



## **“The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products” May 13, 2019**

### **AGENDA** (as of 5/10/2019)

Each presentation is allotted 10 minutes. Five minutes [noted in brackets] are allotted following each presentation to offer an opportunity for the panel to ask clarifying questions. *Please note that times may vary based on participation and other logistics and are subject to change.*

#### **9:00 – 9:10 am Opening Remarks**

Dr. Norman “Ned” Sharpless  
Acting Commissioner

Food and Drug Administration

#### **9:10-9:20 am Introductory Logistics Remarks**

Eva Temkin  
Presiding Officer

Food and Drug Administration

#### **9:20 - 9:30 am [9:30 - 9:35 am]**

Alexander Oshmyansky  
“The Insulin Club – the Future of Insulin Biosimilars”

Osh's Affordable Pharmaceuticals, PBC

#### **9:35 – 9:45 am [9:45 - 9:50 am]**

Dr. Steven Lucio  
“Accelerating Biosimilar Uptake through the Insulin Experience”

Vizient, Inc.

#### **9:50 – 10:00 am [10:00 - 10:05 am]**

Dr. Abhijit Barve  
“The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products”

Mylan

#### **10:05 – 10:15 am [10:15 - 10:20 am]**

Dr. Sherry Martin  
“The Future of Insulin Biosimilars”

Eli Lilly and Company

#### **10:20 – 10:40 am BREAK**

#### **10:40 – 10:50 am [10:50 -10:55 am]**

Dr. Jing Luo  
“The urgent clinical and public health need for interchangeable insulins: a profound opportunity for FDA”

Brigham and Women's Hospital

#### **10:55 – 11:05 am [11:05 -11:10 am]**

Christine Simmon  
“Considerations for Biosimilar and Interchangeable Insulin Products”

Association for Accessible Medicines

**11:10 – 11:20 am [11:20 – 11:25 am]**

Dr. Sundar Ramanan

Biocon

“Patient-first, Science-based Regulatory Approaches for Insulins”

**11:25 – 11:35 am [11:35 – 11:40 am]**

Coby Watier

My Health E

**11:40 – 11:50 am [11:50 – 11:55 am]**

Dr. Marjana Marinac

JDRF

“FDA Public Hearing: The Future of Insulin Biosimilars”

**11:55 – 12:55 pm LUNCH**

**12:55 – 1:05 pm [1:05 – 1:10]**

Dr. Robert Ratner

American Diabetes Association volunteer

“Development of Biosimilar and Interchangeable Insulin Products”

**1:10 – 1:20 pm [1:20 – 1:25]**

Robert Geho

Diasome Pharmaceuticals, Inc.

“The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products”

**1:25 – 1:35 pm [1:35 – 1:40]**

Dr. Mariana Socal

Johns Hopkins University

“Biosimilarity & interchangeability in the case of insulins: Which scientific standards do we want?”

**1:40 – 2:40 pm OPEN PUBLIC HEARING**

**2:40 - 2:45 pm Closing Remarks**

Eva Temkin

Food and Drug Administration

Presiding Officer