosimilar to the reference product and can be expected to produce the same result as the reference product in any given patient.
  - For a biologic product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Biologics vs. Biosimilars *(continued)*

- In the United States, although Federal law gives the FDA authority to license biologic products as **interchangeable**, it is the state laws that govern the substitution of biologics and pharmaceuticals.

- A number of states have passed laws that allow for substitution at the pharmacy counter, without consulting the prescribing physician, only if the biological product has been designated as interchangeable by FDA. In effect, an FDA interchangeability designation is a prerequisite for **pharmacy-level substitution.**

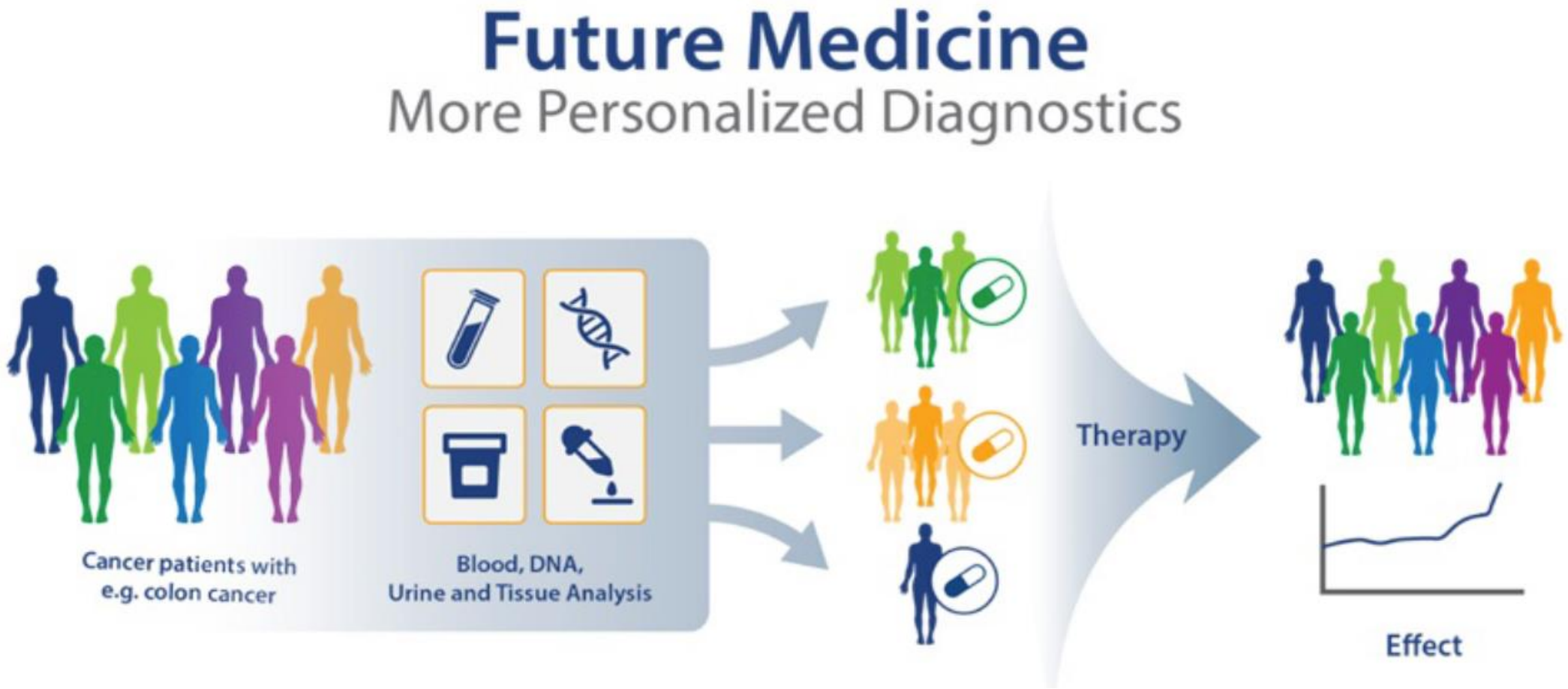
We are No Longer in Population Health…We are Moving to Precision Medicine

- A form of medicine that uses information about a **person's own genes or proteins to prevent, diagnose, or treat disease.** In cancer, precision medicine uses specific information about a person's tumor to help make a diagnosis, plan treatment, find out how well treatment is working, or make a prognosis.

