

Education and debate

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

受動喫煙の健康影響に関する影響力ある研究に対し、タバコ会社はどのように対応したのか

Mi-Kyung Hong, *public administration analyst*, Lisa A Bero, *professor*.

Department of Clinical Pharmacy and Institute for Health Policy Studies, University of California, Box 0613, San Francisco, CA 94143-0613, USA

Correspondence to: L A Bero Bero{at}medicine.ucsf.edu

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

1981年、影響力のある日本の研究が受動喫煙と肺癌の関連を示しました。この論文は、それにとって代わる信頼ある研究を製造することにより、この研究に対抗しようとしたタバコ産業のたくらみを文書で証明しました。

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

1981年 日本の研究者である平山雄は、喫煙者と結婚した喫煙しない妻の間で受動喫煙と肺癌の関連を調べた日本のコホート研究を発表しました¹。この研究はヘビースモーカーの妻は、ノンスモーカーの妻と比べ、肺癌を発症するリスクが最大2倍になり、そのリスクには量反応関係があると結論しました。平山雄の研究は驚くほど多数の批判的論争を引き起こし^{2,3}、規制の過程^{4,5}リスクアセスメント⁶そしてメディア⁷で最も頻回に引用された研究の1つであったため、平山雄の研究は影響力がありました。

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.

タバコ産業は、受動喫煙に何らかの有害な影響があるのかどうかという科学的論争を継続するため

- ▶ [Extract of this article](#)
- ▶ [PDF of this article](#)
- ▶ [Email this article to a friend](#)
- ▶ [Respond to this article](#)
- ▶ [Read](#) responses to this article
- ▶ Related [letters](#) in BMJ
- ▶ [PubMed citation](#)
- ▶ [Related articles in PubMed](#)
- ▶ [Download to Citation Manager](#)
- ▶ This article has been cited by [other articles](#)
- ▶ [Citation Map](#)
- ▶ Search Medline for articles by:
[Hong, M.-K.](#) || [Bero, L. A](#)
- ▶ Alert me when:
[New articles cite this article](#)

- ▶ Collections under which this article appears:
[Smoking](#)
[Other Ethics](#)
[Other Public Health](#)
[Competing interests / conflicts of interest](#)
[Research and publication ethics](#)

に様々な戦略を駆使しました。^{5 6 8-14} 我々は平山雄の研究に対するタバコ産業の反応を記述したタバコ産業の内部文書を同定し分析しました。

Summary points

要点

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

タバコ産業はタバコ煙への二次曝露と肺癌の関連を示した1981年のコホート研究の発見に対抗しようとたくらみ“Japanese spousal study”という研究を生み出しました。

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

タバコ産業の内部文書は、タバコ産業が“Japanese spousal study”への関与を隠すために複数の戦略を検討したことを記述しています。

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

タバコ産業は、タバコ産業が後援しているCenter for Indoor Air Researchという研究組織を通じて、その研究に資金提供することを検討しました。これはタバコ産業の関与を隠すためでした。

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

その研究の実施に関与した関係者にはタバコ産業の科学者、タバコ産業のコンサルタント、タバコ産業の法律事務所、そして2人の日本人研究者が含まれます。そのコンサルタントは最終発表の単独著者でした。

Methods

方法

We retrieved documents from the Legacy Tobacco Documents Library (<http://www.legacy.library.ucsf.edu/>) and tobacco industry websites (<http://www.pmdocs.com/>, <http://www.lorillarddocs.com/>, <http://www.rjrtdocs.com/>, <http://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.

我々は Legacy Tobacco Documents Library (<http://www.legacy.library.ucsf.edu/>) とタバコ産業のウェブサイト (<http://www.pmdocs.com/>, <http://www.lorillarddocs.com/>, <http://www.rjrtdocs.com/>, <http://www.bw.aalatg.com/>, そして www.ctr-usa.org/ctr) から "Hirayama Study," "Japanese Spousal Study," "ETS," そして "meta-analysis" という検索語を利用して文書を検索しました。我々は隣接する bates numbers (係争中に作成されたタバコ産業の文書には数字による識別子が割り当てられており、それぞれのページが固有の識別子を持っている) と名指しされているコンサルタントも調べました。我々は 327 文書を同定し、そのうち 48 文書が平山研究に対抗するための研究を開発するタ

タバコ産業の計画を論じていました。

▶ The tobacco industry's response タバコ産業の反応

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.

