

Evidence Questioning the Fitness of Dr. Stanton A. Glantz to Serve as
a Member of the Scientific Review Panel on Toxic Air Contaminants
of the California Air Resources Board

James E. Enstrom, Ph.D., M.P.H.
University of California
Box 951772
Los Angeles, CA 90095-1772
jenstrom@ucla.edu

June 13, 2005

Background

I am making this submission because I have substantial evidence that questions the fitness of Dr. Stanton A. Glantz (Glantz) to serve as a member of the Scientific Review Panel (SRP) on Toxic Air Contaminants. During the past two years he has engaged in an unprofessional attack on me and my epidemiologic research. This attack bears directly on his ability to objectively evaluate and judge the CARB report on environmental tobacco smoke (ETS). Three events have occurred since March 8, 2005 that are so egregious that I request that this matter be dealt with by the SRP before any decision is made about the ETS report. In the interest of brevity, I have limited this submission to eight pages of text, which includes web links to several important documents. Wherever possible, I have used links to documents from the UCSF Legacy Tobacco Documents Library (<http://legacy.library.ucsf.edu>). Some of the links require journal subscriptions, but most of these links are accessible via connection with the UC library system.

This submission involves the very fundamental issues of academic freedom, scientific integrity, and professional conduct. These issues have gotten the attention of high officials at both the University of California and the National Institutes of Health. Some aspects are discussed in the February 2005 *Nature Medicine*, where Dr. Lawrence B. Coleman, Vice Provost for Research at the University of California, stated “Academic freedom has to be absolute or no one has it” (<http://www.nature.com/nm/journal/v11/n2/pdf/nm0205-106a.pdf>) and in the March 2005 *Nature Medicine*, where NIH Director Elias Zerhouni “has called for an 'ethics summit,' and rules for scientists at outside institutions receiving NIH grants could be heavily scrutinized.” (<http://www.nature.com/nm/journal/v11/n3/pdf/nm0305-235.pdf>).

I would like to begin with a few brief sentences about my background in order to assure you that I am a serious scientist with an important message. I have a Ph.D. from Stanford University, awarded in 1970, and my dissertation advisor is a Nobel Laureate. Also, I have postdoctoral certification in cancer epidemiology and a M.P.H. in epidemiology from UCLA, awarded in 1975 and 1976. Since 1976 I have been on the research faculty at UCLA. I have had a long and successful career as an epidemiologist. I am a Fellow of the American College of Epidemiology and I am listed in *Who's Who in America* in recognition of my epidemiologic research.

During the first 33 years of my professional career no one ever once questioned my honesty or integrity as a scientist. However, that situation changed dramatically in May 2003 when I and my co-author, Dr. Geoffrey C. Kabat, published a paper in the May 17, 2003 British Medical Journal (*BMJ*), “Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-98” (<http://bmj.com/cgi/reprint/326/7398/1057.pdf>), henceforth referred to as “my *BMJ* paper” or “my *BMJ* study.” This paper describes the largest and most detailed epidemiologic study on environmental tobacco smoke (ETS) and tobacco-related mortality ever published in a major medical journal and the second largest study ever published in terms of its statistical power. This study found no relationship between ETS and tobacco-related mortality and instantly became very controversial, as described in the following May 18, 2003 Sunday Telegraph (London) newspaper article:

<http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2003/05/18/nsmoke18.xml>.

Since May 15, 2003 many false and misleading charges have been made against me and my research, primarily because the study was partially funded by the tobacco industry. These charges have damaged my professional reputation and my ability to publish in several journals that are now aware of the unjustified controversy surrounding me. However, in the two years since its publication, no errors have been identified in my *BMJ* paper, the alleged flaws in the study have not been substantiated with any actual evidence, and the *BMJ* editor has strongly defended his decision to publish the paper (<http://bmj.com/cgi/reprint/327/7413/501>).

As evidence that Glantz has engaged in an unprofessional, two-year campaign to discredit me and my research, I document below the initial aspect of his attack, plus the three egregious aspects that have occurred since March 8, 2005. These represent only a portion of his full attack.

Aspect 1) Early Statements by Glantz Meant to Discredit Me and My Research

On May 15, 2003, Glantz participated in a Miami press conference of “international experts” assembled to “debunk” my study before he could have possibly read it in any detail. These “experts” falsely claimed the paper said “Marry a smoker, get less cancer” and falsely claimed it was a “tobacco industry study” (<http://www.no-smoking.org/may03/05-15-03-4.html>). It is not clear how these “experts” learned of the study, but they apparently violated the press embargo on the paper, which lasted until 12:01 AM May 16, 2003 UK time (or 7:01 PM May 15, 2003 Miami time). Glantz could not possibly have read the full version of the *BMJ* paper, which was first posted on bmj.com at this same time.

