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RESEARCH PAPER

The limits of competing interest disclosures

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Tobacco Control 2005;**14**:118–126

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Objective: To assess the effectiveness of conflict of interest disclosure policies by comparing a competing interests disclosure statement that met the requirements established by the journal in a 2003 article on health effects of secondhand smoke based on the American Cancer Society CPS-I dataset with internal tobacco industry documents describing financial ties between the tobacco industry and authors of the study.

Design: Descriptive analysis of internal tobacco industry documents retrieved from the Legacy Tobacco Documents Library, University of California, San Francisco.

Results: Meeting the requirements for financial disclosure established by the journal did not provide the reader with a full picture of the tobacco industry's involvement with the study authors. The tobacco industry documents reveal that the authors had long standing financial and other working relationships with the tobacco industry.

Conclusion: These findings are another example of how simply requiring authors to disclose financial ties with the tobacco industry may not be adequate to give readers (and reviewers) a full picture of the author's relationship with the tobacco industry. The documents also reveal that the industry funds research to enhance its credibility and endeavours to work with respected scientists to advance its goals. These findings question the adequacy of current journal policies regarding competing interest disclosures and the acceptability of tobacco industry funding for academic research.

In May 2003, the *British Medical Journal* (*BMJ*) published "Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960–1998".[1] In this paper, Enstrom and Kabat used a longitudinal cohort collected by the American Cancer Society beginning in 1959 (the CPS-I dataset, Cancer Prevention Study) to conclude that secondhand smoke exposure does not increase the risk of lung cancer and heart disease. This conclusion conflicts with comprehensive reviews which find that secondhand smoke increases these risks by 20–30%.[2] The paper was quickly and widely cited in the lay press[3 4] and by tobacco industry supported journalists who criticise government sponsored "junk science".[5]

Subsequent criticisms of the paper focused on the methodology of the study and the authors' disclosed financial ties. The main methodological issue was that there was no real "unexposed" group in the CPS-I dataset that Enstrom and Kabat used.[6 7]

The article included a lengthy statement of funding sources and competing interests, listing as one of its sponsors the tobacco industry's Center for Indoor Air Research (CIAR). Peer reviewers tend to be more critical of articles with industry sponsorship than those without such sponsorship.[8] One rapid response to the Enstrom and Kabat article suggested that it might be useful for editors to "require a statement about the role of the funding source in the design, conduct, analysis and reporting of the data".[9] Earlier tobacco industry funded studies of the health effects of secondhand smoke have failed to fully disclose the sponsor's role in the research.[10 11] In contrast to these earlier situations, the Enstrom and Kabat paper was consistent with the requirements for such statements established by the *BMJ*.

Financial disclosure policies for authors of journal articles are becoming the norm.[12 13] However, experts on scientific journal disclosure policies have questioned the adequacy of these policies.[14] Studies comparing disclosures of financial ties in research articles with information on the financial ties of authors obtained from independent sources have shown that only a small percentage of research articles (less than 20%) fully disclose the financial ties of authors.[14 15] A more recent study investigated the lead and last authors of research articles who declared that they had no conflicts to disclose in 163 original articles that appeared in four journals (*New England Journal of Medicine*, *Journal of the American Medical Association*, *Environmental Health Perspectives*, *Toxicology and Applied Pharmacology*). By comparing publicly available databases and the journals' conflict of interest policies, the study found 13 articles (8%) where relevant conflicts of interest were not disclosed to readers.[15] In most cases, the authors failed to disclose the relevant information to the journal.[15]

The inadequacy of journal article disclosures when compared to information on financial ties of authors obtained from other sources has led experts on disclosure to suggest more comprehensive policies and stronger enforcement of existing policies.[14 16] For example, experts have suggested that journals require disclosure of exact amounts and duration of financial ties, and that journals clarify how they define the "relevance" of a financial tie to the research.[15] A number of scholars have argued that corporate sponsorship of research or financial ties of authors should be prohibited.[14 17 18] These proposed bans eliminate the need for disclosure to "manage" the conflict of interest and protect against even the appearance of conflict.

The Enstrom and Kabat paper provides an interesting case study to test this suggestion precisely because they provided an extensive disclosure that met the current *BMJ* standards

Editor's note
This article replaces a previous version that was posted on the *Tobacco Control* website on 9 December 2004 and taken down on 11 February 2005.