タバコ産業は平山雄の研究に対抗するため、Japanese spousal study と呼ばれる研究を作ることとを決定しました。¹⁵⁻¹⁸ その研究の目的は、広報活動のツールとして利用できる信用ある、ピアレビューされた論文を作ることでした。¹⁹ 我々はタバコ産業がその研究の資金提供、実施、そして発表に関与したことを述べます。

Funding the Japanese spousal study

Japanese spousal study に資金提供する

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:

Japanese spousal study は、日本の研究者 矢野栄二さんと香川順さんによって Center for Indoor Air Research (CIAR) に提出された研究費をもらうための提案書として始まったようです。²⁰ 1988年に設立されたこのセンターはタバコ産業が屋内空気研究を支援するために出資しており、資金提供するプロジェクトはタバコ産業の幹部によって選ばれていました。⁸ Philip Morris の研究開発チームの Robert Pages さんと T S Osdene さんから Philip Morris のシニア・バイス・プレジデント Steven Parrish さんへのメモには、その研究への CIAR の資金提供に関する審査が記述されています。

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

これは CIAR により資金提供されるべきプロジェクトではありません、とはいえ、（まだ確信出来ませんが）CIAR が後援するのは、タバコ産業の関与を“隠す”ためでしょう[原文は強調印字]。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

ある人がこのプロジェクトを隠すために CIAR を利用したいのでしょうか。私はそれが大至急しなければならない非常に重要なことだと考えています。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

タバコ会社はこの研究に資金提供することを決定しました。Brown and Williamson と British American Tobacco などはその研究を行うべきだと意見が一致したにもかかわらず、これらの会社は “ 分担金 ” が払えないと述べています。²¹ 広範囲な審査の後、Philip Morris は RJ Reynolds, British American Tobacco, Reemtsma, Imperial Tobacco, そして Rothmans とともに、この研究に資金提供することに合意しました。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.

タバコ産業の文書には日本の科学者によって CIAR へ提出された研究費をもらうための提案書が含まれており、²³ この提案書の新しいバージョンはタバコ産業職員によって編集されています(fig 1)。²³ ²⁴ この新しいバージョンは “ 弁護士作成物秘匿特権 ” とラベルされ、一般公開されないよう保護されていました。^{12 25} その編集された提案書には原文の研究目的のいくつかを修正したものが含まれています。

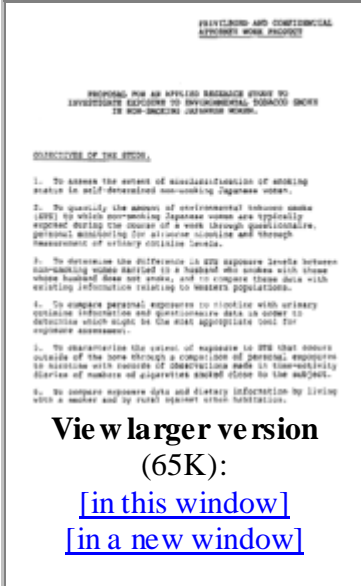


Fig 1. Covington and Burling privileged and confidential attorney work product "Proposal for an applied research study to investigate exposure to environmental tobacco smoke in non-smoking Japanese women." 12 August 1991. (Philip Morris documents website. Bates No 2023544523_4530. 8 page document)

Fig 1. Covington and Burling 弁護士作成物秘匿特権とラベルされた “ タバコを吸わない日本人女性の環境タバ煙暴露を調べる応用研究の提案書 ” 1991年8月12日。(Philip Morris 文書ウェブサイト. Bates No 2023544523_4530. 8 page document)

View larger version
(65K):
[\[in this window\]](#)
[\[in a new window\]](#)

Conducting the Japanese spousal study

Japanese spousal study を実施する

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:

平山雄の発表から約 10 年後、Robert Pages さんから Steven Parrish さんへの下記メモ、2 人とも Philip Morris の社員、は Japanese spousal study を実施する計画を述べています。

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

主たる研究者としてリストされた 2 人の日本人がいます。Chris Proctor さん[British American Tobacco の主任科学者]が “ 黒幕 ” 研究ディレクターになるでしょう ... 私は、それが非喫煙日本人女性の環境タバコ煙曝露がヨーロッパや米国の女性とそれほど変わらないことを示す - 平山雄の弁解者がここ数年主張し続けていることに反するデータを作る非常に良いチャンスになると考えています。¹⁵

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

その文書はタバコ産業が平山雄の結論に対抗するために日本の研究を欲していたことを記述しています。なぜならば、対抗する研究が日本で日本人研究員によって実施されるだけで信用あるものになるだろうとタバコ産業は考えていたからです。¹⁵⁻¹⁷ タバコ産業は平山雄の研究が信用できないことを示したいと思っていました。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:

研究費をもらうための提案書が CIAR に提出されてからタバコ産業によって編集されたバージョンに資金提供されるまでの間、タバコ産業のコンサルタント Peter N Lee さんは、²⁷ その研究費をもらうための提案書原文の批評を依頼されました。Lee さんはそのプロジェクトにおける Proctor さんの役割を知っていました。

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

Japanese spousal study を発表するためのタバコ産業の計画

"Proposal for an applied research study to investigate exposure to environmental tobacco smoke in non-smoking Japanese women." 12 August 1991.²⁴

"タバコを吸わない日本人女性の環境タバコ煙暴露を調べる応用研究の提案書" 1991年8月12日。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.