On May 16, 2003 Glantz told the San Francisco Chronicle: “. . . that because secondhand smoke was so common in the early years of the study, UCLA's research was fatally flawed and could only produce the kind of result the tobacco industry wanted. . . . the British Medical Journal report was a textbook case of why UC researchers should not be allowed to accept funding from the tobacco industry. . . . It is an embarrassment that this came out of UCLA. . . .” (<http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2003/05/16/MN259820.DTL>).

On May 24, 2003 Glantz co-wrote a Rapid Response (electronic letter) to bmj.com entitled “Misleading the public about secondhand smoke . . . again.” He stated “Enstrom and Kabat’s study is the latest in a long string of studies supported by the tobacco industry to deny the

evidence about secondhand smoke and confuse the public. . . . The Enstrom and Kabat study may be another example of the financial disclosure not fully describing the extent of involvement of the tobacco industry in the design, conduct and dissemination of the study. . . . By publishing Enstrom and Kabat's paper, the *BMJ* has helped the tobacco industry mislead the public about the harmful effects of secondhand smoke exposure. Only a retraction could stem some of the damages to public health goals that have already been inflicted by this paper.”
(<http://bmj.bmjournals.com/cgi/eletters/326/7398/1057#32596>)

On June 20, 2003 the following comments involving Glantz and my *BMJ* study were made during the SRP meeting of that day, as taken directly from pages 85 and 86 of the meeting transcript (<http://www.arb.ca.gov/srp/030620.pdf>):

PETERS SHORTHAND REPORTING CORPORATION (916) 362-2345 85
25 CHAIRPERSON FROINES: As a member of the UCLA
1 School of Public Health, I apologize.
2 (Laughter.)
3 PANEL MEMBER GLANTZ: You should.
4 (Laughter.)
5 PANEL MEMBER GLANTZ: We're doing a study of how
6 that paper came to pass. And it's going to get even more
7 unpleasant.
8 CHAIRPERSON FROINES: James Enstrom's paper --
9 PANEL MEMBER GLANTZ: -- that dreamt up by
10 Phillip Morris.
11 CHAIRPERSON FROINES: Go ahead.
12 PANEL MEMBER HAMMOND: How smoking doesn't cause
13 any lung cancer.

On June 23, 2003 Glantz told UPI ". . . . As far as I know, there's no legitimate scientist in the world who doesn't think secondhand smoke causes lung cancer and heart disease. There are a number of people paid by cigarette companies to say that it doesn't. . . . I think it is shameful the British Medical Journal published that study. . . ."
(<http://www.hawaiireporter.com/story.aspx?e3a73f3e-4104-43ba-8ece-a7169b47149c>).

These are all libelous statements that are either false or highly misleading, as I will explain below. They are not befitting a member of a scientific review panel that is charged with objectively evaluating a CARB report on ETS, much of which involves epidemiologic evidence on ETS and tobacco-related mortality. Furthermore, I have learned that Glantz's statements are part of a larger campaign to "silence science" regarding my *BMJ* paper, as documented in the 19-page 2005 paper by two sociologists, Drs. Sheldon Ungar and Dennis Bray, entitled "Silencing science: partisanship and the career of a publication disputing the dangers of secondhand smoke" (<http://pus.sagepub.com/cgi/reprint/14/1/5>). Ungar and Bray described in detail the "efforts to prevent the making of specific scientific claims in any or all of the arenas in which these claims are typically reported or circulated" as they related to my *BMJ* paper.

Aspect 2) March 8, 2005 KQED Radio *Forum*

On Tuesday, March 8, 2005 at 9:00 AM Glantz participated in the San Francisco based KQED Radio *Forum* (<http://www.kqed.org/epArchive/R503080900>). The topic was "**Funders and Academic Research: *Forum*** assesses the controversy surrounding the relationship between

fundings and academic research.” The host was Michael Krasny and the primary participants, in addition to Glantz, were Dr. Max Neiman, Chair of the system-wide University of California Committee on Research Policy, and Dr. Michael Kleinman, Adjunct Professor of Community and Environmental Medicine at UC Irvine. This program can be listened to in its entirety by clicking on the above link.

The program initially discusses Glantz’s attempt to have the California Attorney General’s Office launch a criminal investigation into an epidemiologic review article on ETS and SIDS written by Dr. Frank M. Sullivan, a retired Professor from University of London, who has had a long and distinguished career as a toxicologist in England. During this 52 minute program, the discussion of the “scandal” about me and my *BMJ* study occurred during the following time period (minutes:seconds): 16:57-19:15.

Four examples of libelous statements against me by Glantz, and the exact time at which they begin, are given below.

