ILSI Health and Environmental Sciences Institute: HESI

HESI Annual Meeting
Assembly
June 12, 2013
2013 Annual Meeting Attendees

101 Registered Attendees

- Government (37)
- Industry (33)
- Academia (18)
- Other (13)
2013 AOM Meeting
Welcome

In the Program Book you will find...

- HESI Anti-trust Statement & Code of Ethics
- Draft minutes for June 2012 AOM Meeting
- List of Attendees
- 2013 HESI Scientific Portfolio
- Info on Nominees for Trustee Positions
- HESI Success Stories
- HESI Emerging Science Survey Results
- HESI Strategic Plan Implementation Survey Results
Agenda – Assembly Meeting

- State of the Organization – HESI President, D. Devlin
- Election of Board of Trustees and Emerging Issues Committee – D. Devlin
- Integrated HESI Science and Impact Review – HESI Exec. Director, S. Pettit
- Implementing HESI Strategic Plan - D. Devlin

BREAK

HESI CITE Keynote Lecture: “Innovating Interdisciplinary Science”
Dr. Robert Langer, MIT; Winner of 2013 US National Medal for Technology

Heather Joseph, Executive Director, Scholarly Publishing and Academic Resources Coalition
ACTION:
Approval of 2012 minutes

(in the Program Book)

HESI Assembly Meeting ‘draft minutes’
June 2012

We have a quorum of the Assembly – we need a motion, a second and a vote
ILSI Health and Environmental Sciences Institute: HESI

HESI State of the Organization

Dr. Dennis Devlin, HESI President
June 12, 2013
HESI is Evolving …
Your Input Matters

• Regularly assess our approach and impact

• Your input helped to create new models
  ➢ staffing
  ➢ outreach and communication
  ➢ program development
  ➢ … and this meeting
HESI Annual Meeting: New Formats

**Tuesday:**
- HESI and Translating Science
- Special Lecture – Dr. Harold Zenick, Director NHEERL EPA

**Wednesday:** Special Guest Lectures:
- CITE Lecture Series: Dr. Robert Langer, MIT (today)
- Lunchtime Lecture: Ms. Heather Joseph, SPARC (today)

• Implementing HESI’s Strategic Plan – An Open Discussion on Moving HESI Forward
• HESI Emerging Science Session - Interactive and Prospective Discussions

**Thursday**
• HESI Board of Trustees & Board Committees
  - Strategic Direction, Program Focus, Implementation
New Staffing Model Adopted
January, 2013

New position - Scientific Program Associate
• Admin + science support

Provides:
• More skilled resources
• Maximize contributions from Program Managers
2013 HESI Staff

- **Syril Pettit, MEM**
  Executive Director

- **Nancy Doerrer, MS**
  Associate Director

- **Michelle Embry, PhD**
  Senior Scientific Program Manager

- **Raegan O’Lone, PhD**
  Senior Scientific Program Manager

- **Connie Chen, MPH, PhD**
  Scientific Program Manager

- **Jennifer Pierson, MPH**
  Scientific Program Manager

- **Jennifer Tanir, PhD**
  Scientific Program Manager

- **Cynthia Nobles**
  HESI Branch Administrator

- **Megan Harries, B.A.**
  Scientific Program Associate

- **Brianna Farr, B.S.**
  Scientific Program Associate

- **Alex Keller, B.S.**
  Scientific Program Associate
HESI as Model for Partnership

For almost a quarter century HESI has been a leader in public-private partnership across the globe.

- 90 Universities & Research Centers
- 33 Government Agencies
- 51 Corporate Sponsors
- 16 Scientific Committees
- 77 Distinct Projects

From 14 Countries
From 12 Countries
Across multiple sectors
IMPACT via Quality Science
2013 HESI Scientific Portfolio

Technical Committees
- Animal alternatives in environmental risk assessment
- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Genetic toxicology
- Immunotoxicology
- Protein allergenicity
- Risk assessment for the 21st century (Risk 21)

Project Committees
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation of chemicals
- Use of imaging for translational safety assessment
- Vaccines and adjuvants safety

Emerging Issues Subcommittees
- Evaluating causality in epidemiologic studies
- Frameworks for alternative chemical assessment and selection of safer, sustainable alternatives
- Translational biomarkers of neurotoxicity
The Health and Environmental Sciences Institute (HESI) is a nonprofit institution whose mission is to engage scientists from academia, government and industry to identify and resolve global health and environmental issues.

Learn More

What’s New

2013 HESI Annual Scientific Meeting. Registration now open!

Request for Proposals: Bioinformatics Support

2012 Bioaccumulation Committee Expert Workshop article is now available in the SETAC Globe!!!

HESI Genomics is co-organizing a workshop on Moving Forward in Human Cancer Risk Assessment in the Genomics Era 2.0, May 16-17 in Paris, France.