Abbreviations: ACS, American Cancer Society; *BMJ*, *British Medical Journal*; CIAR, Center for Indoor Air Research; CPS, Cancer Prevention Study; CTR, Council for Tobacco Research; JAMA, *Journal of the American Medical Association*; SRRC, Philip Morris scientific research review committee; TRDRP, California Tobacco-Related Disease Research Program

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for such disclosure. Using methods similar to that of Krimsky, we compared the disclosure in a scientific journal article with information on financial ties of the authors obtained from an independent source.[19 20] We compare the disclosure Enstrom and Kabat provided in their article with internal tobacco industry documents describing their relationship with the tobacco industry in order to obtain details of the history and nature of their association, with the goal of understanding whether a disclosure statement that met *BMJ*'s requirements gave the reader a clear description of the role of the tobacco industry in the study and the historical relationship of the authors with the industry.

METHODS

We retrieved documents from the Legacy Tobacco Documents Library (www.legacy.library.ucsf.edu) using the terms ''Enstrom'', ''Kabat'', ''CIAR'', ''CPSI'', ''CPSII'', ''Womble Carlyle'', and ''Shook, Hardy and Bacon'' and names of key individuals, followed by ''snowball searches''. We collected 156 documents; 81 discussed the development of the CPS-I data analysis or other research by Enstrom or Kabat.

RESULTS

Table 1 summarises financial ties between the authors and the tobacco industry. The disclosure statement was long, 305 words, compared to the average of 127 words in the 20 other research articles published in *BMJ* that month. Of these 305 words, 98 related to the tobacco industry (table 2).

Acknowledgement of American Cancer Society and California Tobacco-Related Disease Research Program

The authors disclosed that the American Cancer Society (ACS) developed the CPS-I dataset.[21] The disclosure notes that some work was funded by the California Tobacco-Related Disease Research Program (TRDRP), then states that continued funding was ''denied''. The renewal for the project was not funded because it had inadequate scientific merit as determined by a peer review panel in a year that TRDRP had an 85% budget reduction.[22]

Early interactions with the tobacco industry

The disclosure states that the research was supported by the tobacco industry after continuing support from TRDRP was denied and that ''[i]n recent years'' Enstrom received research funding from the tobacco industry because he was unable to obtain equivalent funds from other sources. Although these statements are accurate and comply with Enstrom's reporting obligations under *BMJ* policy, the tobacco industry documents also show that Enstrom had a long history of association with the industry. In 1975, he approached the Council for Tobacco Research (CTR), a tobacco industry research organisation, to fund a study of cancer among US Mormons.[23 24] He argued that the study ''should be helpful in assessing the possible role which other factors besides smoking play in the etiology of lung cancer''.[24] The proposal was deferred for discussion by the Executive Committee, Scientific Advisory Board of CTR in June 1975.[25] Although Enstrom requested a letter of support from the Tobacco Institute, the industry's trade organisation in the USA,[26] and modified his experimental design in April 1976,[27] there is no record that the proposal was funded. In 1978, Enstrom submitted another request to CTR to study ''Smoking cessation and mortality trends among California physicians''.[28] There is no record that this proposal was funded.

In 1979, Enstrom published a review article that provoked concern and criticism from the tobacco industry.[29–31] The

Table 1 Financial ties between Enstrom, Kabat and the tobacco industry

Year	Enstrom	Kabat
1975	First record of Enstrom approaching the tobacco industry for funding. Enstrom asks the Council for Tobacco Research (CTR) to fund a study of cancer among Mormons living in the USA	
1978	Enstrom submits another request for funding to CTR for a study entitled ''Smoking cessation and mortality trends among California physicians''	
1979	Enstrom publishes a review article that provokes criticism from the tobacco industry	
1981		Kabat begins collaborations with Ernst Wynder, whose American Health Foundation (AHF) was tobacco industry funded. Tobacco industry support was not acknowledged in subsequent publications
1990	The tobacco industry initiates contact with Enstrom to critique research on secondhand tobacco smoke. Enstrom declines to comment	
1990	Enstrom requests funding from Philip Morris for a study to support his work on lung cancer mortality trends among non-smokers. Enstrom is advised to seek funding from the Center for Indoor Air Research (CIAR)	
1991	Enstrom submits a pre-proposal to the Council for Tobacco Research (CTR) for a study entitled ''Mortality Trends Among Smokers and Nonsmokers Study''	
1991–7	CTR funds the ''Mortality Trends Among Smokers and Nonsmokers Study''	
1996	Enstrom submits to the *Journal of the American Medical Association* (*JAMA*) a reanalysis of an article by Elizabeth Fontham, *et al*. This reanalysis was financially supported by the tobacco industry.	
1997	Enstrom submits a proposal entitled ''Relationship of low levels of active smoking to mortality'' for funding to Philip Morris. The proposal is funded	Kabat co-authors a paper with tobacco industry consultants that criticises the evidence linking secondhand smoke with lung cancer
1996	Enstrom submits pre-proposals to the tobacco industry's CIAR to explore the possibility of funding research related to secondhand smoke using the California CPS-I cohort	
1997 May	CIAR board of directors is informed that discussions had taken place with Enstrom and Kabat about ''the possibility of their collaboration''	
1997 November	Max Eisenberg, director of CIAR, recommends that Enstrom's revised proposal, ''Proposed research on passive smoking'', be considered under the Directed Studies programme	
1997 November	The CIAR board of directors votes to fund Enstrom's proposal with modifications	

