How the tobacco industry responded to an influential study of the health effects of secondhand smoke

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In 1981 an influential Japanese study showed an association between passive smoking and lung cancer. This article documents the tobacco industry's attempts to refute this study by producing a credible alternative study

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Summary points

The tobacco industry generated a study, the "Japanese spousal study," in an attempt to refute the findings of a 1981 cohort study showing an association between secondhand exposure to tobacco smoke and lung cancer

Internal tobacco industry documents describe how the tobacco industry considered multiple strategies to conceal its involvement in the Japanese spousal study

The tobacco industry considered funding the study through the Center for Indoor Air Research, a research organisation supported by the tobacco industry, in order to hide industry involvement

The parties involved in conducting the study included a tobacco industry scientist, a tobacco industry consultant, an industry law firm, and two Japanese investigators. The consultant was the sole author of the final publication

In 1981 Japanese investigator Takeshi Hirayama published a cohort study examining the association of passive smoking and lung cancer among non-smoking wives of smokers in Japan.[1] The study concluded that wives of heavy smokers had up to twice the risk of developing lung cancer as wives of non-smokers and that the risk was dose related. The Hirayama study was influential because it launched an extraordinary amount of critical debate[2 3] and has been one of the most frequently cited studies in regulatory proceedings,[4 5] risk assessments,[6] and the media.[7]

The tobacco industry has used a variety of tactics to maintain scientific debate about whether secondhand smoke has any harmful effects.[5 6 8–14] We identify and analyse internal tobacco industry documents that describe the industry's response to the Hirayama study.

Methods

We retrieved documents from the Legacy Tobacco Documents Library (www.legacy.library.ucsf.edu) and tobacco industry websites (www.pmdocs.com, www.lorillarddocs.com, www.rjrtdocs.com, www.bw.aalatg.com, and www.ctr-usa.org/ctr) using the search terms "Hirayama Study," "Japanese Spousal Study," "ETS," and "meta-analysis." We also searched for adjacent bates numbers (numerical identifiers assigned to tobacco industry documents produced during litigation, each page having a unique identifier) and named consultants. We identified 327 documents, of which 48 discussed the industry's plans to develop a study to counter the Hirayama study.

The tobacco industry's response

The tobacco companies decided to generate a study, called the Japanese spousal study, to counter the Hirayama study.[15–18] The goal of the study was to produce a credible, peer reviewed article that could be used as a public relations tool.[19] We describe how the tobacco industry participated in funding, conducting, and publishing the study.

Funding the Japanese spousal study

The Japanese spousal study seems to have originated as a grant proposal submitted to the Center for Indoor Air Research (CIAR) by Japanese investigators Eiji Yano and Jun Kagawa.[20] This centre, created in 1988, was funded by the tobacco industry to support indoor air research, and some projects were selected for funding by tobacco industry executives.[8] Memos from Robert Pages and T S Osdene of the research and development team at Philip Morris to Steven Parrish, senior vice president of Philip Morris, describe deliberations about CIAR funding for the study:

> 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 [emphasis in original].[15]
>
> 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.[16]

