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ILSI Health and Environmental Sciences Institute

2010 HESI ANNUAL MEETING

Emerging Issues Meeting

13 May 2010

Reston, VA

B. Bhaskar Gollapudi, PhD

(The Dow Chemical Company)

Chair, Emerging Issues Steering Committee



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Meeting Goals

- **Acknowledge the incoming and outgoing membership of the HESI Emerging Issues Steering Committee (EISC)**
- **Outline the Emerging Issues Process**
- **Give reports on existing HESI Emerging Issues Subcommittees**
- **Review the new HESI Resources-at-Initiation process**
- **Explore new topic areas for consideration by HESI constituency**



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Membership

2010 EMERGING ISSUES STEERING COMMITTEE (EISC)



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2010 EISC Leadership

Elected by HESI Assembly of Members, 12 May 2010

CHAIR: **Dr. B. Bhaskar Gollapudi**
(The Dow Chemical Company)
(term expires May 2012)

VICE CHAIR: **Dr. Ernie Harpur**
(sanofi-aventis)
(term expires May 2014)



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2010 EISC Members at Large

Elected by HESI Assembly of Members, 12 May 2010

Dr. Karen L. Blackburn

(The Procter and Gamble Company) (term expires May 2012)

Dr. Werner H. Bomann

(Bayer CropScience) (term expires May 2012)

DR. GEORGE PUGH – newly elected

(The Coca-Cola Company) (term expires May 2013)

Dr. A. Robert Schnatter

(ExxonMobil Biomedical Sciences, Inc.) (term expires May 2011)

DR. JAMES L. STEVENS – re-elected

(Eli Lilly and Company) (term expires May 2011)

DR. MARK TIRMENSTEIN – newly elected

(Bristol-Myers Squibb Company) (term expires May 2013)



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2010 EISC Scientific Advisors

Elected by HESI Assembly of Members, 12 May 2010

Dr. Toshihisa Ishikawa

(RIKEN Yokohama Institute)
(term expires May 2012)

PROF. IAN KIMBER – *re-elected*

(University of Manchester)
(term expires May 2013)

DR. JAMES E. KLAUNIG – *newly elected*

(Indiana University School of Medicine)
(term expires May 2013)

DR. DEREK MUIR -- *newly elected*

(Environment Canada)
(term expires May 2013)

Dr. Serrine S. Lau

(University of Arizona)
(term expires May 2011)

Dr. Leonard V. Sacks

(US Food and Drug Administration)
(term expires May 2011)

Dr. Sally S. Tinkle

(National Institute of Environmental Health
Sciences)
(term expires May 2011)

Dr. Gary M. Williams

(New York Medical College)
(term expires May 2012)

Dr. Hal Zenick

(US Environmental Protection Agency)
(tem expires May 2012)



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Outgoing EISC Participants

(terms ending May 2010)

DR. RUTH LIGHTFOOT-DUNN

Past EISC Chair, Member at Large
(Amgen Inc.)

DR. KLAUS OLEJNICZAK

Scientific Advisor
(German Federal Institute for Drugs and Medical Devices)

DR. KENNETH RAMOS

Scientific Advisor
(University of Louisville)

DR. STUART CAGEN

Member at Large
(Shell Health Services)



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EMERGING ISSUES PROCESS



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Emerging Issues Process: Issue Identification

Annual Survey:

- Distributed to HESI stakeholders (membership and a broad cross-section of the international scientific community).
- In proposing new topics, respondents are asked to consider topics in the context of linkages with issues found on the HESI Scientific Map.
- Results from the survey are examined by the EISC.
- Using established criteria, the EISC determines which proposals are presented at the HESI Annual Meeting.
- After the Annual Meeting, HESI stakeholders vote on the highest priority issue for HESI action that year (*see form in today's meeting packet*).



Criteria for Issue Identification and Prioritization

- 1. The issue should be critical for the general scientific community, as well as for current and potential member companies, and should have current public health significance.**
- 2. The issue should have reasonable potential for resolution.**
- 3. The issue should be an area for which HESI has or can identify expertise to contribute.**
- 4. HESI's efforts to address the issue should not be duplicative of other groups.**



Subcommittee Formation/Operation

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- Based on voting results (post-Annual Meeting), the EISC selects one emerging issue for HESI action. A Subcommittee is formed.
- EI projects are resource intensive. Limitations in budget and/or staffing resources may affect adoption or timeline.
- **Funding:**
 - **Year One:** \$50,000 in funding from HESI; no fees for participation.
 - **Year Two:** HESI matches funding raised by committee up to \$50,000.
 - **Beyond Year Two:** If desired, participants petition HESI Board for Project or Technical Committee status; project is then funded entirely by participant dollars.



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EXISTING HESI EMERGING ISSUES SUBCOMMITTEES



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Subcommittee Reports

Methodologies for Intermittent or Short-term Exposure to Carcinogens (MISTEC)

Dr. Rory Conolly (Co-Chair; US EPA)

Distinguishing Adverse from Adaptive, Non-functional and Pharmacological Changes in Toxicology Studies

Dr. Douglas Keller (Co-Chair; sanofi-aventis)

Identification of Pharmaceuticals for Validation of ToxCast™

Dr. Robert Chapin (Co-Chair; Pfizer Inc.)

State of the Science: Evaluating Epigenetic Changes

Dr. Karen Augustine (Co-Chair; Bristol-Myers Squibb Company)



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NEW HESI OPTION FOR PROPOSING PROJECTS: RESOURCES-AT-INITIATION (RAI)



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New HESI RAI Process

- **Anyone** can bring a proposal to HESI.
- The proposal must meet **key criteria** (e.g., dedicated funding upfront for at least 1 year, tripartite engagement, relevance to HESI mission).
- Review within **4-6 weeks**:
 1. Senior HESI staff determine if staff resources exist.
 2. The EISC leadership evaluates scientific merit.
 3. The Executive Committee of the HESI Board makes a final determination.
- **Self-sustaining HESI Project Committee** is formed, with a review after one year under the HESI Board Stewardship Program.
- **Example**: HESI Project Committee on Use of Imaging in Preclinical Safety Assessment (*presentation on Thurs., May 13*)
- For more information, see www.hesiglobal.org.



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NEW TOPIC PRESENTATIONS

**ONE TOPIC WILL BE SELECTED
FOR HESI ACTION IN 2010.**



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New Topic Presentations

Evaluating Causality in Epidemiology Studies: A Necessary Step for Human Health Risk Assessments

Dr. Stephen Cole (University of North Carolina)

Dr. Carol Burns (The Dow Chemical Company)

Association of Autoimmunity with Adjuvants in Vaccines

Dr. Sarah Gould (sanofi-pasteur)

Dr. Jan Willem van der Laan (RIVM)