



September 2013

FDA and HESI Sign Commitment to Partnership for Drug Safety and Development.

On 19 September 2013, Dr. Janet Woodcock, Director of the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), and Syril Pettit, MEM, HESI Executive Director, signed a Memorandum of Understanding (MOU) committing their organizations to partnership to enhance drug development and drug safety evaluation through shared research, education, and collaborative exchange of expertise across the public and private sectors. This MOU provides a strong context for the expansion of high-impact interactions between HESI and the FDA on pre-competitive drug safety issues. For more details on this important partnership, please contact HESI (cnobles@hesiglobal.org).

Welcome to Five New HESI Sponsors. We are pleased to announce that **Acea Biosciences, Celgene, Collectis, Cellular Dynamics International, and InvivoSciences** and will be joining the HESI organization! We look forward to their contributions to HESI scientific programs.



In Memoriam. HESI is very sad to announce that **Dr. Gary Mihlan** [passed away](#) on 12 September 2013. Gary was a valued contributor to numerous HESI projects during his time at Bayer CropScience and many of us worked closely with him over the years. He will be sorely missed by his friends and colleagues. His family has requested that contributions be made to either [Colorado State University](#) or the [UNC Gillings School of Global Public Health](#) in honor of Gary. Condolences to the family may be made at the Cremation Society of the Carolinas [website](#).

Highlights from Recent Meetings

Eurotox 2013, Interlaken, Switzerland

- Congratulations to Herman Autrup (University of Aarhus), Vice-Chair of the HESI Board of Trustees, who was awarded the "Eurotox Merit Award," the society's annual recognition for scientific contribution and excellence.
- More than 150 individuals attended HESI's keynote lecture given by Dr. David Bell (European Chemicals Agency), who highlighted upcoming chemical regulatory issues for Europe.
- HESI was recognized in the following sessions: the World Health Organization Risk Assessment Network information session, the stem cell applications session, the RISK21 session, the opening ceremonies for the meeting, and the Thresholds for Toxicological Concern session.

246th American Chemical Society National Meeting, Indianapolis, Indiana, USA

- Drs. Michelle Embry (HESI), Keith Solomon (University of Guelph), and Rick Becker (American Chemistry Council) participated in a press briefing on the 21st century vision for toxicity testing and risk assessment for agrochemicals, following a half-day technical session on the topic. Watch it [here](#).
- Dr. Jennifer Young Tanir (HESI) gave an invited presentation on HESI's measures of success

in a session on true stories of success from chemical entrepreneurs.

Environmental Mutagenesis and Genomics Society Annual Meeting, Monterey, California, USA

The HESI Genetic Toxicology Technical Committee held a successful workshop on “New Approaches for Improving Genotoxicity Evaluation” for 85 participants on 21 September 2013. The presentations can be found online [here](#).

UPCOMING HESI WORKSHOPS



HESI, EPA, and NIEHS Co-Sponsor Workshop on Translational Alternative Models and Biomarkers Predictive of Drug or Chemical Cardiovascular Risk.

As a result of the broad current interest in cardiovascular toxicity, the [National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods](#), HESI, and EPA are collaborating to present a workshop addressing development of new methods to assess and predict whether substances might affect cardiovascular safety in humans. The workshop will be held 10–11 October 2013 at NIEHS. Further information and registration are available [here](#).

IWGT and ICEM Meetings in Brazil. Two HESI committees will participate in these meetings. The HESI Genetic Toxicology Technical Committee is sponsoring and participating in the 6th International Workshop on Genotoxicity Testing (IWGT) on 31 October–2 November 2013 and the 11th International Conference on Environmental Mutagens (ICEM) on 3–8 November 2013 in Foz do Iguassu, Brazil. HESI is also planning the following additional events at the ICEM meeting: (1) a lunchtime session on “Advancing Science through International Collaborations: The Health and Environmental Sciences Institute” on Tuesday, 5 November 2013; and (2) a HESI Genomics Committee-sponsored symposium on “Genomic Approaches for Biomarker Development and Safety Assessment” on Thursday, 7 November 2013. Additional information on both meetings can be found [here](#).



SETAC Training Course on *In Vitro* Methods for Bioaccumulation Assessment.

The HESI Bioaccumulation Project Committee will sponsor a professional training course on “*In Vitro* Methods for the Determination of Test Chemical Metabolism Utilizing Fish Liver Subcellular Fractions and Hepatocytes” on Sunday, 17 November 2013, at the SETAC North America Annual Meeting in Nashville, Tennessee. The hands-on course will be hosted in the laboratory of Dr. Frederick P. Guengerich at Vanderbilt University, with lectures and instruction from Drs. Karla Johanning (KJohanning Consultancy LLC), Kellie Fae (US EPA), John Nichols (US EPA), Michelle Embry (HESI), Frederick Guengerich (Vanderbilt University), and Mary Jo Bernhard (Procter & Gamble). Click [here](#) for more information and to register for the course, or contact Dr. Michelle Embry (membry@hesiglobal.org).

Advances in Assessing Adverse Epigenetic Effects of Drugs and Chemicals. The HESI Genomics Committee is organizing this workshop in Washington, DC, on 18 November 2013. This event will address epigenetics and its potential applications in toxicology, discuss the current status of different areas of epigenetics research, provide an overview of available methods, and use case studies to expand on topics with potential relevance for toxicological assessment. For more information, visit the [website](#) or contact Dr. Raegan O’Lone (rolone@hesiglobal.org).



HESI Co-Sponsors SOT CCT FutureToxII Workshop.

HESI will co-sponsor a 16–17 January 2014 Society of Toxicology (SOT) Contemporary Concepts in Toxicology (CCT) Workshop on “*FutureToxII: In Vitro Data and In Silico Models for Predictive Toxicology*” in Chapel Hill, North Carolina. FutureToxII will provide a forum to address progress and advances toward a paradigm in which improvements to predictivity and concordance are based on

in vitro/in silico approaches that are integrated with systems biology. Sponsors include SOT, Elsevier, Hamner Institutes for Health Sciences, HESI, and the University of North Carolina. Registration is open. Click [here](#) for more information.



HESI's 25th Anniversary! Mark your calendars for HESI's 25th anniversary celebration at the 10–11 June 2014 Annual Meeting in Washington, DC.

ILSI Health and Environmental Sciences Institute (HESI)
1156 Fifteenth Street, NW
Suite 200
Washington, DC 20005-1743
202.659.3306 phone
202.659.3617 fax

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FROM THE EXECUTIVE DIRECTOR

HESI's success is built upon commitments to partnership in science. We are thus very pleased that the FDA has further strengthened this commitment to partnership with HESI via this month's MOU. We look forward to enhanced opportunities to prospectively build improved approaches for health and safety with FDA and all of our partner organizations and scientists.

Spir D. Rohit