



Introductory Presentation

Strengthening HESI's Impact through AOM and BOT Involvement

Update on Recent Outreach to Membership

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Background

- ❖ Most recent outreach took place in 2009 from mid-August to the end of October.
 - Objective of 'calls' = to inform ORs about decision to change HESI fee structure in 2010 and beyond.
 - 'Calls' made by HESI ED + President or Treasurer.
 - At the time, 42 companies in AOM – 2 were already confirmed as 'lost' due to M & A.
 - Contact made with 37 / 40 companies. All 40 were notified and informed via short letter from ED + Pres.
 - Typical responses: appreciated being contacted, and the transparency of the process; expressed strong support for HESI, but concerns about current economic situation.



Background

- ❖ Decision by Board in January '08 to implement an aggressive pro-active stewardship strategy for outreach to ALL HESI members.
 - Coordination with Communications Committee to develop materials and talking points.
 - A 'discussion template' was developed (*in mtg. packet*).
 - HESI ED to develop implementation plan with specific targets, milestones, assessment of effectiveness, and feedback to Board.
 - Involvement of Trustees to "call" ORs. 10/31 Trustees participated.



General Outcome of '08 Outreach

- ❖ Number of companies that were contacted = 27/49.
 - 49 companies = 45 current members + 4 recently 'past' members.
 - 27 contacts were made/attempted = 24 reports; 1 company declined comment; 2 attempts w/o success despite repeated effort.
- ❖ A lot of positive comments:
 - HESI tripartite model.
 - Quality of the science.
 - Praise for the staff.
- ❖ But also some issues, recommendations and constructive comments.



HESI Response

- ❖ Gratifying to hear positive feedback on the organization and our approach to addressing key health and environmental issues.
- ❖ However, decision made to focus on the identified areas for improvement to enhance HESI effectiveness.
- ❖ These areas and our responses are presented on the subsequent slides.



Scientific Portfolio

- *“[I am] concerned that there seems to be a "drift" towards the pharmaceutical industry, [...] too many proposals submitted to the Emerging Issues Committee by the chemical/agrochemical companies were rejected.”*
- *“Explain why topics are not selected (e.g. endocrine modulators)”*
- *“Need to stay balanced between the industry sectors “*
- *“The system is not as agile and flexible as it could be. [...] There may be a sufficient level of interest among companies to initiate a project even though it may not be a majority vote collector. Those projects could be very successful even if a minority of companies enlist.”*



HESI Response

- ❖ We assessed statistics regarding EI proposals submitted and accepted by sector over last 3 years. No bias towards pharmaceuticals.
- ❖ We developed a better communication plan about the EI process; specifically how projects are selected to become new subcommittees.
- ❖ We developed a communication plan regarding mechanisms other than the EI process to start new projects, providing for a more flexible and agile process.
- ❖ We implemented the Resources-at-Initiation option.



Project management - efficiency

- *“It is too slow because contributors from other companies are not motivated enough and do not make this project a priority”*
- *“There does not seem to be a sense of urgency”*
- *“Partnership may be restricted due to industrial secrets.”*
- *“Need better goal setting/milestone setting. Transparency and agreement to milestones/deliverables would be helpful [...] Staff needs strong project management skills and to be able to drive people that don't report to them.”*
- *“The HESI staff needs to take a more active role in managing timelines, and HESI leadership needs to be more active in seeing to it that the pledged sweat equity from member companies is delivered.”*



HESI Response

- ❖ We are constantly improving approaches to ensure excellent project management skills for all staff members.
- ❖ We have integrated great use of project management tools to keep us organized and on schedule (e.g., 'Gant charts').
- ❖ We are considering how to maximize communication and expectations for working projects.
- ❖ We believe that the ORs should play a major role in ensuring that companies actively participate.



