Welcome to November *Insights*. Inside this edition: Building a Biomarker, Organ-on-a-Chip, and more!

November Insights

Nutrition Reviews Editor Search

ILSI invites applications and nominations for the position of Editor-in-Chief of *Nutrition Reviews*. Candidates should have a strong record of recognized scholarship, a broad base of knowledge, demonstrated leadership and communication skills, a keen interest in emerging areas of science, and appropriate time to devote to the journal. Click here for more information on the editor role, responsibilities, and application instructions.

Building a Biomarker

Congratulations to the HESI Genomics Committee for receiving a **formal Letter of Support from the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) to encouraging the Committee's continued development of the TGx-DDI biomarker**. The TGx-DDI marker is a safety biomarker panel intended to facilitate genotoxicity hazard assessment in nonclinical studies. The TGx-DDI biomarker panel consists of 64 stress-responsive genes that have been optimized in human TK6 cells, which are commonly employed in standard *in vitro* toxicology assays. The results to date show an excellent capability to distinguish genotoxic agents (i.e., DNA-damaging agents) from other types of stress-inducing chemicals. The biomarker has been submitted by the HESI Genomics Committee for formal review and potential "qualification" by the FDA. The letter of support was offered by the Director of the FDA's CDER Office of New Drugs Biomarker Qualification Program, the Associate Director for CDER Pharmacology/Toxicology (Dr. Karin Davis-Bruno), and the Chair of the CDER Predictive Testing Coordinating Committee for Genotoxicity.

The biomarker was also recently added to the National Toxicology Program's (NTP) website, where it has been translated into an online classification tool. The FDA letter of support is also available at the NTP link.

Exploring New Technologies: Organ-on-a-Chip

HESI recently met with Takashi Inutsuka, MEng, Research Managing Director, Pharmacological Evaluation Institute of Japan (PEIJ), to discuss organ-on-a-chip technology. This microfluidic *in vitro* technology is being developed and tested at a number of different organizations across the globe and could be used for drug development, disease modeling, safety and efficacy studies, and more. The PEIJ Microphysiological System Testing Center (PEIJ MicSTeC) plans to collaborate on an international level to better understand how these organ-on-a-chip systems can be used in the toxicity/safety and efficacy space. PEIJ MicSTeC is also bringing organ-on-a-chip technology to STEM education and offering hands-on learning experience for future scientists.

While HESI does not yet have an organ-on-a-chip project, we remain engaged with partners such as the National Center for Advancing Translational Sciences (NCATS) and PEIJ to determine what role we might play in defining and testing this new technology. HESI will continue to explore this technology, and anyone with questions or input can contact Jennifer Pierson (jpierson@hesiglobal.org).

Don't Miss Your Chance to Submit an Emerging Issues Proposal for 2018!

HESI's call for 2018 Emerging Issues is now open and proposals are due on **15 December 2017**. Proposals will be reviewed in early 2018, and one or more will be selected to form a new scientific collaborative program within HESI. While this is not a grant, the selected program will receive support from HESI for scientific program design, coordination, and staffing.

Looking for somewhere to start? Learn more about HESI's existing scientific activities on our Committees page and in the 2017 Annual Activities Report, as well as our perspectives on important and emerging themes in the Science Foresight document. Learn more about the HESI Emerging Issues Process on our website, download the proposal form here, or contact Ms. Cyndi Nobles (cnobles@hesiglobal.org).

From the Chair

From time to time in *Insights*, we comment on our continuing efforts to engage in scientific foresight and to challenge and revise our strategic plan. Allied to that, we are also now reflecting on whether HESI's current structures and procedures are optimal to deliver the most effective implementation of the plan—specifically the identification and selection of new programs and how they are funded. The Emerging Issues Committee and the Program Strategy and Stewardship Committee have served the organization exceptionally well over many years. Now, we seek to build on that success and ask whether we can improve by doing things differently or in a more holistic manner and *inter alia* should the Board be more directly involved in such decisions? If so, what changes to Board composition and role would be necessary to support such a change in role? These are just some of the questions being posed. This will be a major topic for discussion at the next Board meeting in January 2018. We welcome all ideas and opinions so if you have thoughts on this topic, don't hesitate to send them to Syril, Tim Pastoor, or me.

Dr. Ernie Harpur
HESI Chair

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