プロジェクトの管理は Covington and Burling が引き受けるでしょう。これは適切で詳細な研究デザインと成果を確保し、タイムリーな報告の開発を可能にするでしょう。そのプロジェクトの管理者達は全ての科学発表から遠ざけられるでしょう。彼らはまた2月毎に支援会社へ経過報告書を提出するでしょう。

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.

2人の日本人科学者が主たる研究員になるでしょう。香川順教授は疫学者、医師そして呼吸器専門家で現在、東京女子医科大学の衛生学公衆衛生学教室で医学を教えています。彼の研究室は尿中コチニンを測定した経験があります。このプロジェクトにおける香川教授の最重要責務はサンプル分析のマネジメントと出来上がった科学レポートの主たる著者になることです。

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.

矢野栄二教授は疫学者で呼吸器専門家、東京の帝京大学公衆衛生学教室に所属しています。矢野教授は主に市場調査機関とコンタクトをとり、データ収集、データベース編集、そしてデータ分析を組織するでしょう。

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.

Peter Lee さんもまた研究デザインの批評とデータの解釈の手伝いを求められるでしょう。しかしながら、Lee さんがその研究から流れ出る全ての発表の共著者になることは予想できません。

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

私は実際、アジア、特に日本の女性における誤分類割合に関する好ましいデータの収集が、まさに環境タバコ煙と肺癌問題を更に理解するために必要な最も重要なことであると考えていました。日本における割合が高いことを示すことは、配偶者の喫煙と肺癌のリスクとの間に見られる関連の解釈に劇的な影響を及ぼすでしょう（あるいは、当然影響を及ぼします）。この理由により、私はChris Proctorさんの日本で研究を続ける計画を非常に強力に支援します[原文は強調印字]。²⁸

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

最終的に Peter Leeさんはコンサルタントとしてこの研究の一員となりました。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:

タバコ産業は Japanese spousal studyにおけるその役割を隠そうと計画しました。次のメモの中で Philip Morris の T S Osdeneさんと Robert Pagesさんは Steven Parrishさんに Proctorの役割を隠すつもりであると報告しました。

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

また、私の考えですが、Dr Chris Proctorさんがこの仕事を監督してもよいが、彼の存在は目立たないようにすべきであり、いかなる発表の中にも姿を見せないようにしなければならない。なぜなら特にこれは日本の研究だからです。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

これの実現を助けるために Proctorさん（および彼の報酬）が必要でしょう...しかし、これは日本の研究であるべきです：Proctorさんはそれから出てくるいかなる発表についても共著者になるべきではありません。

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

付け加えて言えば、その調査において研究のために使用された測定機器へのタバコ産業の関与は全く公表されませんでした。²⁹

Publishing the Japanese spousal study

Japanese spousal study を発表する

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.

Japanese spousal study に関与した関係者にはタバコ産業の科学者(Chris Proctor), タバコ産業のコンサルタント(Peter N Lee, コンサルタント報酬として \$5000 が支払われた),²⁴そしてタバコ産業の法律事務所(Covington and Burling, プロジェクト管理費として \$30 000 支払われた)が含まれていました。²⁴日本人研究員の役割はあいまいでした。上のボックスは、Covington and Burling 弁護士作成物秘匿特権とラベルされた、関係者の様々な役割と発表の著者に関するタバコ産業の計画が記述された提案書を引用しています。

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:

Fig 2 に示されたように、Chris Proctor さんは (Covington and Burling の便箋に書かれた) 経過報告書をタバコ産業の幹部に送りました^{30 31}, しかし科学発表の中に彼の研究員としての役割は全く明示されませんでした。1993 年 Chris Proctor さんはタバコ会社の幹部に著者を変えるよう勧めました:




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)

Fig 2. British American Tobacco の主任科学者で Japanese spousal study の研究員である Christopher Proctor さんからタバコ産業幹部へ送られた研究結果に関する手紙 1991 年 12 月 23 日。(Philip Morris documents website. Bates No 2023544474_4475. 2 page document)

