



HESI Annual Meeting

January 19, 2009

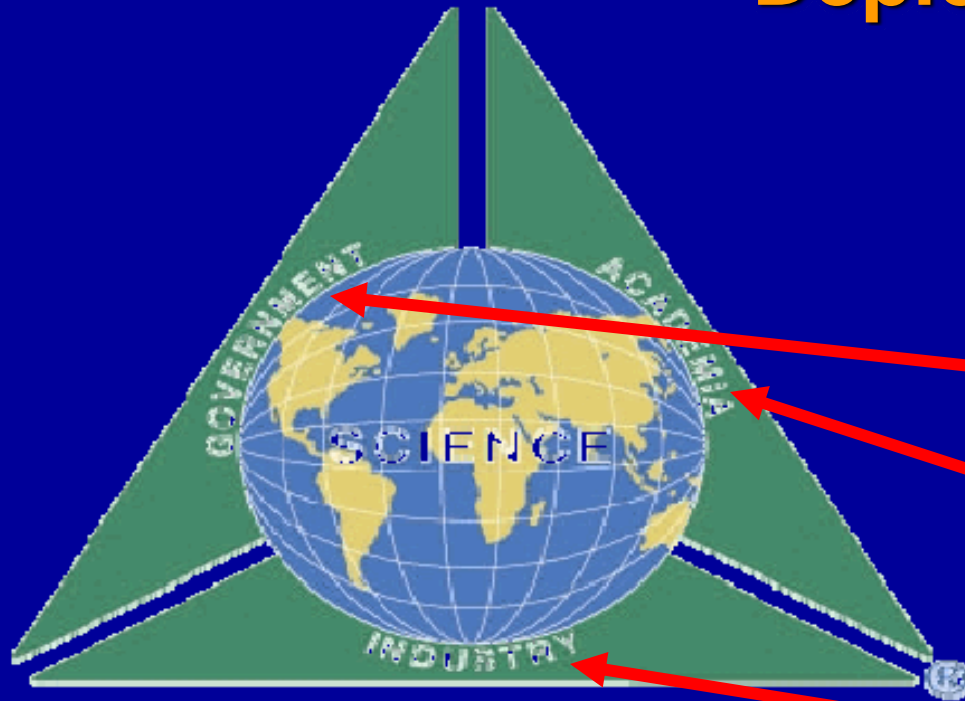
Welcome!!!!

Meeting of the
HESI Assembly of Members

Dr. James MacDonald
President of HESI

The HESI logo . . .

Depicts our commitment
to the "tripartite"
approach . . .



Government!

Academia!

Industry!
(Our AOM)

H E S I®



2008 HESI Assembly of Members

- **Abbott Laboratories**
- **Actelion Pharmaceuticals**
- **Allergan**
- **Amgen Inc.**
- **Arkema, Inc.**
- **Astellas Pharma, Inc.**
- **AstraZeneca AB**
- **BASF Corporation**
- **Bayer Pharmaceutical / Bayer AG**
- **Biogen Idec MA, Inc.**
- **Boehringer Ingelheim GmbH**
- **Bristol-Myers Squibb Co.**
- **The Coca-Cola Corporation**
- **Daiichi-Sankyo Co., Ltd.**
- **Dow Chemical Co. / Dow Agro.**
- **Dow Corning**
- **E.I. du Pont de Nemours & Co.**
- **Eisai Co., Ltd**
- **Eli Lilly and Company**
- **Endo Pharmaceuticals**
- **ExxonMobil Biomed. Sciences**
- **GlaxoSmithKline**
- **Hoffman-La Roche Inc.**



2008 HESI Assembly of Members

- Institut de Recherches Int.
SERVIER
- Johnson & Johnson Pharma.
- Kalypsys, Inc.
- L'Oreal Corporation
- LyondellBasell Industries
- Meiji Seika Kaisha, Ltd.
- Merck & Co., Inc.
- Mitsubishi Tanabe Pharma
Corp. Pharmaceuticals
- Monsanto Company
- Novartis Pharmaceuticals Corp.
- Pepsico
- Pfizer Inc.
- The Procter and Gamble Co.
- Purdue Pharma LP
- Rohm and Haas Company
- sanofi-aventis
- Schering-Plough Research
Inst.
- Shell Chemicals, Ltd.
- Sumitomo Chemical
- Syngenta, Ltd.
- Takeda Pharmaceuticals Co.,
Ltd.
- Valent U.S.A. Corporation



2008 HESI Assembly of Members

- ❖ We had **45 members** in the HESI Assembly in 2008.
- ❖ We thank all of our members for their continued support of HESI.
- ❖ Special thanks to . . .
 - ❖ . . . **sanofi-aventis** for a special contribution to support Epigenetics.
 - ❖ . . . **Chevron** (currently not a HESI member) for a special contribution to HESI.