The HESI ACSA program is the basis for a new OECD reproductive toxicity test guideline.

Quick Links

HESI Annual Meeting 2013
HESI Insights - Monthly News...
HESI Commitment to Tripartite
HESI FAQs
Sponsorship Form
HESI Peer Review Process
Propose a HESI Project

HESI Webinars

In 2010, HESI initiated a series of informational webinars as part of our Asia Outreach efforts. Earlier this month we instituted the practice of live recording of the webinars so all of HESI’s sponsors can access these valuable resources at any time.

To access the full list of webinars for this series, please click here.
Committee Fact Sheet

HESITechnical Committee

DEVELOPMENTAL AND REPRODUCTIVE TOXICOLOGY (DART)

2012-2013 Activities and Accomplishments

Committee leaders:
Dr. Wafa Harbouk
US Food and Drug Administration

Dr. Jane Stawart
AstraZeneca

Pharmaceuticals

HESI manager:
Dr. Constance Chan

This scientific program is committed to:
• Providing a forum in which scientists from industry, government, and academia can exchange information.
• Initiating activities to advance science related to developmental and reproductive toxicology.
• Developing consensus on the appropriate use of experimental toxicity data for human health risk assessment.

Areas of scientific focus:
• Developing a database of pharmaceutical developmental toxicology data from rodent and rabbit species to evaluate concordance.
• Evolving corporate policies and clinical practices for birth control methods and effectiveness in clinical trials.
• Providing a forum for alternative assay developers to assess teratogenicity, and identifying areas of needed research and collaboration.

Key accomplishments:
• Teratogenicity. A manuscript summarizing the workshop co-sponsored by the Johns Hopkins Center for Alternatives to Animal Testing was accepted at ALTEX.
• Consensus List of Developmental Toxicants. Reached consensus on the list of compounds at the September 2012 workshop. Additional developmental and pharmacokinetic data for the compounds are currently being evaluated.
• Inhibitor B. Completed an interlaboratory validation of inhibitor B and teratogenicity in animal models. The February 2013 issue of Birth Defects Research Part B featured 13 manuscripts on this topic.
• Drugtologics in Human Semen. Several experimental research projects to address data gaps and provide supporting evidence for modeling exposure scenarios are nearing completion.

Recent publications:
- Chapin RG, Kim HJ, Introduction to the HESI sponsored inhibition consortium. pp 1-3.
- Moffat JS et al. Assessment of inhibition B as a biomarker of teratogenic injury following administration of carbendazim, carbaryl, or 1,2,5,8,9,10-hexachloro-1,4,4-tridecane. pp 17-28.
- Sonnet M et al. The inhibition B response to the teratogenic twist 1,3 dimethoxybenzenes in male rats. pp 29-34.
- Endo Z et al. Inhibition B response to teratogenic twists halothane, ethane dimethyl sulfonate, di(2-ethylhexyl) phthalate, nitinol, and naphthalene. pp 41-53.
- Chapman RE, Inhibition B response to the teratogenic twists mono-2-ethylhexyl phthalate (MEHP), 1,3 dimethylbenzene (DNB), or carbendazim (CBZ) following short-term repeat dosing in the male rat. pp 72-81.

2012 - 2013 Participating organizations:
Abbott Laboratories
Allergan
Amgen
AstraZeneca Pharmaceuticals
Battelle Memorial Institute
Bayern HealthCare
Beckman Coulter
Belgian Federal Agency for Medicines and Health Products
Boehringer Ingelheim Pharmaceuticals Inc.
Bristol-Myers Squibb Company
Cephalon
Cincinnati Children's Hospital Medical Center
Columbia University
Duke University
Ell Lilly and Company
Epigenome Technologies
ExxonMobil Biomedical Sciences, Inc.
F Hoffmann-La Roche Ltd.
GliaSmethbisine
Innogenics Pharmaceutical
Janssen Pharmaceuticals

For more information, contact the Committee’s manager, Dr. Constance Chan, conch@wtoehs.org
April 2013

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 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 also 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 Chinese government and academic institutions. A number of important connections were made with Chinese scientists and

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

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
HESI on YouTube

Health and Environmental Sciences Institute

Result type: Videos
Uploaded: Anytime
Search options

HESI: HESI 101
45:15
by HESIGlobal
74 views

52:43
by HESIGlobal
41 views

HESI: Assessment of the Zebrafish Model for Developmental Toxicology Screening.
56:03
by HESIGlobal
93 views

HESI: Vaccines as a unique development challenge for nonclinical safety
48:55
by HESIGlobal
29 views
HESI Recognition and Reach

Awards

Federal Agencies & Professional Societies
Providing Direct Resources via Co-Sponsorship of Workshops and Initiatives

Recognition in the Peer-Reviewed Literature
Quality, Relevance, & Uptake
28 HESI pubs in last 12 months!