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Table 2 Comparison of competing interest disclosure with information from internal tobacco industry documents and other sources

Disclosure published in *BMJ* that met *BMJ*'s standards	Findings from tobacco industry documents and other sources that go beyond what was required by *BMJ*
''The American Cancer Society (ACS) initiated CPS-I in 1959, conducted follow up until 1972, and has maintained the original database''	ACS epidemiologists repeatedly cautioned Enstrom before he began the study that the CPS-I dataset was not appropriate to investigate the effects of environmental tobacco smoke (ETS)[21]
''Extended follow up until 1997 was conducted at the University of California at Los Angeles with initial support from the Tobacco-Related Disease Research Program, a University of California research organisation funded by the Proposition 99 cigarette surtax. After continuing support from the Tobacco-Related Disease Research program was denied, follow up through 1999 and data analysis were conducted at University of California at Los Angeles with support from the Center for Indoor Air Research, a 1988–99 research organisation that receive funding primarily from US tobacco companies''	Dr Enstrom's application for continued funding from the California Tobacco-Related Disease Research Program was not funded because it had inadequate scientific merit in a year when the program's budget was drastically reduced.[22] The Center for Indoor Air Research funded grants that were peer reviewed by scientists and ''special projects'' that were reviewed by tobacco industry lawyers and executives.[38] The CPS-I analysis was funded through the same mechanism as the special projects
''In recent years JEE has received funds originating from the tobacco industry for his tobacco related epidemiological research because it has been impossible for him to obtain equivalent funds from other sources''	JEE sought research funding from the tobacco industry beginning in 1975 and received his first funding in 1992. He has also received funding for serving as an expert witness, reviewing dissertation and grant proposals
''GCK never received funds originating from the tobacco industry until last year, when he conducted an epidemiological review for a law firm which has several tobacco companies as clients. He has served as a consultant to the University of California at Los Angeles for this paper''	GCK has had an ongoing indirect relationship with the tobacco industry since at least 1981 though his collaborations with Ernst Wynder whose American Health Foundation was funded by Philip Morris.
''JEE and GCK have no other competing interests. They are both lifelong non-smokers whose primary interest is an accurate determination of the health effects of tobacco.''	The analysis of the CPS-I dataset was also funded by Philip Morris tobacco company and this was not disclosed

article, which was consistent with journal policy at the time, disclosed no sources of funding, used data from the Mormon cohort, US veteran cohort, CPS-I, and National Mortality Survey to conclude that lung cancer rates had been rising among non-smokers between 1914 and 1968 and that this rise was related to factors other than ''personal cigarette smoking'' including ''environmental pollution including environmental tobacco smoke''.[32]

Developing a relationship with the tobacco industry

The industry documents reveal little interaction between the tobacco industry and Enstrom from 1979 until 1990, when the tobacco industry began to recruit Enstrom as a potential critic of research on secondhand smoke. In 1990, Thomas Borelli, Manager Scientific Issues, Philip Morris, asked Enstrom, among others, to comment on a PhD dissertation by Luis Varela.[33 34] Borelli was interested in the dissertation because it contained findings suggesting that secondhand smoke exposure was not associated with disease. The industry frequently cited the dissertation as evidence that should be included in risk assessments of secondhand smoke.[35] In contrast to the preliminary results in the dissertation, however, the final publication in the *New England Journal of Medicine*[36] concluded that childhood exposure to secondhand smoke was associated with adult lung cancer.

