HESI Emerging Issues Session:
Looking Around the Corner

Dr. Stephen J. Newsholme
(GlaxoSmithKline)
Chair, HESI Emerging Issues Committee

HESI Annual Meeting
12 June 2013
Alexandria, VA

ILSI Health and
Environmental Sciences
Institute

What Is the Purpose of Today's Session?

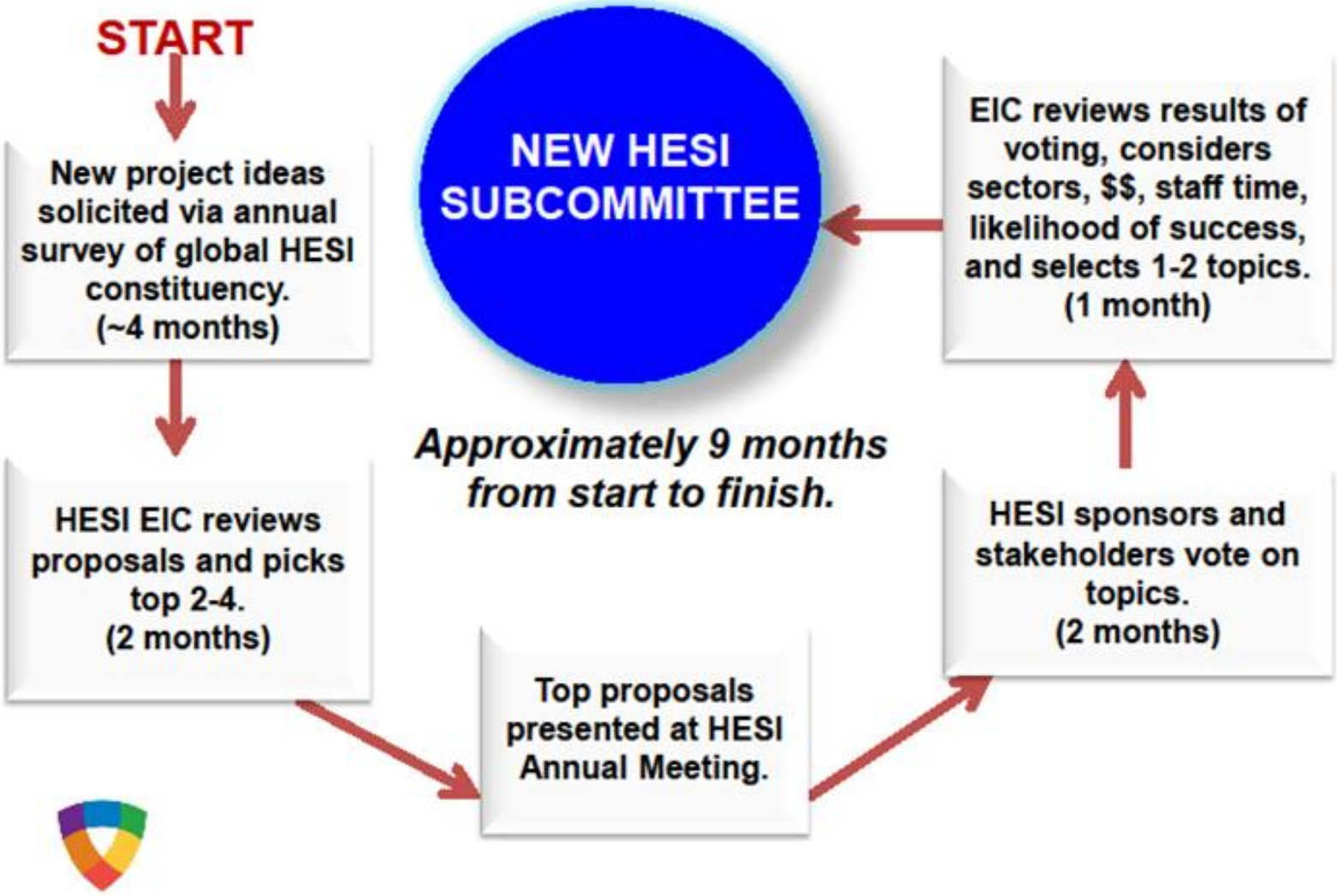
- Learn about the HESI Emerging Issues Committee.
- Hear about new projects recently incorporated into existing HESI committees.
- Become part of an ongoing initiative by the EIC and the Board PSSC to strategically enhance the HESI Scientific Portfolio.

ABOUT THE EIC

What Is the EIC?

