



Tobacco Industry Manipulation of Research and Policy

Lisa A. Bero, Ph.D.

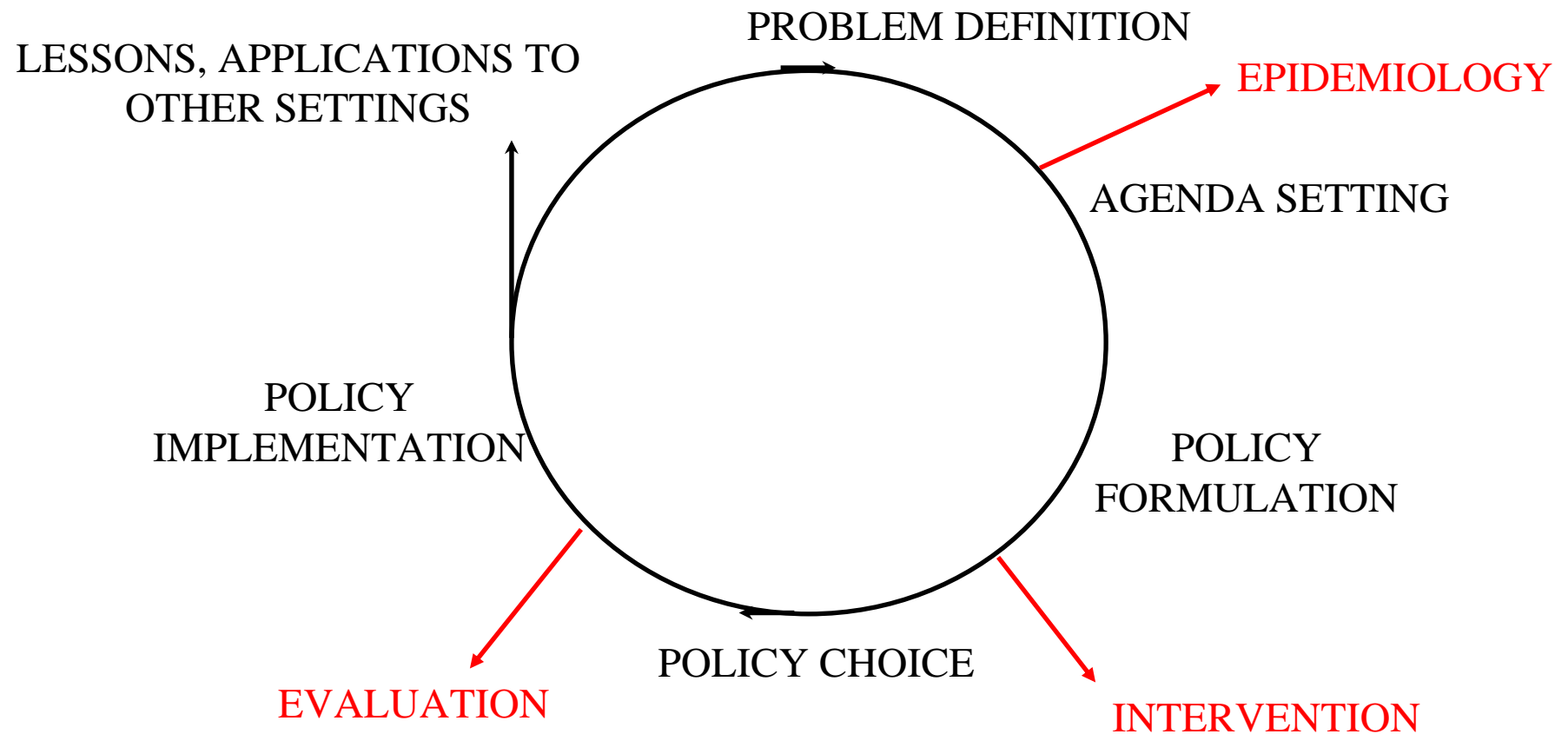
University of California, San Francisco

31 May 2007

Funding Sources: California Tobacco Related Disease Research Program, American Cancer Society, Robert Wood Johnson Foundation, National Cancer Institute



Cycle of Policy Making





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



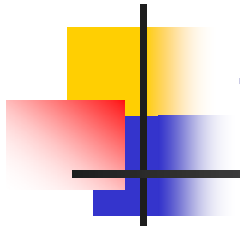
Data sources

➤ Legislation

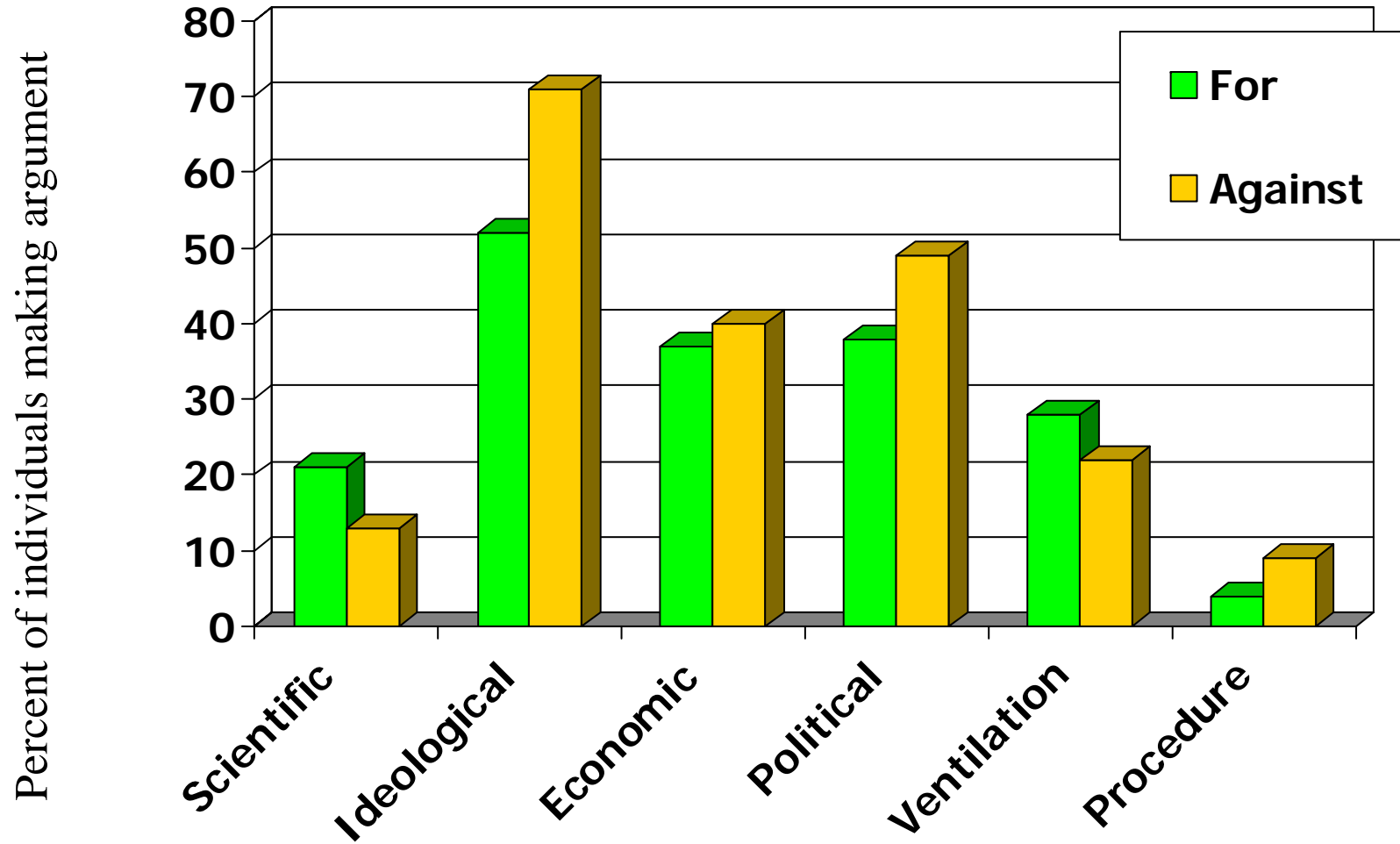
- Text of legislation and amendments
- Floor debates
- Committee hearings
- Other archival materials