Global Reach

In next 4 months alone:
- BRAZIL
- JAPAN
- EUROPE
- KOREA
20+ Country scientists in HESI Awards

Explaining differences between bioaccumulation measurements in laboratory and field data through use of a probabilistic modeling approach

This paper, developed by the HESI Development of the IRBM for a New Approach to Assess Risk Determinants of Chemicals Impact on Humans, makes a unique contribution to the field by reporting new

Recognition of HESI Pubs in last 12 months!

Federal Agencies & Professional Societies
Providing Direct Resources via Co-Sponsorship of Workshops and Initiatives

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2013 Financial Summary

• Overall – financially stable with healthy outlook
• Clean external audit report
• 2013 budget - well positioned to cover anticipated organization and committee expenses
• No increase expected in sponsor Base Fees for 2014
• Reserves have grown due to increased membership and return on investments

➤ proposed Reserve Policy will allow for funds to enhance Strategic Plan implementation
HESI Outlook

• Committed to the tripartite approach to positively impact the most relevant health and environmental issues

• Financially sound, solid and growing membership

• Looking Ahead:
  ➢ Benefit from new organizational structure
  ➢ Enhance member engagement / value
  ➢ Maximize resources to enhance success re. HESI Plan

Your Role Today: Input on how to optimize resources to more effectively implement HESI’s Strategic Plan
Nominating Committee

Dr. Herman Autrup, U Aarhaus
Dr. Dennis Devlin, ExxonMobil – Co-Chair
Dr. Peggy Guizzie-Peck, Johnson & Johnson
Dr. Laurie Hanson, Pfizer
Dr. Tim Pastoor, Syngenta
Dr. Kendall Wallace, U Minnesota – Co-Chair
First, to those leaving the Board:
Thank you for your service

- **Dr. Henry Chin**, Coca-Cola
- **Dr. Ronald Hines**, Medical College of Wisconsin
- **Dr. Masaki Yamamoto**, Takeda Pharmaceutical Co. Ltd.
Nominating Committee Recommendations

(Bios of nominees are in the Program Book)

HESI Board of Trustees
(election by Assembly)

HESI Emerging Issues Committee
(election by Assembly)
HESI Board of Trustees
Re-nominees

- **Prof. Alan Boobis** - Imperial College London (public) – 2 year term
- **Dr. Samuel Cohen** - University Nebraska Medical Center (public) - 3 year term
- **Dr. Dennis Devlin** - Exxon Mobil Corp. (private) –3 year term
- **Dr. Peggy Guzzie-Peck** – Johnson & Johnson (private) - 3 year term
- **Dr. Martin Philbert** - University Michigan (public)- 3 year term
- **Dr. Craig Rowlands** - Dow Chemical Co. (private) - 3 year term
- **Dr. Lewis Smith** – Medical Research Council (public) - 2 year term
- **Dr. James Stevens** - Eli Lilly and Co. (private) - 3 year term
- **Dr. Jan Willem van der Laan** - Medicines Evaluation Board (public) - 3 year term
HESI Board of Trustees
New Nominees

➢ **Prof. dr. Martin van den Berg**
Head, Toxicology and Veterinary Pharmacology Division, Deputy Director
Institute for Risk Assessment Sciences (IRAS)
Utrecht University

➢ **Patrick D Guiney, PhD**
Manager, Environmental Toxicology and Ecological Risk Assessment
SC Johnson & Son, Inc.

➢ **Atsushi Sambuissho, PhD**
Science Advisor, Medicinal Safety Research Laboratory, R&D Division,
DAIICHI SANKYO CO., LTD.
**ACTION:**

Election of HESI Trustees

**HESI Board of Trustees**
(election by Assembly)

We have a quorum of the Assembly – we need a **motion**, a **second** and a **vote**
HESI Emerging Issues Committee Nominees

**VICE CHAIR:**
Dr. Ruth A. Roberts  
AstraZeneca R&D *(term ends June 2016)*

**Public Sector Nominees** *(terms end 2016)*
- Dr. James E. Klaunig  
  Indiana University *(re-nominated)*
- Dr. Derek C.G. Muir  
  Environment Canada *(re-nominated)*
- Dr. Flavio A.D. Zambrone  
  University of Taubaté / Planitox *(Brazil)*

**Private Sector Nominees** *(terms end 2016)*
- Dr. Ann Blacker  
  Bayer CropScience
- Dr. Michael Graziano  
  Bristol-Myers Squibb
- Dr. Kathleen A. Shelton  
  DuPont Haskell Global Centers for Health and Environmental Sciences
ACTION:

Election of Emerging Issues Committee

Public and Private sector
Science Advisors
(election by Assembly)

We have a quorum of the Assembly – we need a motion, a second and a vote
2013 HESI Board Officers:
(Informational)

