Biosimilars 20/20
The Future is at Hand

Welcome to Biosimilars 20/20, presented by the Specialty Pharma Education Center (SPEC) in partnership with the Specialty Pharma Journal (SPJ). Please note that this is a preliminary agenda that is subject to change and will be updated regularly on the conference website, **biosimilars.specialtycme.org**.

If you have any specific questions on any of the sessions or conference programming in general, please email us at **info@specialtycme.org**.

Wednesday, June 3

1:00 - 1:45 PM

Biosimilars Pipeline Update: A look into the Future

Due to the recent FDA approval of the first biosimilar in the United States and the anticipated future growth of biosimilars in the US market, industry stakeholders are focused on what compounds will be next to receive FDA approval. This session addresses upcoming biosimilars, organizations championing biosimilar development and the anticipated sequence of biosimilar approvals.

By attending this session, you should be able to:
- Identify current and upcoming biosimilar therapeutics
- Describe and evaluate which products are in late-stage development
- Review which organizations and companies will be spearheading development
- Describe the expected sequence of biosimilar approvals and compare that to parent drug volume/sales

Speakers

- **Ronny Gal**, PhD
  Senior Analyst, **Sanford C. Bernstein & Co.**

2:00 - 3:15 PM

Regulatory and Legal Challenges in Commercializing Biosimilars in the US

Stakeholders within the US biosimilar market are facing challenges regarding key biosimilar legislation. During the session, panelists will elaborate on such topics, including state adoption of biosimilar substitution laws, issues faced by pharmacies dispensing biosimilar drugs, patent litigation and related FDA guidance/interpretations.

By attending this session, you should be able to:
- Review U.S. Food and Drug Administration (FDA) guidelines and impact on clinical testing
- Describe FDA's lower-cost approval pathway requirements and its "Purple Book" function and utility
- Describe the implications of Biologics Price Competition and Innovation (BPCI) Act
- Review the existing and potential Board of Pharmacy regulations across the U.S.
- Evaluate state regulations for biosimilars, including state guidance that predates Federal guidance
- Consider operational and legal issues for pharmacies dispensing biosimilar drugs
- Evaluate biosimilars in regards to the Patient Protection and Affordable Care Act (PPACA)
- Discuss challenges faced by European Medicines Agency (EMA) that can be expected in the U.S.

Moderator

- **Thomas Sullivan**
  President, **Rockpointe Corp.**

Speakers

- **Steve Miller**, MD, MBA
  Senior Vice President, Chief Medical Officer
  Express Scripts, Inc.
- **Gillian Woollett**, MA, D.Phil
  Senior Vice President, **Avalere Health**

3:15 - 4:15 PM

Challenges Related to Interchangeability of Biosimilars

The FDA's rigorous interchangeability standards has produced challenges related to attaining an "interchangeable biological product" designation. This presentation will review the differences in biologics and interchangeable biologics, effects of blinded clinical trials and cost considerations.

By attending this session, you should be able to:
- Discuss challenges related to interchangeability of biosimilars
- Define biosimilars and how they will fit in the US market
- Describe the difference between biologics and interchangeable biologics
- Discuss the effects of blinded clinical trials on interchangeability
- Review the cost difference between interchangeable biological drugs to other biologics

Speakers

- **Jeffrey Casberg**, MS, RPh
  Director of Clinical Pharmacy, **IPD Analytics**
- **Steven Lucio**, PharmD, BCPS
  Senior Director, **Novation**

4:30 - 5:30 PM

Challenges Hindering Advancement & Approvals of Biosimilars in the United States

Advancement of biosimilars in the US marketplace will require overcoming multiple challenges to gain adoption and acceptance. This session will include a presentation followed by a panel discussion focusing on licensing and price competition, naming conventions, formulary decisions and administration devices relative to innovator patents.

By attending this session, you should be able to:
- Describe challenges facing implementation of Biosimilars
- Describe how to overcome licensing and price competition
- Describe strategies for formulary decisions relative to biosimilar market entries
- Discuss the challenges of naming conventions in advancing Biosimilars in the U.S.
- Describe the impact of administration devices with biosimilars and the patents owned by the innovator, i.e. auto-injectors

Presenters

- **Steve Miller**, MD, MBA
  Senior Vice President, Chief Medical Officer
  Express Scripts, Inc.
- **Robert Stianchi**, MBA
  Director of Market Research, **Merck**

Panel members

- **Saurabh Aggarwal**, PhD
  Principal & Co-Founder,
  Novel Health Strategies
- **Nailesh Bhatt**
  Founder & Managing Director, **Proximare Inc.**

5:30 - 7:30 PM

Reception

Thursday, June 4

9:00 - 10:00 AM

Health Information Technology and Biosimilars

The incorporation of Health Information Technology in healthcare is essential to provide patient-centric care and increase positive patient outcomes. Big data combined with a virtual health assistant has the ability to create an ontology where the efficacy of a biosimilar supersedes that of a legacy drug. This session will focus on data metrics and the extrapolation of data across indications.

