Leading on Biosimilars

2017 AAM Biosimilars Council Conference

MONDAY, SEPTEMBER 11, 2017

3:00 p.m. – 5:00 p.m. **Biosimilars Council Board of Directors Meeting** - Madison

TUESDAY, SEPTEMBER 12, 2017 – CONFERENCE DAY 1

7:30 a.m. ***Registration*** – Thurgood Marshall Foyer

7:30 a.m. – 8:30 a.m. ***Networking Breakfast*** – Marriott Foyer

8:30 a.m. – 8:45 a.m. **AAM Welcome and Introduction** – Thurgood Marshall Ballroom
Christine Simmon, JD
Senior Vice President, Policy & Strategic Alliances, AAM
Executive Director, Biosimilars Council

8:45 a.m. – 9:15 a.m. **Biosimilars Council Chair Welcome**
Bruce Leicher, JD
General Counsel, Senior Vice President and Secretary
Momenta Pharmaceuticals, Inc.

9:15 a.m. – 10:00 a.m. **Regulatory Expectations: Biosimilars and Biologics**
Maria-Teresa Gutierrez-Lugo, PhD
Acting Review Chief, OPQ, OBP, DBRRIII, CDER
U.S. Food and Drug Administration

10:00 a.m. – 10:30 a.m. ***Networking Refreshment Break*** – Thurgood Marshall Foyer

10:30 a.m. – 12:00 p.m. **Market Access, Market Success**

Moderator: ***Elizabeth Jex, JD***
Attorney Advisor, Office of Policy Planning
U.S. Federal Trade Commission

Rachel Sher, JD, MPH
Deputy General Counsel
AAM

Crystal Kuntz
Vice President Policy and Regulatory Affairs
America's Health Insurance Plans

Andrew Mulcahy, PhD
Policy Researcher; Associate Research Department Director
RAND Corporation

12:00 p.m. – 1:15 p.m. ***Luncheon*** – Marriott Foyer

1:15 p.m. – 2:15 p.m. **Delivering Biosimilars Access in Europe**

Adrian van den Hoven, PhD
Director General, Medicines for Europe

2:15 p.m. – 3:15 p.m. **The Promise of Biosimilars: Patient Advocates Educating Around Patient Care**

Moderator: ***Edward Li, PharmD, MPH, BCOP***
Professor, Department of Pharmacy Practice
University of New England College of Pharmacy

Michele McCourt
Senior Director, CancerCare Co-Payment Assistance Foundation
CancerCare

Claire Saxton
Senior Director, Education
Cancer Support Community

Laura Wingate
Senior Vice President, Education, Support & Advocacy
Crohn's & Colitis Foundation

Christy Gamble, JD, DrPH, MPH
Director, Health Policy and Legislative Affairs
Black Women's Health Imperative

3:15 p.m. – 3:30 p.m. ***Networking Refreshment Break***

3:30 p.m. – 4:15 p.m. **The View from Wall Street**
Douglas Tsao, MPH
Director, Senior Research Analyst, U.S. Specialty Pharmaceuticals
Barclays Capital, Inc.

4:15 p.m. – 4:45 p.m. **USP Biologics Program Overview**
Fouad Atouf, PhD
Vice President, Science - Global Biologics
U.S. Pharmacopeial Convention

4:45 p.m. – 6:45 p.m. ***Networking Reception*** – Wardman East Lawn

WEDNESDAY, SEPTEMBER 13, 2017 - CONFERENCE DAY 2

7:30 a.m. – 8:30 a.m. ***Networking Breakfast*** – Marriott Foyer

8:30 a.m. – 9:15 a.m. **Interchangeability – What is Next?**
Hillel Cohen, PhD
Executive Director, Scientific Affairs
Sandoz Biopharmaceuticals

9:15 a.m. – 10:30 a.m. **Lessons Learned from the FDA Approval Process**
Moderator***: David Gaugh, RPh***
Senior Vice President of Regulatory Sciences
AAM

Tracy Dianis
Director, Global Regulatory Affairs Biosimilars
Pfizer Essential Health

Cindy Cao, PhD
Head, U.S. Biopharmaceutical Regulatory Affairs
Sandoz Biopharmaceuticals

10:30 a.m. – 11:00 a.m. ***Networking Refreshment Break*** – Thurgood Marshall Foyer

11:00 a.m. – 12:00 p.m. **Biosimilars at the Bar: Legal Issues**
Stacie Ropka, PhD, JD
Partner
Axinn, Veltrop & Harkrider LLP

12:00 p.m. – 1:15 p.m. ***Luncheon*** – Marriott Foyer

1:15 p.m. – 2:00 p.m.

Rising Drug Costs and Biosimilars – The Federal Perspective

Andrew Slavitt
Senior Advisor, Bipartisan Policy Center
Former Acting Administrator, Centers for Medicare & Medicaid Services

2:00 p.m. – 3:30 p.m.

Biosimilars Discussion with Industry Leaders

Moderator***: Edric Engert***
Managing Director
Abraxeolus Consulting

Mike Woolcock
Senior Vice President, Commercial Operations
Apobiologix

Andrea Miller
Head of Global Biologics Operations
Mylan Inc.

Patrick Lucy
Chief Business Officer
Pfenex Inc.

Carlos Sattler, MD
Vice President and Head of Clinical Development and Medical Affairs
U.S. Sandoz Biopharmaceuticals

3:30 p.m. – 3:45 p.m.

Closing Remarks

Bruce Leicher, JD
General Counsel, Senior Vice President and Secretary
Momenta Pharmaceuticals, Inc.

3:45 p.m.

Conference Concludes