Steps to Reducing Barriers to Biosimilars in the United States

Alex Brill

Matrix Global Advisors

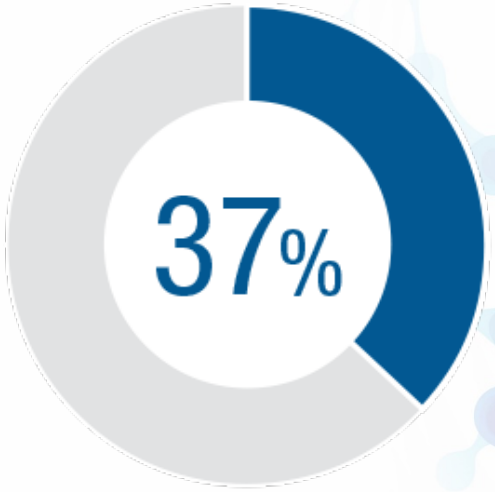
GRx+Biosims 2018 | Baltimore, MD | September 6, 2018

Overview

- Biosimilars Landscape
- Barriers to Biosimilars by Category
    1. *Reference Product Manufacturers*
    2. *Biosimilar Manufacturers*
    3. *Policy*
    4. *Stakeholder Education and Awareness*
- Tipping Points for Biosimilars
- Strategies for Overcoming Barriers

