

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



Contemporary Issues in Risk Assessment

June 17, 2015



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

Welcome from FDA

Suzanne Compton Fitzpatrick, PhD, DABT

Center for Food Safety and Nutrition

College Park, MD





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

Welcome from SOT

Peter L. Goering, PhD, DABT, ATS

President, Society of Toxicology

SOT | Society of
Toxicology



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SOT 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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Colloquium 1

November 7, 2014

Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety Assessment: Partially Hydrogenated Oils (PHOs) As a Case Study

Onsite Participants	95
Webcast	239
Video Recording Views	140
Presentation Slide Downloads	1,278

Video, slides, captioning text available at <http://www.toxicology.org/fda>



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Colloquium 2

February 23, 2015

Application of ADME/PK Studies to Improve Safety Assessments for Foods and Cosmetics

Onsite Participants	46
Webcast	195

Video, slides, available at <http://www.toxicology.org/fda>
(captioning text is pending)



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Colloquium 3

April 23, 2015

Immunotoxicology in Food and Ingredient Safety Assessment: Approaches and Case Studies

Onsite Participants 64

Webcast 192

Video, slides, available at <http://www.toxicology.org/fda>
(captioning text is pending)



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Colloquium 4

June 17, 2015

Contemporary Issues in Risk Assessment



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Perspectives on “Risk Assessment”



Arnold P. Lehman, MD, PhD
Chief, Division of Pharmacology, USFDA
Honorary President, Society of Toxicology (1961-62)
Co-founder, Society of Toxicology (1961)



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Perspectives on “Risk Assessment”



*“You, too, can become
a toxicologist in two
easy lessons...
each one taking about
10 years.”*

Arnold P. Lehman, MD, PhD

Chief, Division of Pharmacology, USFDA

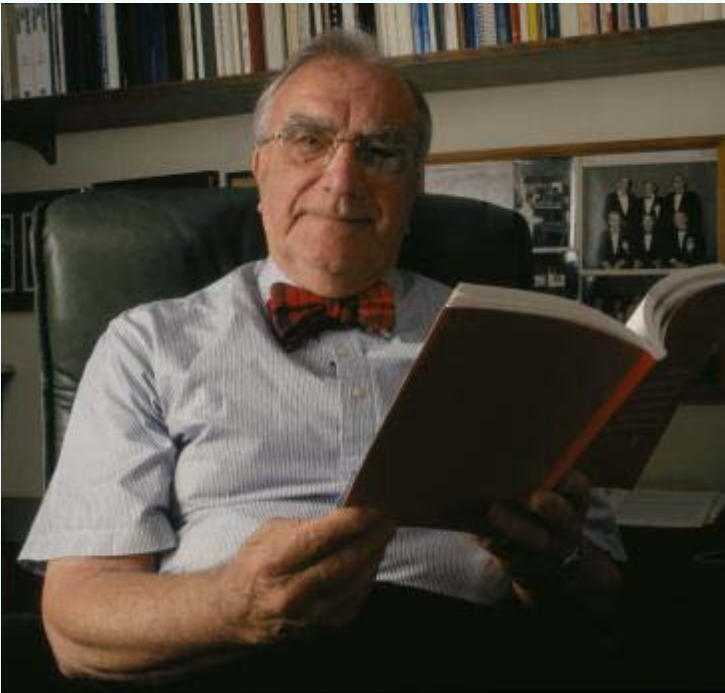
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Perspectives on “Risk Assessment”



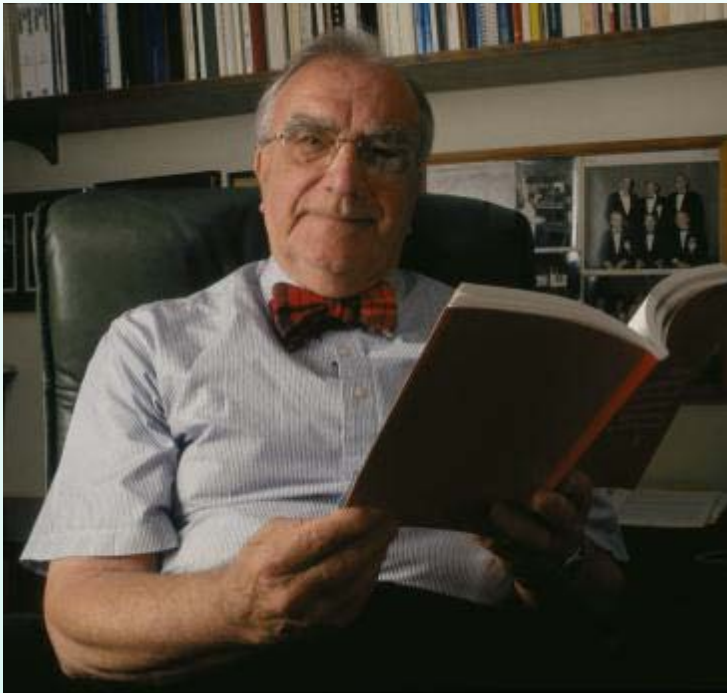
John Doull, MD, PhD

Professor Emeritus, Kansas University Medical School
President, Society of Toxicology, 1986-87



