

BIOMARKERS OF POTENTIAL HARM: A PUBLIC WORKSHOP



CENTER FOR TOBACCO PRODUCTS (CTP)
FDA White Oak Conference Center
Building 31, Room 1503, 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 4 – 5, 2016
Agenda

Monday, April 4, 2016

8:30 am

Welcome and Introduction of Center Director

Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences, Office of Science
FDA Center for Tobacco Products

Opening Remarks

Mitchell Zeller, JD
Director
FDA Center for Tobacco Products

Overview of the Workshop

Cindy M. Chang, PhD, MPH
Epidemiologist, Office of Science
FDA Center for Tobacco Products

8:50 am

Session 1: Biomarkers of Potential Harm Overview

Characterization of Biomarkers of Potential Harm: Perspective from a Clinical Scientist

Dorothy K. Hatsukami, PhD
University of Minnesota

Utility of Biomarkers of Potential Harm in Tobacco Product Regulation

Kimberly Frost-Pineda, PhD, MPH, CPH
Altria Client Services

Surrogate Markers at FDA – Lessons Learned

Robert Temple, MD
FDA Center for Drug Evaluation and Research

9:50 am

Session 1 Panel Discussion

Dorothy Hatsukami, Kimberly Frost-Pineda, Robert Temple

10:10 am

Break

10:25 am

Session 2: Cardiovascular Disease (CVD)

Biomarkers of Potential Harm: Tobacco-induced Cardiovascular Disease

Neal L. Benowitz, MD
University of California, San Francisco

**Biomarkers of Potential Harm Among Users of Different Tobacco Products:
Results of Two Studies Compared with Published Literature**

Bobbette A. Jones, DrPH, CCCRP
RAI Services Company

Biomarkers of Cardiovascular Disease

Thomas J. Wang, MD
Vanderbilt University Medical Center

Biomarkers of Cardiovascular Injury Due to Tobacco Product Use

Aruni Bhatnagar, PhD, FAHA
American Heart Association/University of Louisville

12:00 pm

Lunch

1:00 pm

Tobacco and Biomarkers of Cardiovascular Harm: Many Questions Remain

Shari Targum, MD, MPH, FACC
FDA Center for Drug Evaluation and Research

1:15 pm

Session 2 Panel Discussion on CVD

Neal Benowitz, Bobbette Jones, Thomas Wang, Aruni Bhatnagar, Shari Targum

1:45 pm

Session 3: Chronic Obstructive Pulmonary Disease (COPD)

Tobacco Use and COPD: Overview

James D. Crapo, MD
National Jewish Health

Imaging Biomarkers of Potential Harm: CT and MRI

R. Graham Barr, MD, DrPH
Columbia University Medical Center

Biological Biomarkers of Tobacco-Related Harm in the Lung

Stephen I. Rennard, MD
University of Nebraska Medical Center
AstraZeneca, United Kingdom

3:05 pm

Break

3:20 pm

Tobacco Exposure-Induced Biomarkers of Harm in Human Airway Epithelia

Robert Tarran, PhD
University of North Carolina at Chapel Hill /The UNC School of Medicine
TCORS Program

Forced Expiratory Volume in 1 Second: a Multifunctional Biomarker of Lung Function

Erika Torjusen, MD, MHS
FDA Center for Drug Evaluation and Research

4:00 pm

Session 3 Panel Discussion on COPD

James Crapo, Graham Barr, Stephen Rennard, Robert Tarran, Erika Torjusen

4:30 pm

End of Workshop Day 1

Tuesday, April 5, 2016

8:30 am

Welcome

Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences
FDA Center for Tobacco Products

8:35 am

Public Comment Session

9:35 am

Session 4: Cancer

Biomarkers of Potential Harm Associated with Cigarette Smoking

Stephen S. Hecht, PhD
Masonic Cancer Center/University of Minnesota

Cigarette Smoking and Variation in Circulating Markers of Inflammation and Immunity

Meredith Shiels, PhD
NIH National Cancer Institute

Epigenetic Biomarkers of Tobacco Smoke Exposure

Douglas A. Bell, PhD

NIH National Institute of Environmental Health Sciences

10:45 am

Break

11:00 am

Airway Epithelial Biomarkers of Tobacco Exposure and Risk

York E. Miller, MD

University of Colorado School of Medicine/Denver Veterans Affairs Medical Center

The Airway Transcriptome as a Biomarker of Tobacco Smoke Exposure and Lung Cancer Detection

Avrum Spira, MD, MSc

Boston University School of Medicine

11:50 am

Lunch

12:50 pm

Session 4 Panel Discussion on Cancer

Stephen Hecht, Meredith Shiels, Douglas Bell, York Miller, Avrum Spira

1:20 pm

Session 5: New Areas of Research

Use of Biomarkers of Early Effect in Occupational Exposure Limit Setting

D. Gayle DeBord, PhD

CDC National Institute for Occupational Safety and Health

Biomarkers and AOPs: Bridging Toxicity Pathways & Regulatory Decision Making

Stephen Edwards, PhD

US Environmental Protection Agency

Utility of Biomarkers of Potential Harm as End-Points for the Disease

Relevant Assessment of Novel Tobacco and Nicotine Products as Potentially Reduced Risk Products

Christopher Proctor, BSc (Hon), PhD

British American Tobacco

Tobacco Use and the Human Microbiome

Emily Vogtmann, PhD, MPH

NIH National Cancer Institute

2:45 pm

Break

3:00 pm **Biomarkers of Potential Harm: Tools to Differentiate Tobacco Product Classes**

G. L. Prasad, PhD
RAI Services Company

Biomarker Qualification at CDER, FDA

Shashi Amur, PhD
FDA Center for Drug Evaluation and Research

3:35 pm **Session 5 Panel Discussion**

Stephen Edwards, Gayle DeBord, Christopher Proctor, Emily Vogtmann, GL Prasad, Shashi Amur

4:00 pm **End of Workshop Day 2**

The use of tobacco products, including e-cigarettes, is prohibited in all FDA facilities including buildings, grounds, and parking structures.