



## October Insights



### HESI 2017 Call for Proposals Now Open!

HESI seeks your suggestions for priority emerging scientific issues (human or environmental health) that should be addressed through a focused, multi-sector collaborative program. The most promising proposals will form the basis of new scientific initiatives within HESI and will receive supporting funds to initiate activities in the fall of 2017. Proposal submissions do not require a commitment of resources or any current or prior affiliation with the HESI organization. However, proposals that come with matching resources will be given special consideration. Click [here](#) for frequently asked questions about the HESI proposal solicitation process. **Ready to submit?** Complete the proposal form (or access it [here](#)), and return it to Cyndi Nobles by **Friday, 9 December 2016**. Questions? Contact [Jennifer Pierson](#) to learn more!

### Save the Date!

The 2017 HESI Annual Meeting will be held **13–15 June 2017** in Dublin, Ireland! More details, including a draft agenda and registration, will be available soon.



### DART Awarded Best Poster!

Congratulations to the HESI DART Committee on their recent “Elsevier Best Poster/Free Communications” award for the poster by Davis-Bruno et al. (“[Nondinical Models for Neonatal Pediatric Drug Development](#)”) at the 2016 European Teratology Society Meeting. For more information about this project or other DART Committee activities, contact [Connie Chen](#).

### FDA Report Cites HESI as a Key Partner

The *CDER 2015–2016 Drug Safety Priorities* report provides information on a number of issues, including the importance of public-private partnerships. These public-private partnerships are the cornerstone of HESI and FDA recognizes one of their many partnerships with HESI in this report. Read more [here](#).

### HESI at the ISES Annual Meeting

Several HESI committees will be presenting and represented at the [International Society of Exposure Science \(ISES\) Annual Meeting](#) in Utrecht, The Netherlands, on **9–13 October 2016**. For more information, please contact [Michelle Embry](#) or [Jennifer Tanir](#).

## Monday, 10 October 2016

### Sessions

- 11:00–12:00: Mo-SY-C2: Quantitative In Vitro to In Vivo Extrapolation (QIVIVE): Advances in Tools to Quantify Exposure-Response Relationships for Risk Assessment – I. Co-chaired by Michelle Embry (HESI), Jon Arnot (ARC), and Todd Gouin (Unilever).
- 14:00–15:30: Mo-SY-C3: Quantitative In Vitro to In Vivo Extrapolation (QIVIVE): Advances in Tools to Quantify Exposure-Response Relationships for Risk Assessment – II. Co-chaired by Michelle Embry (HESI), Jon Arnot (ARC), and Todd Gouin (Unilever).
- 16:00–17:30: Mo-SY-C4: Quantitative In Vitro to In Vivo Extrapolation (QIVIVE): Advances in Tools to Quantify Exposure-Response Relationships for Risk Assessment – III. Co-chaired by Michelle Embry (HESI), Jon Arnot (ARC), and Todd Gouin (Unilever).

### Presentation

- 14:18–14:36: Mo-SY-F3.2 Ecological Threshold for Toxicological Concern (Eco-TTC): Assessing the Potential of a New Tool for Environmental Hazard Assessment. Presentation by Michelle Embry on behalf of the HESI Animal Alternatives in ERA Technical Committee.

## Tuesday, 11 October 2016

### Presentations

- 16:00–16:15: Tu-SY-G4.1 Integrating Exposure Into Chemical Alternatives Assessment Using a Qualitative Approach. Presentation by Bill Greggs, Soleil Consulting, LLC, on behalf of the HESI Sustainable Chemical Alternatives Technical Committee.
- 17:15–17:30: Tu-SY-G4.6 Panel Discussion: Challenging and Discussing the Presented Approaches and Tools to Address Exposure in LCA and CAA. Participation on panel by Bill Greggs.
- 16:00–16:18: Tu-PL-H4.1 Using Exposure Bands for Rapid Decision-Making in the RISK21 Tiered Exposure Assessment. Presentation by Bonnie Gaborek, DuPont, on behalf of the HESI RISK21 Technical Committee.

More details are available [here](#).

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## HESI at the SETAC North America Annual Meeting

HESI will have a number of sessions and presentations at the [SETAC North America Annual Meeting](#) in Orlando, Florida, on **6–10 November 2016**. For additional information, please contact [Michelle Embry](#) or [Jennifer Tanir](#).