- Independent, elected science advisory body that reports to the HESI Board of Trustees.
- Composed of a Chair, Vice Chair, Past Chair, and Science Advisors from the public and private sectors
  - Chair and Vice Chair must be a public/private sector team
- Administers the Emerging Issues (EI) process – HESI's traditional and longest-standing project adoption process.

HESI Emerging Issues Process



Other HESI Project Mechanisms

- **Resources-at-Initiation (RAI) process**
  - For well-defined and time-sensitize projects.
  - Includes a requirement for dedicated funding up front by project submitters.
  - Requires tripartite engagements.
  - Must fit within HESI's mission.
  - Example: Vaccines and Adjuvants Safety Project Committee.
- **Integration into existing HESI scientific committees**
  - Must be directly relevant to the mission and objectives of the targeted committee.
  - Should augment the current research portfolio of the committee.
  - Must be approved for adoption by the targeted committee.

2013-2014 EIC Leadership

(elected by the HESI Assembly earlier today)

CHAIR:

Hal Zenick, PhD

US Environmental Protection Agency (term expires 2015)

VICE CHAIR:

Ruth A. Roberts, PhD, FBTS, ATS, ERT, FRCPath

AstraZeneca R&D (term expires June 2016)

PAST CHAIR:

Stephen J. Newsholme BSc, BVetMed, MMedVet (Path), Diplomate ACVP, MRCVS

GlaxoSmithKline (term expires 2014)

2013-2014 EIC Public Sector Science Advisors

***Continuing Advisors*:**

Dr. Darlene Dixon
NIEHS (term ends 2014)

Dr. Jesse L. Goodman
US FDA (term ends 2014)

Dr. George Gray
George Washington University
(term ends 2014)

Dr. Toshihisa Ishikawa
RIKEN Yokohama Institute
(term ends 2015)

Dr. José E. Manautou
University of Connecticut (term ends 2015)

Dr. Russell S. Thomas
Hamner Institutes (term ends 2015)

Re-elected* today *(terms end 2016):

Dr. James E. Klaunig
Indiana University

Dr. Derek C.G. Muir
Environment Canada

Newly elected* today *(term ends 2016):

Dr. Flavio A.D. Zambrone
University of Taubaté / Planitox (Brazil)

2013-2014 EIC Private Sector Science Advisors

***Continuing Advisors*:**

Dr. Cynthia A. Afshari
Amgen Inc. (term ends 2014)

Dr. Robert A. Barter
ExxonMobil Biomedical Sciences (term ends 2015)

Dr. Daniel A. Goldstein
Monsanto Company (term ends 2015)

Dr. Patrick D. Guiney
SC Johnson & Son, Inc. (term ends 2014)

***Newly elected* today**
(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

Outgoing EIC Participants

(terms ending June 2013)

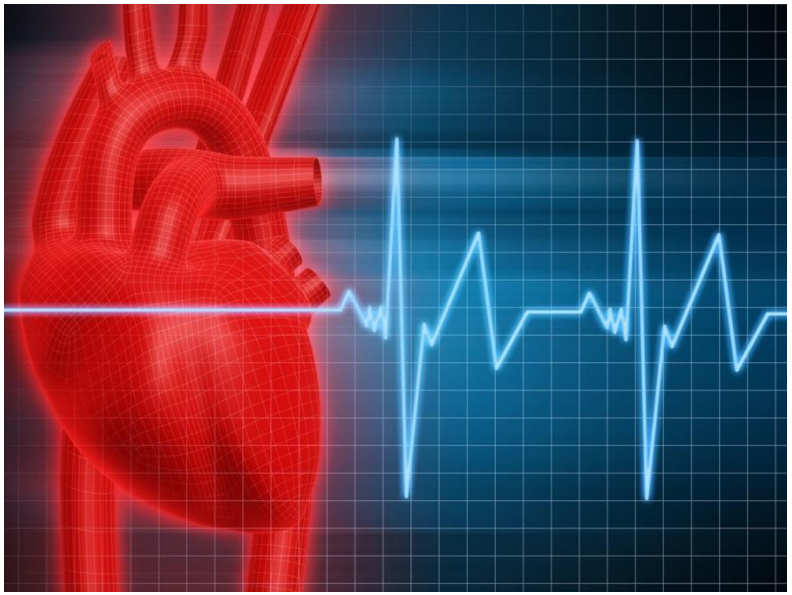
Thanks to all!

