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

Day One

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

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<td>9:00 a.m.</td>
<td>Welcome/Opening Remarks</td>
<td>John Bucher, Ph.D., Associate Director, NTP</td>
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<td>9:10 a.m.</td>
<td>Why Do We Care About Active Constituents?</td>
<td>Paul Howard, Ph.D., FDA</td>
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<td>9:30 a.m.</td>
<td>Challenges to Identifying Active Constituents</td>
<td>Edmund Lui, Ph.D., Schulich School of Medicine &amp; Dentistry at Western University</td>
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<td>9:50 a.m.</td>
<td>Identification of Active Compounds in Botanical Dietary Supplements</td>
<td>Richard van Breemen, Ph.D., University of Illinois at Chicago</td>
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<td>10:10 a.m.</td>
<td>Tracking Toxic Constituents in Botanicals: The Right Sample and the Right Question</td>
<td>Larry Walker, Ph.D., University of Mississippi</td>
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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**