At 17:20 Glantz says the *BMJ* study “was not funded by the American Cancer Society” but by “Philip Morris.” Actually, the inflation-adjusted funding for the study, which began in 1959 and was published in 2003, came from the three primary sources: ~90% ACS, ~5% TRDRP, and ~5% CIAR (the ‘tobacco money’ portion). NO Philip Morris money was used for this study. Glantz, who could not precisely know the 44 year funding history of the study, simply made false statements about the funding of my study.

At 17:50 Glantz says I am “a damn fool” who was told by ACS that I “made inappropriate use of the data.” My use of ACS data began in 1991 and I had the full cooperation of and long standing working relationships with Lawrence Garfinkel and Dr. Clark W. Heath, Jr., now retired ACS Vice Presidents for Epidemiology. I have been conducting important long-term epidemiologic research with the California portion of the CPS I cohort. My dealings with ACS epidemiologists date back to 1978, when I received all my research funding from ACS. I am the ONLY investigator outside of ACS who has ever been allowed to follow ACS subjects. This access was granted largely because of the high quality of my ACS-funded epidemiologic research, begun in 1973. The ACS epidemiologists that I worked with realized the great potential value of long-term follow-up of the CPS I cohort and they would not have given important confidential data to “a damn fool.” Only in May 2003, when the *BMJ* paper was published, did the ACS (most specifically, Dr. Michael J. Thun) complain about my use of their data. I worked with Clark Heath on this study until 2001, when he was no longer able to continue because of his retirement. Heath was a co-author on the first version of the study that was submitted to and given serious consideration by the *New England Journal of Medicine*. I never worked with Thun on this study.

At 18:10 Glantz implies that I am “advocating a pro-tobacco position.” I am a lifelong nonsmoker and have never advocated a pro-tobacco position in my entire 35-year career or in my entire life for that matter. As evidence I am not “pro-tobacco,” I have spent much of my career documenting the health benefits of being a nonsmoker, as can be seen by reading my publications on Mormons, which date back to 1975 (<http://legacy.library.ucsf.edu/tid/gei79c00>). In 1999 I published two papers indicating active smoking may be more dangerous than generally

believed because its impact on mortality was less reversible by cessation than generally believed (<http://legacy.library.ucsf.edu/tid/tbf19c00> and <http://legacy.library.ucsf.edu/tid/wve19c00>). My findings regarding lung cancer and smoking cessation were largely confirmed in a Mayo Clinic study of Iowa women published the May 2003 *Journal of Clinical Oncology* (<http://www.jco.org/cgi/reprint/21/5/921>).

At 18:39 Glantz states “the science that the UCLA study did was crap.” My study is the largest and most detailed epidemiologic study on secondhand smoke and mortality ever published in a major medical journal. It is by far the largest study on Californians. The paper was peer reviewed by two of the world’s leading epidemiologists, Drs. Kenneth Rothman and George Davey-Smith. Rothman is the author of several major textbooks on epidemiology and founding editor of *Epidemiology* and Davey-Smith is co-editor of *International Journal of Epidemiology*. In the interest of transparency, the *BMJ* took the unusual step of posting the entire prepublication history of the paper online (<http://bmj.bmjournals.com/cgi/content/full/326/7398/1057/DC1>).

There might be some logic to Glantz’s attack if he had found a single error in my *BMJ* paper or had proved that the paper was “fatally flawed” because everyone alive in 1959 was equally exposed to ETS. But he has done neither of these things. In my August 30, 2003 *BMJ* letter I clarified the findings of my 1999 follow-up survey, which clearly showed that 1959 spousal smoking history was a valid measure of relative ETS exposure, particularly for females (<http://bmj.bmjournals.com/cgi/content/full/327/7413/504>). Also, I have evidence from three other independent surveys that spousal smoking status is a valid indicator of relative ETS exposure for subjects alive in the 1950s. Keep in mind, all subjects in the other US cohort studies were alive in 1959 and these studies are not considered to be “fatally flawed” by Glantz.

Aspect 3) Glantz’s April 2005 *Tobacco Control* paper

Glantz, along with Dr. Lisa A. Bero and M.-K. Hong, published a 9-page paper in the April 2005 issue of *Tobacco Control (TC)*, entitled “The limits of competing interest disclosures.” It is now posted on the following UCSF web site: <http://www.tobaccoscam.ucsf.edu/pdf/Enstrom-TC.pdf>. This paper questions the veracity of the following 200+ word competing interest disclosure statement made at the end of my *BMJ* paper: “Funding: The American Cancer Society initiated CPS I in 1959, conducted follow up until 1972, and has maintained the original database. 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 (www.ucop.edu/srphome/trdrp). 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 received funding primarily from US tobacco companies. Competing interests: 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. 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. 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.”

