Cycle of Policy Making

LESSONS, APPLICATIONS TO OTHER SETTINGS

PROBLEM DEFINITION

AGENDA SETTING

EPIDEMIOLOGY

POLICY FORMULATION

POLICY IMPLEMENTATION

EVALUATION

INTERVENTION

POLICY CHOICE
Significance

- Assumption: health policy should be evidence based
- Assumption: evidence can be biased
- Influence of scientific evidence and argument has been questioned
- Little empirical investigation of actual use of evidence in legislative or regulatory process
Case Studies

- Risk assessments of secondhand smoke
- State indoor air regulations
- Federal tobacco regulations
  - Occupational Safety and Health Administration (OSHA) Indoor Air Quality Regulation
  - Food and Drug Administration (FDA) regulation of tobacco advertising and youth
  - Airline smoking bans
Data sources

- Legislation
  - Text of legislation and amendments
  - Floor debates
  - Committee hearings
  - Other archival materials

- Regulation
  - Public commentary during the rule-making
  - Agency responses to the commentary
  - Interviews with agency officials
Types of arguments

<table>
<thead>
<tr>
<th>Argument Type</th>
<th>Percent of Individuals Making Argument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific</td>
<td>20</td>
</tr>
<tr>
<td>Ideological</td>
<td>30</td>
</tr>
<tr>
<td>Economic</td>
<td>60</td>
</tr>
<tr>
<td>Political</td>
<td>40</td>
</tr>
<tr>
<td>Ventilation</td>
<td>30</td>
</tr>
<tr>
<td>Procedure</td>
<td>10</td>
</tr>
</tbody>
</table>

- Green: For
- Yellow: Against
Percent of commentators using criteria to evaluate science

For (n = 188)

Against (n = 157)
## Affiliation bias

<table>
<thead>
<tr>
<th>Affiliation</th>
<th>% For n=188</th>
<th>% Against n = 157</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco</td>
<td>1</td>
<td>35</td>
</tr>
<tr>
<td>Business</td>
<td>16</td>
<td>27</td>
</tr>
<tr>
<td>Government</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Lay activist</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>University</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Private citizen</td>
<td>20</td>
<td>22</td>
</tr>
</tbody>
</table>
Study sites/workplace smoking legislation

- Red: strong
- Yellow: weak
- Blue: failed
Legislative cases

- Utah
- South Dakota
- Florida
- Oregon
- Louisiana
- North Dakota
States with more public participation passed stronger legislation

(States ordered from strongest legislation to weakest legislation)
States emphasizing ideological arguments passed weaker legislation

(States ordered from strongest legislation to weakest legislation)
Influences tobacco policy

- Tobacco industry controls public commentary
- Economic and ideological arguments used equally by supporter and opponents; used more often than scientific
- More discussion of science favors stronger public health policy
- Opponents more likely to criticize reliability, validity, and quality of science
- Opponents cite more scientific research
Proportion of lay press articles on passive smoke research emphasizing controversy by year (n = 272)
Strategies to manipulate research

- Fund
- Publish
- Criticize

- Suppress
- Disseminate
Center for Indoor Air Research

1988

Mission

“to create a focal point organization of the highest caliber to sponsor and foster quality, objective research in indoor air issues including environmental tobacco smoke.”

“Specially-reviewed” projects
Fund research: CIAR

- **Types of projects funded**
  - **Peer reviewed**: 70% on indoor air pollutants
  - **Special reviewed**: 63% on passive smoke

- **Use of data from projects**
  - **Peer reviewed**: 48 publications, 81% peer reviewed
    - 1/34 (3%) PIs testified at regulatory hearings
  - **Special reviewed**: 21 publications, 52% peer reviewed
    - 5/18 (28%) PIs testified at regulatory hearings
Publish research: Symposia

- Cited as “gathering of leading experts,” ”consensus of scientific experts”
- Not peer reviewed
- Unbalanced conclusions
- Poor quality

- 0.45 (95% CI: 0.43, 0.47) vs. 0.36 (95% CI: 0.33, 0.40) (p = 0.027)
- Independent of source of funding acknowledged, conclusions, or study design
Hypothesis: Articles concluding that passive smoking is harmful would be high in quality, peer-reviewed, written by non-TI affiliated individuals.