Enstrom declined to review the dissertation, stating: ''My epidemiologic research does not deal directly with the issue of environmental tobacco smoke''.[33] However, he used the invitation to inquire about funding from Philip Morris to update his work on lung cancer mortality trends among non-smokers.[33] Borelli responded that ''Philip Morris does not usually fund research projects'' and referred Enstrom to the industry's CIAR.[37] The CIAR was supported solely by the tobacco industry and funded research projects using two different mechanisms. Some projects were peer reviewed by scientists and were more likely to examine health effects of indoor air contaminants other than secondhand smoke.[38] Other projects, which were more likely to focus on secondhand smoke, were reviewed by tobacco industry executives and lawyers.[38]

Enstrom sent Borelli a number of references that suggested a need for further research on lung cancer trends among non-smokers, noting that ''Attention could be given to the issues of personal smoking and environmental tobacco smoke''.[39] Myron Johnston, Research and Development, Philip Morris, was asked by Bob Pages, Director, Science and Technology, Philip Morris, to comment on the correspondence between Borelli and Enstrom and concluded that:

> [Enstrom] wrote a section of the 1983 Surgeon General's Report but now seems to have changed his mind on the smoking/mortality relationship. I say seems to have changed his mind because his writing is a little obtuse…[40]

Enstrom's section of the 1983 Surgeon General's Report concluded that smoking cessation decreases the risk of heart attack and coronary heart disease. However, the conclusion went on to suggest that other risk factors for heart disease, such as blood pressure and cholesterol levels, needed further study.[41]

Enstrom submitted a pre-proposal to CTR for a study entitled ''Mortality Trends Among Smokers and Non-smokers''. In September 1991, two of the three CTR Scientific Advisory Board executive committee reviewers recommended that Enstrom be encouraged to submit a formal application.[42]

In November 1991, a formal application was submitted to CTR[43] encouraged by the executive committee.[44] The project sought to investigate mortality trends from lung cancer, other smoking related causes, and all causes among smokers and non-smokers between 1966 and 1987 using data from the 1966–68 National Mortality Survey, 1986 National Mortality Survey, 1971–87 NHANES I Follow-up Study, and the American Cancer Society ''follow-up of the 118,000 California residents in the 1959 Cancer Prevention Study (CPS-I)''.[43] CTR funded the study for $34 500 for the first year of a three year project in 1992 and funding was renewed in 1993[45] and 1997[46 47] with a $25 000 supplement in 1997.[48]

Part of the data from the CPS-I portion of the analysis was published in *Epidemiology*, but CTR funding was not acknowledged in the published paper.[49] *Epidemiology* required authors to disclose their funding sources in a cover letter to the editor and the editor decides if these funding sources

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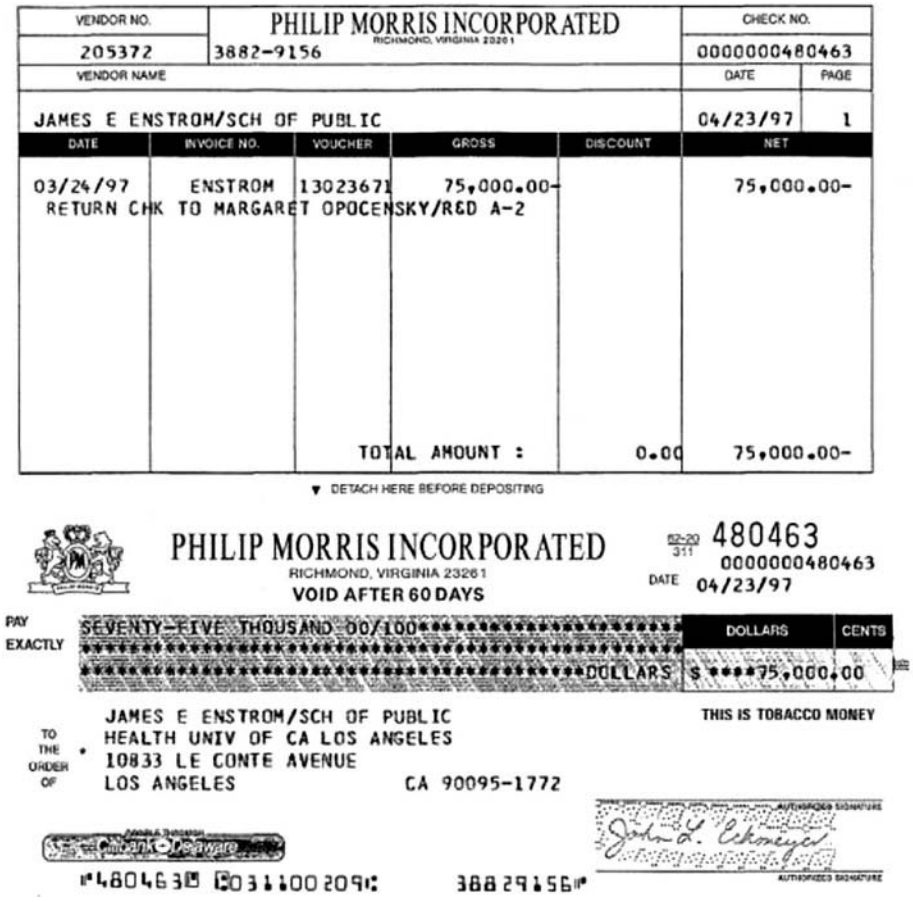
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Figure 1 One of two cheques from Philip Morris funding the project ''Relationship of low levels of active smoking to mortality'' which included an analysis of the CPS-I dataset. Bates No. 2063610868, April 23, 1997. Legacy title: Check No. 0000000480463. Organisation authors: PM, Philip Morris. Person author: Eckmeyer JL.[75]

