

30th Annual Education Meeting for Organization of Teratology Information Specialists Members and MotherToBaby Affiliates

Grand Hyatt Denver

Denver, CO

June 24–June 27, 2017

Friday, June 23, 2017

5:00 PM-9:00 PM OTIS BOARD OF DIRECTORS MEETING

MT. YALE

Presiding: OTIS President: Stephen R. Braddock, Saint Louis University School of

Medicine

Saturday, June 24, 2017

7:15 AM-4:30 PM RSA FETAL ALCOHOL SPECTRUM MEETING OFF-SITE

DISORDERS STUDY GROUP (FASDG)SEPARATE REGISTRATION/FEE REQUIRED

4:30 PM-6:30 PM OTIS MEETING REGISTRATION COLORADO A FOYER

5:00 PM-7:00 PM OTIS RESEARCH TEAM MEETING MT. OXFORD

(OTIS Research Coordinators and Committee Members Only) **Presiding:** *Margaret Adam, University of Washington and*

Alicia Forinash, St. Louis College of Pharmacy

5:00 PM-5:05 PM Welcome

Margaret Adam, University of Washington

5:05 PM-5:25 PM Pregnancy Studies Update

Diana Johnson, University of California, San Diego

5:25 PM-5:35 PM Update on Motherisk Studies

Shinya Ito, The Hospital for Sick Children

5:35 PM-5:45 PM OTIS/ENTIS Collaboration

Christina D. Chambers, University of California San Diego

5:45 PM-6:00 PM Break

6:00 PM-6:10 PM Visions for OTIS—Five Year Strategic Plan

Steve Braddock, Saint Louis University

6:10 PM—6:20 PM Texting/Chatting Quality Control Project

Christine Stallman, University of Arizona

6:20 PM-6:30 PM Conducting Studies on Selected Drugs with No Human Data

Gerald Briggs, MemorialCare Center for Women

6:30 PM—6:40 PM Overview of Drugs Used to Treat Hepatitis C

Alicia Forinash, St. Louis College of Pharmacy

6:40 PM—6:50 PM HRSA Update

Nicole Chavez, Nicole Greer, and Elizabeth Wasternack, OTIS

National Office

6:50 PM-7:00 PM Wrap-Up

Margaret Adam, University of Washington and Alicia Forinash, St. Louis College of Pharmacy

Sunday, June 25, 2017

7:00 AM-8:00 AM OTIS MEETING PLANNING COMMITTEE MT. YALE

MEETING

Presiding: Anna Pupco, The Hospital for Sick Children and

Claire Coles, Emory University

8:00 AM-10:15 AM OTIS MEETING REGISTRATION COLORADO A FOYER

8:15 AM-9:00 AM JOSEF WARKANY LECTURE ASPEN

(Joint with the Teratology Society and DNTS) Where You Live Matters: Why Do Poor Pregnancy

Outcomes Differ by Geography and What Can We Do About It?

Chairperson: Sonja A. Rasmussen, Centers for Disease Control and Prevention

Lecturer: Jose F. Cordero, University of Georgia

9:00 AM-10:00 AM THOMAS H. SHEPARD LECTURE ASPEN

(Joint with the Teratology Society)

From the FAS to OTIS - A Long Strange Trip

Introduction with President's Welcome: OTIS President: Stephen R. Braddock,

Saint Louis University School of Medicine

Lecturer: Buzz Chernoff, California Environmental Protection Agency (Retired)

10:00 AM-10:15 AM BREAK

10:00 AM-10:30 AM SPOUSE AND GUEST MEET-AND-GREET MT. WILSON

(Open to Teratology Society, DNTS, and OTIS Spouses and Guests)

10:15 AM-1:00 PM GERALD G. BRIGGS RESEARCH SYMPOSIUM COLORADO A

Anticoagulants and Neurodevelopmental Outcomes after SRI and

Analgesic Use During Pregnancy

Presiding: Margaret Adam, University of Washington Alicia Forinash, St. Louis College of Pharmacy

10:15 AM-10:20 AM Welcome

Alicia Forinash, St. Louis College of Pharmacy

10:20 AM-11:10 AM New Oral Anticoagulants in Pregnancy: An "Old" Issue Resurfaces