➤ Regulation

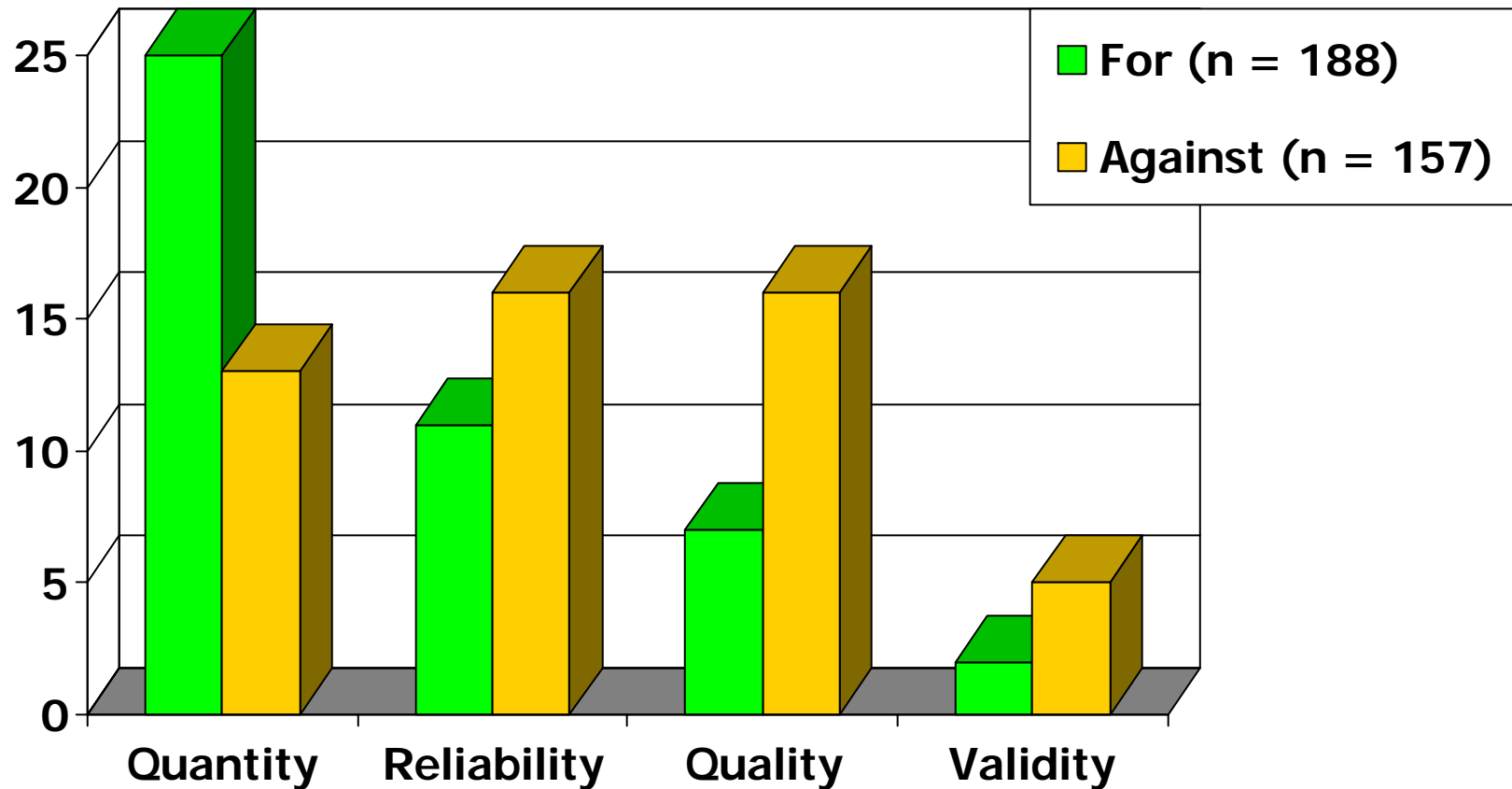
- Public commentary during the rule-making
- Agency responses to the commentary
- Interviews with agency officials



