

1084. As recently as 2000, the paper was cited by industry consultant Roger Jenkins. (no bates at 49) (JD-065013) (O); BR2000545-0785 at 0658 and 0670 (JD-065024) (A).

1085. As late as April 1998, Robertson and HBI continued to act on behalf of Defendants in connection with secondhand smoke and indoor air quality issues. 2072439561-9564 (US 41540) (A). Robertson, a small business ventilation duct inspector in Fairfax had become a worldwide spokesman for the industry's message on indoor air quality. TLT0860122-0129 (US 87341) (A).

(iv) The 2003 Enstrom/Kabat Study

1086. Defendants' efforts to generate industry-favorable ETS science to create a controversy and somehow transform the issue of whether ETS causes disease into an "open question" continued into 2003, when a CIAR-funded and managed study was published in the *British Medical Journal*. James Enstrom's May 2003 article, "Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-1998," concluded that the association between ETS exposure and lung cancer and CHD "may be considerably weaker than generally believed." (no bates) (JD-024496) (A).

1087. The Enstrom/Kabat study seemed like a coup for Defendants who not only touted the study publicly, but used it in this Court (1) to assert that the question of whether ETS causes disease is still an open one and (2) that Defendants' continued public statements disputing the scientific consensus were not fraudulent. Defendants Opening TT, 9/22/04, 0328:8-25; Bradley WD, 101:10-21.

1088. As shown below, the Enstrom/Kabat study is yet another self-serving, unreliable, and scientifically questionable product of the industry's unabated effort to attack the scientific consensus on passive smoking. Internal documents leading up to the funding decision by CIAR

suggest that Enstrom manipulated a data set that he and Defendants knew would produce an unreliable, yet favorable, result.

1089. At least two Enstrom proposals to perform statistical analyses on data from CPS I were sent to the Center for Indoor Air Research (CIAR) for funding in 1996 and 1997.

Enstrom's first proposal to CIAR was included under this cover letter dated July 15, 1996, to Max Eisenberg stating:

For the past three years I have done consulting and research for Jeffrey L. Furr of Womble Carlyle on behalf of R.J. 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.

2063610840-0841 at 0840 (US 85796) (A).

1090. Enstrom also stated in his July 15, 1996 letter to Eisenberg that his proposed CIAR research would "continue and expand upon" the research done for Womble Carlyle.

2063610840-0841 at 0840 (US 85796) (A).

1091. A June 25, 1996 Philip Morris e-mail from Marc Firestone to Richard Carchman stated that Enstrom did work for Philip Morris and Reynolds "in the context of the EPA litigation," and that one of his new proposals was "clearly litigation oriented" and should be "pursued, if at all, in the context of attorney work product." 2063610699-0699 (US 27128) (A).

1092. Thus, Enstrom had already proven his value to Defendants as a consultant to one of their law firms, and Defendants could reasonably expect that they were going to get more research and conclusions helpful to their position.

1093. The final proposal from Enstrom to CIAR is dated October 20, 1997 (see page 2), and resulted in funding of at least \$525,000 from Defendants through CIAR. 566943549-3579 at 3550 (US 85813) (A); 2505442777-2960 at 2815 (US 25643*) (A).

1094. The October 1997 Enstrom proposal was not prepared without Defendants' input. An earlier version of the proposal had already been sent to Philip Morris's secret overseas laboratory INBIFO for comments in October 1996. 250100107-0112 (US 92034) (A). The CIAR Scientific Advisory Board, the group held out by Defendants as the independent reviewers of research funded through CIAR, was left out completely. Max Eisenberg, the former and only executive director of CIAR, testified that he did not forward Enstrom's proposal to INBIFO, he had no idea how it got there, and he never even saw the comments from INBIFO. Eisenberg TT, 11/15/04, 5938:1-5939:9.

1095. The November 1996 minutes of the CIAR Board of Directors reveals that the Board discussed the Enstrom proposal, and that Philip Morris lead scientist Richard Carchman and Reynolds lead scientist Charles Green (two members of the CIAR Board) visited Enstrom at UCLA to discuss the proposal with him personally. 2063650515-0518 at 0515 (US 79212) (A).

1096. Enstrom wrote a January 15, 1997 letter following up on his proposal, not to CIAR or its SAB, but directly to Carchman at Philip Morris. He attached a protocol for a precursor to the study that was eventually published in 2003. This precursor study attempted to prove the hypothesis that there was a threshold dose for active smoking, below which there were no proven health effects. This would then undermine one of the rationales for biological plausibility for harm caused by passive exposure to tobacco smoke. This letter contains Enstrom's cryptic message making clear that he was prepared to do whatever was necessary to make his work favorable to the industry, as long as the tobacco companies were willing to pay for it. He wrote:

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.

2063654073-4073 (US 85811) (A) (emphasis added).

1097. According to the minutes of the May 15, 1997 CIAR Board of Directors meeting, CIAR played found a co-author collaborator for Enstrom, Geoffrey Kabat. Carchman, a member of the Board of Directors, attended the meeting. 517578187-8188 (US 85816) (A).

1098. By letter from Carchman dated April 25, 1997, Philip Morris agreed to fund a precursor study by Enstrom for \$150,000. 2063610867-0867 (US 85787) (A). That same year, Enstrom received funding from CTR, via a letter that proposed paying him an additional \$25,000 in addition to an ongoing CTR grant already in place. 40001769-1769 (US 85804*) (O).

1099. Defendants funded the Enstrom/Kabat project collectively through a 1998 contract with CIAR. The project was directly funded by the CIAR Board of Directors, all tobacco industry executives, as an Applied Project without any review by the CIAR Scientific Advisory Board. Defendants paid \$525,000 for the project through CIAR. 83205526-5581 at 5538 (US 92033) (A); Eisenberg TT, 11/9/04, 5630:22-5631:8; 2505442777-2960 (US 25643*) (A).