- Examples of **precision medicine** include using targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose cancer. **Also called personalized medicine.**

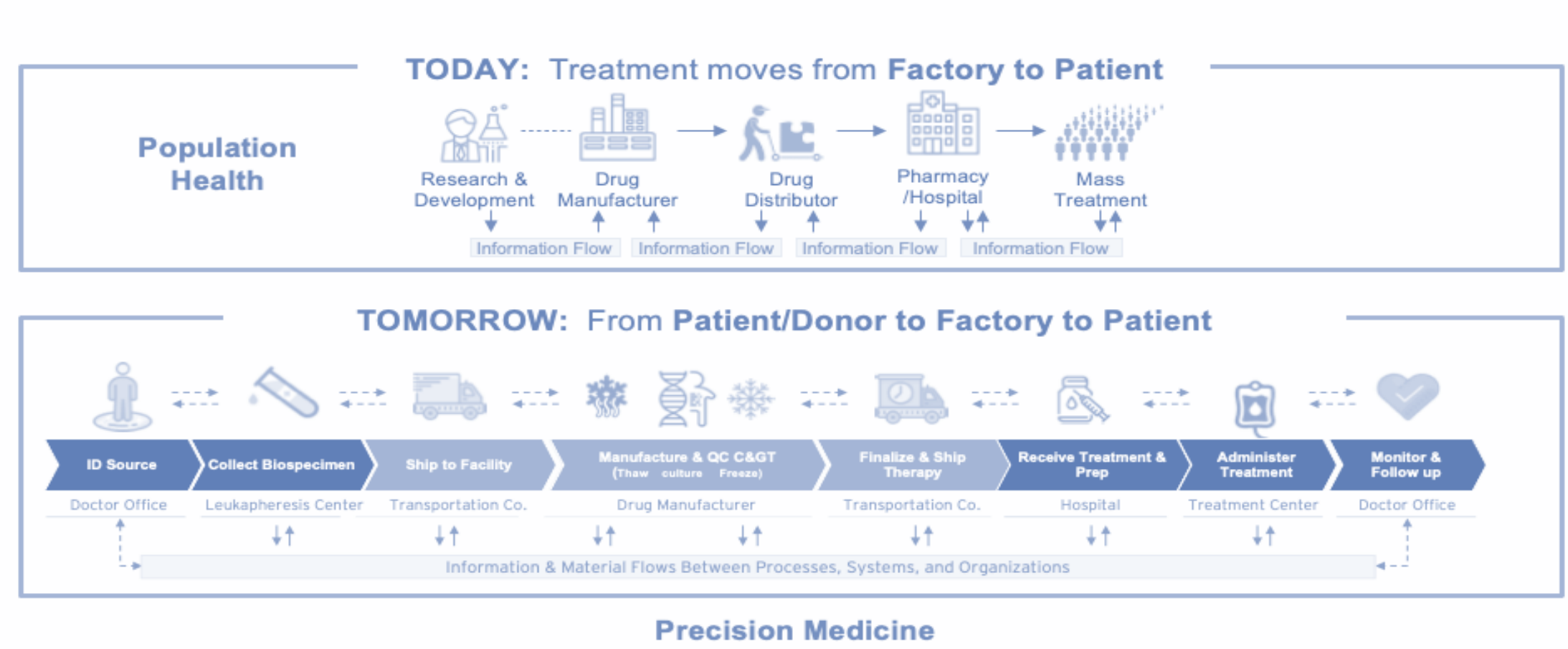
Source: NIH | National Cancer Institute

Future: Precision Medicine



Key Supply Chain Market Trends

Many emerging therapies will also require changes to the supply chain model, with implications for various stakeholders in the traditional pharmaceutical value chain



Biomarkers and Testing

- A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A **biomarker** may be used to see how well the body responds to a treatment for a disease or condition. Also called molecular marker and signature molecule. Biomarker testing is an important part of **precision medicine**, also called **personalized medicine.**

- For **cancer** treatment, **precision medicine** means using biomarker and other tests to select treatments that are most likely to help you, while at the same time sparing you from getting treatments that are not likely to help.

- A sample of your cancer cells will be taken. If you have a solid tumor, they may take a sample during surgery. If you aren't having surgery, you may need to have a biopsy of your tumor.

Source: NIH | National Cancer Institute

Biomarkers and Testing *(Continued)*

- If you have blood cancer or are getting a biomarker test known as a liquid biopsy, you will need to have a blood draw. You might get a liquid biopsy test if you can't safely get a tumor biopsy, for example, because your tumor is hard to reach with a needle.

- Your samples will be sent to a special lab where they will be tested for certain biomarkers. The lab will create a report that lists the biomarkers in your cancer cells and if there are any treatments that might work for you.

