



# Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety

**April 26-27, 2016**

Lister Hill Center Auditorium • National Institutes of Health • Bethesda, Maryland

## Agenda

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### Day One

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- 9:00 a.m. **Welcome**  
Paul Coates, Ph.D., Director, Office of Dietary Supplements (ODS), National Institutes of Health (NIH)
- 9:10 a.m. **Opening Remarks**  
Linda Birnbaum, Ph.D., Director, National Institute of Environmental Health Sciences (NIEHS)  
and National Toxicology Program (NTP), NIH
- 9:20 a.m. **Introduction to the Workshop**  
Cynthia Rider, Ph.D., NIEHS
- Perspectives on the Challenges Associated With Botanicals**  
Moderator: Nigel Walker, Ph.D., NIEHS
- 9:30 a.m. **The Complexity of Herbal Supplements**  
Joseph Betz, Ph.D., ODS
- 9:50 a.m. **The FDA Regulatory Landscape**  
Cara Welch, Ph.D., U.S. Food and Drug Administration (FDA)
- 10:10 a.m. **BREAK**
- 10:30 a.m. **The Quest for Rigor and Reproducibility in Botanical Research**  
Craig Hopp, Ph.D., National Center for Complementary and Integrative Health, NIH
- 10:50 a.m. **Ensuring Safety of Botanical Dietary Supplements – The Industry’s Role**  
Duffy MacKay, N.D., Council for Responsible Nutrition
- 11:10 a.m. **U.S. Pharmacopeia (USP) Botanical Quality Standards for Ensuring Proper Identity**  
Hellen Oketch, Ph.D., U.S. Pharmacopeial Convention
- 11:30 a.m. **LUNCH**

This workshop is sponsored by the National Toxicology Program/National Institute of Environmental Health Sciences



## Topic One: Determining Phytoequivalence of Botanicals

Moderator: Kristine Witt, M.S., NIEHS

- 12:30 p.m. **How Similar Is Similar Enough? Case Studies Exploring Phytoequivalence of Botanicals**  
Cynthia Rider, Ph.D., NIEHS
- 12:50 p.m. **Whole Mixtures Risk Assessment: Considering Sufficient Similarity**  
Glenn Rice, Ph.D., U.S. Environmental Protection Agency (EPA)
- 1:10 p.m. **Characterization of Botanical Materials Using Chemometric Methods**  
James Harnly, Ph.D., U.S. Department of Agriculture (USDA)
- 1:30 p.m. **Targeted Analysis of Herbs: Markers, Actives, Natural Toxins, and More**  
Kerri LeVanseler, Ph.D., NSF International
- 1:50 p.m. **Evaluation of Biological Similarity of *Ginkgo Biloba* Extracts in Sandwich Cultures of Primary Human Hepatocytes**  
Stephen Ferguson, Ph.D., NIEHS
- 2:10 p.m. **Genotoxicity of Cohosh Samples Assessed Using the *In Vitro* Micronucleus Assay**  
Stephanie Smith-Roe, Ph.D., NIEHS
- 2:30 p.m. **BREAK**
- 2:50 p.m. **Statistical Strategy for Determining Sufficient Similarity of Related Botanicals: A Case Study of *Ginkgo Biloba* Extract**  
Chris Gennings, Ph.D., Mount Sinai Hospital
- 3:10 p.m. **Inferring Toxicological Similarity With Multidimensional Relational Analysis**  
Scott Auerbach, Ph.D., NIEHS
- 3:30 p.m. **Panel Discussion**  
Cynthia Rider, Ph.D., NIEHS (*moderator*)  
James Harnly, Ph.D., USDA  
Ikhlas Khan, Ph.D., University of Mississippi  
Kerri LeVanseler, Ph.D., NSF International  
James MacGregor, Ph.D., Toxicology Consulting Services  
Glenn Rice, Ph.D., EPA
- 4:45 p.m. **Adjourn**

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## Day Two

- 9:00 a.m. **Welcome/Opening Remarks** – John Bucher, Ph.D., Associate Director, NTP

## Topic Two: Identifying Active Constituents in Botanical Dietary Supplements

Moderator: Paul Foster, Ph.D., NIEHS

- 9:10 a.m. **Why Do We Care About Active Constituents?**  
Paul Howard, Ph.D., FDA
- 9:30 a.m. **Challenges to Identifying Active Constituents**  
Edmund Lui, Ph.D., Schulich School of Medicine & Dentistry at Western University
- 9:50 a.m. **Identification of Active Compounds in Botanical Dietary Supplements**  
Richard van Breemen, Ph.D., University of Illinois at Chicago
- 10:10 a.m. **Tracking Toxic Constituents in Botanicals: The Right Sample and the Right Question**  
Larry Walker, Ph.D., University of Mississippi



10:30 a.m. **BREAK**

10:50 a.m. **Poisonous Plant Active Constituents: Challenges of Natural Diversity**

Dale Gardner, Ph.D., USDA

11:10 a.m. **Integrating Biological and Chemical Datasets to Identify Active Constituents of Natural Products**

Nadja Cech, Ph.D., University of North Carolina at Greensboro

11:30 a.m. **Panel Discussion**

Scott Auerbach, Ph.D., NIEHS (*moderator*)

Nadja Cech, Ph.D., University of North Carolina at Greensboro

Dale Gardner, Ph.D., USDA

Edmund Lui, Ph.D., Schulich School of Medicine & Dentistry at Western University

Richard van Breemen, Ph.D., University of Illinois at Chicago

Larry Walker, Ph.D., University of Mississippi

12:30 p.m. **LUNCH**

**Topic Three: Best Practices for Assessing Absorption, Distribution, Metabolism, and Elimination (ADME) of Botanical Dietary Supplements**

Moderator: Joseph Betz

1:30 p.m. **Understanding ADME Properties of Botanicals: Challenges, Current Status, and Future Needs**

Suramya Waidyanatha, Ph.D., NIEHS

1:50 p.m. **The Polypharmacokinetics of Herbal Medicines**

Wei Jia, Ph.D., University of Hawaii

2:10 p.m. **Assessing Herb-Drug Interactions: Screening Approaches**

Amy Roe, Ph.D., Procter & Gamble

2:30 p.m. **BREAK**

2:50 p.m. **Quantitative Prediction and Clinical Evaluation of Herb-Drug Interactions**

Mary Paine, Ph.D., Washington State University

3:10 p.m. **Practical Considerations When Designing Clinical Herb-Drug Interaction Studies**

Bill Gurley, Ph.D., University of Arkansas

3:30 p.m. **Achieving Enhanced Benefit From Herbal Products for Personalized Cancer Chemotherapy – Efficacy and Safety Considerations**

Moses Chow, Ph.D., Western University of Health Sciences

3:50 p.m. **Panel Discussion**

Michael DeVito, Ph.D., NIEHS (*moderator*)

Moses Chow, Ph.D., Western University of Health Sciences

Bill Gurley, Ph.D., University of Arkansas

Wei Jia, Ph.D., University of Hawaii

Mary Paine, Ph.D., Washington State University

Amy Roe, Ph.D., Procter & Gamble

Kevin Welch, Ph.D., USDA

4:50 p.m. **Wrap up**