Quality assessed on a scale of 0 (worst) to 1 (best).
<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality score</td>
<td>1.5 (&lt;0.1-67.5)</td>
</tr>
<tr>
<td>Not PR vs PR</td>
<td>1.3 (0.3-5.4)</td>
</tr>
<tr>
<td>TI vs non-TI</td>
<td>88.4 (16.4-476.5)</td>
</tr>
<tr>
<td>Topic</td>
<td></td>
</tr>
<tr>
<td>Lung cancer vs. multiple</td>
<td>1.6 (0.2-10.3)</td>
</tr>
<tr>
<td>Heart disease vs. multiple</td>
<td>1.6 (0.2-14.7)</td>
</tr>
<tr>
<td>Year of publication</td>
<td>1.1 (0.9-1.3)</td>
</tr>
</tbody>
</table>
Why the association?

- Framing / social construction of the research question
- Designing the study
- Conducting the study
- Publishing the study (or not)
What the tobacco documents tell us

- WHY
- HOW
WHY? The motives

- Create controversy - criticize or create counter studies
- Protect industry from litigation and regulation
- Control the research agenda
- Change scientific standards
- Generate credibility / good public relations
The tobacco industry on smoking

- **Doubt** is our product since it is the best means of competing with the “body of fact” that exists in the mind of the general public. It is also the means of establishing a controversy ... If we are successful about establishing a controversy at the public health level, then there is an opportunity to put across the real facts about smoking and health.  

  B&W “Smoking and Health Proposal,” circa 1969
The tobacco industry on passive smoking

- In every major international area (USA, Europe, Australia, Far East, South America, Central America, and Spain) [Philip Morris] are proposing, in key countries, to set up a team of scientists organized by one national coordinating scientist and American lawyers, to review scientific literature or carry out work on ETS to keep the controversy alive.

Boyse, Philip Morris, 17 February 1988 #6
HOW? Who is in control?

- Industry tries to hide involvement
- Controls research from start to finish
- Who’s involved
  - Lawyers
  - Industry scientists
  - Industry executives
Refuting an influential study

- Hirayama study (1981) showing association of secondhand smoke and lung cancer
  - Most frequently cited study in regulatory hearings on indoor air regulation
  - Misclassification: 1 of 9 most frequently used arguments to refute Hirayama (and other studies)

- Tobacco industry created a study to support its arguments about misclassification
A Japanese study … or not?

“Also, I am of the opinion that Dr. Chris Proctor might **supervise this work** but his presence should be low key and **not appear in any of the publications**, particularly since this is a Japanese study”  
[2023544449: April 16, 1991 from T.S. Osdene, R&D at PM to Steve Parrish, Senior VP at PM]

“Proctor (and his fee) may be necessary to help get this done… but **this should be a Japanese study: Proctor should not be a coauthor on any publication** that comes out of it”  
[2023544456: April 15, 1991 from Bob Pages, R&D team at PM reporting to Steve Parrish, Senior VP, PM]
Who should fund it?

“This is NOT a project that should be funded by CIAR, although there MAY be (I’m not convinced yet) a reason to say it was sponsored by CIAR so as to ‘hide’ industry involvement.”

[2023544456: April 15, 1991 from Bob Pages, R&D team at PM reporting to Steve Parrish, Senior VP, PM]

“One may wish to use a CIAR cover for this project. I believe it is very important that this be done with all due haste…”

[2023544449: April 16, 1991 from T.S. Osdene, R&D at PM to Steve Parrish, Senior VP at PM]
December 23, 1991

Re: Japanese Spousal Study

Dear Colleagues:

This brief note is to give you an update on the progress of the spousal study.

All of the questionnaire data is now entered into a database and has been validated. Initial statistical evaluations look very promising, particularly with respect to confounding lifestyle and dietary factors.

Kruskal-Wallis test on the data split by smoker (S) and non-smoker married to smoker (NS/S) and non-smoker married to non-smoker (NS/NS) showed statistically significant differences between NS/S and NS/NS for:

Exercise  NS/NS > NS/S
Fresh Fruit Consumption  NS/NS > NS/S
Dark Green Vegetables  NS/NS > NS/S
Orange Juice  NS/NS > NS/S
Milk  NS/NS > NS/S
Vitamin Supplements  NS/NS > NS/S
Alcohol  NS/3 > NS/NS
Butter  NS/3 > NS/NS
Smoked Fish  NS/3 > NS/NS
Coffee  NS/3 > NS/NS

For all of these factors, the trends follow from NS/NS to NS/S to S. This clearly looks promising, and should form the basis for a telling paper.
Who should design and conduct it?

