ILSI Health and Environmental Sciences Institute: HESI

Official Representatives Business Meeting ‘Assembly Meeting’

10 June 2014
Washington, DC

Health and Environmental Sciences Institute
AGENDA

• Welcome (5 min)
• Official Rep Training (30 min)
• Business Update (10 min)
• Vote (5 min)
• Open Discussion *(to end and as we grab lunch!)*
A New Leaf
HESI ‘Official Representative Training

Understanding and optimizing your roles in HESI
What will we learn?

- HESI structure and governance;
- Roles and responsibilities as an Official Rep (OR);
- Maximizing your value for HESI participation.
Get ready!

When we finish today, you should be able to define the following terms...

✓ Official Representative
✓ HESI Assembly
✓ HESI Member
✓ HESI Sponsor
✓ Trustee
Section 1: Structure & Governance
What kind of organization is HESI?

- Non-profit, global, 501(c)(3)
- Charitable entity, science for public benefit.
- Focus on tripartite+, transparency, credibility
- No product or company specific issues.
- No lobbying or direct influence on policy.
I hear a lot about ‘ILSI’ – What’s that?

International Life Sciences Institute: Formed in 1978, regional branches focused on food and nutrition issues.

HESI established in 1989 as a global branch of ILSI.
The ILSI Network

- HESI, ILSI Research Foundation, and Regional ILSI Branches constitute the ILSI Network

- HESI separately incorporated with own governance and financial oversight.
The ILSI Network

ILSI Global

Regional Branches
ILSI Argentina
ILSI Brasil
ILSI Europe
ILSI Focal Point in China
ILSI India
ILSI Japan
ILSI Korea
ILSI Mexico
ILSI North America
ILSI North Andean
ILSI South Africa
ILSI South Andean
ILSI Southeast Asia Region
ILSI Taiwan
The ILSI Network

ILSI Regional Branches

Local members and efforts. Largely food & nutrition focus.
The ILSI Network

ILSI Research Foundation –

The Center for Environmental Risk Assessment (CERA)
The Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security (CIMSANS)
The Center for Risk Science Innovation and Application (RSIA)
The Center for Safety Assessment of Food and Feed (CSAFF)

Regional Branches
ILSI Argentina
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ILSI North America
ILSI North Andean
ILSI South Africa
ILSI South Andean
ILSI Southeast Asia Region
ILSI Taiwan
How is HESI Governed?

HESI Board of Trustees & Staff are stewards of:

- By-laws
- Anti-trust policy
- Conflict of Interest declaration
- Articles of Incorporation
- Data Sharing Policy (not a legal document)

Participating organizations are not bound to HESI by any type of standing confidentiality agreements.
How does HESI ensure balance in its governance?

- Public > Private on HESI Board
- Board Chair and Vice-Chair always public sector

Public Sector Scientists at HESI = academic, government, NGO, research institute, clinical medicine, etc.

Executive Committee of the Board

- Chair – public sector
- Vice Chair – public sector
- President - private sector
- Vice President – private sector
- Secretary – public or private
- Treasurer – public or private
+ 2-4 members at large (trustees)
Meet the 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,
Branch Administrator

Alex Keller,
Science Program Associate

Brianna Farr,
Science Program Associate

Connie Chan-Le
Science Program Associate
Leadership, stewardship, strategy, and structure

HESI Board of Trustees

Emerging Issues Committee

Finance Committee

Executive Committee

Program Strategy & Stewardship Committee

Communications & Outreach Committee

HESI STAFF

Launching New Scientific Programs

Scoping & Supporting Leading Edge Science Outside of HESI

Membership Development Committee
Section 2: Roles & Responsibilities as an OR
I’m an Official Representative… What does that mean?
First, the formal stuff.
As a HESI OR you...

- Are a member of HESI’s Assembly;
- Your organization’s official Vote!
- Receive the invoices
- Liaison to HESI staff
In addition to voting and paying the bills...

How else can I contribute as an OR?
Be a Voice for your Organization!

- Solicit Ideas for Projects
- Pool and Share Priorities
- Get the word out!
Thank you!!!

