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Association for Accessible Medicines

The Biosimilars Council
A Division of the Association for Accessible Medicines

Leading on Biosimilars

2017 AAM Biosimilars Council Conference

Bruce Leicher

Chair, Board of Directors, The Biosimilars Council
General Counsel, Senior Vice President and Secretary
Momenta Pharmaceuticals, Inc.

Clear Progress for Biosimilars in the U.S.

- FDA Draft Guidance on Interchangeability Published
- Biosimilar User Fees Enacted
- Approvals and Reviews Underway
- Patent Dance Resolution
- Barriers to Biosimilars Under High-Level Scrutiny
- Reimbursement Issues
- Stakeholder Engagement

FDA Guidance on Interchangeability

- The FDA issued draft guidance on interchangeability on Jan. 12, 2017. The Council has submitted comments and is generally supportive, however, there are a few areas for improvement:
    - Ensure the guidance tracks the BPCIA to facilitate innovation of biosimilar science
        - The BPCIA statute does not prescribe the type or amount of information required to make any of the specific showings required for an interchangeability determination.
        - It delegates to the FDA the discretion to determine whether the "information" submitted is "sufficient" on a case-by-case basis depending upon the specific product in question.
    - Complexity of biological products varies widely.
        - We support flexibility in the guidance for variation in the type and amount of data required to demonstrate both biosimilarity and interchangeability.
    - Ensure testing to demonstrate interchangeability is tailored to what is scientifically necessary and does not replicate or exceed what is required to obtain approval of a novel biologic BLA.
        - Excessive testing would erect significant barriers to the development of interchangeable biological products and deter interchangeable applications.

Biosimilar User Fee Act II (BsUFA II)

Enhancements Over BsUFA I

- Program review model adopted
  - Significant regulatory enhancement
  - Greater opportunity for communication and first cycle approvals
- Meeting management enhanced
  - FDA feedback in advance of meetings
  - Timing for various meetings was adjusted to improve performance
- FDA committed to complete important guidances
- User fee adjustments
  - Tied to actual biosimilar program costs (BsUFA I was tied to PDUFA)
  - No establishment or supplement fees
- FDA commits to hiring staff to work on biosimilars;
  - 15 FTEs dedicated to biosimilar coordination and policy, plus additional review staff
- Modernization of FDA resource tracking allocated to biosimilar program
- Annual meeting to review status of BsUFA finances.
- **<u>Supports a sustainable and competitive market for biosimilars for patients</u>**