- HESI Chair: Dr. Kendall Wallace (U Minnesota)
- HESI Vice-Chair: Dr. Herman Autrup (U Aarhaus)
- HESI President: Dr. Laurie Hanson (Pfizer)
- HESI Vice-President: Dr. Tim Pastoor (Syngenta)*
- HESI Past-President: Dr. Dennis Devlin (ExxonMobil)
- HESI Treasurer: Dr. Serrine Lau (U of Arizona)
- HESI Secretary: Dr. Charlene McQueen (RTP)

* Only new nominee for 2013-2015 term. Anticipate election by the Board of Trustees (Thursday)
HESI Executive Director Report: HESI Impact

Assembly

June 12, 2013
Positively Impact the Most Relevant Health and Environmental Issues

1. Create Definitive Scientific Solutions
   - Focus on Program Areas in Translational Biology, Risk Assessment, Environmental Toxicology, and New Technology and Approaches

2. Ensure Recognition of HESI’s Value and Contributions
   - Evaluate and Continuously Improve Recognition of HESI’s Value and Contribution
   - Develop and Implement a Proactive Engagement and Communications Plan for HESI
   - Increase HESI’s Outreach to and Recognition With Key Stakeholders

3. Optimize HESI’s Organizational Effectiveness
   - Align Organizational Structure with Strategic Requirements
   - Attract and Engage Quality Scientists and Optimize Tripartite Composition
   - Ensure Effective Project Management to Deliver Outcomes in a Timely Fashion
   - Ensure Appropriate Staffing and Financial Resources to Support Programs

4. Assure Transparency of Scientific and Communications Processes
Enhancing HESI’s Strategic Plan

• Plan developed by HESI Board, HESI Assembly, staff, and technical experts; June, 2011

• Executive Committee authorized outreach to membership to guide allocation of existing resources for enhanced implementation; March, 2013

• This implementation will not require additional funds from sponsors
Reaching Out

Implementation Survey sent to:

• HESI Board of Trustees
• HESI Emerging Issues Committee
• Official Representatives (sponsors)
• Co-chairs (public/private) of HESI Committees

Response N=58
5 General Areas Queried

- Enhance HESI’s ability to support new and expanding scientific initiatives (Plan Priority 1 & 3)
  - Ex: new programs, more staff, paid advisors / experts

- Support HESI leadership in bridging basic to applied sciences (1 & 2)
  - Ex: CITE workshops/initiatives, translational process, early engagement

- Expand HESI’s role as a global organization (2 & 3)
  - Ex: recruit regional experts, outreach/training, collaborative partnerships

- Enhance HESI ability to reach /impact stakeholders through communications (1 & 3)
  - Ex: contract professionals, opportunities to better engage stakeholders

- Enhance HESI visibility in, and support for, academic/research sector (2 & 4)
  - Ex: lecture series, direct funding, student fund, partner exchanges
## Survey Results
*(percent of responders)*

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>High</th>
<th>Med</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhance HESI’s ability to support new and expanding scientific initiatives <em>(Plan Cat. 1 &amp; 3)</em></td>
<td>81</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Support HESI leadership in bridging basic to applied sciences <em>(Plan Cat. 1 &amp; 2)</em></td>
<td>64</td>
<td>28</td>
<td>8</td>
</tr>
<tr>
<td>Expand HESI’s role as a global organization <em>(Plan Cat. 2 &amp; 3)</em></td>
<td>59</td>
<td>39</td>
<td>2</td>
</tr>
<tr>
<td>Enhance HESI ability to reach and impact stakeholders through communications <em>(Plan Cat. 1 &amp; 3)</em></td>
<td>56</td>
<td>38</td>
<td>6</td>
</tr>
<tr>
<td>Enhance HESI visibility in, and support for, academic/research sector <em>(Plan Cat. 2 &amp; 4)</em></td>
<td>50</td>
<td>40</td>
<td>10</td>
</tr>
</tbody>
</table>
Specific proposals – highly ranked

• Provide resources (staff and $) for new Emerging Issues projects

• Create & fund exchange program for academic/basic research scientists to spend time as visiting research in private sector or related labs

• Provide resources to support HESI outreach in regions with compatible issues but limited current involvement in HESI

• Provide funds to support collaborations with international groups; e.g. WHO

• Support CITE workshops to bridge diverse disciplines, and basic to applied science

• Use resources to support more opportunities to engage HESI stakeholders in dialogue to identify priority issues
Discussion

• What do you agree with?

• What is missing here?

• Other priority areas to consider?
Next Step

• Feedback from today will be a focus for the HESI Board discussion tomorrow

• HESI Board will develop recommendations for priority implementation
FINAL REMARKS
REMINDER

We will take a 15 minute break (no more!) then please join us here for Dr. Langer’s lecture