

Exploration of Innovative Models for Funding Tobacco Control Research

Summary of Workshop Discussions
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Austin, Texas

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1. Background

The issue of tobacco industry funding of research is both important and controversial. It is important because of the science gaps and funding realities, and controversial because of past and current tobacco industry funding mechanisms, such as the Council for Tobacco Research and the Philip Morris External Research Program, that have been used by tobacco companies as a means to gain credibility, respectability, and good PR.

Over the past three years researchers, policy experts, and advocates have convened to debate issues surrounding the offer and acceptance of funding from the tobacco industry. A special post-conference symposium on this subject was held following the annual meeting of the Society for Research on Nicotine and Tobacco (SRNT) in 2003 in New Orleans. Sessions were also held at the 2005 SRNT meeting in Prague and the National Conference on Tobacco or Health in 2005 in Chicago. While these debates were constructive, they did not progress towards an examination of potential funding models by which tobacco industry financial support could be accepted.

The purpose of the most recent workshop was to advance the dialogue on the contentious issue of what to do about the offer and acceptance of tobacco industry money for research. We brought together researchers, advocates, and funders, as well as individuals outside of tobacco control who have experience with alternate funding models, to consider the continuum of possibilities regarding tobacco industry funding of research (see Appendix 1 for list of participants). The objective of the workshop was to identify which funding models, if any, would be acceptable to pursue further.

The workshop goals were:

- To explore possible funding models
- To consider one potential model involving funds from the auto industry, but not to the exclusion of others
- To assess whether there is any interest in continuing the dialogue on alternate funding models for tobacco control research

The workshop was preceded by an online survey. We asked all of the workshop invitees to answer questions pertaining to the following three funding models:

1. **A dedicated tobacco tax earmarked for tobacco-related research.** e.g., legislation that mandates a tax on each cigarette pack, with the money flowing directly to a government funding agency (e.g., NIH) for tobacco-related research.
2. **Legally-mandated funds administered through a 3rd party.** e.g., tobacco company contributions required through a settlement of new litigation or amendment of the Master Settlement Agreement, earmarked for tobacco-related research and administered through a 3rd party that has no ties to tobacco companies.
3. **Voluntary tobacco company contributions administered through a non-tobacco industry 3rd party.** e.g., as above, but the tobacco company contributions would be voluntary.

The workshop attendees represented the full spectrum of views from personally accepting tobacco company money for research, to strongly holding the conviction that tobacco companies only fund research if it helps their bottom line. The discussion was lively but respectful. The workshop began with a presentation of the Health Effects Institute (HEI) model by HEI Vice President Mr. Bob O’Keefe, followed by questions for the presenter and a general discussion.

This document describes the HEI model as presented by Mr. O’Keefe, outlines the issues raised during the discussion, and describes proposed next steps.

2. The Health Effects Institute Model

Background:

HEI is an independent non-profit research institute chartered in 1980 and jointly funded by the auto industry and government. Other HEI sponsors include the chemical industry and the American Petroleum Institute. Its mission is to provide independent research on the health effects of air pollution from vehicles and other sources in the environment through a program of research and synthetic review of the science. HEI does not take or recommend policy positions.

HEI’s Organization:

Funding Model

HEI receives joint and equal core funding by government (through the Environmental Protection Agency) and industry. The research committee prepares specific Requests for Applications which are circulated to sponsors for comment. HEI’s research agenda is administered through contracts to researchers.

Board of Directors

Candidates for board membership are approved by HEI’s core sponsors (both government and industry), and cannot be affiliated with HEI sponsors or be an advocate for one side or another. The board identifies, vets, and votes on new candidates. Once approved, the Board independently oversees all operations of the Institute.

Research Committee

The research committee is made up of independent subject matter experts not affiliated with sponsors. This committee identifies the research agenda (Five Year Strategic Plan), prepares Requests for Applications, and selects investigators through a competitive process and oversees the quality of research.

Peer Review Committee

This committee of non-sponsor affiliated subject matter experts reviews all funded studies and prepares detailed critiques of the studies.

Key Issues:

Transparency

HEI fully discloses results, and sponsors do not review results before publications are complete. Sponsor-investigator contact occurs primarily at large annual research meetings or on occasion at targeted multi-stakeholder workshops. HEI has full access to data; methods and data are available upon request to other investigators (with confidentiality protected) after publication -- in practice, requests are limited.

