



June 2015

Congratulations to Dr. Cohen! Congratulations to Dr. Samuel M. Cohen for receiving the honor of the 2015 STP Lifetime Achievement Award! Dr. Cohen has been actively involved with ILSI, RSIA, and HESI since 1985, serving as a member of the HESI Board of Trustees since 2001 (Vice Chairman, 2004–2006; Chairman, 2006–2008) and the ILSI Board of Trustees since 2007 (Vice Chairman, 2010–2012; Chairman, 2012–2015).



2015 HESI Annual Meeting. The HESI Board of Trustees and staff welcomed over 115 global thought leaders to its HESI Annual Meeting, held 9–12 June 2014 in Washington, DC. Participants represented both public-sector institutions (government, academia, research institutes, and NGOs) and private organizations. The Annual Meeting also featured thought-provoking presentations from three of the current HESI scientific committees as well as a CITE session with invited speakers from the Harris Group, the African Insect Science for Food and Health Center, and the Institute for Health Metrics and Evaluation. The CITE session videos are available on the [HESI website](#) for those who were not able to attend in person.

The HESI Emerging Issues session featured TED Fellow, Dr. Jessica Green (University of Oregon), who presented on “MicroBiome Systems Biology.” Following Dr. Green, the HESI Emerging Issues Committee (EIC) presented the 2015 topics selected for prioritization by stakeholders that would benefit from HESI’s focused, multi-sector collaborative approach. Proposal submitters presented on the following topics: 1) “Models/Tests to Assess Stem Cells as Therapeutic Agents: Using Imaging Technology to Evaluate Stem Cell Safety, Mode of Action, and Efficacy”; and 2) Transforming Exposure Science Through a Strategic Integration of Emerging Technologies and Big Data to Improve Predictive Exposure Capabilities. This year, meeting attendees also heard a third presentation on “Nonclinical Efficacy and Safety Studies in Support of Neonatal Pediatric Therapeutics Use and Development,” a proposal that was submitted through the EIC and ultimately selected as a subproject under the DART Committee umbrella. All three proposals are available on the [HESI website](#). HESI stakeholders are being asked to rank these proposals during the summer. You are invited to submit your ranking [online](#) by **10 July 2015**. The EIC will meet in the fall of 2015 to discuss which, if any, proposals will be selected for further action. Overall, a successful session is attributable to EIC leaders Drs. Ruth Roberts (AstraZeneca) and Jose Manautou (University of Connecticut).

Call for Participants: Framework for Intelligent Non-Animal Methods for Safety Assessment. The Framework for Non-Animal Methods recently held a webinar ([recording available here](#)) open to all HESI members to discuss this latest initiative and receive feedback about the future course of action. As the project moves forward, the committee invites participants to join this initiative. Participation is free to all HESI members for this first year. If you would like to participate, please fill out the [survey](#) indicating which subgroups you would like to join. For more information, please contact Dr. Stan Parish (sparish@hesiglobal.org).

HESI Cardiac Safety Committee Meeting. The HESI Cardiac Safety Committee recently met in person for the first time as a full committee in over 4 years. The committee met on 18–19 June 2015 in Alexandria, Virginia, and heard from three, invited keynote speakers: Dr. Dan Roden (Vanderbilt University) presented on “Unanswered Questions in the Drug-Induced Long QT Syndrome,” Dr. Darrell Abernethy (US FDA) presented on “Integrated Systems Approaches to Understand LV Dysfunction Drug Cardiotoxicity,” and Dr. Mark Mercola (Sanford-Burnham Medical Research Institute) presented on “Applications of Stem Cell-Derived Cardiomyocytes.” The committee also focused on planning for projects and discussing a strategic vision. For more information about the Cardiac Safety Committee, contact Jennifer Pierson (jpierson@hesiglobal.org) or Stan Parish (sparish@hesiglobal.org).

HESI Outreach Webinar. The HESI Outreach Webinar, “Update on the Development and Validation of the *Pig-a* Gene Mutation Assay,” attracted an audience of over 40 people from across Asia and North America on 19 May 2015 (North America) and 20 May 2015 (Asia). Drs. Robert Heflich (US FDA) and Stephen Dertinger (Litron Laboratories) provided an overview of the assay and the HESI Genetic Toxicology Technical Committee’s involvement, the latest research and data gap filling efforts, and the steps recently initiated to develop an OECD test guideline. A recording of the webinar is available [here](#) and on the [HESI website](#). To learn more about HESI’s *Pig-a* assay activities, contact Jennifer Y. Tanir (jtanir@hesiglobal.org).