View larger version
(52K):
[\[in this window\]](#)
[\[in a new window\]](#)

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

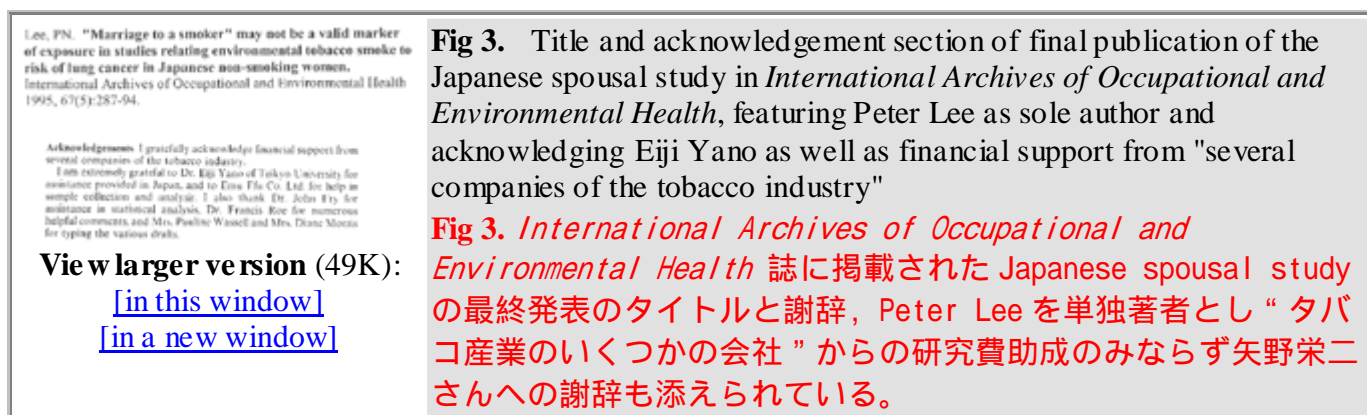
帝京大学の矢野先生とともに作業している多大な業務が終わりましたら、Japanese spousal study の研究を *British Medical Journal* に発表するため Peter Lee さんに投稿を頼むべき時期であると感じております。我々は今日早くから Lee さんと話し、彼はこの方向性に同意しました、しかし最終的な承認をお待ちしています。³²

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

文書は研究の著者の最初の計画を変更する出来事を記述していません。我々は文書の中から日付の付いた7つの研究原稿の草稿を発見しました。最初の草稿は日本人研究員のみが著者であることが特徴です。³³ところが2番目の草稿は共同著者に Peter Lee さんを含んでいます。^{34 35}そして3番目とそれ以降の草稿は Peter Lee さんが単独著者であるという特徴があります。³⁶⁻³⁹4, 5, 6,そして7番目の草稿は矢野先生の貢献とタバコ産業の研究費助成への謝辞が添えられています。6番目の草稿にはこの論文が *American Journal of Epidemiology* に投稿されたことを示す Peter Lee の秘書による短い手紙と “rejected (訳注:審査不合格、掲載不可)” という手書きの注釈を含んでいます。³⁸2番目の別の草稿には、この原稿が *Lancet* 誌に投稿されるだろうと述べるカバー・メモが含まれていました。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.

最初、タバコ産業の幹部は日本人研究員に初期結果を *BMJ* に発表してもらい、続いて疫学誌に完全な発表を行う計画でした。¹⁷ Fig 3 に示すように *International Archives of Occupational and Environmental Health* の最終発表は Peter Lee を単独著者とし矢野栄二先生への謝辞を添えました。“タバコ産業のいくつかの会社”から研究費助成があったという一般的な公開情報も含まれていました。



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.

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"

Fig 3. *International Archives of Occupational and Environmental Health* 誌に掲載された Japanese spousal study の最終発表のタイトルと謝辞, Peter Lee を単独著者とし “タバコ産業のいくつかの会社”からの研究費助成のみならず矢野栄二さんへの謝辞も添えられている。

View larger version (49K):
[\[in this window\]](#)
[\[in a new window\]](#)

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

草稿にはコチニンの測定と喫煙のカット・オフとしての利用に関連するいくつかの変更がありましたが、7つの草案の結論は一貫して全て同じでした。その研究は受動喫煙曝露が肺癌のリスクを増加させるという直接的な証拠は無いと結論しました。⁴⁰最終的な発表は結婚した日本人女性400人の横断研究を報告しました。彼女らは喫煙状況とタバコ煙への二次曝露について質問され、コチニン分析のために尿を採られました。その論文の最大の発見は、コチニン測定により決して喫煙した事が無いと答えた女性106人のうち22人が誤分類されていることを示したことでした。その論文は平山研究のような研究は誤分類バイアスを持つ可能性があり、“科学的根拠に乏しい”と結論しました。⁴⁰

Conclusions

結論

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 study⁴¹ 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.