Balance of Power

There is a defacto balance of power among various interests: industry influence, government authority, and non-government organizations. HEI receives input to its work from its sponsors, and the NGO community also has a role in the process. Investigators are encouraged to publish their findings, and the results of all endeavors have been published in over 200 HEI Research Reports and Special Reports.

See Appendix 2 for a copy of Mr. Bob O’Keefe’s presentation on the Health Effects Institute.

3. Summary of Issues Raised During Discussion

Type of research funded by tobacco industry

Should taxpayer money fund the evaluation of tobacco company products (e.g., PREPs)? Should tobacco company money fund research on other tobacco-related topics (e.g., mechanisms of addiction, advocacy)?

Input from the tobacco industry

Obtaining tobacco money with no input and/or no benefit to the tobacco industry may not be realistic for certain funding models. Assuming the tobacco industry is not interested in conducting research that would lead to decreases in tobacco use, under what conditions would they come to the table? Unlike the HEI model, equal balance of power between the tobacco industry and government is not acceptable to most tobacco control researchers. A competitive peer review process is essential. Are there any acceptable mechanisms by which the tobacco industry could provide some input to the process?

Tobacco industry PR

It is imperative that any new funding model works well in practice and does not slow down research progress. Would the HEI model give the tobacco industry too much credibility? How many degrees of separation are required for the tobacco control community to associate with the tobacco industry? The tobacco industry’s history of fraud, deception, and PR gains from funding research has been well documented. Is any level of tobacco PR acceptable in exchange for good science? At what point do any benefits from tobacco company sponsored research outweigh possible harms to the public’s health?

Conditions required for any type of funding, including funding from the tobacco industry

These conditions may include the following: a competitive process to select applicants; ownership of data; freedom to publish; and, disclosure of competing interests. Are these conditions sufficient to acceptably minimize potential harms from allowing tobacco companies to fund research? Do all universities have the resources and expertise required to understand the implications of tobacco industry funding of research and implement the appropriate safeguards?

4. Next Steps

1. A sub-group will be formed to prepare a document presenting a number of different potential models and outlining relevant issues for each.
2. This document will be circulated widely for comment and input.
3. Another face-to-face meeting will be held to discuss whether and how to move forward (i.e., next steps).

Timelines:

Now until the end of 2007: Prepare document outlining different funding models
February 2008: Face-to-face meeting at SRNT conference

Appendix 1: Workshop Participants

The following is a list of people who attended the workshop. The content of this summary document was not reviewed by any of the participants. By listing their names, we do not intend to imply that they endorse the contents of the report.

Name	Organization
Mr. Scott Ballin	Tobacco and Health Policy Consultant
Dr. Neal Benowitz	University of California, San Francisco
Dr. Francisco Buchting	Tobacco-Related Disease Research Program
Dr. Allison Chausmer	National Institute on Drug Abuse
Dr. Pamela Clark	Battelle Centers for Public Health Research & Evaluation
Dr. Joanna Cohen	Ontario Tobacco Research Unit
Dr. Michael Cummings	Roswell Park Cancer Institute
Dr. Tom Eissenberg	Virginia Commonwealth University
Dr. Roberta Ferrence	Ontario Tobacco Research Unit
Dr. Prakash Gupta	Healis-Sekhsaria Institute for Public Health
Dr. Jack Henningfield	Pinney Associates
Dr. John Hughes	University of Vermont
Ms. Katie Kemper	Campaign for Tobacco-Free Kids
Dr. Lynn Kozlowski	State University of New York at Buffalo
Dr. Bernard le Foll	Centre for Addiction and Mental Health
Dr. Scott Leischow	Arizona Cancer Center
Ms. Agnes O'Donohue	Canadian Tobacco Control Research Initiative
Mr. Bob O'Keefe	Health Effects Institute
Dr. Mark Parascandola	National Cancer Institute
Ms. Lynn Planinac	Ontario Tobacco Research Unit
Dr. Stephen Rennard	University of Nebraska Medical Center
Dr. Jason Robert	Canadian Institutes of Health Research
Dr. Jed Rose	Duke University Medical Center
Ms. Krista Scaldwell	Johnson & Johnson
Dr. Peter Selby	Centre for Addiction and Mental Health
Mr. David Sweanor	University of Ottawa
Dr. Donna Vallone	American Legacy Foundation
Dr. Ken Warner	University of Michigan School of Public Health
Dr. Robert West	University College London
Mr. Mitch Zeller	Pinney Associates