- Project management would be undertaken by **Covington and Burling**. The project managers would remain **remote from any scientific publications**. Two Japanese scientists will be the principal investigators [...will serve as principal authors of the resulting scientific reports]. **Mr. Peter Lee** also will be asked to **assist in reviewing the study design and in interpreting the data**. It is **not anticipated**, however, **that Mr. Lee will serve as a co-author** of any of the publications…”

Who should publish? Who is accountable?

- Draft 1: Yano and Kagawa
- Draft 2: Yano, Kagawa and Lee
- Draft 3 - 7: Lee

Acknowledgements I gratefully acknowledge financial support from several companies of the tobacco industry.

I am extremely grateful to Dr. Eiji Yano of Teikyo University for assistance provided in Japan, and to Emu Efco Ltd. for help in sample collection and analysis. I also thank Dr. John Fry for assistance in statistical analysis, Dr. Francis Roe for numerous helpful comments, and Mrs. Pauline Wassell and Mrs. Diane Morris for typing the various drafts.
Japanese spousal smoking study revisited: how a tobacco industry funded paper reached erroneous conclusions

E Yano

Ten years later ….

- "The present study demonstrated a high reliability of self reported smoking status."
- Previous Lee study did not report:
  - Validity of the self reported smoking status
  - No differences in diet or lifestyle among non-smoking wives with or without ETS exposure
- "Using all the data from this project changes the conclusion of the previous published reports."
May, 1996 – Philip Morris meeting notes.

“Acquisition of data is a major goal for Philip Morris.”

Strategies used to obtain data:

- Direct requests to researchers for data.
- Subpoena researchers for data.
- Legislate “sound science” – data access and data quality laws.
Data Access Act 1998

- Freedom of Information of Act (FOIA) applies to data produced under a federally funded grant - formerly only data possessed by federal agency.

- Federal agency funding the study is required to obtain the raw data from the grantee if a request is made.
Data Quality Act 2000

- Information disseminated by federal agencies must meet standards for:
  - Objectivity
  - Utility
  - Integrity
  - Influential data – “scientific, financial, statistical information that will have or does have a clear and substantial impact on public policies must be reproducible”.
  - Peer review insufficient
“Force Field Analysis”

➢ “despite requests from Congress and the EPA, the researchers of one of the disputed epidemiological studies on air pollution have refused to make public the underlying data from their study. This is remarkably similar to the ETS issue where the tobacco industry has not been able to get the supporting data from the Fontham study …”
“Force Field Analysis”

➢ “Because of the parallels between the ETS issue and the new clean air regulations, we have an opportunity to direct the established political and business coalitions to focus on meeting our objectives.”

➢ “If successful, the plan could ultimately minimize the scientific basis for smoking bans and result in reasonable smoking restriction policies.”
“Best Case” Scenario

- “Federal legislation passes including both criteria for epidemiological studies and a requirement for data sharing.”
- “As a result, smoking ban efforts are either preempted or no longer passed.”
- “We get data from the Fontham study and prove it does not show any association between ETS and disease.”
“Worst Case” Scenario

“Data sharing passes and we get access to the Fontham data. However, without established criteria to evaluate our analysis of the data the EPA and other groups discredits our evaluation and our results are ignored.”
“Worst Case” continued …

- “We do the re-analysis of the Fontham data and an association remains.”
- “Our interest in the EPA rule and our legislative objectives become public knowledge which could prevent / diminish the effectiveness of the legislation.”
Help organize coalitions for other epidemiology issues coming up soon (e.g., fishing industry, mercury, Methylene Chloride)
Funding Research:

The limits of competing interest disclosures …..
Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-98

James E Enstrom, Geoffrey C Kabat
The Limits of Disclosure

- “…initial support from the TRDRP, a University of California research organization funded by the Proposition 99 cigarette surtax. After continuing support from the TRDRP was denied…”

- “… support from the Center for Indoor Air Research, a 1988-99 research organisation that received funding primarily from US tobacco companies.”