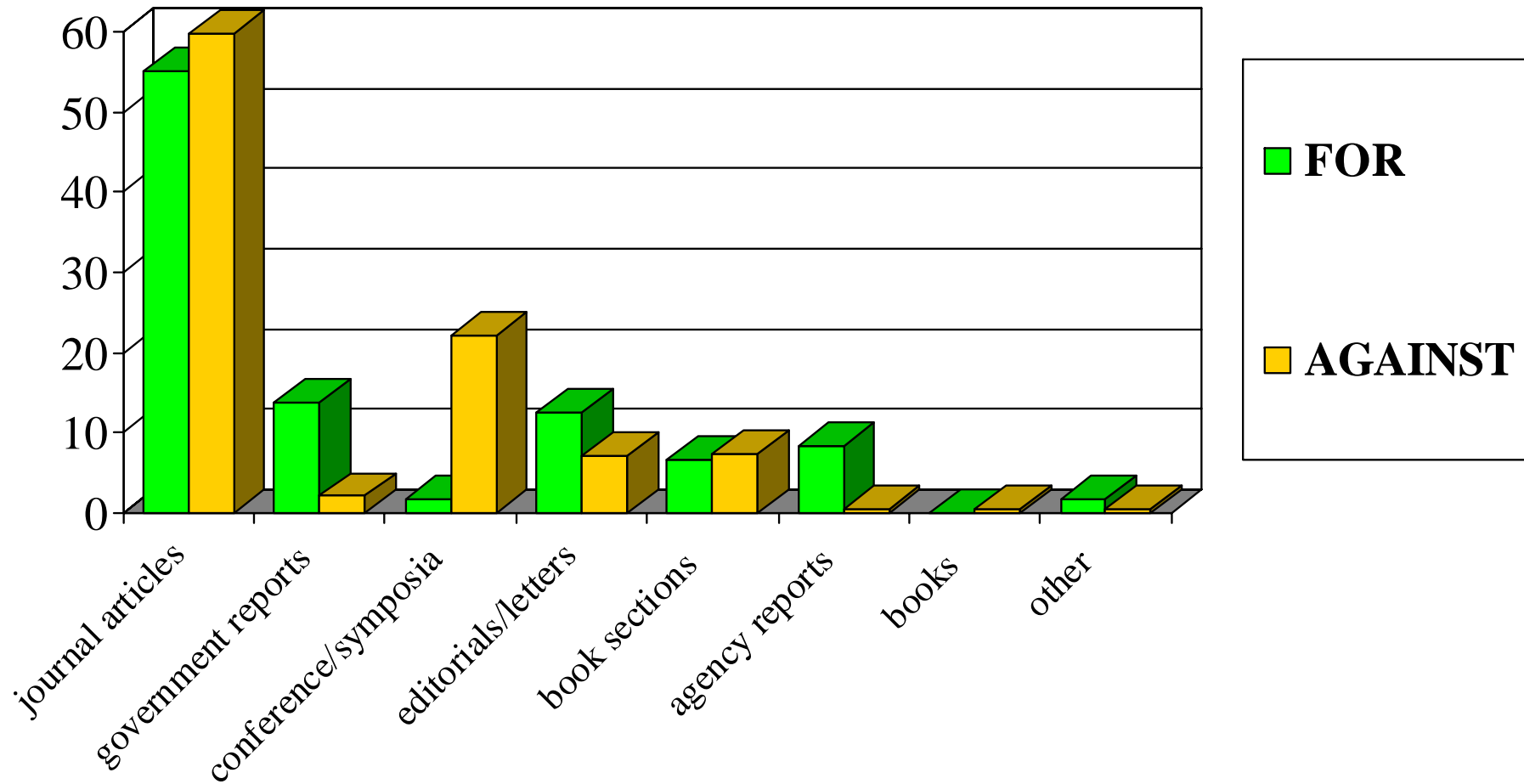
Types of arguments



Percent of commentators using criteria to evaluate science



Percent of types of publications cited

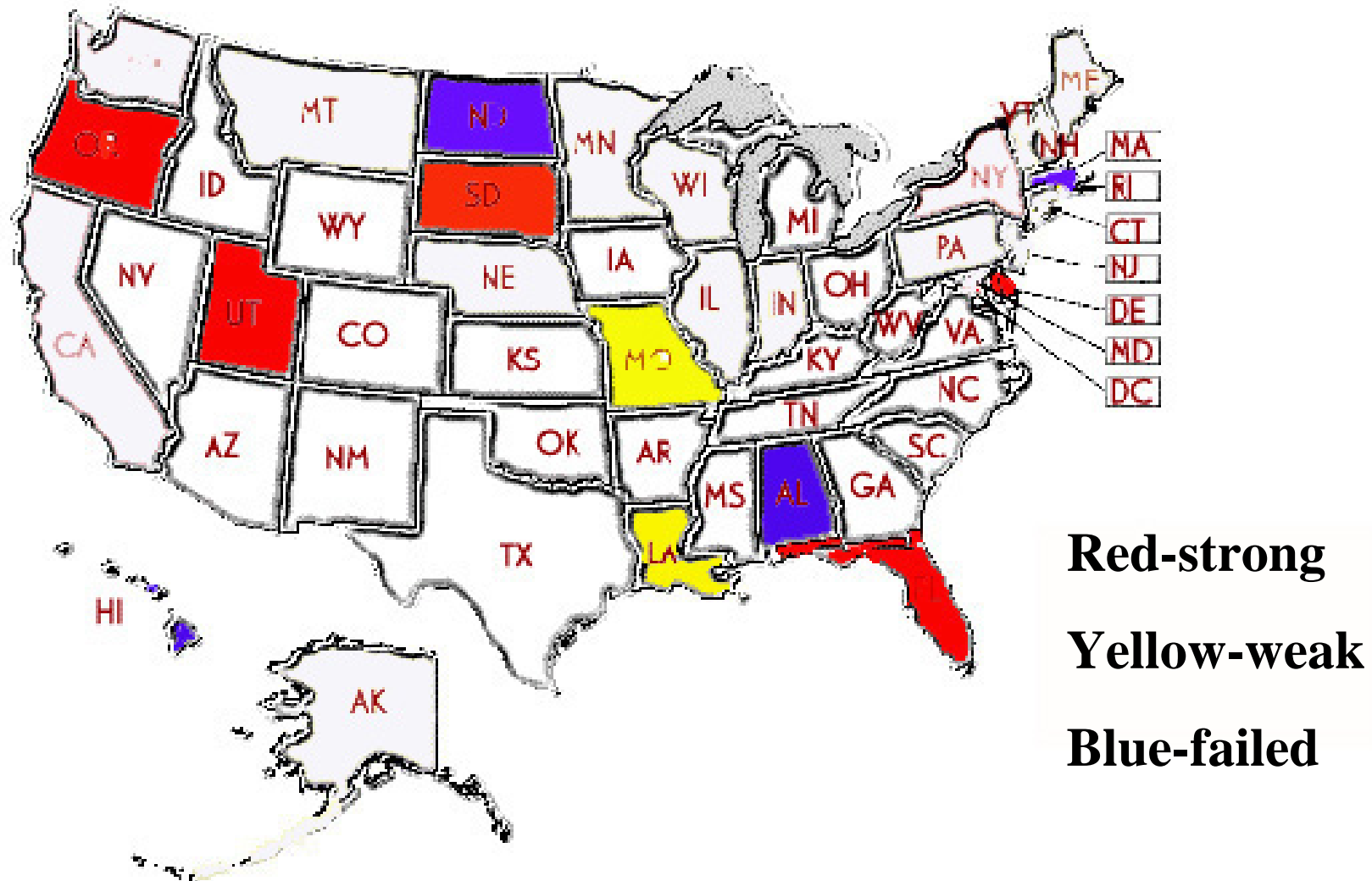




Affiliation bias

Affiliation	% For n=188	% Against n = 157
Tobacco	1	35
Business	16	27
Government	15	4
Lay activist	28	1
University	8	0
Private citizen	20	22

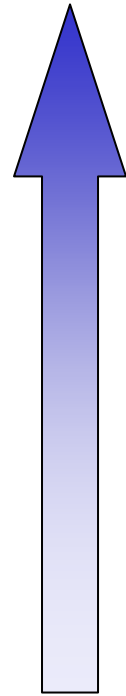
Study sites/workplace smoking legislation