Dr. Karen L. Blackburn
(Past Chair)
The Procter and Gamble Company

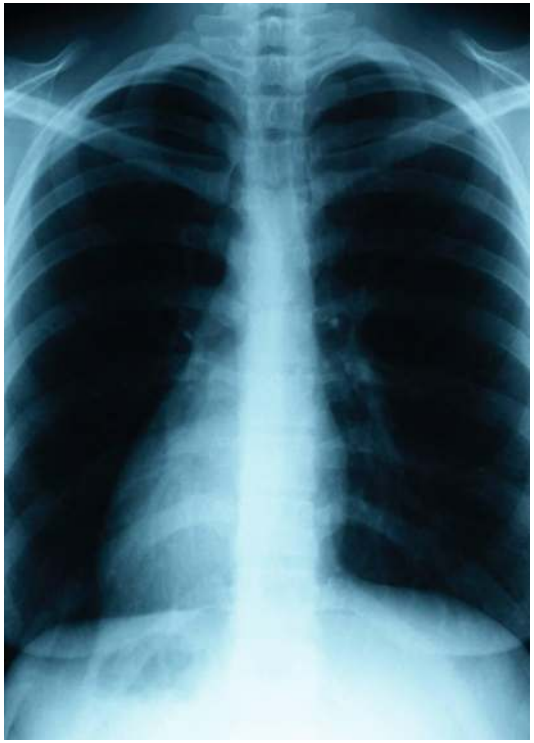
Dr. Ian Kimber
(Public Sector Science Advisor)
University of Manchester

Dr. George Pugh, Jr.
(Private Sector Science Advisor)
The Coca-Cola Company

Dr. Mark A. Tirmenstein
(Private Sector Science Advisor)
Bristol Myers Squibb Co.



NEW HESI PROJECTS FOR 2013



New 2013 Projects

(from Annual Emerging Issues Survey Process)

Recall that there are three ways to bring proposals forward to HESI:

- Emerging Issues Survey process
- RAI process
- Integration into existing HESI committees

The EIC reviewed proposals received through the 2013 Emerging Issues Survey process. **The two proposals selected for action in 2013 were best suited to the third option, i.e., integration into existing HESI committees.**

New 2013 Projects, cont'd.

Integration into existing HESI committees allows new projects to initiate more rapidly by taking advantage of the committee's standing infrastructure and expertise.

To provide better support for this project option, the EIC is conducting a ***pilot process*** that features:

- **Advance discussion with committee leadership** to consider interest in and feasibility of the project.
- **Limited, one-time financial support** to the committee to help initiate the project.

If successful, the pilot process will be formalized. Availability of funding to existing committees for integrating proposals received through the Emerging Issues Survey process will be on a case-by-case basis and at the discretion of the EIC and the HESI Executive Director.

Two New HESI Projects

The following two projects received through the 2013 Emerging Issues Survey process were of interest to existing HESI committees, and have since been adopted:

- Development of a Comprehensive In Vitro Proarrhythmia Assay
- Standard Methods for Identification of Potential Respiratory Sensitizers

Development of a Comprehensive In Vitro Proarrhythmia Assay

Adopted by the **HESI Cardiac Safety Technical Committee**.

Focus: Evaluate and compare current industry practices of cardiac ion channel screening, and design a more predictive nonclinical assay to detect proarrhythmic risk of drugs that may lead to eliminating the need for a TQT study.

Standard Methods for Identification of Potential Respiratory Sensitizers

Adopted by the **HESI Immunotoxicology Technical Committee**.

Focus:

- Provide recommendations for the development of validated testing models or a tiered testing plan.
- Develop a framework for application of evidence to hazard assessments.

EIC / PSSC
STRATEGIC COORDINATION

EIC/PSSC Strategic Coordination

In 2012: Efforts were initiated to establish stronger and more strategic coordination between the HESI **Emerging Issues Committee** (EIC) and the **Board Program Strategy and Stewardship Committee** (PSSC).

Expected to have a significant impact on:

- the quality and strategic direction of the HESI Scientific Portfolio
- the Emerging Issues Survey cycle
- the HESI Combined Challenges Map ***[see EI Session tab of Program Book]***

Implementing EIC / PSSC Strategic Interaction

Planned or in progress:

- Conduct routine reviews of the HESI Combined Challenges Map.
- Identify gaps and opportunities for interdisciplinary and/or cross-project collaboration.
- Cast a wider net for advice and recommendations on identifying critical gaps in the HESI portfolio from committee leaders, the Assembly, and the Board of Trustees.
- On a case-by-case basis, convene joint webinars and/or meetings of the EIC and PSSC, and invite external speakers to explore/define strategic science priorities and new issues.

Thank you!