



OFFICE OF THE PROVOST AND EXECUTIVE VICE PRESIDENT –  
ACADEMIC AND HEALTH AFFAIRS

OFFICE OF THE PRESIDENT  
1111 Franklin Street, 12<sup>th</sup> Floor  
Oakland, California 94607-5200

October 16, 2007

Ms. Alisa B. Klein  
Civil Division, Appellate Staff  
U.S. Department of Justice  
950 Pennsylvania Avenue, NW  
Washington, DC 20530-0001

Re: *USA v. Philip Morris USA, Inc., et al.*, Civil Action No. 99cv02496(GK) (and Consolidated Cases)

Dear Ms. Klein:

I understand that Dr. James E. Enstrom, a UCLA faculty member, spoke to you in August and that you are helping prepare the Government's brief to be filed in the U.S. Court of Appeals for the District of Columbia Circuit in this case. I am writing to convey concerns that Dr. Enstrom has expressed regarding the description of his research in the District Court's Amended Final Opinion and how that research might be characterized in the Government's appeal brief.

Initially, you should be aware that earlier this year, then-Acting UCLA Chancellor Norm Abrams asked two senior campus officials, both scientists, to independently review criticisms that had been raised regarding a May 2003 article that Dr. Enstrom published in the *British Medical Journal* (BMJ) – the same paper that is addressed in the District Court's Opinion. Both officials independently concluded that there was no evidence of scientific misconduct on Dr. Enstrom's part. Instead, they concluded that the criticisms reflected the existence of a robust debate, of the sort that is common in the scientific literature, regarding the scientific methods used in that paper and scientific conclusions that Dr. Enstrom reached.

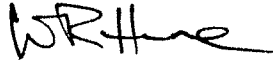
Dr. Enstrom is concerned because he is firm in the belief (which is supported by the University's examination of the matter) that he has done nothing inappropriate in the conduct of his research; because he was unable to defend himself during the trial; and because he believes that the District Court's Opinion has had a negative impact on his reputation." He contests many of the criticisms that have been made about his research in the Opinion and elsewhere. I am enclosing materials prepared by Dr. Enstrom that address statements made in the District Court's Opinion which he contends are in error. In addition, Dr. Enstrom has just published a 14,000 word peer-reviewed paper defending the validity of the 2003 BMJ paper and responding to statements made about it in the above case. See <http://www.epi-perspectives.com/content/4/1/11>.

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Given these circumstances, Dr. Enstrom requests that the Government make no reference to him or his research in its forthcoming brief.

I appreciate your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "WRHume".

Wyatt R. Hume  
Provost and Executive Vice President  
Academic and Health Affairs

Enclosures

cc: President Dynes  
Chancellor Block  
General Counsel Robinson  
University Counsel Patti  
Dr. James Enstrom

## Enstrom Response to Kessler Findings

**False or inaccurate statements about the May 17, 2003 *British Medical Journal* paper by Drs. James E. Enstrom and Geoffrey C. Kabat in the August 17, 2006 Final Opinion by Judge Gladys Kessler regarding USA v. Philip Morris (Civil Action No. 99cv2496 (GK)), primarily in Section III.G.6.b. “Defendants and Their Paid Consultants Controlled ETS Research Findings”** [<http://www.usdoj.gov/civil/cases/tobacco2/amended%20opinion.pdf>].

James E. Enstrom, Ph.D., M.P.H.  
University of California  
Los Angeles, CA 90095-1772  
October 15, 2007

### Kessler Finding (page 1295):

“3529. *CIAR Applied Projects was used by Defendants to fund studies that were previously approved by the TI-ETSAG, or Hoel Committee, and underway at the time of CIAR's formation in early 1988.* These studies included:

1. **James Enstrom (\$525,000);** this study examined the association between spousal smoking and lung cancer using CPS 1 data.”

### Enstrom Response:

I never had any dealings with CIAR [Center for Indoor Air Research] at the time of its formation in early 1988, never received any tobacco industry funding before 1992, and never received any funding from CIAR before 1998. It is false that the statement “*CIAR Applied Projects was used by Defendants to fund studies that were previously approved by the TI-ETSAG, or Hoel Committee, and underway at the time of CIAR's formation in early 1988.*” has any connection to my study.