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Perspectives on “Risk Assessment”



“Toxicology is
what we do.
Risk assessment
is why we do it.”

John Doull, MD, PhD

Professor Emeritus, Kansas University Medical School
President, Society of Toxicology, 1986-87

Today's Agenda

- 8:15 AM-8:25 AM** US FDA Welcome and Overview, Suzanne Fitzpatrick, US FDA, CFSAN, College Park, MD
- 8:25 AM-8:30 AM** Welcome from SOT, Peter Goering, SOT President, US FDA, Silver Spring, MD
- 8:30 AM-8:35 AM** Speaker Introduction, Ivan Rusyn, SOT FDA Colloquium Organizing Committee Chair, Texas A&M, College Station, TX
- 8:35 AM-9:15 AM** Problem Formulation and Scoping for Human Health Assessments, Juleen Lam, University of California San Francisco, San Francisco, CA
- 9:15 AM-10:00 AM** Identification and Selection of the Evidence Base for Human Health Assessments, Kathryn Guyton, International Agency for Research on Cancer Monographs Programme, Lyon, France
- 10:00 AM-10:15 AM** Break



Today's Agenda, continued

- 10:15 AM-11:00 AM** Harmonizing Dose-Response Assessment for Cancer and Non-cancer Endpoints in Human Health Assessments, Weihsueh Chiu, Texas A&M University, College Station, TX
- 11:00 AM-11:45 PM** The Use of the Mechanistic Evidence in Human Health Assessments, J. Vincent Cogliano, US EPA, Crystal City, VA
- 11:45 PM-12:30 PM** Roundtable Discussion
Ivan Rusyn, Moderator
All Speakers
- 12:45 PM-1:30 PM** Optional time for FDA employees with speakers



FDA-SOT Organizing Committee

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

Suzanne Compton Fitzpatrick, PhD, DABT, Colloquium 4 Chair and member, US FDA, CFSAN, College Park, MD

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

Ji-Eun Lee, PhD, DABT, Kellogg, Battle Creek, MI

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

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

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

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

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

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

Sabine Francke-Carroll, DVM, PhD, US FDA, CFSAN, College Park, MD

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





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Moderator

Ivan Rusyn, MD, PhD

Chair, SOT FDA Colloquium Organizing Committee

Texas A&M University

College Station, Texas



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Problem Formulation and Scoping for Human Health Assessments

Juleen Lam

University of California San Francisco

San Francisco, California



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Identification and Selection of the Evidence Base for Human Health Assessments

Kathryn Guyton, PhD

International Agency for Research on Cancer
Monographs Programme

Lyon, France



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Harmonizing Dose-Response Assessment for Cancer and Non- cancer Endpoints in Human Health Assessments

Weihshueh Chiu, PhD

Texas A&M University

College Station, Texas



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The Use of the Mechanistic Evidence in Human Health Assessments

J. Vincent Cogliano, PhD

US EPA

Crystal City, Virginia



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

Roundtable Discussion: Contemporary Issues in Risk Assessment

Moderator: Ivan Rusyn, MD, PhD

All speakers

Questions welcome.



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Colloquia

- Recordings

- Slides

- Captioning Text

are available at

www.toxicology.org

The screenshot shows the SOT (Society of Toxicology) website page for SOT FDA Colloquia. The header includes the SOT logo and navigation links such as 'About SOT', 'Members & Groups', 'Meetings & Events', 'Publications & News', 'Awards & Funding', 'Careers', 'Education', 'Endowment Fund', and 'My Links'. A search bar and social media icons are also present. The main content area features a blue banner with the SOT FDA logo and the title 'SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety'. Below the banner, there is a paragraph of text describing the partnership between SOT and the US FDA Center for Food Safety and Applied Nutrition (CFSAN). A blue button labeled 'Open All' is visible. On the right side, there are sections for 'Annual Meeting & ToxExpo', 'CCT Meetings', and 'Events Calendar', each with a brief description of the events.



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**Thank you for your
participation.**