Wee-Shian Chan, BC Women's Hospital and Health Centre

11:10 AM-12:00 PM The Relationships Between Gestational SRI Exposure, SRI

Bioeffect, and Neurobehavioral Outcomes

Amy Salisbury, Brown University

12:00 PM-12:50 PM The Opioid Epidemic and Impact of Prenatal Exposure on Child

Development

Lynn Singer, Case Western Reserve University

12:50 PM-01:00 PM Discussion

1:00 PM-3:30 PM LUNCH BREAK (LUNCH ON YOUR OWN)

1:15 PM-2:00 PM RESEARCH COMMITTEE MEETING MT. YALE

(OTIS Research Committee Members Only)

Presiding: Margaret Adam, University of Washington Alicia Forinash, St. Louis College of Pharmacy

2:15 PM-3:15 PM OTIS WEBSITE/MARKETING COMMITTEE MEETING MT. YALE

Presiding: Lori Wolfe, UNT Dept. of Biology Texas TIS

3:15 PM-3:35 PM BREAK

3:35 PM-6:30 PM PREGNANCY REGISTRY UPDATES SYMPOSIUM COLORADO A

(Joint with the Teratology Society)

Chairpersons: Christina D. Chambers, University of California San Diego and

Lewis B. Holmes, MassGeneral Hospital for Children

3:35 PM-3:40 PM Welcome and Introduction

Lewis B. Holmes, MassGeneral Hospital for Children

3:40 PM-4:00 PM The Key Role of Social Media in Registry Recruitment

Nicole Chavez, Communications Consultant

4:00 PM-4:20 PM "Drugs in Breast Milk:" Related Data in Pregnancy Registries

Shinya Ito, The Hospital for Sick Children

4:20 PM-4:35 PM Break - Aspen Foyer

4:35 PM-4:55 PM

How to Interpret Different Findings for the Same Medication Across Pregnancy Registries: The Example of Keppra David Miller, UBC

4:55 PM-5:15 PM

Incorporating Registry Data into the Label—Guidance for the PLRR

Leyla Sahin, US Food and Drug Administration

5:15 PM-5:30 PM

Defect Evaluation by Infant Photographs in a Multi-Center Pharmaceutical Clinical Trial

<u>Scheuerle AE</u>¹, Kwon P², Joing M². ¹University of Texas Southwestern Medical Center, Dallas, TX, United States, ²NORA Therapeutics, Inc., Palo Alto, CA, United States

5:30 PM-5:45 PM

Distribution by Week and Trimester of Onset among Pregnant Women, US Zika Pregnancy Registry, 2015–2016

<u>Khan S</u>¹, Rice ME¹, Reynolds MR¹, Reagan-Steiner S¹, Brown CM⁵, Lee EH⁴, Ahmad N², Macdonald J³, Sommer JN², Smith LC², Honein MA¹.

¹Centers for Disease Control and Prevention, Atlanta, GA, United States, ²New York State Department of Health, Albany, NY, United States, ³Virginia Department of Health, Richmond, VA, United States, ⁴New York City Department of Health and Mental Hygiene, Queens, NY, United States, ⁵Massachusetts Department of Public Health, Boston, MA, United States.

5:45 PM-6:00 PM

Prevalence of Small for Gestational Age and Preterm Birth Among Infants Born to Women with Laboratory Evidence of Possible Zika Virus Infection During Pregnancy, US Zika Pregnancy Registry, December 2015–December 2016

Fleck-Derderian S¹, Jones AM¹, Simon EL¹, Newsome K¹, Lee EH², Ahmad N³, Dunn JE⁴, Smith LC³, White JL³, Honein MA¹. ¹Centers for Disease Control and Prevention, Atlanta, GA, United States, ²New York City Department of Health and Mental Hygiene, New York City, NY, United States, ³New York State Department of Health, Albany, NY, United States, ⁴Massachusetts Department of Public Health, Boston, MA, United States

6:00 PM-6:15 PM

Pregnancy and Lactation Labeling Rule (PLLR) in Practice: More Human Observational Data Needed

<u>Wurst KE</u>¹, Cunnington M³, Powell M², Lee TJ¹. ¹GlaxoSmithKline, Collegeville, PA, United States, ²GlaxoSmithKline, Research Triangle Park, NC, United States, ³GlaxoSmithKline, Stevenage, United Kingdom.