### Kessler Finding (page 1364):

3731. *Several projects managed by Defendants as part of their worldwide ETS program illustrate the degree to which Defendants closely supervised and, when necessary, altered the research on the question of ETS and disease.* Four of these ETS projects -- the 1995 Japanese Spousal Study, the 1989 Malmfors/SAS paper, the 1992 HBI 585 Building Study, and the 2003 Enstrom/Kabat paper -- are described in detail below.”

### Enstrom Response:

The sentence “*Several projects managed by Defendants as part of their worldwide ETS program illustrate the degree to which Defendants closely supervised and, when necessary, altered the research on the question of ETS and disease.*” is false as it relates to “the 2003 Enstrom/Kabat paper.” This paper was never “managed” by the Defendants, as explained in my response to finding 3781 below. Furthermore, it is false that “Defendants closely supervised and, when necessary, altered the research on the question of ETS and disease” with regard to my paper. I independently conceived the entire ETS project and Geoffrey Kabat and I independently

conducted it and the Plaintiffs have produced no evidence to the contrary. The only role of the Defendants was to provide a portion of the funding of the study that lead to my paper.

Kessler Finding (page 1380):

**“(4) The 2003 Enstrom/Kabat Study**

3781. 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." *This study was CIAR-funded and managed* and was published in the British Medical Journal. (no bates) (JD 024496).”

Enstrom Response:

The statement “*This study was CIAR-funded and managed*” is false. The California (CA) CPS I study upon which my May 2003 article is based was conducted and funded by the American Cancer Society (ACS) during 1959-1990. The study has been conducted at UCLA since 1991 and was funded by the University of California Tobacco-Related Disease Research Program (TRDRP) during 1991-1997 and by CIAR during 1998-2003. Adjusting for inflation, the total funding for the entire 1959-2003 study was ~90% from ACS, ~5% from TRDRP, and ~5% from CIAR. The study was never “managed” by CIAR. Indeed, just before it was dissolved in 1999, CIAR gave its entire award to UCLA and I did not have to report to anyone about my study from 1999 until it was published in May 2003.

Kessler Finding (page 1382):

“3789. As originally planned, the researchers conducted a study using 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 and 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).

Enstrom Response:

This finding contains several inaccurate statements, all of which indicate that Judge Kessler did not correctly understand my May 2003 article. The sentence “As originally planned, the researchers conducted a study using 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.*" should read “As originally planned, the researchers conducted a study using California CPS I data to ascertain rates of reported *deaths from* coronary heart disease, lung cancer, and chronic obstructive pulmonary disease for study participants identified as "*35,561 never smokers who had a spouse in the study with known smoking habits.*” The sentence “*The study yielded the following results: never smokers married to smokers had a relative risk of 0.94 for developing coronary heart disease*

and 0.75 for developing lung cancer.” should read “*Results: For participants followed from 1960 until 1998 the age adjusted relative risk (95% confidence interval) for never smokers married to ever smokers compared with never smokers married to never smokers was 0.94 (0.85 to 1.05) for coronary heart disease, 0.75 (0.42 to 1.35) for lung cancer, and 1.27 (0.78 to 2.08) for chronic obstructive pulmonary disease among 9619 men, and 1.01 (0.94 to 1.08), 0.99 (0.72 to 1.37), and 1.13 (0.80 to 1.58), respectively, among 25,942 women.*” The sentence “*Thus, according to the study, the relative risk of developing coronary heart disease and lung cancer decreased for never smokers married to smokers.*” should read “*Conclusions: The results do not support a causal relation between environmental tobacco smoke and tobacco related mortality, although they do not rule out a small effect. The association between exposure to environmental tobacco smoke and coronary heart disease and lung cancer may be considerably weaker than generally believed.*”

Kessler Finding (page 1382):

“3790. When the Enstrom/Kabat paper was published in the May 2003 issue of the British Medical Journal, *it was roundly criticized in the scientific community.* Members of the 2002 working group on involuntary smoking and cancer for the International Agency for Research on Cancer (IARC) made the following statement:

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). *The American Cancer Society had repeatedly warned Enstrom that using its CPS-I data in the manner he was using it would lead to unreliable results.* Enstrom used only 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. TL0961621-1623 (US 86735); (no bates at 502-503) (JD 024502).”