Invitations to our Official Reps . . .

- ❖ Plan to attend the meeting of the full Board of Trustees on Wednesday, January 21st.
- ❖ You are also invited to participate as an *ex officio* member of any of the following Board committees:
Finance, Communications, Membership Development, and Program Strategy & Stewardship (PSSC).



HESI in 2008: Some highlights . . .

- Extensive portfolio of technical committees, project committees and subcommittees – activities to be described in the HESI sessions at this meeting – including today.
- Outstanding productivity – 29 papers underwent HESI peer review in 2008 (44 papers in 2007).
 - Dedicated professional staff with excellent scientific credentials and strong project management skills.
 - Member participation through “sweat equity” on projects/committees is very high.
 - HESI’s finances are sound.
- Increased our commitment to “tripartite” – outreach has resulted in greater gov’t and academic participation.



HESI Staff in 2008:

- ❖ **Nancy G. Doerrler, MS**
Associate Director, Scientific Program Stewardship
- ❖ **James Kim, Ph.D., DABT**
Scientific Program Manager
- ❖ **Michelle R. Emery**
Senior Scientific Manager
- ❖ **Regina G. Graham**
Administrative Assistant
- ❖ **Michael Holsapple, Ph.D., Fellow, ATS**
Executive Director
- ❖ **James Kim, Ph.D., DABT**
Senior Executive Assistant
- ❖ **Raegan O'Lone, Ph.D.**
Scientific Program Manager
- ❖ **Syril D. Pettit, MEM**
Associate Director, Scientific Outreach

Welcome to
Dr. Raegan O'Lone



Special Introduction to Tucson, AZ

Agenda Item II

Dr. Jack Dean
University of Arizona

HESI Trustee



Approval of the Minutes

Agenda Item III (in the AOM packet)

*HESI Assembly of Members Meeting
January 21, 2008*

In the AOM packet, you will also find:

- ❖ ILSI Anti-trust Statement
- ❖ ILSI Code of Ethics



HESI Nominations Report - 2008

Agenda Items IV.A. & B. (in the AOM packet)

HESI Board of Trustees (election by AOM)

**HESI Emerging Issues Steering Committee
(election by AOM)**



But first . . .

*With special thanks to our trustees
whose terms are completed
at the close of this Ann. Meeting:*

- **Dr. Joe DeGeorge**, Merck & Co., Inc.
- **Dr. Sandra Kennedy**, GlaxoSmithKline



Renominated to the HESI Board

- **Dr. Herman Autrup**, University of Aarhus.
- **Dr. Jack Dean**, University of Arizona.
- **Dr. Shoji Fukushima**, Japan Bioassay Research Center.
- **Dr. Jay Goodman**, Michigan State University.
- **Dr. Laurie Hanson**, Pfizer, Inc.
- **Dr. Norbert Kaminski**, Michigan State University.
- **Dr. Sunao Manabe**, Daiichi-Sankyo Co., Inc.
- **Dr. Peter Moldeus**, AstraZeneca R&D.



New nominees to the HESI Board

- **Dr. Bhaskar Gollapudi**, The Dow Chemical Company.
- **Dr. Lois Lehman-McKeeman**, Bristol-Myers Squibb Company.



Election of new HESI Trustees

Agenda Item IV.A. (in the AOM packet)

HESI Board of Trustees (election by AOM)

**We have a quorum of the AOM –
we need a motion, a second and a vote.**



Nominated to the EISC

Vice Chair:

- **Dr. Ernie Harpur**, sanofi-aventis.

Members-at-Large:

- **Dr. Karen Blackburn**, Procter & Gamble, Co.
- **Dr. James Stevens**, Eli Lilly & Co. (*one-year term*)
- **Dr. Werner Bomann**, Bayer CropScience.

Scientific Advisors:

- **Dr. Toshihisa Ishikawa**, Tokyo Institute of Technology.
- **Dr. Gary Williams**, New York Medical College.
- **Dr. Harold Zenick**, U.S. Environ. Protection Agency.



HESI Nominations Report

Agenda Item IV.B. (in the AOM packet)

HESI Emerging Issues Steering Committee
(election by AOM)

**We have a quorum of the AOM –
we need a motion, a second and a vote.**



HESI Nominations Report

For Informational Purposes

HESI Board Officers

(election by the HESI Board on 1/21/09)

HESI Executive Committee

(election by the HESI Board on 1/21/09)

HESI representatives to the ILSI Board

(election by the ILSI Board on 1/17/09)



Nominees for HESI Board Officers

HESI Leadership Succession Plan:

- Elect new Vice President (an industry member in odd yrs) or Vice Chair (a public member in even yrs).
- Elect new Treasurer and Secretary, as needed.
- All officers elected to two-year terms.