タバコ産業の内部文書は、タバコ産業が平山研究に対抗する際、関与を隠そうとしたことを示しています。Japanese spousal study 当時の研究発表のための著者判断基準と、⁴¹より新しい協力者ガイドラインによれば、^{42 43}この研究に関与した何人かの関係者は明らかに著者として適格でしたが、著者はたったの1名でした。

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

隠れ著者、あるいは“ゴースト”著者は大学の研究員ばかりでなく他の企業利害による助成研究でも発生します。⁴² 研究のデザイン、実施、そして報告に関与した者が隠されると、その仕事に対する信用と責任を評価することが出来ません。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.

最終発表された Japanese spousal study のタバコ会社からの研究費助成に対する謝辞は、資金的な情報公開がスポンサーの研究への関与を示す不完全な指標になることを示しています。著者が“タバコ産業のいくつかのタバコ会社から研究費”⁴⁰を受け取ったという公開された情報は、タバコ産業がその研究に関与したことを完全に記述していません。

Acknowledgments

We thank Jim Repace, Stanton Glantz, Drummond Rennie, Ruth Malone, Josh Dunsby, Jim Lightwood, and Anh Le for commentary and guidance on the manuscript. We thank Martha Michel and Stella Bialous for technical support.

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.

Footnotes

Funding: This work was supported by grants from the National Cancer Institute (Grant No CA-87472] and the California Tobacco-Related Disease Research Program (Grant No 9RT0193]

Competing interests: None declared.

▶ References

- 1 Hirayama T. Non-smoking wives of heavy smokers have a higher risk of lung cancer: a study from Japan. *BMJ* 1981; 282: 183-185 [[ISI](#)] [[Medline](#)].
- 2 Non-smoking wives of heavy smokers have a higher risk of lung cancer [correspondence]. *BMJ* 1981; 283: 1464-1466 [[Medline](#)].
- 3 Non-smoking wives of heavy smokers have a higher risk of lung cancer [correspondence]. *BMJ* 1981; 283: 914-917 [[Medline](#)].
- 4 Bero L, Glantz SA. Tobacco industry response to a risk assessment of environmental tobacco smoke. *Tobacco Control* 1993; 2: 103-113 [[Free Full Text](#)].
- 5 Bero LA, Montini T, Bryan-Jones K, Mangurian C. Science in regulatory policy making: case studies in the development of workplace smoking restrictions. *Tobacco Control* 2001; 10: 329-336 [[Abstract/Free Full Text](#)].
- 6 Schotland MS, Bero L. Evaluating public commentary and scientific evidence submitted in the development of a risk assessment. *Risk Analysis* 2002; 22: 131-140 [[CrossRef](#)] [[ISI](#)] [[Medline](#)].
- 7 Malone RE, Boyd E, Bero L. Science in the news: journalists' constructions of passive smoking as a social problem. *Soc Stud Sci* 2000; 30: 713-735 [[Abstract/Free Full Text](#)].
- 8 Barnes DE, Bero LA. Industry-funded research and conflict of interest: an analysis of research sponsored by the tobacco industry through the Center for Indoor Air Research. *J Health Polit Policy Law* 1996; 21: 515-542 [[ISI](#)] [[Medline](#)].
- 9 Bero LA, Galbraith A, Rennie D. Sponsored symposia on environmental tobacco smoke. *JAMA* 1994; 271: 612-617 [[Abstract](#)].
- 1 Misakian AL, Bero LA. Publication bias and research on passive smoking: comparison of published and 0 unpublished studies. *JAMA* 1998; 280: 250-253 [[Abstract/Free Full Text](#)].
- 1 Barnes DE, Hanauer P, Slade J, Bero LA, Glantz SA. Environmental tobacco smoke. The Brown and 1 Williamson documents. *JAMA* 1995; 274: 248-253 [[Abstract](#)].
- 1 Bero L, Barnes DE, Hanauer P, Slade J, Glantz SA. Lawyer control of the tobacco industry's external research 2 program. The Brown and Williamson documents. *JAMA* 1995; 274: 241-247 [[Abstract](#)].
- 1 Drope J, Chapman S. Tobacco industry efforts at discrediting scientific knowledge of environmental tobacco 3 smoke: a review of internal industry documents. *J Epidemiol Community Health* 2001; 55: 588-594 [[Abstract/Free Full Text](#)].
- 1 Muggli ME, Forster JL, Hurt RD, Repace JL. The smoke you don't see: uncovering tobacco industry scientific 4 strategies aimed against environmental tobacco smoke policies. *Am J Public Health* 2001; 91: 1419-1423 [[Abstract/Free Full Text](#)].
- 1 Pages R. Re: Japanese spousal study and Chris Proctor as the 'behind the scenes' study director and potential 5 CIAR funding [letter]. Philip Morris. 15 Apr 1991. Philip Morris documents website. Bates No 2023544456. <http://www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=202354446&docid=2023544456&docnum=1&summary=0&sell> (accessed 7 Aug 2001).
- 1 Osdene TS. Investigation of exposure to ETS in nonsmoking Japanese women. Philip Morris. 16 Apr 6 1991. Philip Morris documents website. Bates No 2023544449. <http://www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544449&docid=2023544449&docnum=3&summary=0&sell> (accessed 7 Aug 2001).
- 1 Pages R. Re: Japanese spousal study and plans to publicize in *BMJ* and eventually publish in epidemiological

