AGENDA

TUESDAY, DECEMBER 10, 2013

Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition

8:30am **Welcome Remarks and Announcements**

Andrew I. Gavil
Director, Office of Policy Planning
Federal Trade Commission

8:40am **Opening Remarks**

Edith Ramirez
Chairwoman
Federal Trade Commission

8:50am **Road Map to Morning Presentations**

Susan DeSanti
Federal Trade Commission

9:00am **Lessons for Regulation of Follow-On Biologics from Experiences with Small Molecule Drugs**

Aaron Kesselheim, M.D., J.D., M.P.H
Assistant Professor of Medicine
Brigham and Women's Hospital/
Harvard Medical School

9:15am **The Rigorous FDA Review Process for Biosimilars and Interchangeables**

Emily Shacter, Ph.D.
Independent Consultant
ThinkFDA, LLC

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9:35am	**Consumer Overview of Biosimilars**	**Leigh Purvis**, M.P.A. Senior Strategic Policy Advisor AARP
9:50am	**Current State of Follow-On Biologics in the United States and Europe**	**Ronny Gal**, Ph.D. Senior Research Analyst Bernstein Research
10:10am	**10 Minute Break**	
10:20am	**Introduction to State Biosimilar Substitution Laws**	**Jessica S. Mazer**, J.D. Assistant Vice President of State Affairs Pharmaceutical Care Management Association
10:35am	**Industry Perspective on State Substitution Laws**	**Geoffrey Eich**, M.B.A. Executive Director, R&D Policy Amgen, Inc.
10:50am	**Customer Perspective on Biosimilars**	**Steven B. Miller**, M.D., M.B.A. Senior Vice President & Chief Medical Officer Express Scripts
11:05am	**Innovation of Interchangeable Biosimilars**	**Bruce Leicher**, J.D. Senior Vice President & General Counsel Momenta Pharmaceuticals, Inc.
11:20am	**10 Minute Break**	

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11:30am **Panel Discussion – State Substitution Laws**

Moderators: **Elizabeth Jex**, Office of Policy Planning
Susan DeSanti, Western Regional Office

Panelists: **Geoffrey Eich**, M.B.A.
Executive Director, R&D Policy
Amgen, Inc.

Ronny Gal, Ph.D.
Senior Research Analyst
Bernstein Research

Aaron Kesselheim, M.D., J.D., M.P.H.
Assistant Professor of Medicine
Brigham and Women's Hospital/Harvard Medical School

Bruce Leicher, J.D.
Senior Vice President & General Counsel
Momenta Pharmaceuticals, Inc.

Jessica S. Mazer, J.D.
Assistant Vice President of State Affairs
Pharmaceutical Care Management Association

Mark McCamish, M.D., Ph.D.
Global Head, Biopharmaceutical Development
Sandoz International GmbH

Steven B. Miller, M.D., M.B.A.
Senior Vice President & Chief Medical Officer
Express Scripts

Leigh Purvis, M.P.A.
Senior Strategic Policy Advisor
AARP

Sumant Ramachandra, M.D., Ph.D., M.B.A.
Senior Vice President & Chief Scientific Officer
Hospira, Inc.

Emily Shacter, Ph.D.
Independent Consultant
ThinkFDA LLC

Gillian Woollett, M.A., D.Phil.
Senior Vice President
Avalere Health

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12:30pm **Lunch Break (On Your Own)**

1:30pm **Road Map to Afternoon Presentations**

Elizabeth Jex
Federal Trade Commission

1:40pm **Introduction to Drug Naming**

Roger Williams, M.D.
Chief Executive Officer
United States Pharmacopeia

1:55pm **Effect of Naming on Competition and Innovation**

Mark McCamish, M.D., Ph.D.
Global Head, Biopharmaceutical Development
Sandoz International GmbH

2:10pm **Industry Perspective on Naming Conventions**

Paul Eisenberg, M.D., M.P.H., F.A.C.P., F.A.C.C.
Senior Vice President, Global Regulatory Affairs & Safety
Amgen, Inc.

2:25pm **Lessons for the U.S.: Biosimilar Market Development Worldwide**

Sumant Ramachandra, M.D., Ph.D., M.B.A.
Senior Vice President & Chief Scientific Officer
Hospira, Inc.

2:40pm **Reference Biologic Perspectives On Naming**

Emily Alexander, J.D.
Director of U.S. Regulatory Affairs
Biologics Strategic Development, AbbVie Inc.

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2:55pm **Consequences of Biologics Naming Policies**

Gillian Woollett, M.A., D.Phil.
Senior Vice President
Avalere Health LLC

3:10pm **Private Payor Perspective on Growth of Specialty Medicines and Naming**

Harry Travis, B.S. Pharm., M.B.A.
Vice President, General Manager
Aetna Specialty and Home Delivery Pharmacy

3:25pm **15 Minute Break**

3:40pm **Panel Discussion – Naming and Pharmacovigilance**

Moderators: **Elizabeth Jex**, Office of Policy Planning
Susan DeSanti, Western Regional Office

Panelists: **Emily Alexander**, J.D.
Director of U.S. Regulatory Affairs
Biologics Strategic Development, AbbVie Inc.

Paul Eisenberg, M.D., M.P.H., F.A.C.P., F.A.C.C.
Senior Vice President, Global Regulatory Affairs & Safety
Amgen, Inc.

Helen Hartman, Ph.D.
Director, Worldwide Regulatory Strategy
Pfizer Inc.

Aaron Kesselheim, M.D., J.D., M.P.H.
Assistant Professor of Medicine
Brigham and Women's Hospital/Harvard Medical School

Mark McCamish, M.D., PhD.
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4:45pm **Concluding Remarks**

Andrew I. Gavil
Director, Office of Policy Planning
Federal Trade Commission