- The results of a biomarker test could show that your cancer has a certain biomarker that is targeted by a known therapy. That means that the therapy may work to treat your cancer.

- The results could also show that your cancer has a biomarker that may prevent a certain therapy from working. This information could spare you from getting a treatment that won't help you.

- Some biomarker tests can find genetic changes that you may have been born with (inherited) that increase your risk of cancer or other diseases.

Source: NIH | National Cancer Institute

How Many Approvals and Launches in the U.S. Biosimilar Market to Date?[3]

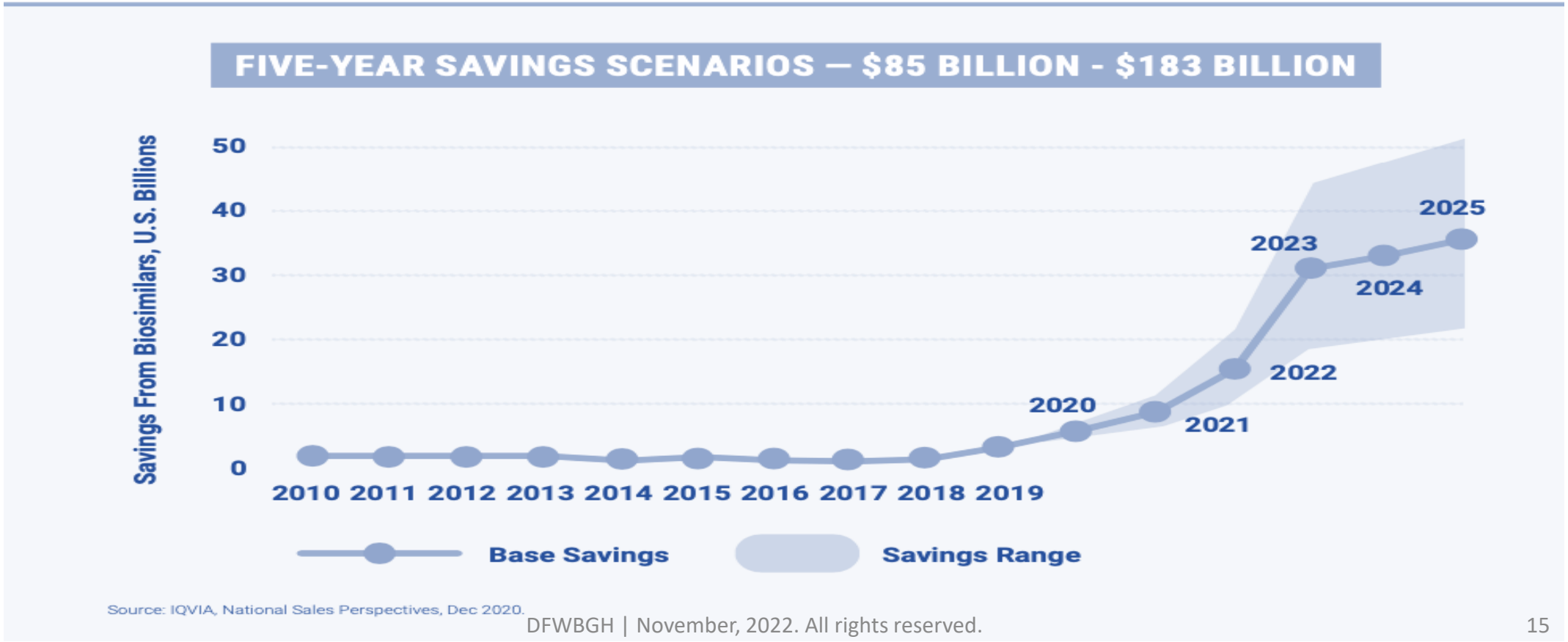
39 Approvals

24 Launches

What are the Projected Savings by 2025 with Biosimilars?[4]