- 7 journal [letter]. Philip Morris. 8 Nov 1991. Philip Morris documents website. Bates No 2023544508.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544508&docid=2023544508&docnum=1&summary=0&sell (accessed 7 Aug 2001).
- 1 Green CR. ETS Division weekly highlights [week of November 12, 1991] RJ Reynolds. 12 Nov 8 1991. Legacy Tobacco Documents Library/ RJ Reynolds Documents. Bates No 507984189_4190.
. <http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=lea14d00&fmt=gif&ref=results&title=ETS%20DIVISION%20WEEKLY%20HIGHLIGHTS.&bates=507984189/4190> (accessed 29 Jan 2002).
- 1 Sadler PA. Re: Publicizing Japanese spousal study at the International Scientific Media Workshop [letter]. 9 Imperial Tobacco. 5 Oct 1993. Philip Morris documents website. Bates No 2025495799.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2025495799&docid=2025495799&docnum=1&summary=0&sell (accessed 8 Aug 2001).
- 2 Green CR. Re: Japanese spousal study proposal to be presented at CIAR. Proctor will present it at CIAR [RJR 0 fax sheet]. Philip Morris. 5 Apr 1991. Philip Morris documents website. Bates No 2023544450.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544450&docid=2023544450&docnum=1&summary=0&sell (accessed 7 Aug 2001).
- 2 Pages R. Japan exposure assessment study. Philip Morris. 12 Aug 1991. Philip Morris documents website. 1 Bates No 2023544519.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544519&docid=2023544519&docnum=1&summary=0&sell (accessed 7 Aug 2001).
- 2 Marcotullio RJ. International ETS Management Committee budget for Japanese spousal study. RJ Reynolds. 22 Aug 1991. Legacy Tobacco Documents Library; RJ Reynolds Documents. Bates No 507782317_2318.
. [http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=nwp14d00&fmt=gif&ref=results&title=INTERNATIONAL%20ETS%20MANAGEMENT%20COMMITTEE%20\(IEMC\).&bates=507782317/2318](http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=nwp14d00&fmt=gif&ref=results&title=INTERNATIONAL%20ETS%20MANAGEMENT%20COMMITTEE%20(IEMC).&bates=507782317/2318) (accessed 28 Jan 2002).
- 2 Philip Morris. Proposal for an applied research study to investigate exposure to environmental tobacco smoke 3 in non-smoking Japanese women. Covington and Burling. 5 Apr 1991. Philip Morris documents website. Bates No 2023544477_4481.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544477&docid=2023544477/4481&docnum=1&summary=0&sell (accessed 3 Oct 2001).
- 2 Philip Morris. Proposal for an applied research study to investigate exposure to environmental tobacco smoke 4 in non-smoking Japanese women [privileged and confidential attorney work product]. Covington and Burling. 12 Aug 1991. Philip Morris documents website. Bates No 2023544523_4530.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544523&docid=2023544523/4530&docnum=1&summary=0&sell (accessed 3 Oct 2001).
- 2 Hanauer P, Slade J, Barnes D, Bero L, Glantz S. Lawyer control of internal scientific research to protect 5 against products liability lawsuits: The Brown and Williamson documents. *JAMA* 1995; 274: 234-240[Abstract].
- 2 Green CR. ETS Division weekly highlights [April 9, 1991] RJ Reynolds. 9 Apr 1991. Legacy Tobacco 6 Documents Library/RJ Reynolds documents. Bates No 513238393_8394.
. <http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=vtf23d00&fmt=gif&ref=results&title=ETS%20DIVISION%20WEEKLY%20HIGHLIGHTS.&bates=513238393/8394> (accessed 29 Jan 2002).
- 2 Glantz S, Slade J, Bero L, Hanauer P, Barnes D. *The cigarette papers*. Berkeley, CA: UC Press, 1996.
7
- 2 Lee PN. Draft proposal for study to investigate exposure to ETS in non-smoking Japanese women. 8 International ETS Management Committee. 25 Apr 1991. Philip Morris documents website. Bates No 2023544457_4461.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544457&docid=2023544457/4461&docnum=1&summary=0&sell (accessed 7 Aug 2001).
- 2 Philip Morris. Lifestyle questionnaire. Covington and Burling. October 17, 1991. Philip Morris documents 9 website. Bates No 2023544534_4544.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544534&docid=2023544534/4544&docnum=1&summary=0&sell (accessed 2 Oct 2001).
- 3 Proctor C. Re: Study results and the Japanese spousal study [letter to tobacco industry executives]. Covington