6:15 PM-6:30 PM

Lactation Study Challenges and Solutions

<u>Hurst N</u>¹, Covington D². ¹PPD, Inc., Morrisville, NC, United States, ²Evidera, Wilmington, NC, United States.

6:30 PM-7:00 PM CELEBRATING THE LIFE OF THOMAS H. SHEPARD ASPEN

(Joint with the Teratology Society)

Chairpersons: Sonja A. Rasmussen, Centers for Disease Control and Prevention and

Stephen R. Braddock, Saint Louis University School of Medicine Speakers: Elaine M. Faustman, University of Washington and

Godfrey P. Oakley, Jr., Emory University

7:30 PM-9:30 PM OTIS WELCOME RECEPTION OFF-SITE (EARL'S KITCHEN & BAR)

Monday, June 26, 2017

7:00 AM-8:45 AM OTIS EDUCATION/PUBLIC AFFAIRS COMMITTEE MT. WILSON

MEETING

Presiding: Myla Ashfaq, The University of Texas Health Science Center At Houston

Jennifer Lemons, The University of Texas Health Science Center At Houston

8:45 AM-9:15 AM OTIS MEETING REGISTRATION COLORADO A FOYER

9:00 AM-9:15 AM BREAK

9:15 AM-12:00 PM RSA/FASD-SG, Teratology Society, OTIS, and ASPEN

DNTS Exchange Symposium

Evaluation of Fetal Risk in the Context of Multiple Co-Exposures

(Joint with the Teratology Society, DNTS & RSA)

Chairpersons: Ludmila Bakhireva, University of New Mexico and Jeffrey R.

Wozniak, University of Minnesota

9:15 AM-9:25 AM Introduction: Methodological Challenges of Evaluating the Effect of

Multiple Exposures

Ludmila Bakhireva, University of New Mexico

9:25 AM–9:50 AM Defining the Human Exposome

Cynthia F. Bearer, University of Maryland

9:50 AM-10:15 AM PK/PD Modelling for Multiple Exposures in Pregnancy

Donald R. Mattison, Risk Sciences International

10:15 AM-10:40 AM Networking Break—Aspen Foyer

10:40 AM-11:05 AM Alcohol and Nicotine-Induced Epigenetic Changes (miRNAs)

Rajesh C. Miranda, Texas A&M Health Sciences Center

11:05 AM-11:30 AM Epigenetic Changes Induced by Prenatal Nicotine and Cocaine Exposure

Pradeep Bhide, Florida State University

11:30 AM-11:35 AM Concluding Remarks

Jeffrey R. Wozniak, University of Minnesota

11:35 AM-12 Noon Panel Discussion

12:00 Noon-1:30 PM LUNCH BREAK (LUNCH ON YOUR OWN)

12:15 PM-1:15 PM OTIS BOARD OF DIRECTORS MEETING MT. WILSON

Committee Reports

Presiding: OTIS President: Stephen R. Braddock, Saint Louis University School of

Medicine

1:30 PM-1:35 PM

1:30 PM-4:50 PM MARCH OF DIMES SYMPOSIUM ASPEN

The Complexities of Caring for the Pregnant and Lactating Patient with Chronic Inflammatory Disease: Maternal and Fetal Considerations

(Joint with the Teratology Society)

Chairpersons: Christina D. Chambers, University of California-San Diego and

Melissa S. Tassinari, Independent Consultant

Introduction

1:35 PM-1:55 PM

Overview: Complexity of Disease Management in Pregnancy and Lactation, Consequences of Chronic Disease Itself and Polypharmacy, Use of Asthma and Lupus As Examples

Megan E.B. Clowse, Duke University

1:55 PM-2:15 PM Case Study: Asthma in Pregnancy

Jennifer A. Namazy, Scripps Clinic Mission Valley

2:15 PM-2:35 PM Case Study: Lupus in Pregnancy *Megan E.B. Clowse, Duke University*

2:35 PM-2:55 PM Missing Data

Christine Stallman, University of Arizona, MotherToBaby Arizona

2:55 PM-3:15 PM Long Term Effects of Maternal Factors on Child's Risk for

Autism and Other Neurodevelopmental Concerns Irva Hertz-Picciotto, UC Davis MIND Institute

3:15 PM-3:35 PM Chronic Maternal Immune Mediated Diseases and Their

Treatments: How Do We Design Good Quality Studies to

Evaluate Neurodevelopment in the Offspring?