Enstrom Response:

Regarding my study, the statement “*it was roundly criticized in the scientific community*” is inaccurate. The criticism of my study has come from only a select portion of the scientific community and no errors have been identified in my paper. Furthermore, the critics have largely been persons who strongly dislike my findings and who have competing interests that might influence their criticism. For instance, one prominent signer of the 2002 IARC working group statement above was Jonathan M. Samet, a key Plaintiff witness upon whom Judge Kessler relied heavily to conclude that “*exposure to secondhand smoke causes lung cancer and coronary heart disease in adults . . .*” (see page 1234). Samet has a serious competing interest because he receives substantial funding from FAMRI [[www.famri.org](http://www.famri.org)], an organization which assumes that these diseases are “*caused from exposure to tobacco smoke.*” The statement “*The American Cancer Society had repeatedly warned Enstrom that using its CPS-I data in the manner he was using it would lead to unreliable results.*” is false and unsupported by actual evidence.

Additional background on and response to the Kessler Final Opinion can be found in this paper: James E. Enstrom, “**Defending legitimate epidemiologic research: combating Lysenko pseudoscience**” [<http://www.epi-perspectives.com/content/4/1/11>] (October 10, 2007).

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OFFICE OF THE PROVOST AND EXECUTIVE VICE PRESIDENT –  
ACADEMIC AND HEALTH AFFAIRS

OFFICE OF THE PRESIDENT  
1111 Franklin Street, 12<sup>th</sup> Floor  
Oakland, California 94607-5200

March 22, 2007

John R. Seffrin, PhD  
Chief Executive Officer  
American Cancer Society  
1599 Clifton Road, NE  
Atlanta, GA 30329

Dear Dr. Seffrin:

I am writing to follow up on the January 24, 2007 letter from Dr. Michael J. Thun of your office, who responded on your behalf to my letter of January 19, 2007, asking that you send me any specific information you have supporting an allegation of scientific misconduct against UCLA researcher Dr. James Enstrom. As you know, my request was in response to your October 12, 2006 letter to the Regents about tobacco industry funding for academic research, in which you expressed concerns about specific research conducted by Dr. Enstrom.

I forwarded Dr. Thun's letter and all of its attachments to UCLA Acting Chancellor Norm Abrams, who is responsible for ensuring appropriate handling of allegations of scientific misconduct on the UCLA campus. Chancellor Abrams initiated a thorough review of the materials forwarded by Dr. Thun. He asked two senior campus officials, both of them scientists, to independently review the materials. Both officials independently reached the conclusion that these materials provide no evidence of scientific misconduct.

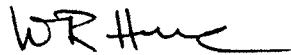
The materials Dr. Thun provided reflect the robust debate in the scientific literature about the research methodologies used by Dr. Enstrom in conducting the work that was the basis for his 2003 article published in the British Medical Journal. Disagreements regarding research methodology, and disputes about the soundness of scientific conclusions do not, however, constitute scientific misconduct. There is room for vehement and heartfelt disagreement about the soundness of particular scientific analysis and conclusions, and the scientific and academic community has well-established mechanisms for judging which results are ultimately deemed to withstand close and sustained scientific scrutiny. Indeed, the material Dr. Thun provided regarding the published criticisms and defenses of Dr. Enstrom's work is one example of how research can be refuted (or upheld) in open peer-reviewed scientific literature.

The University of California takes allegations of scientific misconduct seriously. I appreciate your sharing your concerns with me. I am satisfied that Chancellor Abrams conducted a careful and thorough review of the materials that were the basis of your concerns, and I support his conclusion that there is no basis for initiating a formal inquiry or investigation of scientific misconduct against Dr. Enstrom.

Dr. John R. Seffrin  
March 22, 2007  
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Please feel free to contact me if you have further questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "WR Hume", with a long horizontal flourish extending to the right.

Wyatt R. Hume  
Provost and Executive Vice President  
Academic and Health Affairs

cc: Regent Blum  
President Dynes  
Chancellor Abrams  
Academic Council Chair Oakley  
General Counsel Robinson  
University Auditor Reed