FDA's Facilitating Competition and Innovation in the Biological Products Marketplace
Part 15 Public Hearing

September 4, 2018
FDA White Oak Campus
10903 New Hampshire Ave, Building 31, Room 1503, Section B and C
Silver Spring, Maryland 20993

AGENDA

Each presentation is allotted eight minutes. Three minutes [noted in brackets] are allotted following each presentation to offer an opportunity for the panel to ask clarifying questions.

9:00 – 9:10 am Opening Remarks
Dr. Rachel Sherman — Food and Drug Administration
Presiding Officer
Principal Deputy Commissioner

9:10 - 9:18 am [9:18 - 9:21 am]
Dr. Andrew Greenspan — Johnson & Johnson
"Facilitating Competition and Innovation: Perspectives from an Innovator Biologics Company"

9:21 – 9:29 am [9:29 - 9:32 am]
Randall Rutta — American Autoimmune Related Disorders Association
"FDA's approach to enhancing competition and innovation in the biological products marketplace: Priorities for Autoimmune Patients"

9:32 – 9:40 am [9:40 - 9:43 am]
Juliana Reed — Biosimilars Forum
"The Biosimilars Forum – Assisting Agency Efforts to Promote Biosimilar Biological Products"

9:43 – 9:51 am [9:51 - 9:54 am]
Dr. Cartier Esham — BIO
"BIO's Comments on Facilitating Competition and Innovation in Biological Products Marketplace"

9:54 – 10:02 am [10:02 -10:05 am]
Sarah Aoanan — Global Healthy Living Foundation
"Patients' Perspectives on Biosimilars and Interchangeability and the Importance of Education"

10:05 – 10:13 am [10:13 -10:16 am]
Samantha Reid — Patients for Affordable Drugs
"Drugs Don't Work if People Can't Afford Them"

10:16 – 10:26 BREAK

10:26 – 10:34 am [10:34 – 10:37 am]
Nathan Doty — AbbVie, Inc.
"Interchangeability of Biosimilars in a Complex Marketplace"

10:37 – 10:45 am [10:45 – 10:48 am]
Dr. Steven Lucio — Vizient, Inc.
"Accelerating Biosimilar Adoption by Demystifying the Science"

10:48 -10:56 am [10:56 – 10:59 am]
Kathleen A. Arntsen — Lupus and Allied Diseases Association
"Realizing the Promise of Biological Products"

10:59 – 11:07 am [11:07 – 11:10 am]

Dr. Richard Markus — Amgen

"Perspectives from Amgen as a Biosimilar and Originator Manufacturer with Key Considerations for a Robust and Sustainable Biosimilar Environment"

11:10- 11:18 am [11:18 – 11:21 am]

Dr. Harry Gewanter — Medical Home Plus, Inc.

"Furthering Biosimilar Acceptance and Use Through Harmonization & Transparency"

11:21 - 11:29 am [11:29 – 11:32 am]

Bruce A. Leicher — Momenta Pharmaceuticals, Inc.

"Facilitating Competition and Innovation in the Biological Products Marketplace"

11:32 – 11:40 am [11:40 - 11:43 am]

Dr. Lisa Skeens — Pfizer, Inc.

"Access to and Acceptability of Biosimilars through Regulatory Reform"

11:43 – 1:51 pm [11:51 – 11:54 am]

Dr. Richard Dolinar — Heartland Institute

"Clinical Perspectives on Biosimilars"

11:54 am– 12:45 pm LUNCH

12:45 - 1:00 pm Comments from the Commissioner

1:00 – 1:08 pm [1:08 – 1:11 pm]

Dr. Mariana Socal — Johns Hopkins Bloomberg School of Public Health

"Improving Information Availability and Accessibility in the FDA Purple Book"

1:11 – 1:19 pm [1:19 – 1:22 pm]

Michelle Cope — National Association of Chain Drug Stores

"Chain Pharmacy's Recommendations for Promoting Biosimilars Uptake and Facilitating a Robust Biological Product Market"

1:22 – 1:30 pm [1:30 – 1:33 pm]

Christine Simmon — Biosimilars Council, a Division of the Association for Accessible Medicine

"Supporting Market Competition for Biosimilars to Enhance Patient Access"

1:33 – 1:41 pm [1:41 – 1:44 pm]

Dr. Meni Melek — Novartis

"Novartis Perspective on Facilitating Competition and Innovation Across Originator and Biosimilar Products"

1:44 – 1:52 pm [1:52 – 1:55 pm]

Andrew Spiegel — Global Colon Cancer Association

"The Promise of Biosimilars; a Patient Advocate's Perspective"

1:55 – 2:03 pm [2:03 – 2:06 pm]

Dr. Soumi Saha — Premier Health Alliance

"Ensuring a Competitive Biosimilars Marketplace"

2:06 – 2:14 pm [2:14 – 2:17 pm]
Dr. Madelaine Feldman — Alliance for Safe Biologic Medicines
"Promoting Biosimilar Development, Access and Uptake"

2:17 – 2:27 pm BREAK

2:27 – 2:35 pm [2:35 – 2:38 pm]
Dr. Wayne Winegarden — Pacific Research Institute
"The Economic Impediments to a Stronger Biosimilars Market: Lessons from Infliximab"

2:38 – 3:06 pm [3:06 – 3:09 pm]
Molly Burich — Boehringer Ingelheim Pharmaceuticals Inc.
"Boehringer Ingelheim's Commitment to and Key Perspectives on Biosimilars"

3:09 – 3:17 pm [3:17 – 3:20 pm]
David Korn — PhRMA
"Views of the Pharmaceutical Research and Manufacturers of America"

3:20 – 3:28 pm [3:28 – 3:31 pm]
Chrys Kokino — Mylan
"Fostering Biosimilar Market Competition"

3:31 – 4:30 pm OPEN PUBLIC HEARING

4:30 – 4:40 pm Concluding remarks
Dr. Rachel Sherman — Food and Drug Administration
Presiding Officer
Principal Deputy Commissioner