## Monday, 7 November 2016

- **111:** Integrating Exposure Into Chemical Alternatives Assessment Using a Qualitative Approach. Platform presentation by Bill Greggs (Soleil) on behalf of the HESI Sustainable Chemical Alternatives Technical Committee.
- **Poster Session:** Business Examples of Chemical Alternatives Assessment. Session co-chaired by Jennifer Tanir (HESI) and Ann Mason (ACC).

## Tuesday, 8 November 2016

- **227:** Mode of Action (MOA) Assignment Classifications for Ecotoxicology: Evaluation of Available Methods. Platform presentation by Michelle Embry (HESI) on behalf of the HESI Animal Alternatives in ERA Technical Committee.
- **228:** Ecological Threshold for Toxicological Concern (eco-TTC): Assessing the Potential of a New Tool for Environmental Hazard Assessment. Platform presentation by Amy Beasley (Dow Chemical) on behalf of the HESI Animal Alternatives in ERA Technical Committee.
- **229:** Animal Alternatives for Whole Effluent Toxicity Testing: Perspectives from a Global Workshop. Platform presentation by Teresa Norberg-King (USEPA) on behalf of the HESI Animal Alternatives in ERA Technical Committee.
- **TP014:** Construction and Curation of a Large Ecotoxicological Dataset for the Eco-TTC. Poster presentation by Amy Beasley (Dow Chemical) on behalf of the HESI Animal Alternatives in ERA Technical Committee.

## Thursday, 10 November 2016

- **Session:** Differing Biotransformation Capacity Across Species: Measurements, Modeling, and Implications for Decision-Making. Session co-chaired by Jon Arnot (ARC), Michelle Embry (HESI), and

Henriette Selck (Roskilde University).

- **RP062:** In Vitro to In Vivo Extrapolation of Hepatic Metabolism in Fish: An Inter-Laboratory Comparison of In Vitro Methods. Poster presentation by Michelle Embry (HESI) on behalf of the HESI Bioaccumulation Technical Committee.

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## SPS 2016 HESI Highlights

The 2016 Safety Pharmacology Society (SPS) Annual Meeting was convened jointly with the Japanese Safety Pharmacology Society and the Canadian Society of Pharmacology and Therapeutics in Vancouver, British Columbia, on **18–21 September 2016**. The HESI Cardiac Safety and Translational Biomarkers of Neurotoxicity Committees presented [CW1] at this meeting. SPS members can log in and view posters and presentation abstracts [online](#). In addition to the great science, the meeting provided a forum for continued collaboration with our colleagues in Japan and Canada. For more information about the HESI work presented at this meeting, contact [Jennifer Pierson](#).



*Omotenashi or Japanese hospitality at the SPS 2016 opening ceremonies.*



*Dr. Syed Imam (US FDA-NCTR) presents preliminary findings of the recent pilot study conducted by the HESI NeuTox Committee at SPS 2016.*

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## Upcoming Events

### Final Agenda Now Available for HESI Protein Allergenicity Workshop

**NON-IG E MEDIATED IMMUNE REACTIONS TO FOODS:  
RESEARCH NEEDS AND SCIENTIFIC APPROACHES TO ASSESSING SAFETY.**  
A FAAM 2016 pre-meeting workshop, organized by:  
ILSI Health & Environmental Sciences Institute (HESI)  
Protein Allergenicity Technical Committee (PATC)



**12-13 October, 2016**

Sheraton Roma Hotel & Conference Centre,  
Rome, Italy.



Renowned allergy experts will present the state of the science on non-IgE immune reactions and celiac disease at the "PATC Non-IgE Mediated Immune Reactions to Foods Workshop" on **12–13 October 2016** in Rome, Italy. Industry and regulatory experts will address the safety assessment of newly expressed proteins and non-IgE mediated immune response, and an overview of current trends in gluten-free foods will also be provided. All attendees will join the panel of speakers for an interactive discussion of this scientific program, intended to elicit participant feedback on current data gaps, research needs, and the potential for integration of new data into the food safety assessment process. The objective is to generate a series of specific recommendations or consensus conclusions by the end of this workshop. We are still able to take a few registrations! [Register here](#) as soon as possible (registration is free but required for logistical purposes).

## HESI Framework for Intelligent Non-Animal Methods for Safety Assessment Workshop

The Frameworks subcommittee is planning to hold a two-day workshop on **15–16 November 2016** in Rockville, Maryland. The event will provide an opportunity for both committee members and outside stakeholders to discuss the work to date and to gather input from the participants present. During these two days, multiple case studies and breakout[CW1] sessions will take place in order to disseminate the information presented and allow consideration for its incorporation into a final framework. For more information or to register, please click [here](#) or contact [Dr. Stan Parish](#).