Nominees for HESI Board Officers

President (roles and responsibilities):

- Serves as HESI's Chief Executive Office (CEO).
- Serves as HESI's principal fundraiser & assists in membership recruitment.
- Chairs AOM Mtg. & Appoints Nominating Committee.

Vice President (roles and responsibilities):

- As with President, an elected industry member.
- Assists President (especially in fund-raising & membership recruitment activities).
- Co-chairs HESI PSSC with Vice-Chair.



Nominees for HESI Board Officers

- ✓ '09 PRESIDENT: Dr. Marc Bonnefoi.
- ✓ '09 VICE PRESIDENT: Dr. Dennis Devlin.



Nominees for '09 HESI Exec. Comm.

- ✓ **Dr. Marc Bonnefoi**, President.
- ✓ **Dr. Dennis Devlin**, Vice President.
- ✓ **Prof. Alan Boobis**, Chair.
- ✓ **Dr. Kendall Wallace**, Vice Chair.
- ✓ **Dr. Norbert Kaminski**, Secretary.
- ✓ **Dr. Jack Dean**, Treasurer.
- ✓ **Dr. James MacDonald**, Past-President.
- ✓ **Dr. Henry Chin**, Member-at-Large.
- ✓ **Dr. Sam Cohen**, Member-at-Large.
- ✓ **Dr. Jay Goodman**, Member-at-Large.
- ✓ **Dr. Ruth Lightfoot-Dunn**, Member-at-Large.
- ✓ **Dr. Lewis Smith**, Member-at-Large.



HESI Representatives on ILSI BOT

New Nominee:

- ✓ **Dr. Alan Boobis**, Term expires after 2012 A.M.

Renominated:

- ✓ **Dr. Lewis Smith**, Term expires after 2012 A.M.

Current Representatives:

- ✓ **Dr. Marc Bonnefoi**, Term expires after 2011 A.M.
- ✓ **Dr. Jay Goodman**, Term expires after 2011 A.M.
- ✓ **Dr. Samuel Cohen**, Term expires after 2010 A.M.
- ✓ **Dr. James MacDonald**, Term expires after 2010 A.M.



HESI Financial Report

Agenda Item IV.C.

Dr. Jack Dean
HESI Treasurer



2009 Annual Meeting Overview

Agenda Item IV.D.

Dr. James MacDonald
HESI President



2009 HESI Scientific Program

- ❖ **Scientific Session #1** – Monday, 2:00-5:30
"The NIH Genes, Environment and Health Initiative."
- ❖ **Emerging Issues Session** – Tuesday, 8:30-12:00 Hear about the new HESI EI topics!!
- ❖ **Scientific Session #2** – Tuesday, 2:00-5:30:
"State-of-the-Science within HESI." Hear about Bioaccumulation, Developmental & Reproductive Toxicology and Genomics.



Upcoming Annual Meetings

- ❖ **January 22 – 28, 2010** – Wyndham Rio Mar Beach Resort. **Puerto Rico.**
- ❖ **January 21 – 27, 2011** – Buena Vista Palace. **Lake Buena Vista, FL.**



Introduction to HESI Portfolio

Agenda Item V.A.

Dr. James MacDonald
HESI President



2008 HESI Scientific Portfolio

Technical Committees

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Some Project and Technical Committees Reviewed on Tuesday.

- Immunotoxicology.
- Integration of biomonitoring exposure data into the risk assessment process.
- Nonclinical/clinical safety correlations.
- Protein allergenicity.
- Risk assessment methodology.

Project Comm

- Biological significance of DNA adducts.
- Cancer hazard identification strategies.
- Development of a tiered approach

El subcommittees Reviewed on Tuesday.

- and
- PPA agents
- Relevance and follow-up of positive results from *in vitro* genotoxicity testing.

Some Activities will be 'sunset' in early 2009.

- Risk as populati
- Emergence of animal alternative needs in environmental risk assessment.

Subcommittees

- State of the science: evaluating epigenetic changes.
- Short-term exposure to carcinogens.
- Distinguishing adverse from non-adverse effects.



2008 HESI Scientific Portfolio

Technical Committees

- Development and application of biomarkers of toxicity.

- Immunotoxicology.
- Integration of biomonitoring exposure data into the risk assessment process.
- Protein allergenicity.
- Risk assessment methodology.

Project Committees

- Biological significance of DNA adducts.

- CV safety – Proarrhythmia models.
- Nanomaterial environmental, health and safety.
- PPAR agonist tumorigenicity.
- Relevance and follow-up of positive results from *in vitro* genotoxicity testing.

**We still have a lot
to cover!!**



Keynote Address

Agenda Item VI.

Introduction of 'keynote speaker'

Dr. Jack Dean



Keynote Address

Agenda Item VI.

**“The Globalization of
Cancer Diagnosis and
Treatment.”**

Prof. Thomas Grogan



'Special Presentation'

Agenda Item VII.

Dr. Marc Bonnefoi