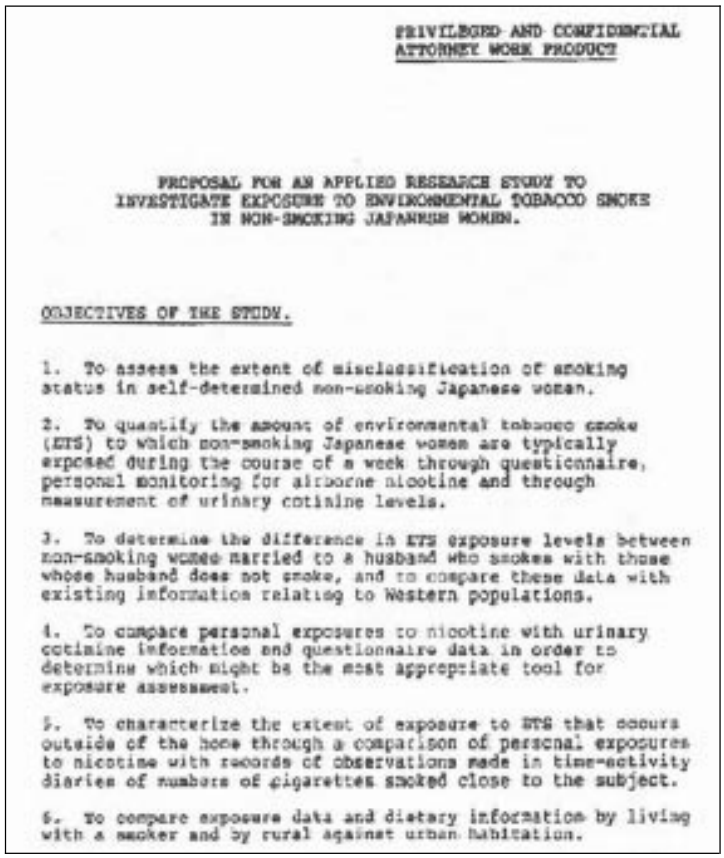
The tobacco companies decided to fund the study themselves. Although there was unanimous agreement from companies such as Brown and Williamson and British American Tobacco that the study should be conducted, these companies stated that they could not "pay their share."[21] After extensive deliberations, Philip Morris agreed to fund the study, with additional support from RJ Reynolds, British American Tobacco, Reemtsma, Imperial Tobacco, and Rothmans.[22]

The tobacco industry documents include the grant proposal submitted to CIAR by the Japanese scientists,[23] and a later version of this grant that had been edited by tobacco industry officials (fig 1).[23 24] This later version was labelled as a "privileged and confidential attorney work product," thus protecting it from public disclosure.[12 25] The edited proposal contained modifications of some of the original study objectives.

Conducting the Japanese spousal study

Almost 10 years after Hirayama's publication, the following memo from Robert Pages to Steven Parrish, both of Philip Morris, described the plan for conducting the Japanese spousal study:

There are two Japanese listed as co-principal investigators. Chris Proctor [chief scientist, British American Tobacco] would be a "behind-the-scenes" study director … I think there's a very good chance that it will generate data which shows that ETS exposure in nonsmoking Japanese women is not much different from that of European or US women—contrary to what the apologists for Hirayama have been saying all these years.[15]



PRIVILEGED AND CONFIDENTIAL
ATTORNEY WORK PRODUCT

PROPOSAL FOR AN APPLIED RESEARCH STUDY TO INVESTIGATE EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE IN NON-SMOKING JAPANESE WOMEN.

OBJECTIVES OF THE STUDY.

1. To assess the extent of misclassification of smoking status in self-determined non-smoking Japanese women.

2. To quantify the amount of environmental tobacco smoke (ETS) to which non-smoking Japanese women are typically exposed during the course of a week through questionnaire, personal monitoring for airborne nicotine and through measurement of urinary cotinine levels.

3. To determine the difference in ETS exposure levels between non-smoking women married to a husband who smokes with those whose husband does not smoke, and to compare these data with existing information relating to Western populations.

4. To compare personal exposures to nicotine with urinary cotinine information and questionnaire data in order to determine which might be the most appropriate tool for exposure assessment.

5. To characterize the extent of exposure to ETS that occurs outside of the home through a comparison of personal exposures to nicotine with records of observations made in time-activity diaries of numbers of cigarettes smoked close to the subject.

6. To compare exposure data and dietary information by living with a smoker and by rural against urban habitation.

Fig 1 Covington and Burling privileged and confidential attorney work product "Proposal for an applied research study to investigate exposure to environmental tobacco smoke in non-smoking Japanese women." 12 August 1991. (Philip Morris documents website. Bates No 2023544523_4530. 8 page document)

The tobacco industry's plan for publishing the Japanese spousal study

"Proposal for an applied research study to investigate exposure to environmental tobacco smoke in non-smoking Japanese women." 12 August 1991.[24]

Project management would be undertaken by Covington and Burling. This would ensure appropriate detailed study design and performance, and enable timely report development. The project managers would remain remote from any scientific publications. They also would provide status reports to the supporting companies every two months.