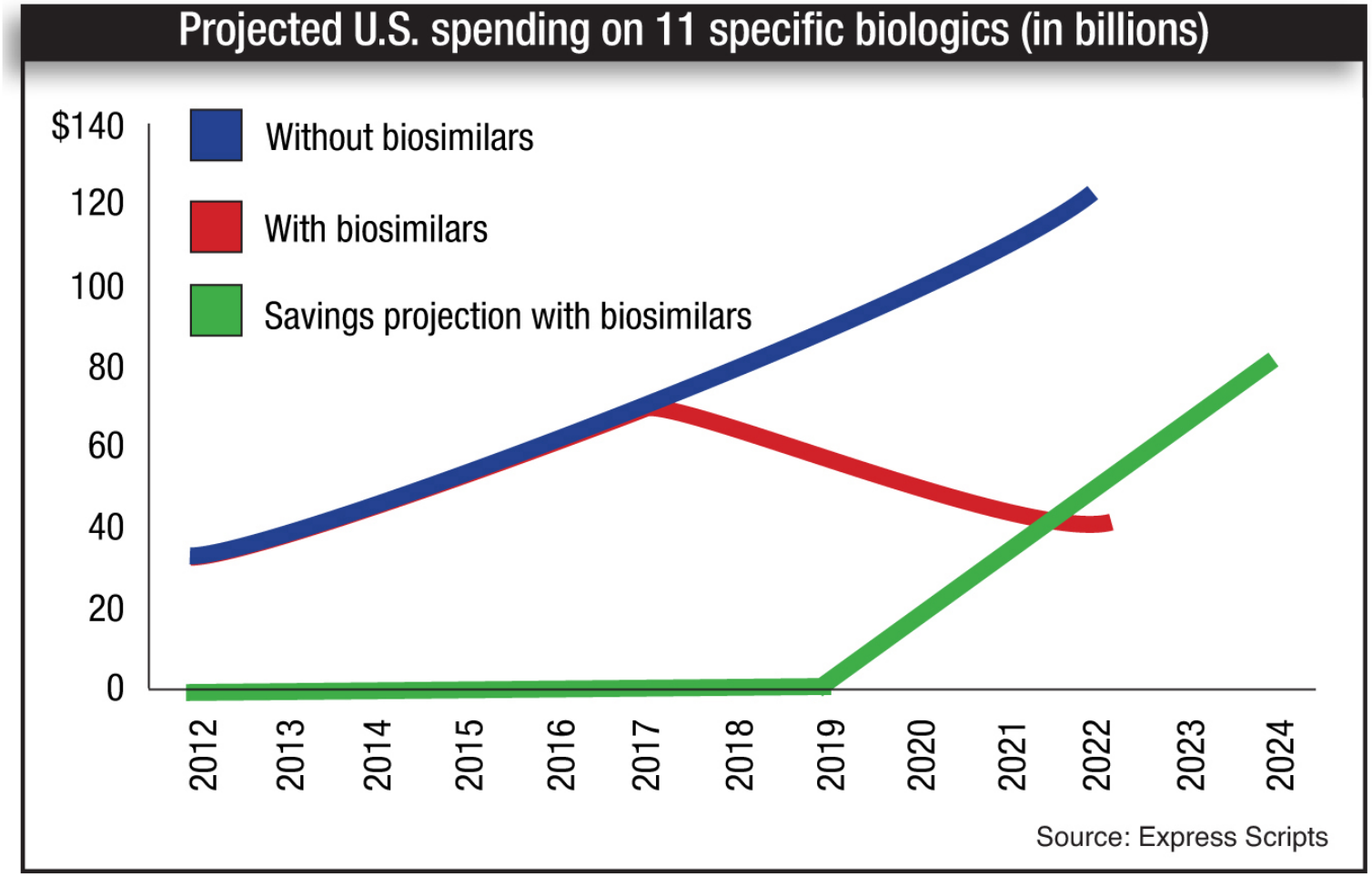
Biosimilar Approvals in the U.S.

To date, FDA has approved 6 biosimilar applications in the U.S. with more than 60 potential biosimilars in various stages of development and review:

Approval Date	Biosimilar Product	Brand Product	Patient Population
March 6, 2015	Filgrastim-sndz/Zarxio* (Sandoz)	Filgrastim/Neupogen (Amgen)	Oncology
April 5, 2015	Infliximab-ddyb/Inflectra* (Celltrion/Pfizer)	Infliximab/Remicade (Johnson & Johnson)	Autoimmune
August 30, 2016	Etanercept-szzs/Erelzi (Sandoz)	Etanercept/Enbrel (Amgen)	Arthritis/Psoriasis
September 23, 2016	Adalimumab-atto/Amjevita (Amgen)	Adalimumab/Humira (AbbVie)	Arthritis/Psoriasis
April 24, 2017	Infliximab-abda/Renflexis* (Samsung Bioepis)	Infliximab/Remicade (Johnson & Johnson)	Autoimmune
August 25, 2017	Adalimumab-adbm/Cyltezo (Boehringer Ingelheim)	Adalimumab/Humira (AbbVie)	Autoimmune

*Due to ongoing litigation intellectual property disputes, Zarxio, Inflectra and Renflexis are the only products currently marketed in the U.S.

Biosimilars Offer Significant Opportunity for Savings



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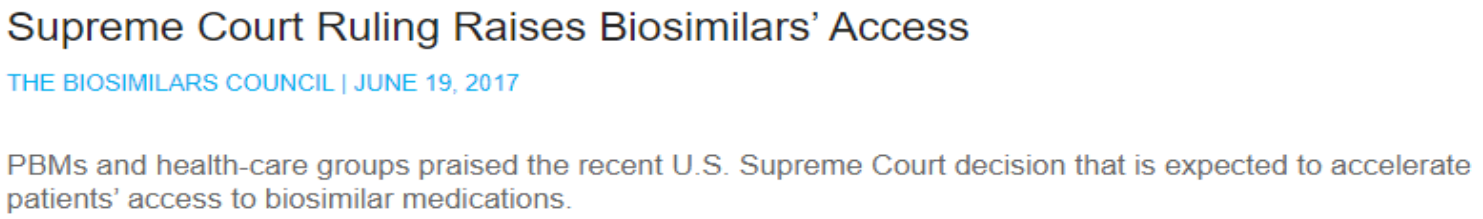
“Patent Dance” Views Confirmed by Supreme Court in Sandoz v. Amgen