Biosimilars Are Projected to Provide $133 Billion in Savings by 2025

SAVINGS WILL DEPEND ON APPROPRIATE POLICIES TO SUPPORT ADOPTION

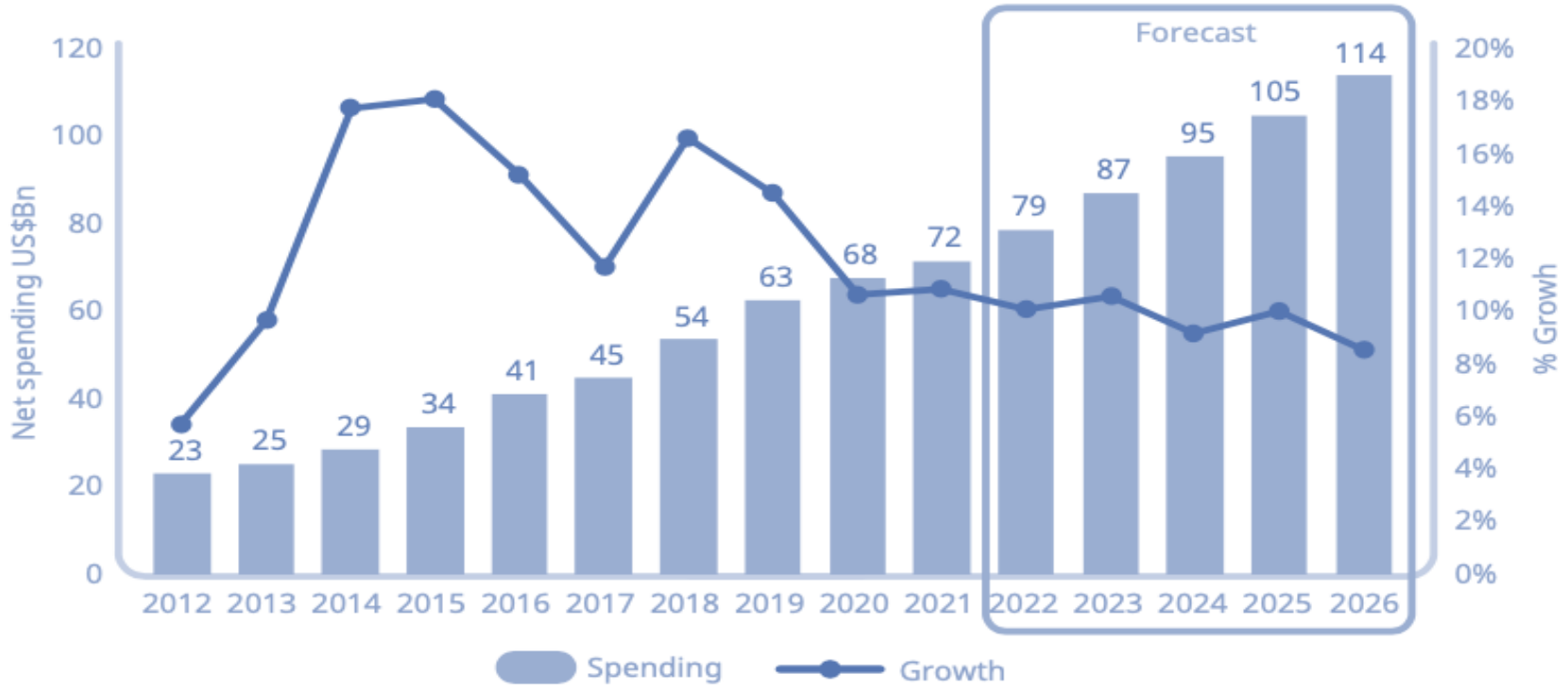


Source: IQVIA, National Sales Perspectives, Dec 2020.

Will U.S. Oncology Spending Slow with Biosimilars?[5]

U.S. oncology spending to reach $114Bn by 2026, with growth slowing to 10% from biosimilar savings

Exhibit 44: Oncology spending at estimated manufacturer net prices, US$Bn



2022–2026 Key metrics

- **+59% total spending growth (8–11% CAGR)**
- **+$42Bn by 2026**
- **~+100 new oncology drugs**

Source: IQVIA Institute, Mar 2022.

What Changes Could We See with Oncology Uptake of Biosimilars?[6]

- Oncologists' have had positive perceptions of Biosimilars, but uncertainty lies ahead due to the changing value-based care landscape.
- The **Oncology Care Model** (OCM), a value-based care payment model, pays some cancer clinics via a reimbursement system that incentivized doctors to use lower-price drugs.
- As of June 30, 2022, 126 practices and five commercial payers participated in the program according to CMS, including the U.S. Oncology Network, owned by McKesson.
- The Centers for Medicare & Medicaid Services (CMS) has announced a new, voluntary alternative payment model, to replace the Oncology Care Model (OCM) that ended on June 30, 2022.
- The OCM's successor is the **Enhancing Oncology Model** (EOM), will not begin until July 1, 2023 and will last for 5 years.
- Oncology practices may see a gap for as long as 12 months, which could result in prescribing patterns reverting to prior brand preferences.

