August 2013



HESI at Eurotox, Interlaken, Switzerland. Dr. David Bell (European Chemicals Agency, Finland) will give an ILSI/HESI lecture on "Emerging Needs for Chemical Safety and Risk Assessment in Europe" on 2 September 2013 at the 49th Congress of the European Societies of Toxicology (Eurotox). Additional

HESI activities from the RISK21, Cardiac Safety, Genomics, and Imaging for Translational Safety Assessment committees are scheduled for 2–4 September 2013. Visit the HESI <u>website</u> for additional details.



HESI at European Teratology Society Meeting, Stresa, Italy. The HESI Developmental and Reproductive Toxicology Technical Committee is sponsoring the 9 September 2013 symposium on "Cross-Industry Data Survey of the Value of Rabbit

Developmental Toxicity Data in the Risk Assessment for Pharmaceuticals" at the 41st Annual Meeting of the European Teratology Society. This symposium is co-chaired by Drs. Alan Hoberman (Charles River Laboratories), Jane Stewart (AstraZeneca), and Aldert Piersma (RIVM, The Netherlands). Presenters include Drs. Jane Stewart (AstraZeneca), Aldert Piersma (RIVM, The Netherlands), Peter Theunissen (RIVM, The Netherlands), Gregg Cappon (Pfizer), and Sonja Beken (Federal Agency for Medicines and Health Products, Belgium). Visit the **ETS website** for full program details.



HESI at International Congress of Nutrition, Granada, Spain. Dr. Greg Ladics (DuPont), co-chair of the HESI Protein Allergenicity Technical Committee, will present an overview of scientific approaches to evaluating novel proteins expressed in biotechnology products and the development of reliable and accurate methodologies

for characterizing the allergenic potential of novel proteins at a joint Food Allergy session on 19 September 2013 at the 20th International Congress of Nutrition (ICN 2013) in Granada, Spain. The Food Allergy session is jointly sponsored by HESI, ILSI Europe, and ILSI North America. Two other ILSI-sponsored sessions will be held at ICN 2013 (15–20 September 2013), and multiple ILSI branches, including HESI, will co-host a booth at the meeting (#47). Click here for more information about HESI and ILSI activities at ICN 2013.

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 <u>National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods</u>, 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 <u>here</u>.

HESI WORKSHOPS (CONT'D)

Cytokine Release: State of the Science, Current Challenges, and Future Directions. The HESI Immunotoxicology Technical Committee is organizing this workshop in Silver Spring, Maryland, on 22 October 2013. This workshop will focus on cytokine storm risk assessments with an objective to bring together academic, industry, and regulatory agency scientists to discuss current technologies, practices, and scientific challenges. Space is limited—register today. For more information, visit the website or contact Dr. Raegan O'Lone (rolone@hesiglobal.org).



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). The deadline for early course registration is 10 September 2013. Click here for more information or 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. The HESI Project Committee on Distinguishing Adverse from Non-Adverse/Adaptive Effects

will co-host a 16–17 January 2014 Society of Toxicology (SOT) Contemporary Concepts in Toxicology (CCT) workshop titled "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. An overarching goal is to clarify the usefulness and validity of new and emerging technologies and approaches, so that expectations can be managed in both the regulatory and regulated scientific communities. Breakout groups will provide an opportunity for detailed scientific discussion on how the biological pathways of interest will be elucidated, characterized, and qualified for adverse outcome pathways and their applications in basic research and safety assessments. The Organizing Committee for the FutureToxII workshop includes Dr. Douglas Keller (Sanofi US), co-chair of the HESI Adverse/Adaptive Project Committee, and Ms. Nancy Doerrer (HESI). 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-CSRC-FDA Workshop Slides Available

Online. Presentation slide sets are now available from the 23 July 2013 workshop on "Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study" sponsored by HESI, FDA, and the Cardiac Safety Research Consortium (CSRC). Visit the HESI website to view the available slides. The CSRC will also post a meeting summary on its website.

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FROM THE EXECUTIVE DIRECTOR

A busy summer is leading into an even busier fourth quarter for 2013! In addition to the ongoing research across the technical programs and the scientific workshops described above, the Board and staff are actively developing steps toward further implementation of HESI's Strategic Plan. More details are forthcoming in early 2014, but look to these activities to enhance the impact and expediency of HESI's current programs as well as to augment HESI's role and reputation as a global organization dedicated to improving science for public health.