1100. Enstrom's relationship to the tobacco industry expressed itself in other ways. For example, Philip Morris paid Enstrom to make a presentation at a June 2000 conference in Richmond on the health impact on smokers and nonsmokers from changes in cigarette design and use. 2073736520-6520 (US 27396) (O); 2073736523-6523 (US 85795) (O).

1101. The Enstrom/Kabat paper was published under the title, "Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-98," and appeared in the May 2003 issue of the *British Medical Journal*. TKT0500029-0038 (US 65086) (A).

1102. As originally planned, the researchers conducted a study using only California CPS I data to ascertain rates of reported cases of coronary heart disease, lung cancer, and chronic obstructive pulmonary disease for study participants identified as "never smokers married to smokers." The study yielded the following results: Never smokers married to smokers had a relative risk of 0.94 for developing coronary heart disease; 0.75 for developing lung cancer. Thus, according to the study, the relative risk of developing coronary heart disease and lung cancer *decreased* for never smokers married to smokers. Based on these results, the researchers concluded that there is no significant association between passive smoking and tobacco-related diseases in never smokers married to smokers. TKT0500029-0038 (US 65086) (A).

1103. The Enstrom paper was published in 2003 after the American Cancer Society had repeatedly warned him that using its CPS-I data in the manner he was using it would lead to unreliable results. Enstrom only used a small subset of the overall data, and, more importantly, the data corresponded to participants who enrolled in 1959, a time when exposure to tobacco smoke was common. This is critical when comparing, as Defendants had Enstrom do, lung cancer and CHD in spouses married to smokers versus spouses married to non-smokers. If a spouse married to a non-smoker gets lung cancer, that lung cancer could very well have been the result of exposure to ETS (for example at the workplace or socially), but Enstrom's study would not detect this, and his relative risk number would be lowered by this omission. See also discussion of bias above at US FF § III.A(2)(b)(ii). Moreover, no data was collected on the smoking status of the spouses from 1972 to 1999 at all. Enstrom used the CPS-I data anyway. TLT0961621-1623 (US 86735) (O); (no bates at 502-503) (JD-024502) (A).

1104. The study was roundly criticized in the scientific community, including this statement from the members of the 2002 working group on involuntary smoking and cancer for

the International Agency for Research on Cancer (IARC):

Enstrom and Kabat's conclusions are not supported by the weak evidence they offer, and although the accompanying editorial alluded to "debate" and "controversy", we judge the issue to be resolved scientifically, even though the "debate" is cynically continued by the tobacco industry.

(no bates) (JD-024496) (A).

1105. Dr. Samet testified at trial that Enstrom's evidence was weak and that in any event, his conclusions were not supported by the evidence. Samet WD, 184:4-13; Samet TT, 9/30/04, 1245:18-1249:20.

1106. Defendants, of course, promoted the study. For example, BATCo even advertised the study on its website in October 2003, citing the report on its website in support of its position that "the claim that ETS exposure has been shown to be a cause of chronic disease is not supported by the science." BATCo stated that a "very large study published in the *British Medical Journal* in May 2003 on environmental tobacco smoke in the home has found no increases in risk for the key smoking related diseases." The website even provided a hyperlink to BAT's summary of the study:

In our view, this is an important study which confirms that many of the estimates of the risks of public smoking are overstated in the extreme, and that considerable doubts remain as to whether ETS exposure is associated with any risk of chronic diseases such as lung cancer and heart disease. **We believe the study illustrates that calls for bans on public smoking cannot be justified on the basis of the suggestion of chronic health risk for non-smokers,** although of course we believe that the needs of non-smokers should be also catered for with solutions such as good ventilation.

ARG0412302-2303 (US 86747) (O) (emphasis added); TLT1020487-0488 (US 88461) (O).

1107. Counsel for Defendants argued that the 2003 Enstrom paper was evidence that all of Defendants' statements denying the health effects of ETS were made in good faith:

And Your Honor, if it is fraud, as the government seems to maintain, to doubt the quantity and quality of evidence linking ETS to diseased non-smokers, the record will show that the defendants were in pretty good company. . . . In 2003, Your Honor, two scientists, Dr. James Enstrom and Dr. Geoffrey Kabat published a review article. They reviewed most of the literature on ETS. Their conclusion was, "It seems premature to conclude that ETS causes death from coronary heart disease and lung cancer."

Defendants Opening TT, 9/22/04, 0328:8-25.

1108. Defendants' statistician Edwin Bradley relied on the Enstrom paper in his written direct testimony submitted to this Court during Defendant' case-in-chief, in support of his opinion that bias and confounding explain the elevated observed risks in epidemiological studies finding an association between spousal smoking and lung cancer. Bradley WD, 100:36-101:21.

(I) The EPA Risk Assessment: A Case Study of Defendants' Use of Their ETS Products to Derail Public Health Conclusions

1109. On June 25, 1990, the EPA released for public comment its Risk Assessment of ETS-related lung cancer in adults. The Agency's draft risk assessment classified ETS as a Group A carcinogen and attributed approximately 3800 nonsmoker lung cancer deaths per year to ETS. 2046522986-3260 at 3002-3010 (JD-004716) (A). The June 1990 draft Risk Assessment followed the release of a draft "Compendium" of passive smoking data and information in November 1989.

1110. After a period of public review and comment, EPA issued its second draft of the ETS Risk Assessment or Review Draft in May 1992 entitled "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders. 2504201767-2298X (JD-004717) (A).

1111. The EPA published the final ETS Risk Assessment in December 1992. The EPA concluded: "ETS is a human lung carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers." TLT0780160-0684 at 0175, 0180 (US 78711) (A).