- 0 and Burling. 23 Dec 1991. Philip Morris documents website. Bates No 2023544474_4475.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544474&docid=2023544474/4475&docnum=1&summary=0&sell = (accessed 7 Aug 2001).
- 3 Proctor C. Re: Questionnaire development and the Japanese spousal study [letter to tobacco industry
1 executives]. Covington and Burling. 11 Oct 1991. Philip Morris documents website. Bates No 2023544533.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544533&docid=2023544533&docnum=1&summary=0&sell = (accessed 30 Jan 2001).
- 3 Proctor C. [letter to tobacco industry executives to change authorship] Philip Morris. 26 Jul 1993. Philip
2 Morris documents website. Bates No 2023544546.
. www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023544546&docid=2023544546&docnum=1&summary=0&sell = (accessed 7 Aug 2001).
- 3 Yano E, Kagawa J. Confounding factors in epidemiologic studies of spousal smoke exposure in Japanese
3 women. Covington and Burling. 21 Apr 1992. RJ Reynolds documents website. Bates No 510627012_7023.
. <http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=ttz53d00&fmt=gif&ref=results&title=CONFOUNDING%20FACTORS%20IN%20EPIDEMIOLOGIC%20STUDIES%20OF%20SPOUSAL%20SMOKE%20EXPOSURE%20IN%20JAPANESE%20WOMEN.&bates=510627012/7023> (accessed 29 Jan 2002).
- 3 Yano E, Kagawa J, Lee PN. Confounding factors in epidemiologic studies of spousal smoke exposure in
4 Japanese women. Covington and Burling. 27 May 1992. RJ Reynolds documents website. Bates No
. 509810529_0541.
<http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=bow63d00&fmt=gif&ref=results&title=CONFOUNDING%20FACTORS%20IN%20EPIDEMIOLOGIC%20STUDIES%20OF%20SPOUSAL%20SMOKE%20EXPOSURE%20IN%20JAPANESE%20WOMEN.&bates=509810529/0541> (accessed 29 Jan 2002).
- 3 Yano E, Kagawa J, Lee PN. Lack of validity of marriage to a smoker as a marker of environmental tobacco
5 exposure among Japanese non-smoking women. Covington and Burling. 8 Jul 1992. RJ Reynolds documents
. website. Bates No 509810603_0630.
<http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=cow63d00&fmt=gif&ref=results&title=LACK%20OF%20VALIDITY%20OF%20MARRIAGE%20TO%20A%20SMOKER%20AS%20A%20MARKER%20OF%20ENVIRONMENTAL%20TOBACCO%20EXPOSURE%20AMONG%20JAPANESE%20NON-SMOKING%20WOMEN.&bates=509810603/0630> (accessed 29 Jan 2001).
- 3 Lee PN. Limitations of studies of lung cancer and environmental tobacco smoke exposure in Japanese non-
6 smoking women. PN Lee Statistics and Computing. RJ Reynolds documents website. Bates No
. 508728884_8905.
<http://dlxs.ckm.ucsf.edu/cgi/getdoc?tid=pxz83d00&fmt=gif&ref=results&title=LIMITATIONS%20OF%20STUDIES%20OF%20LUNG%20CANCER%20AND%20ENVIRONMENTAL%20TOBACCO%20SMOKE%20EXPOSURE%20IN%20JAPANESE%20NON-SMOKING%20WOMEN.&bates=508728884/8905>
(accessed 29 Jan 2002).
- 3 Lee PN. Limitations of studies of lung cancer and environmental tobacco smoke exposure in Japanese non-
7 smoking women. PN Lee Statistics and Computing. 15 Aug 1993. Philip Morris documents website. Bates No
. 2023053346_3367.
www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2023053346&docid=2023053346/3367&docnum=1&summary=0&sell = (accessed 29 Jan 2002).
- 3 Lee PN. Limitations of studies of lung cancer and environmental tobacco smoke exposure in Japanese non-
8 smoking women. Philip Morris. 18 May 1994. Philip Morris documents website. Bates No
. 2050751646_1666.
www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2050751646&docid=2050751646/1666&docnum=1&summary=0&sell = (accessed 29 Jan 2002).
- 3 Lee PN. Is environmental tobacco smoke a workplace hazard? Limitations of studies of lung cancer in
9 Japanese non-smoking women using "marriage to a smoker" as an index of exposure. Philip Morris. 14 Oct
. 1994. Philip Morris documents website. Bates No 2050751521_1546.
www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2050751520&docid=2050751521/1546&docnum=2&summary=0&sell = (accessed 29 Jan 2002).
- 4 Lee PN. "Marriage to a smoker" may not be a valid marker of exposure in studies relating environmental
0 tobacco smoke to risk of lung cancer in Japanese non-smoking women. *Int Arch Occup Environ Health* 1995;
. 67: 287-294 [[ISI](#)] [[Medline](#)].