- *Role of sponsor? Complete and accurate disclosure?*
<table>
<thead>
<tr>
<th>VENDOR NO.</th>
<th>PHILIP MORRIS INCORPORATED</th>
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<tbody>
<tr>
<td>205372</td>
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<td>JAMES E ENSTROM/SCH OF PUBLIC</td>
<td>0000000480463</td>
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<th>DATE</th>
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RETURN CHK TO MARGARET OPOCENSKY/R&D A-2

**TOTAL AMOUNT:** 

0.00   75,000.00

© DETACH HERE BEFORE DEPOSITING

---

**PHILIP MORRIS INCORPORATED**

RICHMOND, VIRGINIA 23261

VOID AFTER 60 DAYS

PAY EXACTLY

SEVENTY-FIVE THOUSAND 00/100

THIS IS TOBACCO MONEY

TO

JAMES E ENSTROM/SCH OF PUBLIC

HEALTH UNIV OF CA LOS ANGELES

* 10833 LE CONTE AVENUE

LOS ANGELES

CA 90095-1772

AUTHORIZED SIGNATURE

John L. LeMay
GENERAL PROCEDURES

1. Develop plan and methods for completion of specific aim.
2. Obtain human subjects approval, if necessary.
3. Obtain necessary data set(s) and documentation if they already exist.
4. Collect data according to plan if it does not already exist.
5. Analyze data according to plan and carefully assess quality of data and results.
6. Prepare results in the form of a scientific paper that may be submitted for publication: Introduction, Methods, Results, Discussion.
7. Prepare documentation and summary data set that can be used by designated others for reanalysis and prepare summary of results that can be used for presentation.

BUDGET

General Conditions and Considerations

Since the scope of the research is large and diverse, only an

The most appropriate means of funding needs to be determined, but an unrestricted gift to Dr. James E. Enstrom / UCLA with mutual understanding/trust would minimize University restrictions and eliminate overhead costs.

The most appropriate means of funding needs to be determined, but an unrestricted gift to Dr. James E. Enstrom / UCLA with mutual understanding/trust would minimize University restrictions and eliminate overhead costs.

Independence of investigator and right to publish.
Sufficient resources to mount a strong research program.
Reasonable consideration of long term commitment.
Regular progress reports, final reports, and/or publications.
“Flawed science”

EPA report is “preposterous”

Enstrom and Kabat study: “women married to nonsmokers had same risk of lung cancer and heart disease as women married to smokers”

- David Kuneman, Retired Pharmaceutical Researcher, March 2, 2005
“The authors made another interesting little discovery. They discovered that the University of California was going to stop their funding when the University of California found out that they were going to publish a study that did not support the claim that secondhand smoke causes disease.”

David Kuneman, Retired Pharmaceutical Researcher March 2, 2005
Current issues

- Continued use of tobacco industry arguments about flawed science / controversy
- Usefulness of disclosure for managing financial conflicts of interest
- Debate about restrictions on tobacco industry funding for research
Tobacco $ 

Zap

Normal Person

I guess I shouldn't do that

UC Academic Senate

I wonder if that happens every time

adapted from "the difference" on xkcd.com
What we need more of ....

- More science, less ideology
- More criticism of tobacco industry science
- Acknowledge that different groups use science in different ways – More research on framing
- More comparisons across industry groups
Thank you!!!!!

- Annamaria Baba
- Deborah Barnes
- Mildred Cho
- Dan Cook
- Miki Hong
- Gail Kennedy
- Christina Mangurian
- Stacey Misakian
- Theresa Montini
- Marieka Schotland
- Jenny White
People quoted in lay press articles on passive smoke

<table>
<thead>
<tr>
<th>Type of person quoted</th>
<th>Newspapers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n = 180$</td>
</tr>
<tr>
<td>Government officials</td>
<td>56% (101)</td>
</tr>
<tr>
<td>Tobacco industry officials</td>
<td>52% (94)</td>
</tr>
<tr>
<td>Scientists / researchers</td>
<td>46% (82)</td>
</tr>
<tr>
<td>Other</td>
<td>4% (8)</td>
</tr>
</tbody>
</table>
Bruce,

I plan to be at my house for the conference call at 1:00 EST today. However, I have an appointment with my physician at 5:00, and although I do not expect that to run more than 30 minutes, if I am not at home, that will be my excuse.

Now a few thoughts from the top of my shiny head.

1. I generally support the concept of collaborative investigations with SELECTED scientists whether they tend to agree with provided
   a. they are qualified
   b. they have demonstrated significant objectivity in the past
   c. they collaborate and not just take our money.
   I put Benowitz and Jacob in this category.