Gail S. Ross, Cornell University

3:35 PM – 3:50 PM Break – Aspen Foyer

3:50 PM-4:10 PM Lactation and Medications

Philip O. Anderson, University of California - San Diego

4:10 PM-4:30 PM Pregnancy and Lactation Labeling Rule (PLLR): Placement of

Human Data in Labeling

Tamara Johnson, US Food and Drug Administration

4:30 PM-4:50 PM Panel Discussion

5:30 PM-7:30 PM POSTER SESSION 1 AND EXHIBITS OPEN MT. SPORIS

(Joint with the Teratology Society and DNTS)

6:30 PM-7:30 PM OTIS MEMBERSHIP COMMITTEE MEETING MT. YALE

Presiding: Marsha Leen-Mitchell, MotherToBaby Utah and

Mark Roth, Pregnancy Risk Network

7:30 PM - 10:00 PM

TS/MARTA STUDENT CAREER EVENT

CRYSTAL PEAK B

(Open to the Teratology Society, DNTS, and OTIS Student and Postdoctoral Fellows)

Tuesday, June 27, 2017

7:00 AM-7:45 AM OTIS OCCUPATIONAL AND ENVIRONMENTAL

MT. YALE

COMMITTEE MEETING

Presiding: Ginger Nichols, UConn Health

7:45 AM-8:45 AM OTIS/ENTIS RESEARCH CONSORTIUM

MT. WILSON

COMMITTEE MEETING

Presiding: Christina D. Chambers, University of California San Diego

8:00 AM-8:30 AM OTIS MEETING REGISTRATION

COLORADO A FOYER

8:00 AM-9:00 AM ROBERT L. BRENT LECTURE—TERATOGEN UPDATE

ASPEN

In Bed with the Devil: Recognizing Human Teratogenic Exposures

(Joint with the Teratology Society)

Chairperson: Sonja A. Rasmussen, Centers for Disease Control and Prevention

Speaker: Jan M. Friedman, University of British Columbia

9:00 AM-9:15 AM BREAK

9:15 AM-11:00 AM OTIS ABSTRACT SESSION

COLORADO A

Moderator: Sharon Lavigne, University of Connecticut Health

9:15 AM-9:25 AM

Drug Monitoring and Physiologically-Based Pharmacokinetic Modeling of Escitalopram in Breast Milk: Predicting Plasma Exposure in Breast-Feeding Infants.

<u>Delaney S¹</u>, Malik P², Takeuchi M³, Wong E⁴, Stefan C⁴, Edginton A², Colantonio D^{1,3}, Ito S^{1,3}. ¹University of Toronto, Toronto, Ontario, Canada ²University of Waterloo, Waterloo, Ontario, Canada ³Hospital for Sick Children, Toronto, Ontario, Canada, ⁴ Centre for Addiction and Mental Health, Toronto, Ontario, Canada.

9:30 AM-9:40 AM

Child Neurodevelopment Following In-Utero Exposure to Pharmacotherapy for Inflammatory Bowel Disease.

<u>Nulman I¹</u>, Barrera M², Maxwell C³, Nguyen G⁴, ¹Division of Clinical Pharmacology and Toxicology, The Hospital for Sick Children, University of Toronto, Toronto, Ontario, Canada, ²Division of Psychology, The Hospital for Sick Children, University of Toronto, Toronto, Ontario, Canada, ³Maternal Foetal Medicine, Mount Sinai Hospital, University of Toronto, Toronto, Ontario Canada, ⁴Division of Gastroenterology, Mount Sinai Hospital, University of Toronto, Toronto, Ontario, Canada.

9:45 AM-9:55 AM

Quality Assurance Is Not Quality Control: Where does

OTIS/MotherToBaby Fit In?

Wolfe L^1 , ¹University of North Texas, Denton, Texas.