### CiPA Update Meeting Sponsored by CSRC and HESI

The next CiPA Update Meeting will be held on **6 December 2016** in Rockville, Maryland, at the [Hilton Washington, DC/Rockville Hotel and Executive Meeting Center](#). The meeting will feature an update from all of the CiPA work groups as well as panel discussions and an opportunity to discuss the scientific progress. CSRC will also convene a follow-on meeting on **7 December 2016** focused on QTc Exposure Response Modeling. The final agenda is [available online](#). Click here to register today. Contact [Jennifer Pierson](#) to learn more.

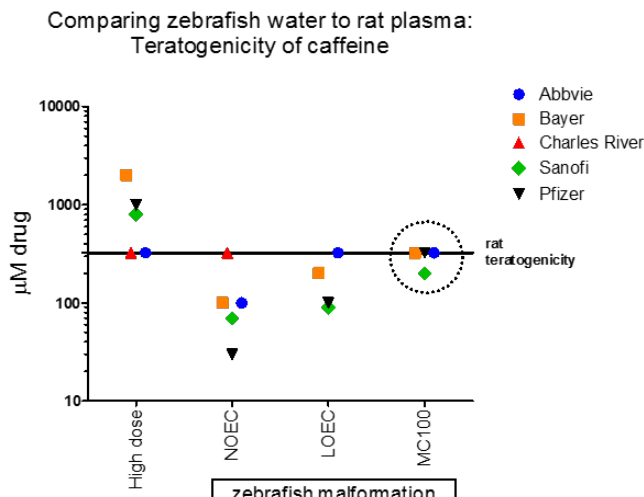
### Mark Your Calendars! DART Blank Page Workshop

The thalidomide tragedy galvanized regulatory agencies into action to develop a testing scheme to identify the potential teratogenicity of new drugs. The outcome was the three-segment testing scheme that covered the reproductive cycle, including the Segment II protocol. Although there have been some modifications to the protocol over time, it is largely the same method that was developed in 1965. What if we were responding to the thalidomide tragedy today instead of 50 years ago, with the 21st-century science and technology available to us? Would we design the same protocol? If not, would it be radically different or just an updated version of the 1965 design? The Blank Page project is intended to address that question. The Blank Page workshop will be held **19–20 April 2017** and will consider new strategies to identify developmental hazards taking into account the current state of science, which may include alternative possibilities or improvements to the current Segment II design. For additional information, visit the workshop's [website](#) or contact [Connie Chen](#).

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### Looking for Additional Partners!

A DART workgroup has completed the first round of testing of the consensus list of developmental toxicants in the zebrafish embryogenesis assay. The initial results were very promising (see image for representative results) and the group would like to add to the number of participating labs to help us complete the testing. If you have a zebrafish embryogenesis assay running in your lab and would like to contribute, we invite your participation! Note that the participating labs are all running different assays and protocols, so any zebrafish developmental toxicology assay would be a valuable addition! Please contact [Connie Chen](#) if you would like additional information or are interested.



DART DASTON results.

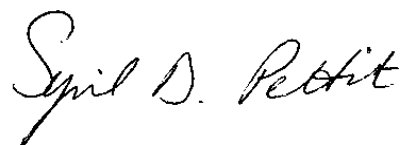
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## Recent Publications

Dearfield KL, Gollapudi BB, Bemis JC, Benz RD, Douglas GR, Elespuru RK, Johnson GE, Kirkland DJ, LeBaron MJ, Li AP, Marchetti F, Pottenger LH, Rorije E, Tanir JY, Thybaud V, van Benthem J, Yauk CL, Zeiger E, and Luijten M (2016) Next-generation testing strategy for assessment of genomic damage: a conceptual framework and considerations. *Environmental and Molecular Mutagenesis*. Early View 21 September 2016. Available through open access [here](#).

## FROM THE EXECUTIVE DIRECTOR

It has been an incredibly busy fall as always. The HESI staff have attended or directed meetings in at least five countries in the last month alone—a testament to the activity and global outreach of our scientific programs. At the Board level, your leadership is working hard to implement the new Strategic Plan. Exciting new efforts to grow HESI's scientific foresight, enhance organizational efficiency, diversify funding streams, and deepen and broaden our scientific impact are actively in development. We look forward to sharing these with you over the coming months. If you have interest in learning more about any of these initiatives, please don't hesitate to contact me directly.



Syril D. Pettit, HESI Executive Director

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