Landscape: U.S. Sales of Reference Biologics

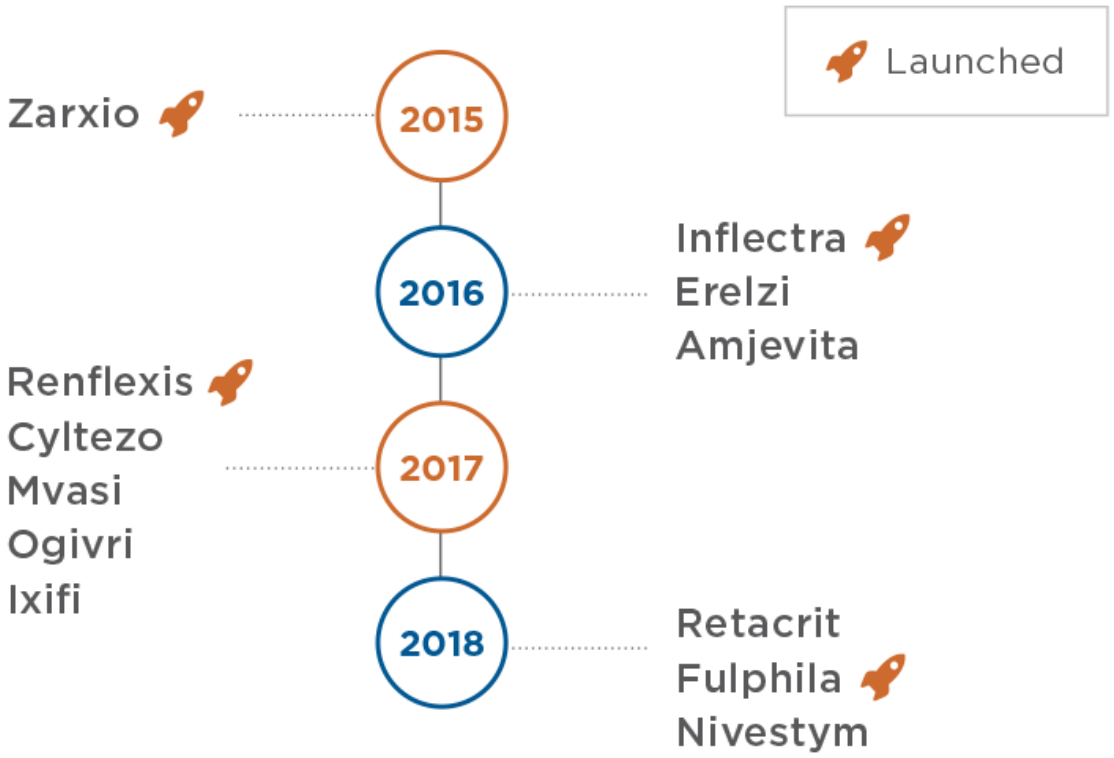
U.S. BIOLOGICS SALES



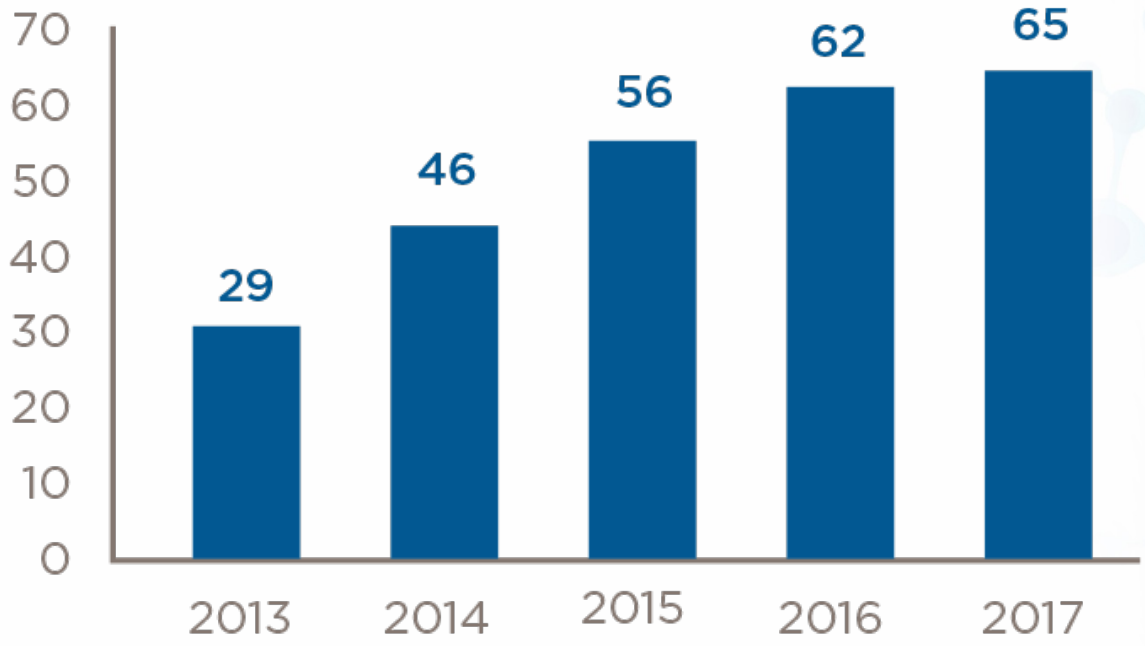
BIOLOGICS SALES AS SHARE OF TOTAL U.S. DRUG MARKET

Source: IQVIA Institute for Human Data Science.

Landscape: U.S. Biosimilars Approved



Landscape: U.S. Biosimilars in Development



Source: FDA.

Barriers to Biosimilars by Category

#1: Reference Product Manufacturers

- Rebate practices
- Lifecycle management (e.g., late-stage patents)

#2: Biosimilar Manufacturers

- Market uncertainty
- Limited discounting and low volume

Barriers to Biosimilars by Category

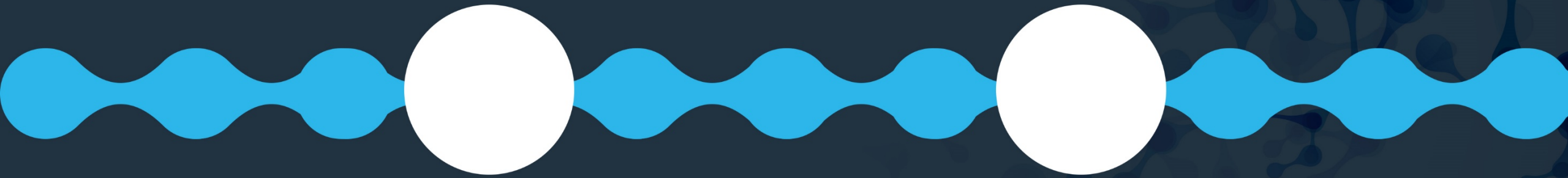
#3: Policy

- Patent thickets
- FDA guidance

#4: Stakeholder Education and Awareness

- Lack of education and awareness
- Limited prescribing experience

Tipping Points for Biosimilars



Market, regulatory, legal, perception, and reimbursement issues are reduced so biosimilars can enter the market with ease

Sufficient competition to a reference biologic exists to achieve meaningful savings

Strategies to Overcome Barriers, by Category

#1: Reference Product Manufacturers

Brand biologics manufacturers use contracting practices and lifecycle management strategies to protect market share, including penalties for customers who move patients to a biosimilar and additional patents late in a reference product's life

Strategies

- **Payors:** Adopt longer-term perspective in contracts/formularies
- **Employers:** Identify cost-saving opportunities
- **Policymakers:** Ensure fair market access for biosimilars

Strategies to Overcome Barriers, by Category

#2: Biosimilar Manufacturers

Biosimilars are expensive to develop, the market is uncertain, and biosimilars' price discounts at launch have not been steep enough to capture market share

Strategies

- **Payors:** Institute policies to drive biosimilar utilization
- **Biosimilar manufacturers:** Offer competitive contracting terms
- **Employers:** Require biosimilar coverage in contracts

Strategies to Overcome Barriers, by Category

#3: Policy

The threat of patent litigation can deter biosimilar development; lack of guidance on interchangeability and state restrictions on substitution will limit development

Strategies

- **Congress:** Limit frivolous late-stage patents
- **FDA:** Continue to support and clarify interchangeability

Strategies to Overcome Barriers, by Category

#4: Stakeholder Education and Awareness

Physicians, patients, and employers lack awareness about the safety of and savings opportunity from biosimilars

Strategies

- **Biosimilar manufacturers:** Provide patient and physician education
- **Payors:** Incentivize stakeholders to gain experience
- **Employers:** Share biosimilar savings with employees
- **Policymakers:** Promote biosimilars as safe and effective

Thank you.

Alex.Brill@GetMGA.com