Two Japanese scientists will be the principal investigators. Professor Jun Kagawa is an epidemiologist, physician and respiratory specialist currently teaching medicine at the Department of Hygiene and Public Health, Tokyo Women's Medical College. His research laboratory has experience with measuring urinary cotinine. Professor Kagawa's prime responsibilities within this project will be the management of sample analysis and being principal author on the resulting scientific reports.

Professor Eiji Yano is an epidemiologist and respiratory specialist based at the Department of Public Health at Teikyo University, Tokyo. Professor Yano will be the principal contact with the market research agency, will organise the data collection, the compilation of a database, and the data analysis.

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 flowing from the study.

The documents describe that the industry wanted a Japanese study to counter Hirayama's conclusions because it believed that a counter-study would be credible only if it was conducted in Japan by Japanese investigators.[15–17] The industry hoped to show that the Hirayama study was unreliable.[26]

During the time between the submission of the original grant to CIAR and the funding of the version edited by the tobacco industry, Peter N Lee, an industry consultant,[27] was asked to review the original grant proposal. Lee was aware of Proctor's role in the project:

> I in fact would regard the collection of good data on misclassification rates in Asian, and particularly Japanese, women as just about the most important thing that needs doing to further understanding of the ETS/lung cancer issue. Demonstration of high rates in Japan would (or ought to) dramatically influence interpretation of the association seen between spouse smoking and lung cancer risk. For this reason I am *very strongly supportive* of Chris Proctor's plans to get a study going in Japan [emphasis in original].[28]

Peter Lee was eventually incorporated into the study as a consultant.[24]

The tobacco industry planned to conceal its role in the Japanese spousal study. In the following memos, T S Osdene and Robert Pages (Philip Morris) reported to Steven Parrish that Proctor's role would be hidden:

> 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.[16]

> Proctor (and his fee) may be necessary to help get this done … but this should be a Japanese study: Proctor should not be a co-author on any publication that comes out of it.[15]

In addition, the survey instrument used for the study did not disclose any tobacco industry involvement in the research.[29]

Publishing the Japanese spousal study

The parties involved in the Japanese spousal study included a tobacco industry scientist (Chris Proctor), a tobacco industry consultant (Peter N Lee, paid $5000 in consultation fees),[24] and an industry law firm (Covington and Burling, paid $30 000 for "project management").[24] The role of the Japanese investigators was ambiguous. The box quotes a proposal, labelled as a Covington and Burling attorney work product, describing the various roles of the participants and the industry's plans for authorship of publications.

As shown in fig 2, Chris Proctor delivered progress reports (on Covington and Burling stationery) to tobacco industry executives,[30 31] but his role as acting investigator was never disclosed in scientific publications. In 1993 Chris Proctor recommended a change in authorship to tobacco company executives:

> After considerable effort working with Dr Yano at Teikyo University, we feel it is time to recommend that Mr Peter Lee be asked to submit the Japanese spousal study research for publication in the *British Medical Journal*. We spoke with Mr Lee earlier today, and he has agreed with this course of action, but will await final approval.[32]

The documents do not describe what happened to alter the original plans for authorship of the study. We found seven dated drafts of the study manuscript in the documents. The initial draft featured only the Japanese investigators as authors,[33] whereas the second draft included Peter Lee as coauthor,[34 35] and the third and subsequent drafts featured Peter Lee as the sole author.[36–39]

Drafts four, five, six, and seven acknowledged Dr Yano's contribution and the tobacco industry's financial support. The sixth draft included a note from Peter Lee's secretary indicating that the paper had been submitted to the *American Journal of Epidemiology*, with the handwritten notation "rejected."[38] Another draft, the second, included a cover memo stating that the manuscript would be submitted to the *Lancet*.[34]

Originally, industry executives planned to have the Japanese investigators disseminate preliminary results in the *BMJ*, followed by full publication in an epidemiological journal.[17] As shown in fig 3, the final publication in the *International Archives of Occupational and Environmental Health* had Peter Lee as sole author and acknowledged Dr Eijo Yano. A general disclosure of financial support from "several companies of the tobacco industry" was also included.

