Insights

Your Monthly Update of News and Notes from HESI

April 2013

HESI in China. The HESI Protein Allergenicity Technical Committee (PATC) co-sponsored a "Food Allergy and Safety Assessment Workshop" on 15-16 April 2013 in Beijing, China. The workshop was co-sponsored by the ILSI Focal Point in China, the ILSI International Food Biotechnology Committee (IFBiC), the China National Center for Food Safety Risk Assessment, and the China Key Laboratory on Food Safety Risk Assessment of the Ministry of Health. The objectives of the workshop were to describe the state of the science in assessing protein allergenicity, toxicity, and composition analysis of biotechnology-based food crops; identify and discuss accepted standards as well as innovative approaches being utilized to address clinical allergy; and discuss the safety framework for genetically modified crops, the regulatory approval processes, and how they are implemented globally. Clinicians reviewed allergy prevalence and study design strategies. Approximately 180 participants attended, most of whom were from

Speakers at the April 2013 Beijing Food Allergy and Safety Assessment Workshop.

Chinese government and academic institutions. A number of important connections were made with Chinese scientists and regulators who expressed interest in working with HESI in the future on food allergy and safety assessment. After the workshop, HESI PATC representatives toured the China National Center for Safety Evaluation of Drugs and engaged in technical discussions on food safety and project collaboration. For more information, contact Ms. Nancy Doerrer, (ndoerrer@hesiglobal.org).

HESI Annual Meeting.

Registration now **OPEN** and **FREE**. Join us on 11-12 June 2013 in Alexandria, Virginia for dynamic speakers, great science, and to help shape the future of HESI's scientific programs. Registration and additional information can be found here.

HESI Technical Committees Launch Two New Work Groups

The Cardiac Safety Technical Committee convened a workshop on Stem **Cell-Derived Cardiomyocytes as Models of Cardiac Pathobiology and Toxicity** 18-19 March 2013 in Cambridge, MA. Over 100 multidisciplinary scientists from across the globe attended this innovative meeting. The workshop focused on evaluating the use of stem cell platforms and associated technologies in the nonclinical cardiovascular risk assessment of pharmaceuticals and environmental chemicals. Following this workshop, HESI held a teleconference to initiate next steps based on workshop recommendations and form a new subteam. Interested members should contact Ms. Jennifer Pierson (jpierson@hesiglobal.org) for an opportunity to get involved with the subteam and help shape the focus of this new group.

At its spring committee meeting, the Developmental and Reproductive Toxicology (DART) Technical Committee approved a new workstream on **Obesogens**. This new workgroup's primary goal will be to perform a critical evaluation of the existing literature on links between exposures to exogenous chemicals and pharmaceutical agents and obesity, identify existing data gaps and outline a high-level vision for addressing these gaps. If you are interested in participating or have additional questions, please contact Dr. Connie Chen (cchen@hesiglobal.org).

HESI Science Featured at Upcoming Conferences

ISMRM. Dr. Paul Hockings (AstraZeneca) will give a presentation on behalf of the Imaging for Translational Safety Assessment Project Committee on **24 April 2013** to the MR in Drug Research Study Group at the International Society for Magnetic Resonance in Medicine (ISMRM) Annual Meeting in Salt Lake City, UT.

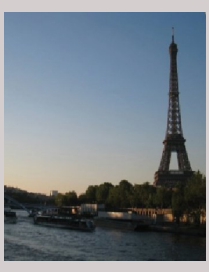
Teratology Society. The Developmental and Reproductive Toxicology (DART) Technical Committee is co-sponsoring a symposium on *Communication of Risk for Medication Use in Pregnancy and Lactation* on **24 June 2013** in Tucson, AZ at the Teratology Society Annual Meeting. Dr. Jane Stewart (AstraZeneca), DART co-chair, is one of the chairpersons.

Japan Society of Toxicology. Ms. Syril Pettit will deliver a lecture on *The Translational Knowledge Cycle: Innovations in Moving Science from Discovery to Application* on **19 July 2013** in Chiba, Japan and Dr. John Koerner (US FDA) will present results from the HESI Proarrhythmia Cardiac Safety Committee Study.

Japan Teratology Society. The Developmental and Reproductive Toxicology (DART) Technical Committee has been invited to present its activities at an educational session at the Japanese Teratology Society Annual Meeting in Osaka, Japan from **21-23 July 2013**. Dr. Kok-Wah Hew (Takeda) will speak on behalf of the DART committee.