should be published (www.epidem.com/pt/re/epidemiology/authorinfo.htm). Enstrom's cover letter is not available among the tobacco industry documents. Some of the data also are reported in the recent *BMJ* article by Enstrom and Kabat without acknowledging CTR funding (table 2). The analysis from the NHANES data was published with an acknowledgement of CTR funding.[50]

Reanalysis of Fontham article

In April 1996, Enstrom submitted to the *Journal of the American Medical Association* (*JAMA*)[51] a reanalysis of a major cohort study linking secondhand smoke and lung cancer published by Fontham and colleagues.[52 53] The paper disclosed that the reanalysis was ''supported in part by a special grant form the R.J. Reynolds Tobacco Company and Philip Morris''.[54] Enstrom's analysis was conducted for Womble and Carlyle, one of the industry's law firms.[64] Before Enstrom submitted the manuscript to *JAMA*, he circulated it for comment among tobacco industry law firms, executives, and INBIFO (a Philip Morris scientific laboratory in Germany).[56]

JAMA rejected the paper.[65] Although Enstrom's response to the peer reviewers' comments was circulated within the law firm Womble and Carlyle,[66] it is unclear whether the paper was resubmitted to *JAMA*. It was not published.

Strengthening the relationship with the tobacco industry

Relationship of low levels of active smoking to mortality

In January 1997, Enstrom submitted a research proposal to the Philip Morris Research Center,[67] where it was reviewed by the Scientific Research Review Committee (SRRC), a committee whose purpose was to ''ensure that all scientific research, related to tobacco or smoking, conducted or funded by Philip Morris, …serves relevant business needs''.[68] The proposal, ''Relationship of low levels of active smoking to mortality'', sought to analyse data from four epidemiological cohorts: 1980–94 US Veterans study, 1971–92 NHANES I, 1976–92 NHANES II, and 1960–94 CPS-I in California. The CPS-I analysis was an expansion of the analysis funded by CTR. In his cover letter to Richard Carchman, Director of Scientific Affairs, Philip Morris, Enstrom stated:

> These data are highly relevant to the ETS issue… A level of trust must be developed based on my past research on passive smoking and epidemiology in general in order to work out the best way for me to conduct this research. A substantial research commitment on your part is necessary in order for me to effectively compete against the large mountain of epidemiologic data and opinions that already exist regarding the health effects of ETS and active smoking.[69]

Despite his status as a faculty member, Enstrom noted that a relationship of ''mutual trust'' with the tobacco industry in the context of its funding of his proposed research would minimise university involvement in the project. The proposal stated: ''an unrestricted gift to James E. Enstrom / UCLA with mutual understanding/trust would minimize university restrictions and eliminate overhead costs.''[67] During January and February 1997, the proposal was reviewed by high level Philip Morris executives, lawyers and scientists who comprised the SRRC.[70 71] At this time, the SRRC consisted of R Carchman, R Cox, C Ellis, A Kassman, J Nelson, GM Nixon, H Reif, W Reininghaus, and R Walk.[72] Personnel at INBIFO

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commented that the amount of money requested seemed high when considering the amount of new scientific information that would likely be produced by the research, but stated that Enstrom ''seems to have good connections/resources which might be useful in the future for other issues''.[73]

Philip Morris funded the project in April 1997 for $150 000 to be paid in two instalments.[74–79] (fig 1)

Research on secondhand smoke

During the 1990s, Enstrom also began to seek funding from the CIAR. In May and June 1996, Enstrom submitted a pre-proposal to CIAR for research on secondhand smoke,[80 81] including the re-analysis of the Fontham study (subsequently funded by RJ Reynolds and Philip Morris, as described above), reanalysis of the Varela dissertation data, a new case–control study, and follow up of several cohort studies.[81] One of the proposed cohort studies was:

> Conduct analysis of California CPS I cohort (51,000 males and 67,000 females) from 1960–94 and conduct follow-up of CPS I from selected states where individualized computerized death records are available (up to 200,000 and 300,000 females). Analysis will examine spousal smoking and death from lung cancer, coronary heart disease, and all causes.[81]

A formal proposal was submitted to Max Eisenberg, director CIAR, on 15 July 1996. In his cover letter, Enstrom noted that the results of his past research were favourable to the industry:

> For the past three years I have done consulting and research on passive smoking for Jeffrey L. Furr of Womble Carlyle [law firm] on behalf of RJ Reynolds and Philip Morris. This research has found a number of results that raise serious questions about several published findings on the relationship of passive smoking to lung cancer and other diseases[64]

Enstrom's proposal was discussed at the meeting on 14 August 1996 of CIAR's board of directors (consisting of tobacco industry executives and lawyers), which agreed that Eisenberg would meet with Enstrom to discuss the proposal in more detail.[82 83]

Two sets of review comments on the 1996 Enstrom proposal were in the industry documents. One set, from INBIFO,[84] was critical of the proposal for its lack of a hypothesis and vague description of methods. The other review, probably from the CIAR board of directors,[85] was critical for similar reasons, as well as the fact that Enstrom once had acknowledged that secondhand smoke might be harmful. It noted:

> Engstrom [sic] says that ''[I]t is not possible to rule out a very weak relationship between passive smoking and mortality, especially for individual causes of death.'' How he reached a relationship for individuals when the statistics are not significant cannot be seen.[85]

The reviewer went on to recommend an entirely different study for Enstrom:

> In order to achieve something really new, CIAR could head for a pre-project which would check the protocols used for the above mentioned studies and put together the ''ideal protocol'' with all unthinkable adjustments for confounders and necessary investigations. This would give CIAR a ''model protocol'' which could then be used in order to create a ''gold standard'' against which other study protocols could be evaluated.[85]

We did not find any documents showing that this ''model protocol'' was developed.

At its meeting on 25–26 November 1996, the CIAR board of directors decided that Max Eisenberg (Director, CIAR), Richard Carchman (Vice President, Scientific Affairs, Philip Morris), and Charles Green (CIAR, Chairman of Board and Principal Scientist, Research and Development, RJ Reynolds)[86] would visit Enstrom at the University of California, Los Angeles. Enstrom's proposal was not funded at that time.

One result of the UCLA meeting was apparently to encourage Enstrom to collaborate with Geoffrey Kabat.[87 88] Enstrom and Kabat had no prior record of collaboration. A search of PubMed on 25 July 2003 revealed that their only joint publication was the article in *BMJ* in 2003.[1]

Kabat's ties with the tobacco industry

The documents provided no evidence that Kabat received any direct funding from the tobacco industry. Kabat had an ongoing indirect relationship with the tobacco industry since at least 1981, through Ernst Wynder, whose American Health Foundation had been funded by Philip Morris.[89] Two of the 21 papers Wynder and Kabat co-authored between 1981 and 1995 were related to passive smoking, concluding that there was no association of secondhand smoke with lung cancer.[90 91] He and Wynder published a review of secondhand smoke and lung cancer in a symposium proceeding[92] which concluded that further evaluation of secondhand smoke and lung cancer risk was necessary. Although the symposium had been organised by individuals who were affiliated with the industry, tobacco industry funding was not expressly acknowledged in the symposium publication.[92a,b,c 93]

In 1997 Kabat co-authored a paper with several members of the tobacco industry's secret International ETS Consultants Project[94] critical of the evidence linking secondhand smoke with lung cancer. The project was run by industry lawyers to recruit, train, and pay scientists who would advocate the industry's position.[11 95]

Receiving funding from CIAR

In September 1997, Carchman and Eisenberg had additional face-to-face meetings with Enstrom to discuss possible CIAR funding.[96–103] On 3 November 1997, Eisenberg recommended that Enstrom's revised proposal, ''Proposed research on passive smoking'', be considered under the Directed Studies Program which is controlled by high level industry executives.[104] The revised proposal only included the analysis of the CPS-I dataset.[105] The proposal stressed Enstrom's past relationship with the ACS, noting that he ''made use of this large and rich data base [CPS-I] with the cooperation of ACS''.[105] Although Enstrom listed former ACS Vice Presidents for Epidemiology Clark Heath and Lawrence Garfinkel as unpaid consultants in the proposal (and in the *BMJ* disclosure, table 2), the proposal in the industry documents did not include letters of support from them, as is usual with consultants. In addition, ACS had advised against the use of the CPS-I dataset for Enstrom's analysis.[6]