Four Strategies Employers May Use to Promote and Manage Biosimilars

- Increase understanding of Biosimilars by health plan members and healthcare providers (Use participant education & provider incentives)
- Adopt Clinical Management Programs (Medical channel management, site-of-care management, etc.)
- Design the payment features of prescription drug benefits (Plan design and formulary strategy)
- Address Biosimilars when negotiating PBM contracts (Manufacturer rebates, value-based pricing, inflation-protection caps)

Source: Employer Strategies or Use of Biosimilar Pharmaceuticals prepared for The ERISA Industry Committee (ERIC) by Segal, March, 2020

What Can Employers Do to Include Biosimilars on Formulary?

- Insist on **preferential coverage** for lower-priced alternatives on formularies. This will force the market to lower prices of biosimilars. Insurers and PBMs tend to prefer more expensive medicines over lower-cost alternatives like biosimilars.
- **Carve-out** your specialty benefits and in your contract language – specify the "pass-through" of the spread, rebates, etc. go to you.
- Ensure that Biosimilars are included in rebate payment calculations.
- Include biosimilars in their pharmacy benefit strategy.
- Identify which PBMs are promoting greater use of Biosimilar drugs and include Biosimilar provisions and competitive payment features in PBM contracts.
- Employers could see a 50% decrease in pharma spend.

DYK: Did You Know?[6]

- For years, copycat competition failed to significantly lower the costs of some of the best-selling prescription medicines in the U.S.
- Years of disappointment followed, as new competitors were either blocked from entering the market or unable to gain traction once they got there.
- The arrival of biosimilars in areas like cancer and autoimmune disease, where the annual cost of brand name drugs can exceed $100,000 annually, has given patients, doctors and insurers added incentive to make the switch.
- The first wave of biosimilars has also been held back by aggressive rebating and pricing strategies by branded drugmakers, as well as insurer policies that together helped nullify the 15% to 30% discounts typically offered at first by the copycat drugs.

DYK: Did You Know?

- A tsunami of options will bring the costs of Biosimilars down.
- Biosimilars in most cases will be under the medical benefit and will be bundled in the unit bill.
- Biosimilar discontinuation rates are high, but similar to reference biologics.[7]
- The FDA considers Biosimilars highly similar but not interchangeable with reference biologics, unless it specifically grants that status after switching studies and a review.
- Doctors and healthcare institutions can make substitutions as they like. Once a drug is labeled interchangeable, pharmacists can then substitute without a physician's permission, subject to individual state rules.[8]

DYK: Did You Know?[10]

- Although there has been stronger use of Biosimilars in oncology, the payer landscape continues to be complex, with formulary decisions that challenge the uptake and management of Biosimilars and policies varying across plans.
- Biosimilars will expand into new therapeutic areas including growth hormone, infertility, bone health, and immunosuppressants.
- Adoption of biosimilars will depend on education, payer influence, and price.
- Biosimilar adoption can be affected by three general areas: education and/or misinformation, provider reimbursement and health plan formulary decisions.
- As such, policies are needed to continue provider and patient education and combat misinformation about biosimilars, while providing appropriate incentives for provider and plan adoption.

References

1. Humira rings up $20.7B in 2021, but AbbVie still mum on post-biosimilar expectations, By Kevin Dunleavy, Published in Fierce Pharma, Feb. 2, 2022

2. As Congress weighs drug price restraints, ICER calls out ‘unsupported’ increases, By Jonathan Gardner, Published in BioPharma Dive, Nov. 16, 2021

3. U.S. Biosimilar Report, AmerisourceBergen, Oct. 17, 2022

4. IQVIA, National Sales Perspectives, Dec. 2020

5. IQVIA Institute: The Use of Medicines in the U.S. 2022

6. Can biosimilars, after years of limited impact, finally make a mark in the US?, By Jonathan Gardner, Published in BioPharma Dive, Sept. 7, 2022

7. Biosimilar Discontinuation Rates Are High But Comparable to Those for Reference Biologics: Review, By Tony Hagen, Published in Managed Healthcare Executive, Sept. 14, 2022

8. How the Inflation Reduction Act May Affect Biosimilars, By Tony Hagen, Published in Managed Healthcare Executive, Sept. 13, 2022

9. Hadlima is Getting Into Interchangeability Game, By Tony Hagen & Peter Wehrwein, Published in Managed Healthcare Executive, Oct. 7, 2022

10. 2022 Biosimilars Report: The U.S. Journey and Path Ahead, Cardinal Health

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