Researchers watching the webinar from the National Shanghai Center for New Drug Safety Evaluation & Research in Shanghai, China

HESI RISK21 Case Study/Web Tool Workshop. A 1.5-day hands-on case study workshop was hosted at the US FDA’s Center for Food Safety and Applied Nutrition in College Park, Maryland, on 28–29 May 2015. The workshop was attended by 28 scientists from the US FDA and the US EPA and involved 11 case examples designed to illustrate the RISK21 approach and the use of the online RISK21 matrix web tool (available at <http://risk21.sciome.com>). Follow-up case study workshops are planned for October 2015 in Taiwan and China. For more information, please contact Michelle R. Embry (membry@hesiglobal.org).

HESI Sustainable Chemical Alternatives Committee Working Meeting. The HESI Sustainable Chemical Alternatives Technical Committee held a Working Meeting on 28–29 May 2015 in Washington, DC, at the American Chemical Society. The purpose of the meeting was to develop a new, draft work plan to improve the predictivity of assessment approaches by defining sources of variability and identifying core data elements/types for hazard assessment, identifying opportunities to appropriately include environmental data/considerations in these assessments, and exploring methods of integrating exposure into alternatives assessment. Over 30 attendees included a mix of committee members and other invitees, with experience in exposure, ecotoxicity, toxicology, and assessment tool use and development. The committee will refine, prioritize, and launch the next steps of the work plan in the coming months. If you are interested in becoming involved with the project, please contact Jennifer Y. Tanir (jtanir@hesiglobal.org).

DART Workshop Provides Practical PLLR Training. Over 80 scientists from around the world attended "Labels Without Categories: A Workshop on FDA's Pregnancy and Lactation Labeling Rule (PLLR)." During this 2-day workshop, sponsored by the DART Technical Committee, participants were able to familiarize themselves with the new drug labeling requirements as they wrote labels based on fictionalized drugs. The workshop also provided an open forum to openly discuss the impact of the new rule, which requires significant changes to the current Pregnancy and Nursing Mothers sections of US package inserts of prescription drugs with key FDA officials. Speaker presentations are available [here](#). For more information, please contact Connie Chen (cchen@hesiglobal.org).

UPCOMING EVENTS

Interested in Neonatal Pediatric Therapeutics? The DART Technical Committee recently adopted a new project on nonclinical efficacy and safety studies to support neonatal therapeutics. The project aims to 1) identify major gaps in pre-term and term neonatal drug developmental and neonatal animal models of human disease and 2) address how to best leverage neonatal nonclinical models to support safety and proof of concept for human neonatal disease. The project ultimately aims to develop relevant study designs and data that can be obtained from nonclinical models. The informational presentation from the HESI Annual Meeting can be found [here](#). Contact Connie Chen (cchen@hesiglobal.org) if you have additional questions or are interested in participating.

Green Chemistry and Engineering Conference (14–16 July 2015, Bethesda, Maryland). The HESI Sustainable Chemical Alternatives Technical Committee will be sponsoring and presenting a poster at the ACS GCI Roundtable Poster Reception on the evening of 15 July 2015, in conjunction with the [19th Annual GC&E Conference](#). The poster will highlight the outcomes of the committee's recent working meeting on 28–29 May 2015, which focused on the integration of hazard, environmental considerations, and exposure into chemical alternatives assessment (described above). If you would like additional information or are interested in joining the project, please contact Jennifer Y. Tanir (jtanir@hesiglobal.org).

RECENT PUBLICATIONS

Whitwell J, Smith R, Jenner K, Lyon H, Wood D, Clements J, Aschcroft-Hawley K, Gollapudi B, Kirkland D, Lorge E, Pfuhrer S, Tanir JY, Thybaud V (2015) Relationships between p53 status, apoptosis and induction of micronuclei in different human and mouse cell lines in vitro: Implications for improving existing assays. *Mutat Res Genet Toxicol Environ Mutagen*. [In press](#).

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FROM THE EXECUTIVE DIRECTOR

We extend a special thank you to all who helped make this month's Annual Meeting such an exceptional event. The Annual Meeting provides the organization an opportunity to reflect on scientific accomplishments, intellectual partnerships, and commitment to its mission. In addition to the great science and networking, HESI conducted strategic planning with the Board of Trustees, members, and staff, and we are grateful for all of the thoughtful input received. As we embark on drafting the new strategic plan, we look forward to your continued involvement in HESI and sharing in our future opportunities and challenges.

Spencer D. Pickett