In a memo commenting on the Enstrom proposal in November 1997, Chris Coggins of Lorillard Tobacco recommended funding the proposal.[106] An (unsigned) internal industry critique of the final proposal raised many of the same concerns about the Enstrom study that were subsequently raised by ACS[6] and in the *BMJ* rapid responses

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(http://bmj.bmjjournals.com/cgi/eletters/326/7398/1057). For example,

> The proposal fails to distinguish between ''ETS exposure'' and ''living with a spouse who smokes,'' makes light of substantial loss-to-follow-up expected in this cohort [CPS-I], freely assumes adequate adjustment can be made for the non-representativeness of the initial cohort, underplays the import of smoking cessation on the analysis, and is uncritical of positions established by anti-smoking community.[107]

Despite these concerns, the critic was ''impressed'' with the listing of Heath and Garfinkel from ACS as consultants on the proposal, as well as Kabat.[107] The reviewer suggested that their participation ''should add credibility to the interpretation of the results''.[107]

On 19 November 1997 the CIAR board of directors voted to fund the Enstrom CPS-I proposal with modifications[108] for $525 000 from 1 June 1998 through 31 May 31 2001.[109]

Additional financial ties

Enstrom had numerous other financial ties with the industry. He was paid to prepare analyses of scientific documents for tobacco industry law firms and served as a peer reviewer for Philip Morris' external research programme.[110] In 1998, Bill Rickert, chair of the consulting firm Labstat, Inc, was asked by the Canadian government to convene an expert committee to examine and make recommendations concerning cigarette toxicity.[111] Carchman, of Philip Morris, recommended Enstrom and long time tobacco industry consultant Peter Lee to serve on this committee.[112] Enstrom was a presenter at a scientific meeting organised by the tobacco industry, a June 2000 epidemiology conference organised by Philip Morris at which he discussed CPS-I results.[113 114]

DISCUSSION

The published disclosure in the Enstrom and Kabat paper,[1] which meets the requirements established by *BMJ*, does not reveal the full extent of the relationship the authors had with the tobacco industry. Tobacco industry funding of research is associated with favourable outcomes for the industry.[115–117] Reasons for this observed association are complex and include sponsor involvement in the research questions asked, design, conduct, and publication of the study.[118] The Enstrom and Kabat paper is another example of how the content of even an extensive funding disclosure that meets the journal's requirements may not allow readers to understand fully the nature of the relationship between the authors and the research funder.[10 11 119] The history of Enstrom's contacts and collaborations with the tobacco industry illustrates several reasons why the industry funds scientific research. First, although industry insiders were critical of Enstrom's methods, they nonetheless funded the research to enhance the industry's credibility, particularly by touting an association with the American Cancer Society. Second, the industry funded Enstrom because it perceived that his connections might be useful in the future. Enstrom had contributed to a Surgeon General's report on smoking and some of his early work suggested that secondhand smoke might be associated with cancer. Funding Enstrom allowed the industry to work with a scientist to advance its goals, as it has with other scientists.[89] Third, funding Enstrom provided access for industry executives to seek to influence his research protocols by suggesting modifications. Lastly, funding Enstrom allowed the industry to connect him with other tobacco industry affiliated researchers, such as Kabat.

What this paper adds

Earlier studies of the health effects of secondhand smoke funded by the tobacco industry have failed to fully disclose the sponsor's role in the research. In addition to incomplete disclosures, industry sponsorship of research is often not entirely disclosed. Disclosure of financial ties can make reviewers more critical of manuscripts.

Comparing internal tobacco industry documents with a disclosure in a peer reviewed publication reveals that even an extensive financial disclosure statement that meets the journal's requirements can still provide an incomplete understanding of the tobacco industry's relationship with a project. The documents show how the tobacco industry funds research for multiple reasons, including gaining credibility or developing relationships with scientists that might be useful to the industry in the future. In addition to requiring financial disclosure, journals should require a statement in the Methods section of papers that clearly delineates the sponsor's role in designing, conducting, and reporting the results of a study.

The Enstrom and Kabat *BMJ* disclosure statement, when compared to the full extent of funding for the study as revealed in the internal industry documents, suggests that competing interest disclosures can be an inadequate mechanism for obtaining a complete understanding of the role of the sponsor in research. *BMJ*'s competing interest disclosure policy specifically asks authors to disclose only competing financial interests related to their article; the disclosure of any other competing interests is left to the judgment of the author. Although the *BMJ*, like many other journals, asks for disclosure of relevant financial ties within the last five years, a requirement with which *BMJ* found that Enstrom and Kabat had complied, it might be more informative for readers to know that an author has a long, steady history of funding from a particular sponsor. Thus, journals could ask for disclosures of financial ties over a longer period of time.