Although there were several changes in the drafts related to how cotinine was measured and used as a cut off for smoking, the conclusions of all seven drafts remained consistent. The study concluded that there was no direct evidence that secondhand exposure to tobacco smoke increased risk of lung cancer.[40] The final publication reported a cross sectional study of 400 married Japanese women. They were questioned about their smoking status and secondhand exposure to smoke and supplied urine for cotinine analysis. The major finding of the paper was that the cotinine measurements indicated that 22 out of 106 women who claimed never to have been smokers were misclassified. The paper concluded that studies like the Hirayama study have a potential for misclassification bias and have "little scientific basis."[40]

Conclusions

Internal tobacco industry documents show how the industry tried to hide its involvement in refuting the Hirayama study. According to authorship criteria for research publications that were current at the time of the Japanese spousal study[41] and more recent contributorship guidelines,[42 43] several of the parties involved in the study were apparently eligible for authorship, but only one was an author.

Hidden or "ghost" authorship occurs in studies funded by other corporate interests, as well as among academic researchers.[42] When the participants in the design, conduct, and reporting of a study are hidden, credit and accountability for the work cannot be assessed.[42]

The acknowledgement of financial support from tobacco companies in the final publication of the Japanese spousal study shows how financial disclosure is an imperfect indicator of a sponsor's involvement in the research. The published disclosure that the author received "financial support from several companies of the tobacco industry"[40] does not fully describe the industry's involvement in the study.

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Contributors: M-KH conducted the document search, read and analysed the documents, and drafted the manuscript. LAB advised on the search, read and analysed documents, and revised the paper; she is also the primary investigator of the larger study from which this project is derived. Both authors are guarantors for the study.

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Competing interests: None declared.

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COVINGTON & BURLING

CHRISTOPHER A PROCTOR

RECEIVED DEC 2 1991 MATTHEW R. WINKLER

December 23, 1991

BY PACKENGER

Dr. S. Boyse, BAT
Mr. R. Marcotullio, RJR
Dr. P. Sadler, ITL
Dr. W. Böger, Reemtsma
Dr. D. Rowland, RI
Dr. R. Thornton, BAT
Mr. W. Winkler, PM

Fyi J. Goodhead - BAT
S. Parrish

Jan - Fyi only; no need to return.

Re: Japanese Spousal Study

OTM

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.

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Fig 2 Letter from Christopher Proctor, chief scientist at British American Tobacco and acting investigator of the Japanese spousal study, to tobacco industry executives with regard to study results. Covington and Burling document. 23 December 1991. (Philip Morris documents website. Bates No 2023544474_4475. 2 page document)

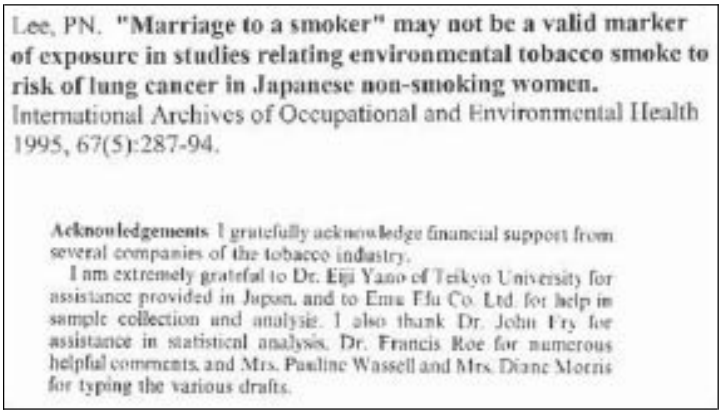

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Fig 3 Title and acknowledgement section of final publication of the Japanese spousal study in *International Archives of Occupational and Environmental Health*, featuring Peter Lee as sole author and acknowledging Eiji Yano as well as financial support from "several companies of the tobacco industry"

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