UPCOMING HESI WORKSHOPS

HESI PATC / IFBiC Biotech Workshop. On 7-8 May 2013, the HESI Protein Allergenicity Technical Committee (PATC) and the ILSI International Food Biotechnology Committee (IFBiC) will co-host a Biotechnology Update Symposium in Arlington, VA. The purpose of the symposium is to discuss biotechnology priorities and challenges in North America. In addition to presentations from government scientists from Mexico, Canada, and the US, participants will hear research updates from academic grantees of the US EPA Science to Achieve Results (STAR) program in the area of Food Allergy / Genetically Engineered Food. The symposium is by invitation only, but limited space is available for new registrants. Contact Ms. Nancy Doerrer (ndoerrer@hesiglobal.org) if you are interested in attending.



Workshop on "Moving Forward in Human Cancer Risk Assessment in the Genomics Era 2.0." On 16-17 May 2013, the HESI Application of Genomics to Mechanism-based Risk Assessment Technical Committee and the Maastricht University's Department of Toxicogenomics will co-sponsor a workshop on "Moving Forward in Human Cancer Risk Assessment in the Genomics Era 2.0" at the OECD Congress Center, Paris, France." ***Registration is open.*** Please register by **30 April 2013**. For more information, please click here or contact Dr. Raegan O'Lone (rolone@hesiglobal.org).

HESI Risk21 Workshop in Japan. On 5 July 2013, the HESI RISK21 Technical Committee will hold a workshop at TKP Otemachi Conference Center, in Tokyo, Japan. The purpose of the workshop is to share the RISK21 strategies and approaches for chemical risk assessment and discuss their applicability in Japan and globally. If you are interested, please contact Dr. Michelle Embry (membry@hesiglobal.org) or Ms. Ayako Takei (atakei@hesiglobal.org), HESI Scientific Advisor in Japan.

Workshop on a New Cardiac Risk Paradigm. On 23 July 2013, a workshop on "Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study", co-organized by the ILSI-Health and Environmental Sciences Institute (HESI), Cardiac Safety Research Consortium (CSRC) and US Food and Drug Administration (FDA) will be held at the US FDA White Oak Conference Center, Silver Spring, Maryland, USA. This workshop will introduce a new paradigm to assessing TdP risk that will work toward obviating clinical TQT studies by renovating and strengthening non-clinical proarrhythmia screening efforts. Experts and opinion leaders from academia, industry and regulatory agencies in the US, EU, Canada, and Asia will convene to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the critical need for a uniform assay schema. The workshop will seek input from all participating attendees. Please contact Ms. Jennifer Pierson for more information (jpierson@hesiglobal.org).

New HESI Publications

Berridge BR., Hoffmann P, Turk JR., Sellke F, Gintant G, Hirkaler G, Dreher , Schultze AE, Walker D, Edmunds N, Halpern W, Falls J, Sanders M, and Pettit SD. (2013). Integrated and Translational Nonclinical In Vivo Cardiovascular Risk Assessment: Gaps and Opportunities. *Regulatory Toxicology and Pharmacology*, 65(1), 38-46.

Reagan WJ, York M, Berridge B, Schultze E, Walker D, and Pettit SP. (2013). Comparison of Cardiac Troponin I and T, Including the Evaluation of an Ultrasensitive Assay, as Indicators of Doxorubicin-induced Cardiotoxicity. *Toxicological Pathology*. (e-pub March 26, 2013)

Saldutti LP, Beyer, BK, Breslin W, Brown TR, Chapin RE, Campion S, Enright B, Faustman E, Foster PMD, Kelce W, Kim JH, Loboa EG, Piersma AH, Seyler D, Turner KJ, Yu H, Yu, X, and Sasaki JC. (2013). In vitro Testicular Toxicity Models: Opportunities for Advancement via Biomedical Engineering Techniques. *ALTEX: Alternatives to Animal Experimentation*. (accepted)

New HESI Staff. Please join us in welcoming Brianna Farr as a Scientific Program Associate for HESI. Brianna brings experience working in environmental consulting and holds a BS in Environmental Policy and Planning from Virginia Polytechnic Institute.

FROM THE EXECUTIVE DIRECTOR

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