For more information visit [www.hesiglobal.org](http://www.hesiglobal.org)

Or contact [cnobles@hesiglobal.org](mailto:cnobles@hesiglobal.org)
Are you ready for the quiz?

- Official Representative
- HESI Assembly
- HESI Member
- HESI Sponsor
- Trustee
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Business Update
2014 Financial Report
(Budget approved by BOT in Jan 2014)

• Overall – Financially stable and healthy

• Clean external audit report.

• Early projections for 2014 of…..

• In Jan 2014, BoT approved use of unallocated Operating Reserve Funds for Strategic Plan Implementation – discussions to follow today.

• New funding allocations to benefit projects
  • FAST Fund
  • Open Access
  • EIC Scoping Funds
  • Global Platforms Initiative
  • Considering Future Leaders Travel Fund
Reminder of Timelines

- **June**: HESI Board of Trustees to approves 2015 corporate Sponsorship dues - Proposing NO CHANGE.
- **July**: Official Representatives notified of 2015 corp dues
- **July/August**: Scientific Committees set draft assessments
- **September/October**: Scientific Committees finalize budgets
- **October**: Corporate Sponsorship invoices distributed
- **October/November**: HESI Organizational Budget prepared by the HESI Finance Committee.
- **November**: Scientific Committee invoices distributed.
- **January**: HESI Organizational Budget approved by BoT
- **March 1**: All Corporate Sponsorship and Scientific Committee invoices due for payment to HESI.
Growth in Corporate Sponsorship

Why?
- Project Scope
- Emphasis on Recruitment
- Welcoming Large & Small Organizations
- Recognition of Impact
- Resource Sharing Opportunities

Number of Sponsor Organizations

Year

2011 44
2012 49
2013 53
2014 60?
2015 ??
Resources for HESI Programs

In-kind resources (analytical and experimental) across sectors in 2013/2014

- represent millions in pooled research effort;

Private sector sponsor dollars

- support infrastructure for program coordination, meetings, outreach, & some outsourced research;

Partnered Public Funding for 2013/14

- Financial contributions from NIEHS, NGOs, for the 2013 Cancer Genomics workshop
- Funding from Environment Canada to support an academic working on research in collaboration with HESI Bioaccumulation Committee;
- Grants from Canada’s Environmental Health Science and Research Bureau (EHSRB) Chemicals Management Plan (CMP) Research Program to Health Canada staff for projects conducted in direct collaboration with the HESI GTTC;
- FDA hired internal ‘Fellow’ to work on data analysis as a partner in the HESI Cardiac Safety ProA project;
- HESI DART Committee and University Utrecht Grant funding supporting a postdoctoral researcher to conduct analyses in support of the DART 2nd species project.
Intellectual Partnership

A Banner Year for HESI...
WHO & ILSI HESI Announce Collaborative Agreement

In November 2013, the ILSI Health and Environmental Sciences Institute finalized a collaborative agreement with the World Health Organization to jointly develop and maintain a freely-available on-line database of chemical risk assessment training courses. This publicly accessible resource is anticipated to facilitate access to training by providing searchable information on educational opportunities available around the globe. The Training Database Project will provide access to information regarding in-person and online post- and undergraduate, continuing education, and society-sponsored not-for-profit training courses related to human health chemical risk assessment. Via this collaborative agreement, WHO will provide regular input and guidance on the overall database project activities and ILSI will provide financial and in-kind support for development and implementation of this collaborative resource. This project is part of the recently-formed WHO Chemical Risk Assessment Network, to which ILSI was invited as an official participant. For more information on the WHO-HESI Training Database Project of ILSI’s HESI Chemical Risk Assessment Network, please visit the website chemicalriskassessmentnetwork.org.

