

SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety



Safety Assessment Approaches in Young Children

May 20, 2016



SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety

Welcome

Suzanne Fitzpatrick, PhD

Senior Advisor for Toxicology

CFSAN, US FDA, College Park, MD





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Colloquium Series

- Partnership SOT and US FDA Center for Food Safety and Applied Nutrition (CFSAN)
- High-quality, cutting-edge, future-oriented toxicological science
- Information for FDA employees and the public
- Not a public forum for discussion of toxicology regulatory issues



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Welcome from SOT

Peter L. Goering, PhD, DABT, ATS

Past President, Society of Toxicology

SOT | Society of
Toxicology



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Society of Toxicology Mission

To Create a Healthier and Safer World by
Advancing the Science and Increasing the Impact
of Toxicology

Strategic Priorities

- Strengthen the Relevance and Impact of Toxicology
- Develop and Support Toxicologists to Capitalize on Future Opportunities
- Expand Outreach and Impact Globally



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Seven Previous Colloquia: Topics

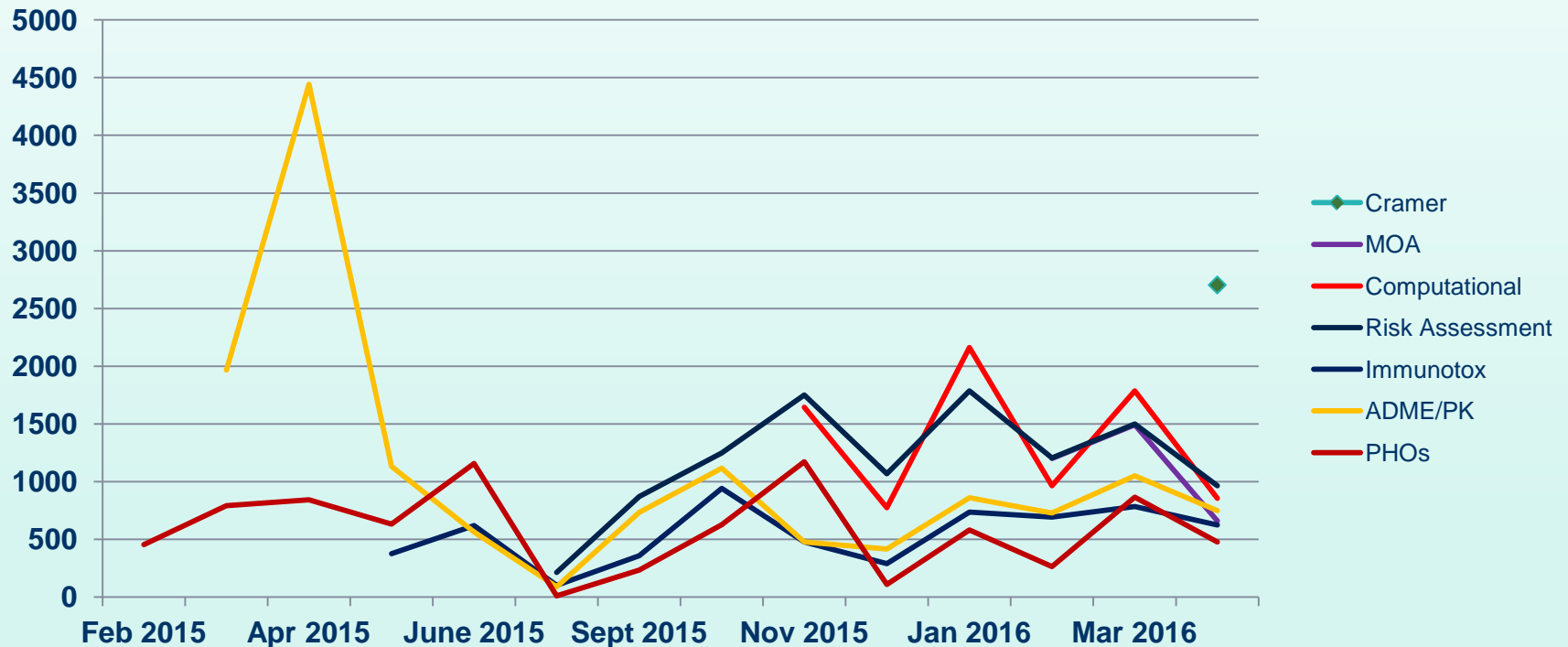
- Cramer Classification and Threshold of Toxicological Concern
- Mode of Action in Dose-Response Assessment for Carcinogens
- Computational and *In Vitro* Methods for Assessments
- Contemporary Issues in Risk Assessment
- Immunotoxicology in Safety Assessment:
- ADME/PK Studies to Improve Safety Assessments
- Clinical and Observational Data for Safety Assessment: Partially Hydrogenated Oils



