

# 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**