Legislative cases

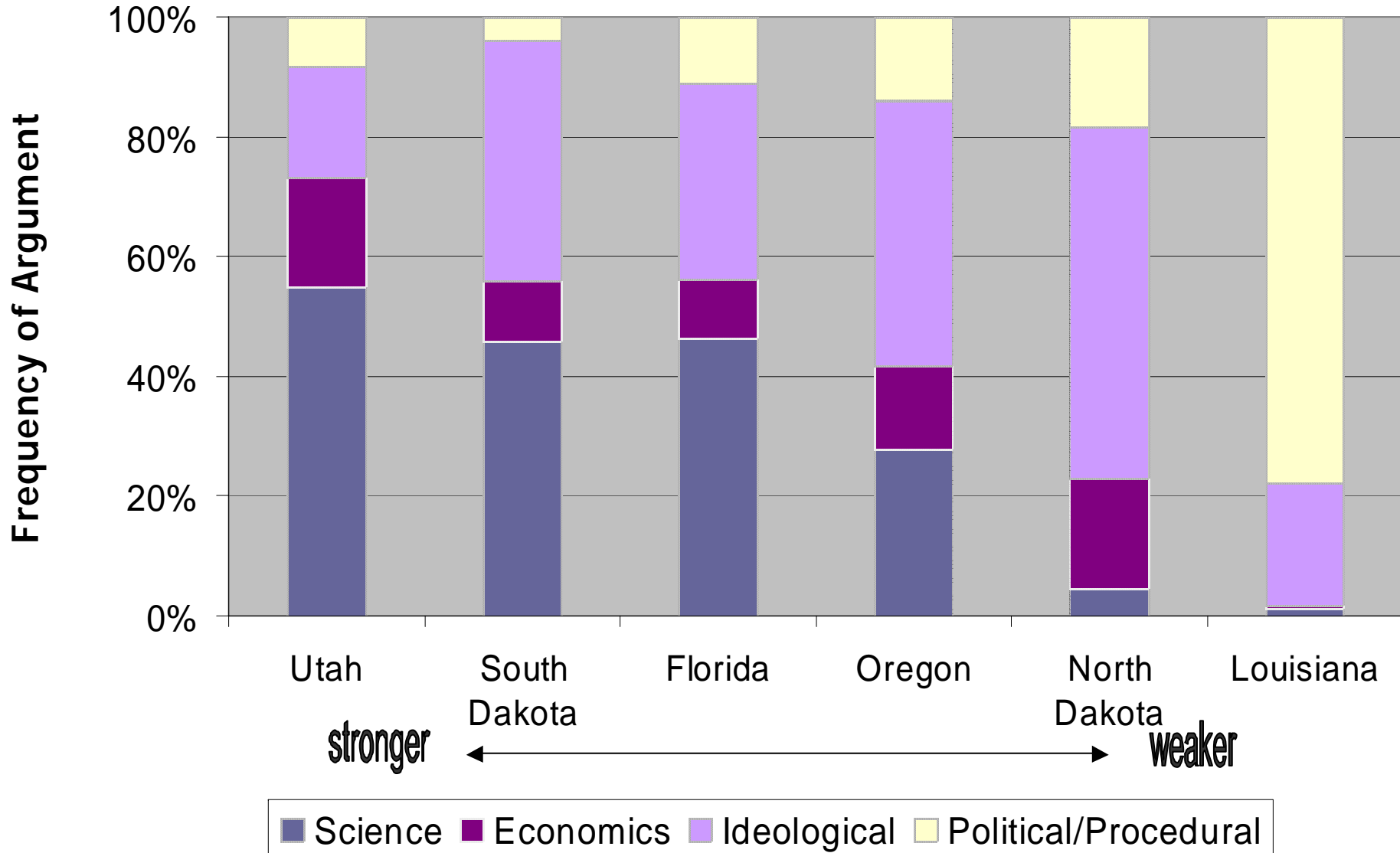
- Utah
- South Dakota
- Florida
- Oregon
- Louisiana
- North Dakota