10:00 AM-10:15 AM BREAK

10:15AM-10:25AM Teratogenicity of Second Generation Antiepileptic Drugs in EURAP

Netherlands.

TeWinkel B¹, Vorstenbosch S¹, Van Puijenbroek E, ^{1,2}, ¹Netherlands Pharmacovigilance Centre Lareb, Goudsbloemvallei 7, 5237MH's Hertogenbosch, the Netherlands, ²PharmacoTherapy, Epidemiology and Economics, Groningen Research Institute of Pharmacy, University of Groningen, Antonius Deusinglaan 1, 9713 AV Groningen, The Netherlands.

10:30 AM-10:40 AM Tools to Facilitate Implementation of Clinical Guidance during CDC's Zika

Virus Response.

<u>Polen K¹</u>, Hillard C¹, Johnston E¹, Abercrombie J¹, Moore J¹, ¹Pregnancy and Birth Defects Task Force, 2016 Zika Virus Response, Centers for Disease Control and Prevention, Atlanta, Georgia.

10:45 AM-11:00 AM Discussion of All

11:00 AM-11:15 AM **BREAK**

11:15 AM-12:30 PM OTIS BUSINESS MEETING COLORADO A

Presiding: OTIS President: Stephen R. Braddock, Saint Louis University School of

Medicine

12:30 PM-12:45 PM **BREAK**

OTIS LUNCH BOX TRAINING SESSION 12:45 PM-2:45 PM COLORADO A

> **Lactation and Medications: What's in that Milk? Communicating benefits and risks to moms** Serving OTIS Members and MotherToBaby Affiliates

Presiding: Myla Ashfaq, The University of Texas Health Science Center At Houston

Jennifer Lemons, The University of Texas Health Science Center At Houston

12:45 PM - 12:50 PM **Participants Select Lunch**

12:50 PM - 1:00 PM Welcome and Introduction

> Myla Ashfaq, The University of Texas Health Science Center At Houston Jennifer Lemons, The University of Texas Health Science Center At Houston

1:00 PM- 1:25 PM **Breastfeeding: Health Benefits to Mother and Baby**

Leyla Sahin, MD, FACOG, Division of Pediatric and Maternal Health,

OND/CDER/FDA

1:25 PM - 2:05 PM **Drug Use During Breastfeeding**

Philip O. Anderson, Pharm.D., FASHP, UCSD Skaggs School of Pharmacy &

Pharmaceutical Sciences

2:05 PM - 2:40 PM Workshop on Exposure Counseling and Breastfeeding

Bethany Kotlar, MPH, MotherToBaby Georgia, Emory University School of

Medicine

2:40 PM - 2:45 PM **Concluding Remarks**

> Myla Ashfaq, The University of Texas Health Science Center At Houston Jennifer Lemons, The University of Texas Health Science Center At Houston

2:45 PM-3:05 PM **BREAK**

3:05 PM-5:30 PM	MARIJUANA AND CHILD DEVELOPMENT SYMPOSIUM Joint with the Teratology Society and DNTS Chairpersons: Diana Dow-Edwards, SUNY/Downstate Medical Center Susan L. Makris, US Environmental Protection Agency
3:05 PM-3:10 PM	Introduction Diana Dow-Edwards, SUNY/Downstate Medical Center
3:10 PM-3:35 PM	Dynamic Changes in Endocannabinoid Signaling During Adolescence: Implications for Substance Use and Psychopathology BJ Casey, Yale University
3:35 PM-4:00 PM	Counseling Women About Prenatal Marijuana Use: Weeding through the Data Torri D. Metz, University of Colorado-Denver

Cannabis and the Adolescent Brain: What does the Evidence Say?

4:40 PM-5:05 PM Cannabinoids for Treatment of Pediatric Epilepsy: The Hype and the Evidence

Amy R. Brooks-Kayal, University of Colorado-Denver

Break

5:05 PM-5:30 PM Cannabis Policy: Challenges and Future Directions Susan R.B. Weiss, National Institute on Drug Abuse

5:30 PM ADJOURN

4:00 PM-4:15 PM

4:15 PM-4:40 PM

Conflict of Interest Forms held by the Organization of Teratology Information Specialists National Office