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Wide-Reaching Impact

- Total attendance: Webcast 1813, onsite 430
- Slide downloads



SOT FDA Organizing Committee

Ivan Rusyn, MD, PhD, Chair, Texas A&M University, College Station, TX

Jason L. Aungst, PhD, US FDA, CFSAN, College Park, MD

Ronald Chanderbhan, PhD, US FDA, CFSAN, College Park, MD

Bryan Delaney, PhD, DABT, ATS, DuPont Pioneer, Johnston, IA

Suzanne Compton Fitzpatrick, PhD, DABT, Colloquium Chair and Committee Member, US FDA, CFSAN, College Park, MD

Kristi Muldoon Jacobs, PhD, US FDA, CFSAN, College Park, MD

Norbert Kaminski, PhD, Michigan State University, East Lansing, MI

Jieun Lee, PhD, DABT, Kellogg, Battle Creek, MI

James J. Pestka, PhD, Michigan State University, East Lansing, MI

Allen Rudman, PhD, FDA Lead, US FDA, Office of Food Additive Safety, CFSAN, College Park, MD

Catherine Whiteside, PhD, US FDA, CFSAN/OFVM/CFSAN, College Park, MD

April Neal-Kluever, US FDA, CFSAN, College Park, MD, for this colloquium





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Colloquium Leads

**Chair: Allen Rudman, FDA
CFSAN, College Park, MD**

**Co-chair: Elaine Faustman,
University of Washington,
Seattle, WA**

Agenda

8:50 AM–9:30 AM

Children Matter: Using a Lifecourse Approach to Understanding Safety Assessment Needs for Children, Elaine Faustman, University of Washington, Seattle, WA

9:30 AM–10:10 AM

Early Life Development of Pharmacokinetic Pathways: Framework and Case Examples with Implications for Safety Assessment, Gary Ginsberg, Connecticut Department of Public Health, Hartford, CT

10:30 AM-11:10

Ensuring Safety for Early Life Exposures: Adequacy of Current Methods and Opportunities to Advance the Science, Susan Felter, Procter & Gamble Company, Mason, OH

11:10 AM-11:50 PM

Regulatory Toxicology Challenges in Lifestage-Specific Safety Assessments, April Neal-Kluever, US FDA, College Park, MD

11:50 AM-12:50 PM

Roundtable Discussion, Peter Goering, Moderator, All Speakers





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Children Matter: Using a Lifecourse Approach to Understanding Safety Assessment Needs for Children

Elaine Faustman

University of Washington



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Colloquium May 20, 2016

Safety Assessment Approaches in Young Children



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Roundtable Discussion: Safety Assessment Approaches in Young Children

11:50 AM-12:50 PM

Peter Goering, Moderator

Elaine Faustman

Gary Ginsberg

Susan Felter

April Neal-Kluever

Questions welcome.



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Future Colloquia 2016-2017

- Watch for Schedule and Topics

Colloquia Materials

- Recordings
- Slides
- Captioning Text

The screenshot shows the SOT (Society of Toxicology) website. The header includes the SOT logo and navigation links: Contact Us | Help | Admin | Logout. A search bar is present on the right. Below the header is a navigation menu with links: About SOT, Members & Groups, Meetings & Events, Publications & News, Awards & Funding, Careers, Education, Endowment Fund, and My Links. The main content area features a section titled "SOT FDA Colloquia" with a sub-header "SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety" and the location "FDA, College Park, Maryland". A paragraph below describes the partnership between SOT and the US FDA Center for Food Safety and Applied Nutrition (CFSAN) to provide high-quality, cutting-edge, future-oriented toxicological science. A blue button labeled "Open All" is visible. On the right side, there are social media sharing icons and a section titled "Annual Meeting & ToxExpo" with a reminder to update contact information.

are available at no charge at www.toxicology.org



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**Thank you for your
participation.**

**We appreciate your input. We will send you a link
and we appreciate your completing the survey.**