Ability to participate in projects

- *“[I am] concerned that the necessary expertise is no longer available in the companies.”*
- *“Efficiency initiatives within companies can reduce the number of scientists available to work the HESI.” committees, and also reduces the available expertise over time.”*
- *“currently limited by personnel and time. Cost is not necessarily an issue”.*
- *“Because of limited human resources [we] participate only in IMI”.*
- *“[He] suggested that HESI consider some decrease in annual dues and/or committee membership fee for the really small companies.”*



Priority Membership Targets (2009)

❖ Small Pharma (*feedback from someone familiar with HESI*):

- **Communication?** Are they on our mailing list? Small companies can't participate in programs they aren't aware of. How to track? - there are about 1000 biomedical start-ups in the US.
- **Money?** Consortia efforts and organizers need money to operate, and small companies certainly don't have the budgets that big companies do and we'll need a different financial model - maybe through collectives.
- **Image?** There's a perception that we only target large companies as participants. Odd, since small companies are close to half the industry's pipeline (i.e., by Tufts data).



HESI Response

- ❖ We believe that active participation by individual company reps is critical for our continued success.
- ❖ We have modified the format of our Annual Meeting to encourage that participation.
- ❖ We support the promotion of the involvement of 'younger' company staff by our membership. In many cases they will have a broad range of new skills, with the energy and interest in applying them to our issues. We believe that engaging younger staff will allow them to expand their network.
- ❖ We are considering changing our approach to 'associate membership' to target small companies.



Role of Official Representative

- *"[I have] never been to an Annual meeting"*
- *"[I have] limited interest in knowing more about HESI" (from a company that participate in only one project)*
- Suggestion: *"Have special functions for company reps at the annual meeting"*
- *"Email updates would be nice on projects"*
- *"One of the things that [I] would like from HESI is a more cohesive and specific document that is targeted for upper management."*
- *"Feels his role as company rep would be different if the company doesn't have someone on the board. Board is driving force, but could more effectively leverage members. Feels there may be a gap between the Board and committee participants that is supposed to be filled by the company rep. Not sure what company rep roles and responsibilities are. Suggests having a representative job description ."*



HESI Response

- ❖ We have modified the format of our Annual Meeting to encourage that participation, including a special 'combined session' of the AOM and the Board.
- ❖ We anticipate that one of the outcome of the 'combined session' will be a better understanding for the roles and responsibilities of the OR.
- ❖ We are examining how to promote HESI work products. Press releases are being considered.
- ❖ Communication Committee is working to enhance our communication to members, including documents targeted to company management.



Regional presence

- *“Please establish close relationship between membership companies in Japan. [...] Please advertise ILSI activity in Japan.”*
- *“Feels HESI has a narrower scope because it's taking on North America based activities”*
- *“HESI remains “an American thing” for my company’s top management who is “very” French. Value of HESI would be higher if visibility in Europe were more obvious”*
- *“more and more important initiatives in terms of safety starts in Europe”*
- *“Being on the West Coast is a “huge barrier” to participating on HESI committees. Moving some of the meetings to west coast sites might help increase involvement.”*



HESI Response

- ❖ We are continuing to look for opportunities to encourage membership from outside the U.S. and to address important issues globally to the benefit of all members.
- ❖ We also continue to look for ways to maximize member participation, regardless of location.
- ❖ We are making greater use of teleconferences and webinars and the use of technology for “virtual meetings.
- ❖ We are relying less on face-to-face meetings to control our costs.



Other participant types?

Other membership sectors?

- *“Political change could bolster the NGO's challenge regarding regulators and academics working with industry-funded activities. We need to stay vigilant on this issue.”*
- *“We need to consider adding NGO scientists to address the concern/accusation that all interested parties are not represented”*
- *“Do not include NGO as members because it would affect the “format” significantly and negatively. Instead, consider public external debate with NGO”*
- *“Consider CRO involvement; CROs have good scientists and data. [...] Conflict of interest could be managed.”*
- *“Could we tap into other sectors: Biotechs, CROs?”*