Appendix 2: The Health Effects Institute – Presentation by Mr. O’Keefe

The Health Effects Institute As Public-Private Model to Obtain Credible Science

Robert O'Keefe, Vice President
Health Effects Institute

SRNT Meeting
Austin, Texas
February 2007



HEI-The Idea

- 1977 Clean Air Act Requirements (s.202a4) Auto companies to test health effects of emissions
 - EPA-Industry relationship poor, science contentious, litigious
- Industry CEOs \ EPA Administrator
 - ...There must be a better way to produce science we can trust
- HEI independent non-profit research institute
- Jointly funded by industry & government
- Mission: provide independent research on the health effects of air pollution from vehicles (1990s “and other sources in the environment”)
- Support meets s.202a4 testing requirements



HEI – Science Products

- Four key areas:
 - **Targeted Research** - Primary role,
 - Criteria pollutants, toxics, fuels and additives, methods
 - Across disciplines, toxicology, epidemiology, exposure
 - **Special Literature Reviews** - e.g.
 - Health Effects of Inhaled MTBE; Diesel Exhaust,
 - Exposure to Traffic
 - **Reanalysis** of key studies e.g.
 - Harvard Six Cities, Pope ACS, Time Series Methods (GAM)
 - **Pollution effects in developing countries** (With WHO, others)
 - Impact Assessment, Capacity building
- Over 30-40 Studies underway worldwide on average
- Budget \$8-12 Million\Yr
- Emphasis on studies relevant to regulatory agenda



HEI Studies Underway

To Inform Increasingly International Decisions



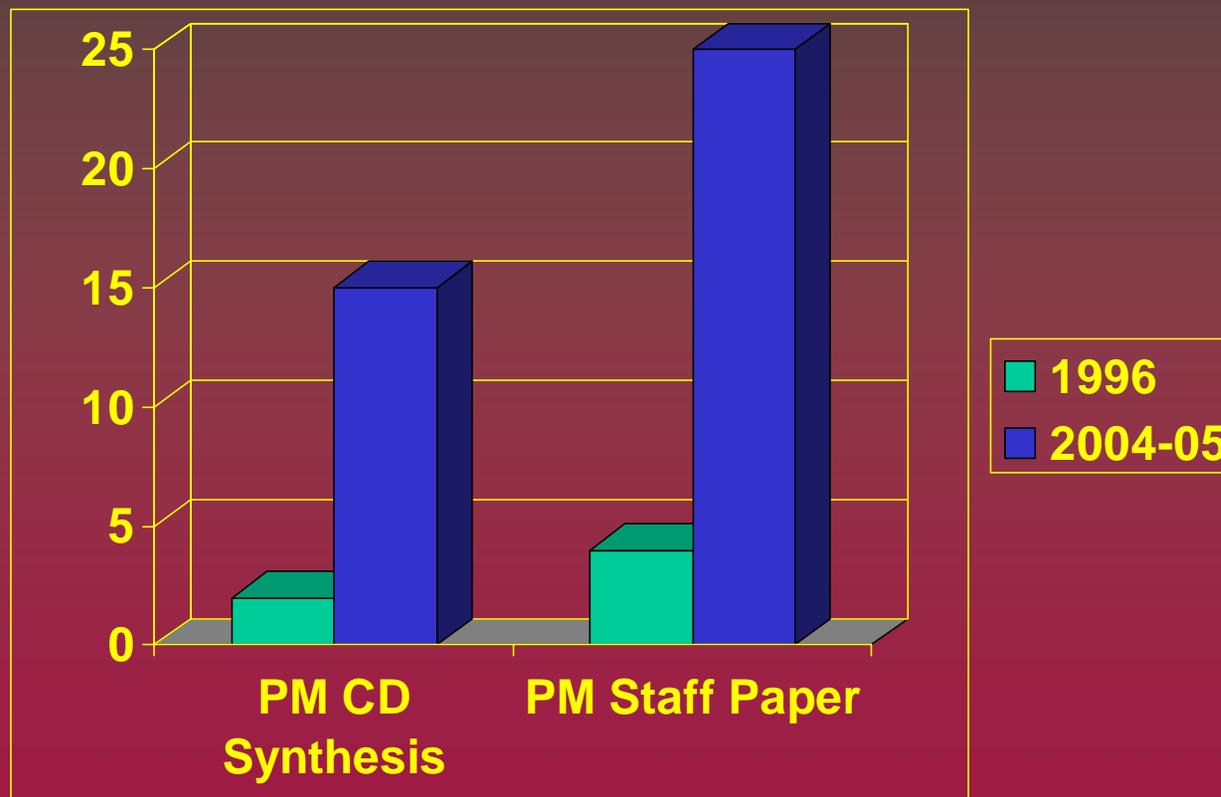
★ = HEI Study



Having an Impact:

EPA's Growing Reliance on HEI in the PM NAAQS

(Number of HEI Reports cited in U.S. EPA PM NAAQS Documents)



HEI-The Organization

- *HEI structured to maintain credibility in often controversial national regulatory debates*
 - Independent Board of Directors
 - Approved by, but not affiliated with sponsors
 - Separate Research and Peer Review Committee
 - Independent subject matter experts – no perceived “point of view”
 - Joint and equal funding
 - High degree of transparency
 - *Do not take policy positions*



HEI-Funding Model

Joint and equal core funding by government and industry (~ 7.5 million\yr)

- Worldwide vehicle industry:
 - apportioned based on market share
- US EPA
- Multi-year Commitment to 5 year *“Strategic Plan for Research”*
 - long term commitment insulates HEI from either side “pulling plug” over single study
- Joint and equal funding addresses perception, reality of bias associated with single interest support
- Enhances credibility to those outside, but also to industry and government sponsors themselves,
 - ultimately more likely to trust, act on science they are part of funding

Other partners over years

-State and National Governments, Industry, Foundations, Lenders, International Health (WHO)

In balanced partnerships, for program of research, not specific studies



HEI-Organization: Board

- Characteristics:
 - Respected senior leaders recognized for integrity, public policy and/or science experience
 - Not affiliated with HEI sponsors in industry, government
 - Not advocate for one or another side
- Appointment
 - Current Board identifies, vets, votes on new candidates
 - Candidates must be ratified by HEI's core sponsors (EPA Administrator and majority of members of the vehicle industry)
- *Once elected Board oversees operation of all aspects of operation of HEI without further sponsor approvals*



HEI Board of Directors

- Founding Board
 - Archibald Cox, Harvard
 - William Baker, Bell Labs
 - Donald Kennedy, Stanford, FDA
- Current Board
 - Queta Bond, - Burroughs Welcome Foundation
 - Richard F. Celeste, Chair - *Ambassador of the USA India (retired)*
 - Jared Cohon – Carnegie Mellon
 - Purnell W. Choppin - *Howard Hughes Medical Institute*
 - Gowher Rizvi – Ash Institute, Harvard; Ford Foundation
 - Linda Rosenstock – UCLA, NIOSH
 - Prof. Richard B. Stewart - *New York University School of Law*
 - Dr. Robert M. White - *The Washington Advisory Group LLC*



HEI Organization: Research Committee

- Impartial, internationally-regarded subject experts
 - Regular disclosure of funding, conflicts
- Appointed by Board, (no sponsor concurrence)
 - Four year term - depth & commitment to an area
- Responsibilities:
 - Identifies research agenda (Five Year Strategic Plan)
 - Prepares Requests for Applications
 - Selects investigators through competitive process
 - » Oversees quality and timeliness of research
 - » Independent QA\QC Audits, Site Visits
 - » Detailed report by investigators



HEI Research Committee

- Mark J. Utell Chair *University of Rochester*
- Melvyn C. Branch, *University of Colorado, Boulder*
- Ken Demerjian, *University at Albany - SUNY*
- Peter B. Farmer, *University of Leicester*
- Helmut Greim, *Technical University Munich*
- Grace LeMasters, *University of Cincinnati*
- Sylvia Richardson, *Imperial College London*
- Howard Rockette, *University of Pittsburgh*
- James Swenberg, *University of North Carolina at Chapel Hill*
- Ira Tager, *University of California, Berkeley*



HEI Organization: Peer Review Committee

- Separate panel of respected, impartial experts
 - Not affiliated with Research Committee
- Responsibilities
 - Independently peer review all major studies
 - Publishes detailed critique of studies
 - Publishes detailed commentary outlining how research has or has not contributed to the state of knowledge in a given area, and the implications for regulations
 - Reports concise, understandable with executive summary intended for lay decision makers