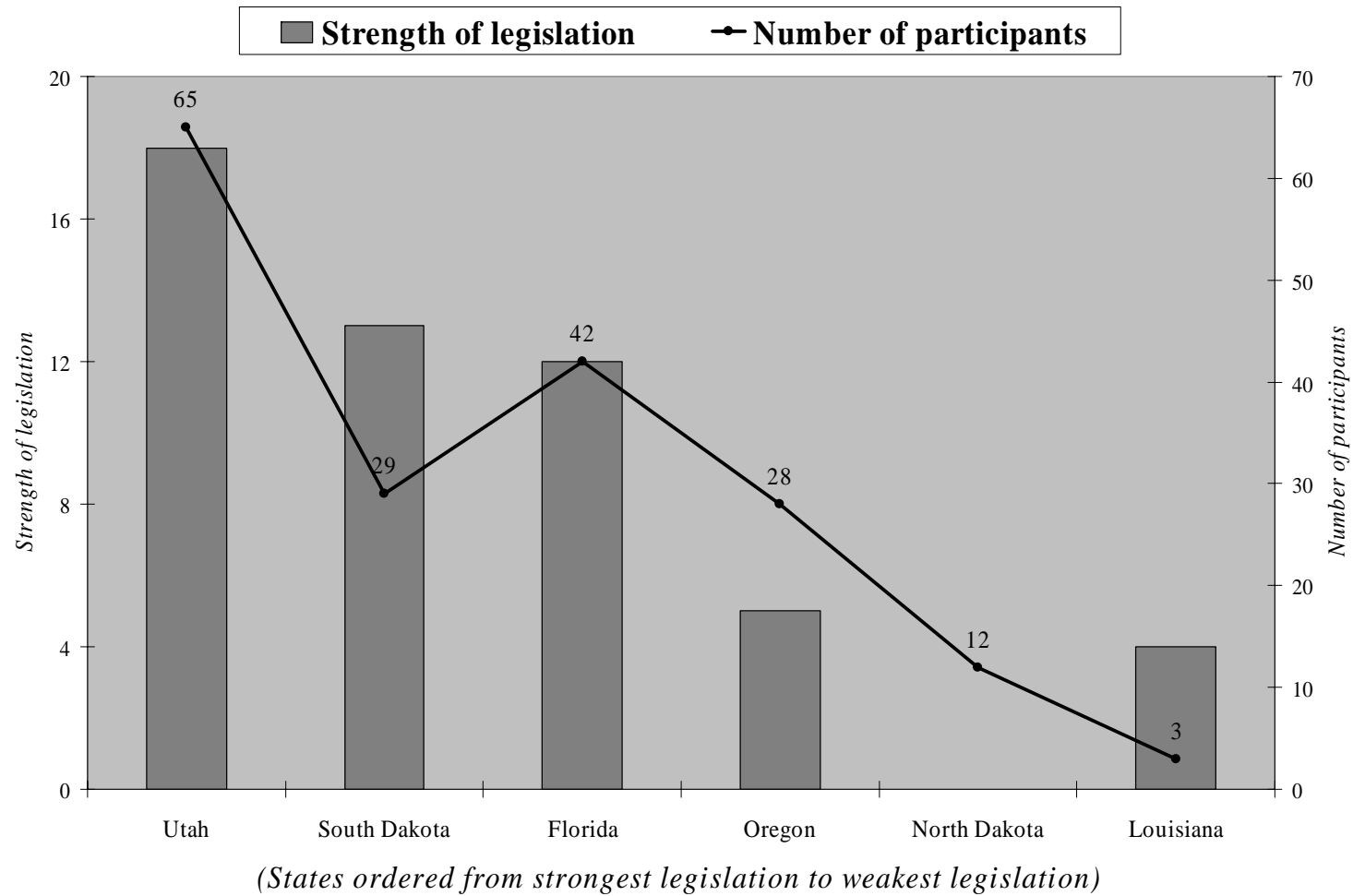
RESISTANCE



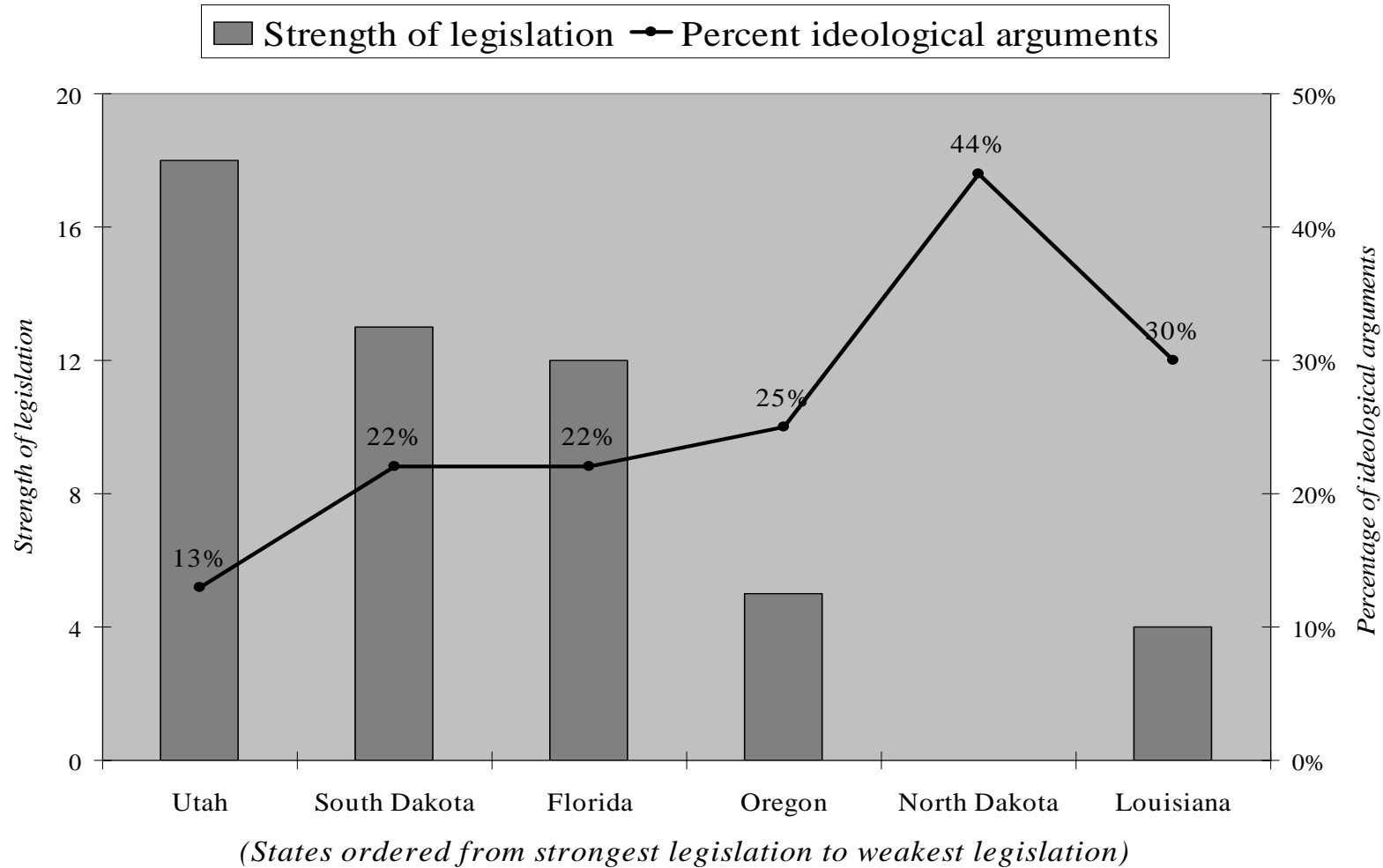
Argument Types by State



States with more public participation passed stronger legislation



States emphasizing ideological arguments passed weaker legislation

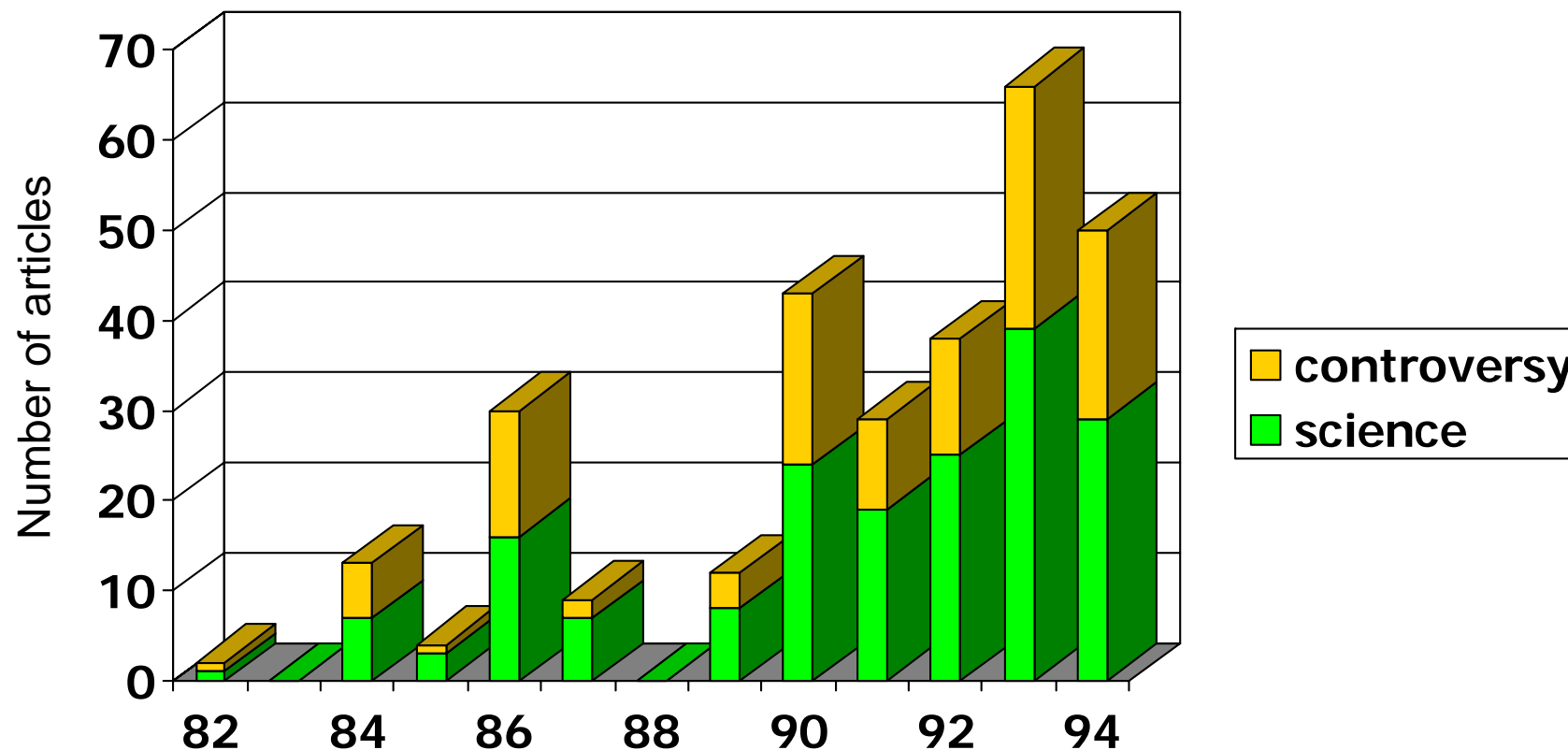




Influences tobacco policy

- 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

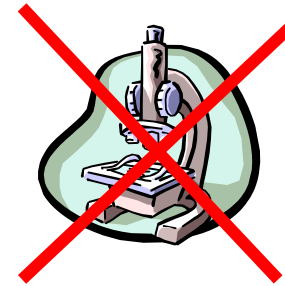
Proportion of lay press articles on passive smoke research emphasizing controversy by year (n = 272)



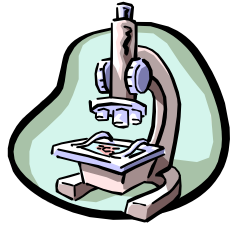
Strategies to manipulate research



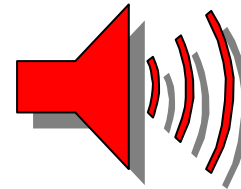
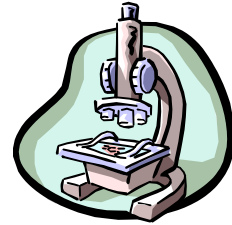
➤ Fund