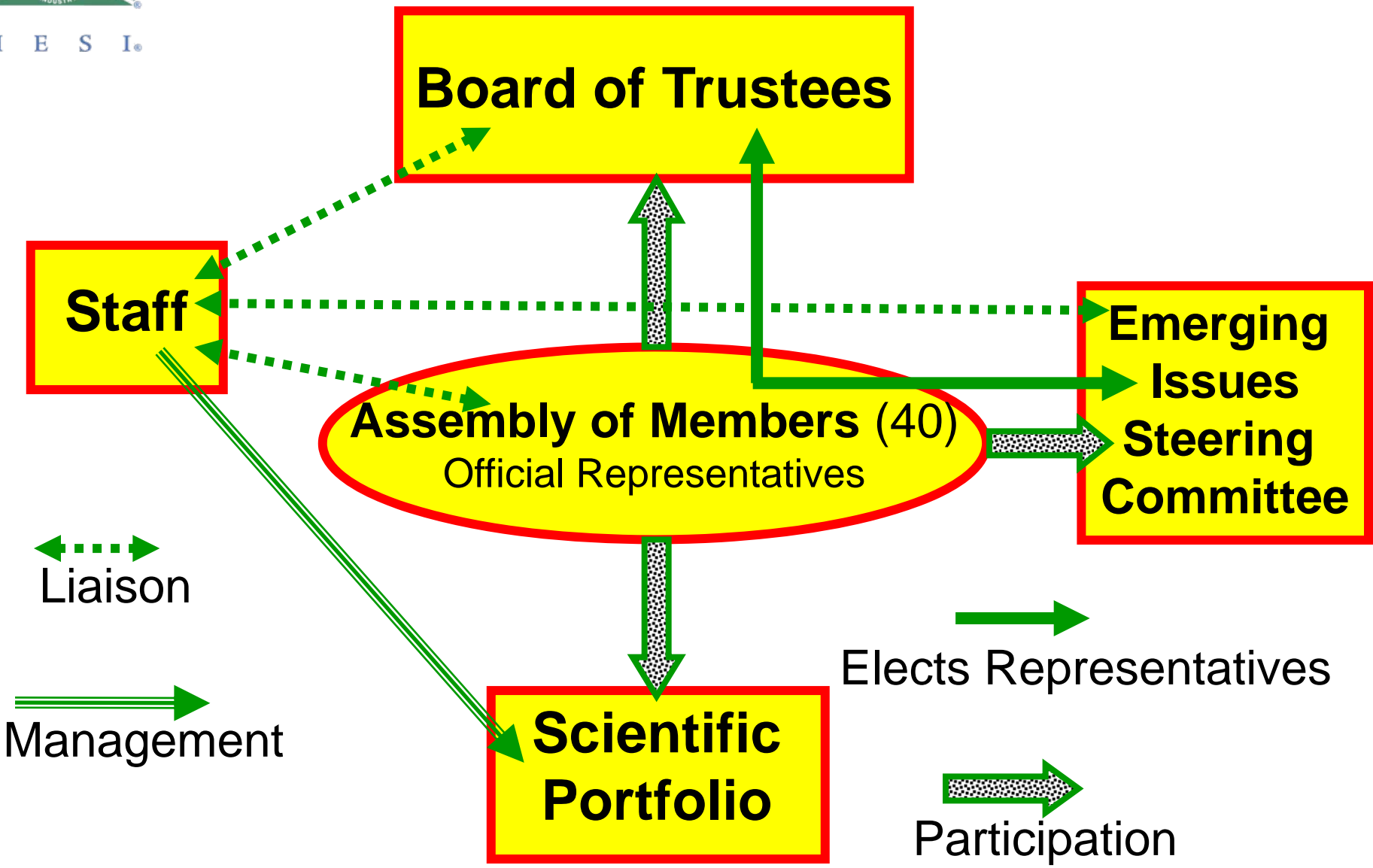


HESI Response

- ❖ We changed our by-laws to allow CROs to join HESI and successfully recruited some new members.
- ❖ We recognized that other industry sectors have health and environmental issues that are being addressed by HESI. We changed our bylaws to include new membership sectors.
- ❖ Our government colleagues have also encouraged us to engage NGOs who have an interest in advancing the science. We are continuing to examine the implications of including NGO scientists in our activities.



2010 ILSI HESI Organizational Chart





Closing Remarks

- ❖ We value your input.
- ❖ Any questions?
- ❖ Any comments?
- ❖ Any concerns?