By attending this session, you should be able to:
- Evaluate the role of technology and data metrics and how they can be used to beat the branded products in proven outcomes
- Discuss the extrapolation of data across indications and its effects on the Biosimilars market

Speakers

- **Stanley Campbell**
  Chairman & CEO, **EagleForce Health**
- **Tom Morrow**, MD
  Chief Medical Officer, **Next IT**

10:00 - 10:45 AM

Research & Development: Scientific Challenges in Biosimilars

The presenters will address research related to biosimilarity and discuss the reliability of data results from proof of bioequivalence studies. Session presenters will discuss topics related to biobetters vs. biosimilars, leading therapy areas in biosimilar development and cost challenges in biosimilar research.

By attending this session, you should be able to:
- Discuss research and development of biosimilars
- Evaluate the demonstration of biosimilarity
- Biobetters vs. biosimilars: Discuss the effects of biobetters on the advancement of biosimilars
- Evaluate the reliability of data results from proof-of-bioequivalence studies
- Discuss some of the leading therapy areas
- Describe and evaluate the cost challenges facing research in biosimilars

Speakers

- **Javier Coindreau,** MD
  Vice President, Global Medical Affairs, Biosimilars, **Pfizer**
- **Ali McBride**, PharmD, MS, BCPS
  Clinical Coordinator, **University of Arizona**

11:00 AM - 12:00 PM

Biosimilars in the Market: A discussion on the Evolving Market Response from Innovator Biologic Manufacturers

Because biosimilars are new to the US market, stakeholders have been witness to the rapidly evolving biosimilars market response. This presentation will review the evolving biosimilars market response relative to innovator biologic manufacturers, with a focus on biosimilar portfolios and profitability, EU biosimilar market vs. the US and insights on the development of a marketable biosimilar product.

By attending this session, you should be able to:
- Review the Market dynamics of biosimilars
- Review the profitability of investing and establishing a biosimilar portfolio
- Discuss E.U.'s huge portfolio vs U.S. as well as E.U. spending and developments vs. U.S.
- Describe how to create a marketable biosimilars product
- Discuss the potential market response from innovator biologic manufacturers

Speakers

- **Ajay Ahuja**, MD, MBA
  Vice President, Medical Affairs, **Hospira, Inc.**
- **Joseph Fuhr**, PhD
  Professor of Economics, **Widener University**

Thursday, June 4

12:00 - 1:15 PM

Lunch

1:15 - 2:00 PM

Biosimilars Case Study: Oncobiologics

Oncobiologics, established in 2011, is a biopharmaceutical firm focused on the development, manufacture and commercialization of high-value complex biosimilars. The company's current pipeline represents more than $100 billion in global revenue at time of patent expiry. Hear the inside story of this firm's remarkable evolution directly from its CEO.

Speakers

- **Pankaj Mohan**, PhD, MBA
  Founder & CEO, **Oncobiologics**

2:00 - 3:00 PM

Improving Patient Outcomes: Perspectives from Physicians and the Value of Patient Education

Physicians are at the forefront of patient care and improving patient outcomes. This presentation will focus on physician's perspectives regarding patient and prescriber acceptance of biosimilars, medication adherence, safety, efficacy, and patient resources.

By attending this session, you should be able to:

- Describe the effects of prescriber and patient acceptance of biosimilars and why physicians may hesitate to prescribe them
- Evaluate how patients can overcome barriers for treatment initiation and adherence to biologics
- Discuss whether a central source for biosimilars research studies and clinical trials may be beneficial to prescribers
- Review how prescribers view safety and efficacy given abbreviated development pathways
- Review the need for Patient education, resources for patients to access information, and the impact of patient support programs
- Describe the value for patients in adopting biosimilars in terms of effectiveness, quality, safety, ease of use, and cost

Speakers

- **Gaurang Gandhi**, PharmD, CSP
  Independent Consultant
- **Bimal Shah**, MD, MBA
  Senior Vice President, Applied Research
  Premier, Inc.

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Thursday, June 4

3:15 - 5:00 PM

Payer Perspectives: Insights on Biosimilars

Pricing and reimbursement are crucial factors impacting the growth of US biosimilars industry. This session will focus on how payers perceive biosimilars and offer insights on the management of the emerging US biosimilar market. The presentation will encompass anticipated savings potential, market forces driving decisions and market access implications.

By attending this session, you should be able to:

- Discuss how payers view the savings potential from the implementation of biosimilars in the US
- Describe what challenges are faced by payers and what aspect of biosimilars implementation they view to control
- Discuss what the driving decisions will be in covering biosimilar drugs
- Discuss if there is a need for payer education on biosimilars
- Review payer strategies with biosimilars and formulary management

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Speakers

- **John Carlsen**, MHA
  Vice President
  Covance Market Access Services, Inc.
- **Richard Cook**, PharmD
  Manager, Clinical & Quality Programs
  Blue Care Network of Michigan
- **Dean Erhardt**, MBA
  Principal, **D2 Pharma Consulting, LLC**
- **Lee Goldberg**, MBA
  Director, Syndicated Research
  Zitter Health Insights