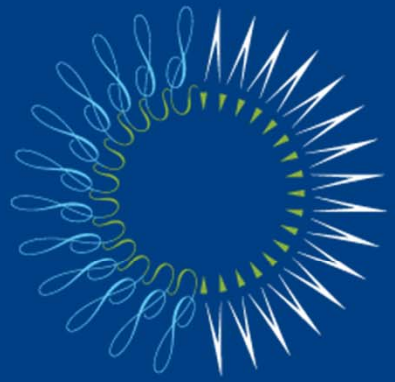

THE PEW CHARITABLE TRUSTS

Report on Pew, Nature and IFT cosponsored workshop on Non-Monotonic Dose Responses: Relevance and Implications for Food

Maricel Maffini
Senior Officer, Food Additives Project
Pew Health Group

June 14, 2012

Food Additives Project

- Launched in 2010 to:
  - Conduct a comprehensive analysis of the existing U.S. regulatory program
  - Determine if the system works and whether chemicals added to food are safe as required by law
  - Develop policy recommendations to address any gaps or problems
- Transparent process engages industry, academic, government and public interest stakeholders
- Project staff convene workshops and publish articles, primarily in peer-reviewed journals

THE PEW CHARITABLE TRUSTS

Comprehensive REVIEWS in Food Science and Food Safety

Vol. 10, 2011 • Comprehensive Reviews in Food Science and Food Safety

Enhancing FDA's Evaluation of Science to Ensure Chemicals Added to Human Food Are Safe: Workshop Proceedings

Maricel V. Maffini, Heather M. Alger, Erin D. Bongard, and Thomas G. Neltner

Navigating the U.S. Food Additive Regulatory Program

Thomas G. Neltner, Neesha R. Kulkarni, Heather M. Alger, Maricel V. Maffini, Erin D. Bongard, Neal D. Fortin, and Erik D. Olson

Non-monotonic dose responses: Relevance and implications for food

- April 20, 2012 at the Pew Conference Center in Washington, D.C.
- Co-sponsored by the journal *Nature*, the Institute of Food Technologists (IFT) and the Pew Health Group.
- Participants included more than 60 leading scientists from government, academia, private sector and non-profit organizations.

Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses

Laura N. Vandenberg, Theo Colborn, Tyrone B. Hayes, Jerrold J. Heindel, David R. Jacobs, Jr., Duk-Hee Lee, Toshi Shioda, Ana M. Soto, Frederick S. vom Saal, Wade V. Welshons, R. Thomas Zoeller, and John Peterson Myers

Endocrine Reviews, June 2012, 33(3):378–455

Speakers and Topics

- **Tom Zoeller** (University of Massachusetts – Amherst)
  - Principles of Endocrinology
- **Laura N. Vandenberg** (Tufts University)
  - Non-monotonicity in endocrine disrupting chemical studies: examples and mechanisms
  - Demonstrating low-dose effects using a weight of evidence approach: examples and mechanisms
  - Examples of non-monotonicity in epidemiologic studies
- **Lorenz R. Rhomberg** (Gradient)
  - Non-monotonic dose-response: Has the case been made?
- **J. Peterson (Pete) Myers** (Carnegie Mellon University and Environmental Health Sciences)
  - Challenges and summary
- **Iona Pratt** (FDA of Ireland) and **Jerry Heindel** (NIEHS)
  - A path forward

Pew's take away

- The potential public health implications of non-monotonicity at doses relevant to human exposure are significant enough to warrant making the issue a priority.

- There is a need to improve the interdisciplinary communication of endocrinologists, toxicologists, and risk assessors to better evaluate these implications.

- Addressing non-monotonicity will likely require a rethinking of most current risk assessment approaches.

To Learn More

Contact Maricel Maffini
at mmaffini@pewtrusts.org
or 202-540-6520

or go to

www.pewhealth.org/topics/