4 International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to 1 biomedical journals. *JAMA* 1993; 269: 2282-2286[[Abstract](#)].

4 Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. *JAMA* 2 1997; 278: 579-585[[Abstract](#)].

4 Smith R. Authorship: time for a paradigm shift? *BMJ* 1997; 314: 992[[Free Full Text](#)].

3

© [BMJ 2002](#)

Related letters in BMJ:

Passive smoking: Background must be examined

Martin McKee

BMJ 2003 327: 503. [[Letter](#)]

This article has been cited by other articles:



Tobacco Control

[HOME](#)

E K Tong and S A Glantz

ARTIST (Asian regional tobacco industry scientist team): Philip Morris' attempt to exert a scientific and regulatory agenda on Asia
Tob. Control, December 1, 2004; 13(suppl_2): ii118 - ii124.

[[Abstract](#)] [[Full Text](#)] [[PDF](#)]



ACADEMIC MEDICINE

[HOME](#)

N. Wander and R. E. Malone

Selling Off or Selling Out? Medical Schools and Ethical Leadership in Tobacco Stock Divestment
Acad. Med., November 1, 2004; 79(11): 1017 - 1026.

[[Abstract](#)] [[Full Text](#)] [[PDF](#)]



Tobacco Control

[HOME](#)

K Neilsen and S A Glantz

A tobacco industry study of airline cabin air quality: dropping inconvenient findings
Tob. Control, March 1, 2004; 13(90001): i20 - 29.

[[Abstract](#)] [[Full Text](#)] [[PDF](#)]



The NEW ENGLAND JOURNAL of MEDICINE

[HOME](#)

S. A. Schroeder

Tobacco Control in the Wake of the 1998 Master Settlement Agreement
N. Engl. J. Med., January 15, 2004; 350(3): 293 - 301.

[[Full Text](#)] [[PDF](#)]



BMJ

▶ HOME

M. McKee

Passive smoking: Background must be examined

BMJ, August 30, 2003; 327(7413): 503 - 503.

[\[Full Text\]](#)



JECH Online

▶ HOME

R E Malone and L A Bero

Chasing the dollar: why scientists should decline tobacco industry funding

J. Epidemiol. Community Health, August 1, 2003; 57(8): 546 - 548.

[\[Full Text\]](#) [\[PDF\]](#)

Rapid Responses:

Read all [Rapid Responses](#)

Cilia-a Missing Link

John L. Evers, et al.

bmj.com, 16 Dec 2002 [\[Full text\]](#)

Passive smoking and tobacco money

Hiroshi Kawane, et al.

bmj.com, 8 Jan 2003 [\[Full text\]](#)

- ▶ [Extract of this article](#)
- ▶ [PDF of this article](#)
- ▶ [Email this article to a friend](#)
- ▶ [Respond to this article](#)
- ▶ [Read](#) responses to this article
- ▶ Related [letters](#) in BMJ
- ▶ [PubMed citation](#)
- ▶ [Related articles in PubMed](#)
- ▶ [Download to Citation Manager](#)
- ▶ [Citation Map](#)
- ▶ Search Medline for articles by:
[Hong, M.-K.](#) || [Bero, L. A](#)
- ▶ Alert me when:
[New articles cite this article](#)

- ▶ Collections under which this article appears:
[Smoking](#)
[Other Ethics](#)
[Other Public Health](#)
[Competing interests / conflicts of interest](#)
[Research and publication ethics](#)

Home

Help

Search

Archive

Feedback

Table of Contents