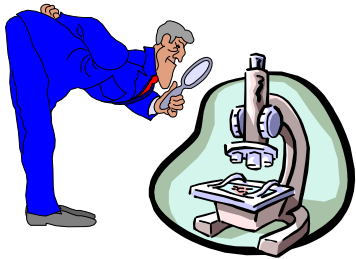
• Suppress



➤ Publish

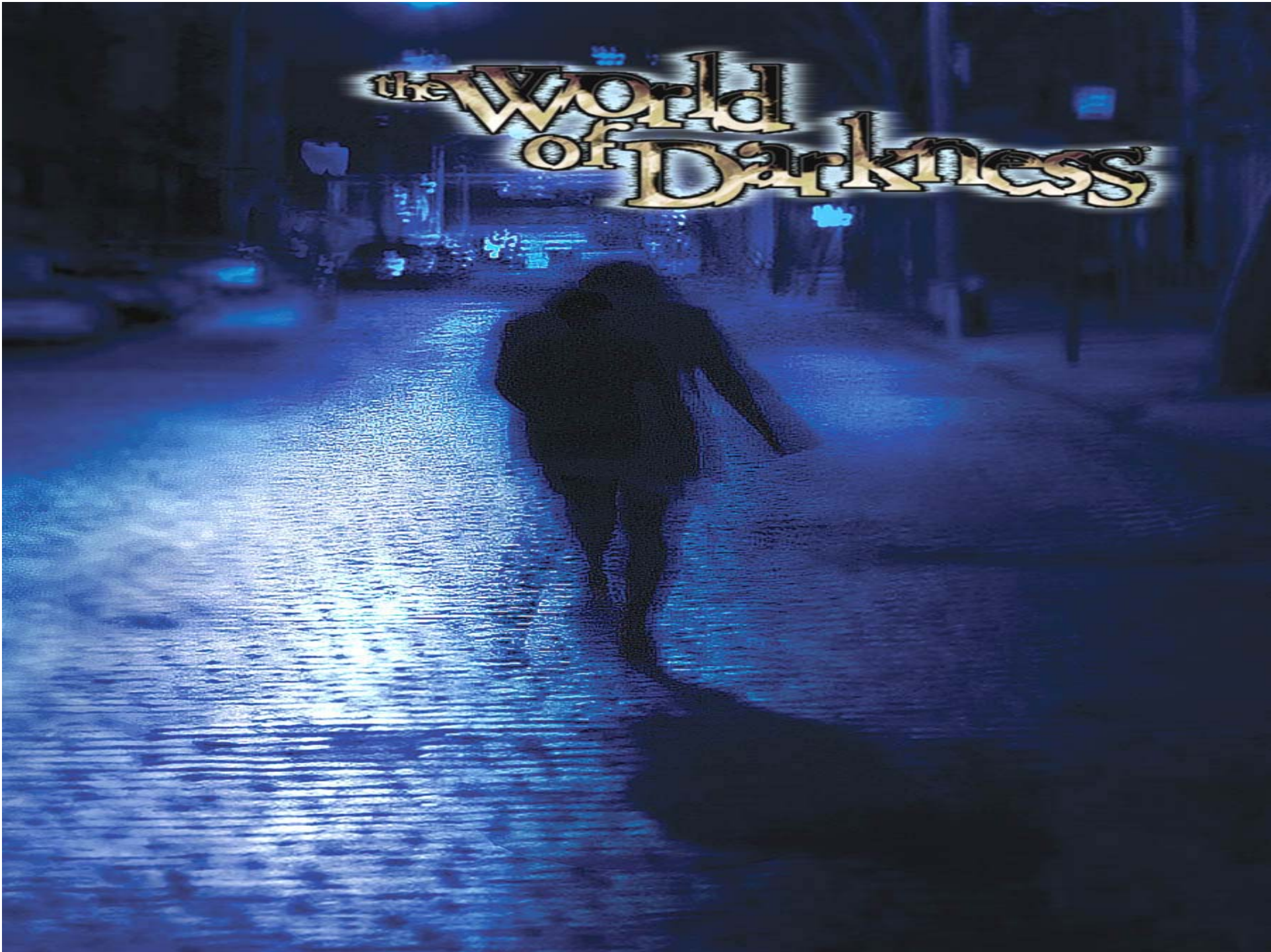


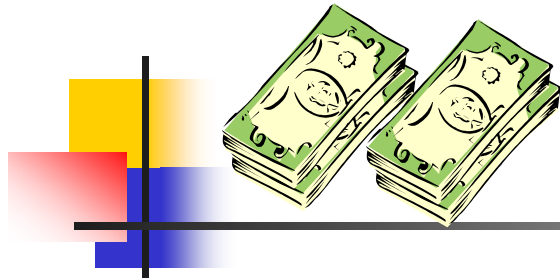
• Disseminate



➤ Criticize

the World of Darkness





Fund research: CIAR

Center for Indoor Air Research

➤ 1988

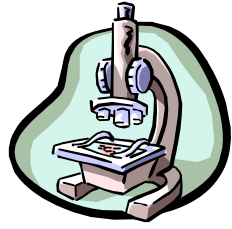
➤ Mission

- "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



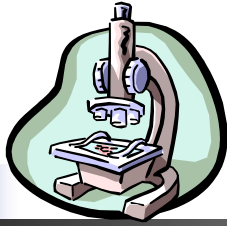
Fund research: CIAR

- 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



Publish research: Quality

- Hypothesis: Articles concluding that passive smoking is harmful would be high in quality, peer-reviewed, written by non-TI affiliated individuals
- Review articles ($n = 106$) on health effects of passive smoking published from 1980 to 1995
- Quality assessed on a scale of 0 (worst) to 1 (best)



Review articles on secondhand smoke

<u>Factor</u>	<u>Odds Ratio (95% CI)</u>
Quality score	1.5 (<0.1-67.5)
Not PR vs PR	1.3 (0.3-5.4)
TI vs non-TI	88.4 (16.4-476.5)
Topic	
Lung cancer vs. multiple	1.6 (0.2-10.3)
Heart disease vs. multiple	1.6 (0.2-14.7)
Year of publication	1.1 (0.9-1.3)



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

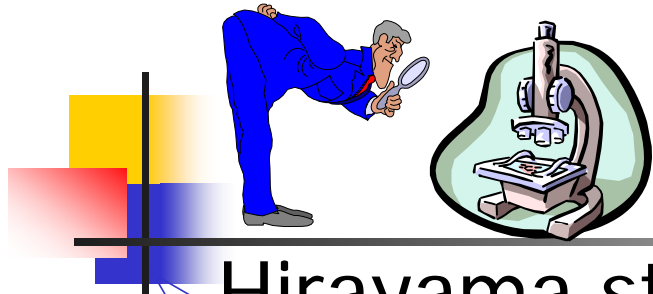
- In every major international area (USA, Europe, Australia, Far East, South America, Central America, and Spain) [Philip Morris] are proposing, in key countries, to set up a team of scientists organized by one national coordinating scientist and American lawyers, to review scientific literature or carry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

COVINGTON & BURLING

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P.O. BOX 7568

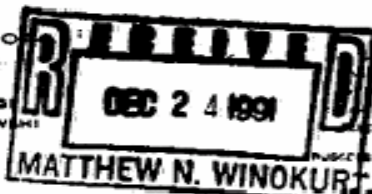
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RISTOPHER J. PROCTOR

SENIOR SCIENTIFIC ADVISOR

DIRECT DIAL NUMBER

(202) 662-8603

December 23, 1991

BY FACSIMILE

- Dr. S. Boyse, BAT
- Mr. R. Marcotullio, RJR
- Dr. P. Sadler, ITL
- Dr. W. Röper, Reemtsma
- Dr. D. Rowland, RI
- Dr. R. Thornton, BAT
- Mr. M. Winokur, PM

FAX J. Goodheart - PMKK
S. Parrish.

Jan - FYI only; no need to retain.

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), 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/S > NS/NS
Butter	NS/S > NS/NS
Smoked Fish	NS/S > NS/NS
Coffee	NS/S > 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.

2023544474



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..." [2023544523: Aug.12,1991 from Covington and Burling Attorney Work Product re: proposal to study ETS exposure in non-smoking Japanese women]



Who should publish? Who is accountable?

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

Lee, PN. **"Marriage to a smoker" may not be a valid marker of exposure in studies relating environmental tobacco smoke to risk of lung cancer in Japanese non-smoking women.**
International Archives of Occupational and Environmental Health
1995, 67(5):287-94.

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

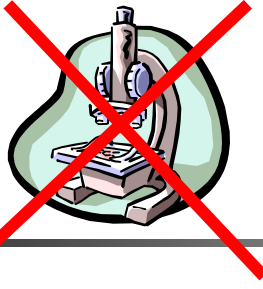
I am extremely grateful to Dr. Eiji Yano of Teikyo University for assistance provided in Japan, and to Emu Efu Co. Ltd. for help in sample collection and analysis. I also thank Dr. John Fry for assistance in statistical analysis, Dr. Francis Roe for numerous helpful comments, and Mrs. Pauline Wassell and Mrs. Diane Morris for typing the various drafts.

RESEARCH PAPER

Japanese spousal smoking study revisited: how a tobacco industry funded paper reached erroneous conclusions

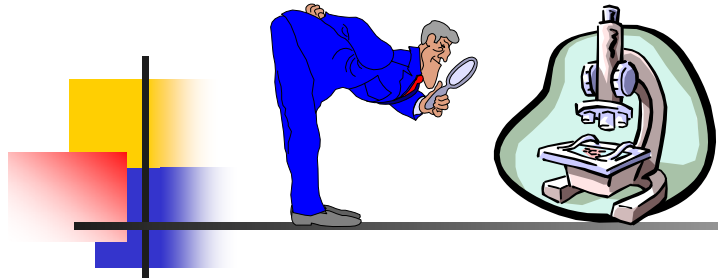
E Yano

Tobacco Control 2005;14:227-233. doi: 10.1136/tc.2003.007377



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.”



Criticize Research

- 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.”

Questions for Data Disclosure

As conf. call

Questions regarding academic/scientific community:

- What position has the American Society of Epidemiologists taken on the issue?
- What positions have committee members of the Committee on Issues in the Transborder Flow of Scientific Data taken? Specifically, what is R. Stephen Berry's (University of Chicago) position?
- What is the position of the National Science Foundation?