MOU NUMBER

MEMORANDUM OF UNDERSTANDING BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE FOOD AND DRUG ADMINISTRATION
ILSI HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

I. Purpose

The United States Food and Drug Administration (FDA) and ILSI Health and Environmental Sciences Institute (HESI) share interests in promoting scientific progress through the exchange of scientific capital to address and reach consensus on scientific questions impacting the development of FDA regulated products and the evaluation of human safety. Both institutions foresee benefits from the mutual exchange of training and research expertise in pharmacology, toxicology, and translational science. This
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2013-14 Nominating Committee

Dr. Laurie Hanson—Pfizer (Chair)
Dr. Kendall Wallace, U Minnesota
Dr. Martin Philbert, U Michigan
Dr. Tim Pastoor, Syngenta
Dr. Herman Autrup, U Aarhus
2013/2014 Nominations Process

(Bios of nominees are in the Program Book)

HESI Board of Trustees
(election by Assembly)

HESI Emerging Issues Committee
(election by Assembly)
First, thank you for your service to those leaving the Board

- Dr. Jay Goodman, Michigan State University (since 1997!)
- Dr. Cynthia Afshari, Amgen
- Dr. Robert Rickard, DuPont
- Dr. Hiroyuki Tsuda, Nagoya City University
- Dr. Jiro Seki, Astellas
- Dr. Douglas Wolf, EPA
Proposed Re-nominees to HESI Board

Dr. Scott Belanger, Procter & Gamble
Dr. Ernie Harpur, Newcastle University
Dr. Serrine Lau, University of Arizona
Dr. Charlene McQueen, RTP
Dr. Angelo Moretto, University of Milan
Dr. Timothy Pastoor, Syngenta
Dr. Kendall Wallace, U Minnesota
Proposed New Nominees to HESI BOT

Keiichiro Sato, PhD
Director, Drug Safety Research Laboratories, Takeda Pharmaceutical Company Limited

Myrtle Davis, DVM, Ph.D.
Chief, Toxicology and Pharmacology Branch Developmental Therapeutics Program Division of Cancer Treatment and Diagnosis, The National Cancer Institute

Sonja Beken, PhD
Coordinator Non-Clinical Assessors, Coordinator Oncology Division Evaluators, DG PRE Authorisation, Belgium

David Brewster, Ph.D., D.A.B.T.,
VP and Global Head Drug Safety Evaluation, Global Exploratory Development, Vertex Pharmaceuticals

David L. Eaton, Ph.D.,
Dean and Vice Provost, The Graduate School, University of Washington

Stefan Platz, PhD
Global Head of Drug Safety and Metabolism, AstraZeneca.
ACTIONS:
Election of HESI Trustees

HESI Board of Trustees
(election by Assembly)

We need a motion, a second and a vote
HESI Emerging Issues Committee Nominees 2014

Vice Chair Nominee:
José Manautou, PhD, ATS Fellow
University of Connecticut (term ends June 2017)

Public Sector Nominees
(terms end 2017)

Suzanne C. Fitzpatrick, PhD, DABT
US Food and Drug Administration

Timothy Gant, PhD
CRCE, Public Health England

George Gray, PhD
George Washington University
(re-nomination)

Ronald N. Hines, PhD
US Environmental Protection Agency

Private Sector Nominees
(terms end 2017)

Matthew S. Bogdanffy, PhD, DABT, FATS
Boehringer-Ingelheim

Jon C. Cook, PhD, DABT
Pfizer, Inc.

Andrew Glickman, PhD
Chevron Energy Technology Company
ACTION: (motion, second, and vote)

Election of public and private sector Science Advisor nominees to the HESI Emerging Issues Committee.
Next Steps

(for informational purposes only)

HESI Board Officers
(to be elected by the HESI Board Thursday)

HESI Executive Committee
(to be elected by the HESI Board Thursday)

HESI representatives to the ILSI Board
(already elected by the ILSI Board in January 2012)
Nominees for 2014 HESI Executive Committee (informational)

- Dr. Laurie Hanson, President
- Dr. Tim Pastoor, Vice President
- Dr. Ken Wallace, Past Chair
- Dr. Herman Autrup, Chair
- Dr. Ernie Harpur, Vice Chair (New Nomination!)
- Dr. Charlene McQueen, Secretary
- Dr. Serrine Lau, Treasurer
- Dr. Peggy Guzzie-Peck, Member-at-Large
- Dr. Brian Berridge, Member-at-Large.
- Dr. Martin Philbert, Member-at-Large (New Nomination!)
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