2. I think we should be very cautious about entering in such collaborations.

   1. I generally support the concept of collaborative investigations with SELECTED scientists whether they tend to agree with provided
      a. they are qualified
      b. they have demonstrated significant objectivity in the past
      c. they collaborate and not just take our money.

I hope to talk with you later.

Don

With Best Regards,
Don Leyden
Philip Morris Europe
Scientific Affairs EU EEMA Regions
# WSA Categorization Form

**Date:** 02-22-99  
**Title:** Ventilation Technology

**Related to:** Health/Safety ☑  Regulatory ☐  Product Change ☐  Credibility ☑

<table>
<thead>
<tr>
<th>Scientific Review</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</thead>
<tbody>
<tr>
<td>Completeness of Scientific Information Review</td>
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<td>☑</td>
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<tr>
<td>Completeness of Internal Knowledge</td>
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<tr>
<td>Scientific Evaluation</td>
<td>Quality: 1 ☑ 2 ☑ 3 ☑ 4 ☑ 5 ☑ 6 ☑ 7 ☑ 8 ☑ 9 ☑ 10 ☑</td>
<td>Completeness: 1 ☑ 2 ☑ 3 ☑ 4 ☑ 5 ☑ 6 ☑ 7 ☑ 8 ☑ 9 ☑ 10 ☑</td>
<td></td>
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</tbody>
</table>

(Click on grey area to begin entering text. Do not use hard returns. You are limited to 1,200 characters.)

There is a modest amount of quality literature on the applications of ventilation technology to ETS. An example of outstanding questions are:

1. Can ETS vapor be removed by filtration in a practical manner?
2. Does displacement ventilation lower ETS exposure?

Work that PMI has sponsored with SEMCO and Georgia Tech over the past few years has provided some of the best data on how increased ventilation reduces exposure.

The cost of exposure measurement is high and it is technically demanding. Without assistance, technology vendors are unlikely to provide quality research demonstrating the efficacy of their projects. We currently have a project underway to help and encourage vendors to conduct and publish research.

**Potential Contribution to a PMI Smoking/Health Program:** 1 ☑ 2 ☑ 3 ☑ 4 ☑ 5 ☑ 6 ☑ 7 ☑ 8 ☑

**Importance:** (Click on grey area to begin entering text. Do not use hard returns. You are limited to 750 characters.)

PMI sponsors the Options program in the US, and funds the Courtyard of Choice program internationally to promote accommodation. Ventilation is a key feature of both programs. Also, ventilation provides a middle-ground when smoking bans are an issue, as they are across the world, and especially in the US. These programs are strengthened by PMI's contribution to the science and technology of ventilation. Let me quote from a memo from Geoff Biddle from August of 1999: "...we need to identify and evaluate existing and emerging technologies and support their development and application in a variety of venues." Finally, ventilation provides an opportunity for dialogue with Corporate Affairs and WSA.

**Monitor Literature** ☑  
Type: monitor and expand the literature

**Research** ☑  
Type: exposure measurement, technology evaluation

**Likely to be done elsewhere** ☑  
Type: case studies (before and after tests)

**Product Identification Effort** ☑  
Type: help vendors evaluate their own technologies by providing access to HQ researchers

**Anticipated Duration of the Work** ☑  
Type: as long as ventilation is part of Options accommodation

**Proposed Work** ☑

**Justification:** (Click on grey area to begin entering text. Do not use hard returns. You are limited to 750 characters.)

In my opinion, ventilation is not a direct smoking and health issue, but it is a scientific issue. It provides an opportunity for dialogue between PMI and smoking ban advocates and between WSA and other PMI departments.

The proposed work is intended to address any deficiencies in the literature and to demonstrate PMI's commitment to accommodation.

**Critical** ☑  **Moderate** ☐  **Low** ☑

1 = Low 5 = High

2078462882
Influences on legislative process

- Voting behavior of state legislators
  - Ideological position
  - Party affiliation
  - Campaign contributions
Criticize research: “Publication bias”

- Are statistically nonsignificant results published? **Yes.**
  - 43% of peer-reviewed and 53% of symposium articles had statistically non-significant results
- Do statistically nonsignificant results remain unpublished? **No.**
  - Mean time to publication:
    - 5 years for statistically nonsignificant results
    - 3 years for statistically significant results