3

- How do
Does ca
- What is
data? A

- American Petroleum Institute
- National Rifle Association
- American Iron and Steel Institute
- Statistical Assessment Service
- Electric Power Research Institute

een tested?
ponsored

Help organize coalitions for other epidemiology issues coming up soon (e.g., fishing industry, mercury, Methyline Chloride)



Funding Research:

The limits of competing interest disclosures

BMJ VOLUME 326 17 MAY 2003

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?***

VENDOR NO.		PHILIP MORRIS INCORPORATED RICHMOND, VIRGINIA 23261			CHECK NO.	
205372		3882-9156			0000000480463	
VENDOR NAME					DATE	PAGE
JAMES E ENSTROM/SCH OF PUBLIC					04/23/97	1
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03/24/97	ENSTROM	13023671	75,000.00-		75,000.00-	
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TOTAL AMOUNT :				0.00	75,000.00-	

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EXACTLY

SEVENTY-FIVE THOUSAND 00/100*****

THIS IS TOBACCO MONEY

TO THE ORDER OF
* JAMES E ENSTROM/SCH OF PUBLIC
HEALTH UNIV OF CA LOS ANGELES
10833 LE CONTE AVENUE
LOS ANGELES CA 90095-1772

THIS IS TOBACCO MONEY



⑈480463⑈ ⑆031100209⑆

38829156⑈

AUTHORIZED SIGNATURE
John L. Eckmeyer
AUTHORIZED SIGNATURE

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.

2074067449



St. Louis County Clean Air Act, 2005

- “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



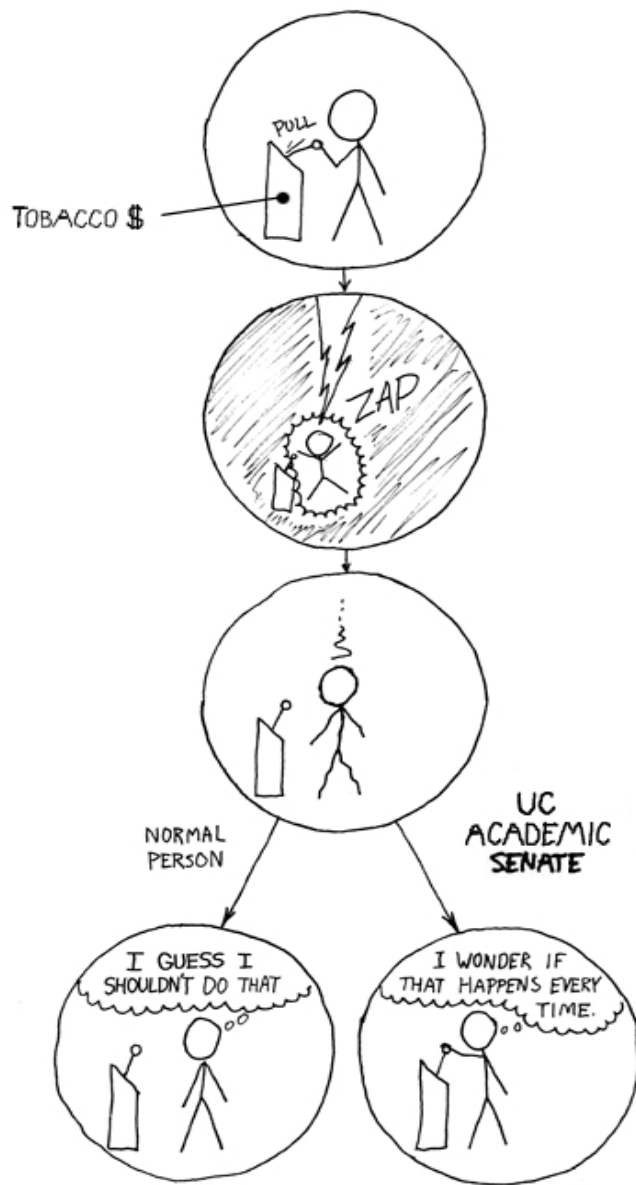
St. Louis County Clean Air Act, 2005

- “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



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

<i>Type of person quoted</i>	<i>Newspapers n = 180</i>
Government officials	56% (101)
Tobacco industry officials	52% (94)
Scientists / researchers	46% (82)
Other	4% (8)

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

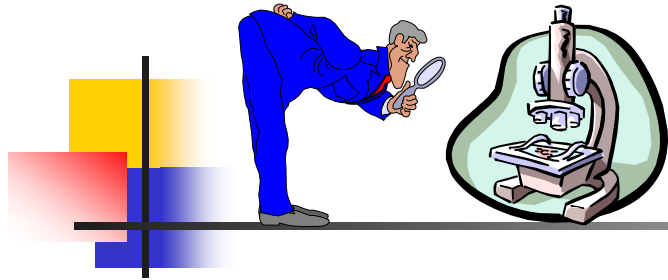
Date: <u>10-22-99</u> Title: <u>Ventilation Technology</u>	Reviewer: <u>Lipcaloz</u>
Related to: Health/Safety <input type="checkbox"/> Regulatory <input checked="" type="checkbox"/> Product Change <input type="checkbox"/> Credibility <input checked="" type="checkbox"/>	
S C I E N T I F I C E V A L U A T I O N	Completeness of Scientific Information Review: 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input checked="" type="checkbox"/> 5 <input type="checkbox"/> Not Reviewed <input type="checkbox"/> Completeness of Internal Knowledge: 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input checked="" type="checkbox"/> 5 <input type="checkbox"/> Not Reviewed <input type="checkbox"/>
	Scientific Evaluation: Quality 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> Completeness 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> <i>(Click on gray area to begin entering text. Do not use hard returns. You are limited to 1200 characters.)</i> 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 PM 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 such research.
I M P O R T A N C E	Potential Contribution to a PM Smoking/Health Program: 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> Importance: <i>(Click on gray area to begin entering text. Do not use hard returns. You are limited to 750 characters.)</i> PM sponsors the Options program in the US, and funds the Courtesy 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 PM's contribution to the science and technology of ventilation. Let me quote from a memo from Geoff Bible from August of 1996: "...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 WRA.
	Monitor Literature <input checked="" type="checkbox"/> Type: <u>monitor and expand the literature</u> Research <input checked="" type="checkbox"/> Type: <u>exposure measurement, technology evaluation</u> Likely to be done elsewhere <input checked="" type="checkbox"/> Type: <u>case studies (before and after tests)</u> Product Modification Effort <input type="checkbox"/> Type: _____ Other: <u>help vendors evaluate their own technologies by providing access to IAQ researchers</u> Anticipated Duration of the Work: <u>as long as ventilation is part of Proaccommodation programs</u>
J U S T I F I C A T I O N	Justification: <i>(Click on gray area to begin entering text. Do not use hard returns. You are limited to 750 characters.)</i> 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 PM and smoking ban advocates and between WSA and other PM departments. The proposed work is intended to address mostly the deficiencies in the literature and to demonstrate PM's commitment to accommodation.
	CRITICAL <input type="checkbox"/> MODERATE <input type="checkbox"/> LOW <input type="checkbox"/> 1 = Low 5 = High

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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