HEI Review Committee

- Homer Boushey Chair
University of California, San Francisco
- Ross Anderson, *St. George's, University of London*
- Ben Armstrong, *London School of Hygiene & Tropical Medicine*
- Alan Buckpitt, *University of California, Davis*
- John R. Hoidal, *University of Utah Health Sciences*
- Brian Leaderer, *Yale Medical School*
- Edo D. Pellizzari, *Research Triangle Institute*
- Nancy Reid, *University of Toronto*
- William N. Rom, *New York University Medical Center*
- Sverre Vedal, *University of Washington*



HEI

*Science Agenda, Research, Review,
Who does what.....*



The HEI Model

Board
(Oversees all operations)

Sponsor\NGO\Science

Sponsors Fund
(Agree on Board only)

Action\Strategic Plan

Research

Final Report

Review Committee

Staff

Research Committee

Draft Report

Stringent Peer Review

Research Oversight

RFA\ Selection

Public Meetings

Contract

Investigators



Choosing the Future: The Strategic Plan

Topics for Consideration

Major Opportunities

- Air pollution mixture
 - PM and gases
 - Components research
 - Air toxics
 - Exposure and health research
 - Review and synthesis
 - Diesel
- Emerging technologies
 - ACES
 - Special reviews
- Accountability
 - Research
 - Development of long-term methods, and studies
- Enhanced international perspective

Other Possibilities

- Sensitive populations
- Reproductive effects
- Gases
- Health effects of climate change
- Innovative methods

Planning Process and Selection Criteria

Input from

- Sponsors
 - EPA
 - Motor vehicle industry
 - California Air Resources Board
 - Oil and chemical industry
- Scientific community
- Environmental community
- International agencies
- Others

Selection Criteria

- Importance to public health
- Importance to regulation, technology (short and long term)
- Importance to science
- Work of others
- Possibility of a scientific contribution

HEI Strategic Plan 2005–2010

Infusing innovation and validation in all HEI science

Priority Research Areas

- Air pollution mixture (PM components/gases and their sources, and air toxics)
- Emerging technologies
- Accountability
- Enhanced international perspective

Special Reviews

- PM Perspectives
- Air toxics
- Traffic and health
- Key fuels, fuel additives, technologies

Cross-Cutting Issues

- Susceptible populations (elderly, children, others)
- Mechanisms
- Extrapolation

Lower-Priority Items (to be monitored)

- Health effects of climate change
- Diesel signatures
- Single pollutants

Roles

Sponsors:

Fund, Agree Board:

Comment: Draft Strategic Plan, RFA

Participation: attend Annual Conference; pre-release briefings on all major studies; *annual sponsors meeting to report progress*; periodic HEI staff briefings; participation on occasional advisory panels (i.e. Reanalysis scope)

Stakeholders (NGOs, states Congress etc):

Comment: Strategic Plan; Draft RFA (relevant areas);

Participation: attend Annual Conference (HEI funds); Pre release briefings on key major studies; Periodic HEI staff briefings; participation on occasional advisory panels (i.e. Reanalysis scope)

No external involvement in: research selection, contracting, oversight, review of investigators reports, HEI peer review, commentary, publication etc.

-All *decisions* by Research Committee\Board



Key Issues - Transparency

- Full public disclosure of results
 - Comprehensive final reports
 - Positive *and* negative findings reported
 - Sponsors do not review results before publications are complete
- Sponsor\Investigator Contact
 - Primarily at large annual meetings, poster sessions
 - Both EPA and Industry (and NGOs, science etc) present
- Access to Data
 - HEI itself has full access to all underlying data for review
 - Following publication, access to data, methods can be provided to other investigators (with confidentiality protected) on request
 - In practice limited requests
- *Process more extensive than most journals*



HEI - Key Issues

- Balance of power among interests helps independent research organization maintain independence
 - Industry resources balanced by
 - Government jurisdiction
 - and/or
 - NGOs bully pulpit (depending on NGO)
 - Balanced comments; broader universe of issues; less ability for one side or another to exert undue influence
- HEI industry \ government model benefits from
 - NGO, state involvement



Becoming a Trusted Organization

- HEI's original Board, joint funding, balance of competing interests all important
- Regardless of organizational and financial structure
 - Communication to range of decision makers & stakeholders critical regulatory traction
 - Long before results
 - Who is HEI
 - Why are these studies relevant?
 - Pre-Release Briefings (no surprises)
 - *Ongoing responsibility to monitor correct inaccurate characterization of HEI research by one side or another*
 - Trust built over time:
 - Models are important, but results over time make the case



Thank You!

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