Our findings raise the question of what additional steps journals can take to obtain the most meaningful disclosures from authors. An elaborate policing operation is not feasible or necessarily desirable, but a simple search could provide additional information. At least if the paper in question relates to tobacco, *BMJ* and other journals could conduct a quick search of the tobacco industry documents for the names of authors of papers on tobacco. The documents are freely available on the internet at legacy.library.ucsf.edu and bat.library.ucsf.edu. The industry documents could identify more details of the relationship between researchers and the tobacco industry than required in a simple funding disclosure. Beyond the possibility of identifying undisclosed funding, such searches could provide a description of the tobacco industry's role in the design, conduct or dissemination of the research. As an alternative to conducting tobacco industry document searchers themselves, journals could seek a peer reviewer with tobacco industry document research experience. Journals should discuss how the tobacco industry documents can be used most effectively to improve and inform the peer review process.

Journals should be alert to disclosures of funding from tobacco industry supported research organisations such as CIAR or the more recently formed Philip Morris External Research Program. Journals could keep on file peer reviewed articles that have investigated these tobacco industry programmes. These articles would describe the involvement of tobacco industry lawyers and executives in selecting projects for funding.[38 120]

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Readers of the Enstrom and Kabat paper are likely to critique it more rigorously if they are aware of the authors' long standing relationship with the tobacco industry and lack of support from the ACS. A randomised experiment to test the effects of financial disclosures on readers' evaluations of scientific journal articles found that readers rated articles with financial tie disclosures as less interesting, important, relevant, valid, and believable than those without financial disclosures.[8] Requiring the disclosure of financial ties in all academic publications and presentations is frequently used as a way to manage financial conflicts of interest of researchers.[14 16 121] An increasing number of scientific and medical journals are instituting requirements of disclosure of financial ties by authors of articles in the journals. Although a number of journals were initially opposed to financial disclosure policies,[122] journal editors have begun to acknowledge that scientists might be influenced by financial interests and that disclosure is becoming the norm.[12 13]

In addition to reporting financial ties, it is also important to know what, if any, involvement the sponsor had in the design, conduct, and presentation of the research. One rapid response to the Enstrom and Kabat article suggested that it might be useful for editors to "require a statement about the role of the funding source in the design, conduct, analysis and reporting of the data".[9] We believe that journals should require such a description as part of the Methods section in the paper, as required by *Lancet* (http://www.thelancet.com/authorinfo).

The case of the Enstrom and Kabat paper also raises the issue of whether academic researchers should accept funding from the tobacco industry. A number of universities have adopted policies refusing tobacco industry funding for research.[123] These institutions have decided to stop the tobacco industry's long standing efforts to manipulate research while hiding behind the respect and credibility of the academic institutions.

FINANCIAL DISCLOSURE AND ACKNOWLEDGEMENTS

Dr Bero receives about $80 US per year in royalty fees for the publication of *The Cigarette Papers*, which contains sections on tobacco industry funding of research. Dr Bero has accepted honoraria from: (1) the University of Colorado for conducting workshops in evidence-based medicine; (2) the Friends Research Institute for a talk on financial conflicts of interest and clinical trials; (3) The Association of Medical Writer and Dartmouth University for talks on reporting of scientific research in the lay press; (4) the World Health Organization and Pomona University - European Union Center for talks on public commentary on the Framework Convention on Tobacco Control; (5) Kaiser Permanente for talks on evaluating the quality of research, and tobacco industry manipulation of research; and (6) the World Conference on Clinical Pharmacology and Therapeutics for a talk on managing financial conflicts of interest in clinical trials. None of these presentations were related to the topic of this paper. Ms Hong has never received royalties, honoraria or fees for any presentations or consulting related to the topic of this paper. Dr Glantz also receives royalties from publication of *The Cigarette Papers*. Dr Glantz has received honoraria from various health departments, non-governmental organisations, and academic institutions for making presentations on a variety of topics related to secondhand smoke and tobacco control.

Contributorship statement—L Bero conceived and designed the study, advised on the search, read and analysed documents, and drafted the paper. M Hong conducted the document search, read and analysed the documents, and revised the manuscript. S Glantz conceived and designed the study, advised on the search, read and analysed documents, and edited the paper. All three authors take responsibility for the content of the paper.

Research support—California Tobacco-Related Disease Research Program grant 9RT0193 and National Cancer Institute grant CA-87472.

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