Supreme Court Ruling Raises Biosimilars’ Access

THE BIOSIMILARS COUNCIL | JUNE 19, 2017

PBMs and health-care groups praised the recent U.S. Supreme Court decision that is expected to accelerate patients’ access to biosimilar medications.

Patent Dance Requirements

- The BPCIA allows ABLA applicants to elect to share the ABLA with the originator BLA holder in order to engage in a “patent dance” and pre-approval litigation.
- The Supreme Court confirmed this exchange is not mandatory but a condition precedent to the right to litigate prior to approval under the BPCIA

Notice Requirements

- The Supreme Court confirmed that a biosimilar applicant can provide the 180 day notice of commercial launch prior to approval of the ABLA.
- The reading is consistent with the clear intent to have 12 year limit to reference product regulatory exclusivity.

Persistent Barriers to Biosimilar Development Under Scrutiny

- The Council supports passage of legislation that will eliminate barriers to biosimilar development, including:
  - Restrictions on reference product distribution
  - Abuse of FDA Risk Evaluation and Mitigation Strategy (REMS) programs
- Restricted access blocks biosimilars development and patients are denied access to life saving, affordable medicines.
- Anticompetitive abuse of REMS and restricted distribution systems affect approximately 120 products that total $30 Billion per year in costs.

CREATES Act

"**C**reating and **R**estoring **E**qual **A**ccess to **E**quivalent **S**amples Act of 2017" (CREATES) was introduced by bi-partisan Senate & House members.

- Addresses restricted access to reference products and REMS abuses
- Empowers courts to award damages that would incentivize good-faith dealing.
- Ensures patient safety by requiring authorization from FDA for sample recipients.
- Congressional Budget Office (CBO) unofficially scored it as a $3.3 billion saver.
- House Judiciary Committee held a hearing highlighting the REMS issue and CREATES.
- Similar legislation addressing the REMS issue also introduced in the House.

FDA Public Meeting
"The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access"

- On July 18, 2017, FDA's new Commissioner, Scott Gottlieb, convened a public meeting to discuss barriers to affordable medicine competition, with biosimilars development being a major theme
- Commissioner Gottlieb stated FDA will focus on expediting the process of bringing affordable medicines to market, including
    - Addressing Restricted Access and REMS Abuse
    - Accelerating review and approval of affordable medicines
    - Taking regulatory action to remove barriers to affordable medicine approval
- Significant Public Participation and Support

Reimbursement Policy

- Federal payment policy is emerging
- Now is the time to engage with the Biosimilars Council regarding:
  - Medicare Part B – coding and payment
  - Medicare Part D
    - E.g., Coverage Gap Discount Uncertainty
  - Medicaid Rebates

The Biosimilars Council Stakeholder Engagement Atlantic Events Series

- Series of three Atlantic***LIVE*** events underwritten by the Council aimed at educating a wide variety of stakeholders around the issue of biosimilars and the Council.
- Speakers included Members of Congress, Industry Leaders, and other prominent members of the biosimilars community.

AtlanticLIVE

The Next Drugs Series

Total Series Impact

340+
in-person attendees

545+
tweets on #ATLPoliticsPolicy

2.8K+
total video views

3.6K+
website page views

346K
social accounts reached

2.3M+
social media impressions

AtlanticLIVE

Audience Feedback: Event Reactions

How would you describe the event?

100%
left the event feeling more knowledgeable about the topic

86%
substantive

73%
editorially balanced

100%
relevant to their work

*Source: Post-event survey distributed on-site and online; response rate of 28%

Building on Biosimilars Momentum

- With the biosimilars market in the U.S. positioned to explode over the next decade, and the potential of billions of dollars in savings and expanded access for patients, now more than ever is it time to lend your voice and engagement.
- Stay Connected with The Biosimilars Council
  - biosimilarscouncil.org
  - @BiosimsCouncil
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Thank You.

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