



Leading on Biosimilars

2017 AAM Biosimilars Council Conference

AAM Welcome and Introduction

Christine Simmon

Senior Vice President, Policy & Strategic Alliances, AAM Executive Director, Biosimilars Council

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Significant Growth at The Biosimilars Council and AAM

- Strong AAM Support
- New Dedicated Staff
- AAM Rebranding **Explicitly Supports Biosimilars**

"AAM works to ensure more generic and biosimilar medicines are more accessible to more people who need them."



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The Biosimilars Council Member Companies

































Patient Access Study Release

"Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines"

- Patient Access Study done on behalf of the Biosimilars Council by Avalere Health
- Report indicates that 1.2 million U.S. patients could gain access to biologics by 2025 as the result of biosimilar availability.
- The report also suggests that women, lower income, and elderly individuals would particularly benefit from access to biosimilar medicines.





Updated Handbook



An educational resource for patients, policymakers and health professionals.





Conference Day 1 Agenda

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

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

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, Ph.D.

Acting Review Chief, OPQ, OBP, DBRRIII, CDER

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

Attorney Advisor, Office of Policy Planning

Federal Trade Commission

Rachel Sher

Deputy General Counsel

AAM

Crystal Kuntz

Vice President Policy and Regulatory Affairs

America's Health Insurance Plans

Andrew Mulcahy

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

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, Pharm.D., 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, J.D., 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, Ph.D.

Vice President, Science - Global Biologics

U.S. Pharmacopeial Convention

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