Any doubts that a reasonable person might have had regarding our competing interest disclosures were addressed in my August 30, 2003 *BMJ* letter: “We want to make clear that the tobacco industry

played no part in our paper other than providing the final portion of the funding. The tobacco industry never saw any version of our paper before it was published, never attempted to influence the writing of the paper in any way, and did not even know the paper was being published until it became public. In addition, we have never testified on behalf of the tobacco industry, never owned any stock in the tobacco industry, never been employees of the tobacco industry, and would never have accepted tobacco industry funds if there had been any other way to conduct this study.” (<http://bmj.bmjournals.com/cgi/content/full/327/7413/504>).

In spite of our clear and unequivocal statement above, Glantz still went ahead and published a paper that completely mischaracterized the relationships that Dr. Kabat and I have had with the tobacco industry. This paper is simply an *ad hominem* attack designed to impugn our scientific integrity and damage our professional reputations. It is clearly libelous by the common definition of libel, “a written or oral defamatory statement or representation that conveys an unjustly unfavorable impression” (*Webster’s New Collegiate Dictionary*). In fact, I believe it contains the greatest amount of malicious libel ever published in a single peer-reviewed paper.

One particularly reprehensible example of the libel is Table 1, which shows “Financial ties between Enstrom, Kabat, and the tobacco industry” dating back to 1975. Although I actually had no “financial ties” of any kind with the tobacco industry before July 1, 1992, Glantz listed six alleged ties under “Enstrom” in Table 1 that were dated before 1992. To illustrate the maliciousness of his libel, I will discuss his first entry in detail.

As my first alleged “financial tie,” Glantz cited my 1975 correspondence with the Council for Tobacco Research (CTR), a research organization funded by the tobacco industry, regarding proposed epidemiologic research on Mormons (*TC* references 23-25). However, Glantz failed to mention that the actual December 1975 grant application to CTR was submitted by Dr. Lester Breslow, then Dean and Professor at the UCLA School of Public Health (<http://legacy.library.ucsf.edu/tid/bei79c00>). Breslow, a world-renowned public health authority, was my mentor and the principal investigator on several grant applications that we submitted to potential funding agencies. Next, Glantz failed to cite Breslow’s July 6, 1976 letter withdrawing the CTR application once we had received funding for this Mormon research from the ACS (<http://legacy.library.ucsf.edu/tid/sei79c00>). Then, Glantz failed to mention my 1978 *CANCER* publication on cancer mortality among active Mormons (<http://legacy.library.ucsf.edu/tid/msd3aa00>), which acknowledged on the first page the funding received from the ACS (Grant PDT-51).

Finally, Glantz failed to mention that Mormons are a religious group that advocates ABSTENTION from tobacco and that I was (and still am) studying them because their unusually low cancer rates offer an excellent opportunity to better understand etiologic factors associated with the prevention of cancer. If Glantz had any interest in fairly and accurately portraying me and my epidemiologic research interests during the past 30 years he would have cited my initial findings on Mormons that appeared on the front page of the Washington Post on November 18, 1974 (<http://legacy.library.ucsf.edu/tid/liw1aa00>). This one example related to one line in Table 1 of his *TC* paper indicates how he has selectively used tobacco industry documents in order to deliberately distort my career and my relationship with the tobacco industry. On its surface the *TC* paper purports to provide evidence of the inadequacy of the *BMJ*’s requirements concerning competing interest disclosures. However, beneath this veneer, the paper’s true objective is to

smear the reputations of two honest scientists who had the temerity to publish an influential paper reporting results which run counter to Glantz's firmly held beliefs.

In comparison with our 107-word *BMJ* funding statement shown above, please note Glantz's 15-word *TC* funding statement: "Research support – California Tobacco-Related Disease Research Program grant 9RT0193 and National Cancer Institute grant CA-87472." Missing from this brief statement is any clarification that NCI Grant 5R01CA087472 is a multi-million dollar NIH grant awarded to Glantz for "Analysis of Tobacco Industry Documents." It is part of a large NCI program on "Review and Analysis of Tobacco Industry Documents"

(http://cancercontrol.cancer.gov/tcrb/grant_doc.asp). Thus, Glantz has a direct financial interest in writing a paper designed to justify his examination and analysis of tobacco industry documents. Furthermore, Glantz has failed to follow the NIH regulation requiring that the following disclosure statement be included in NIH-funded papers: "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [NCI]." (http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm).

Regarding the *TC* paper, I believe that NIH funds have been inappropriately used for the writing of a paper that contains malicious libel and that has no direct connection to the mission of NIH. I find it particularly offensive that American taxpayers like myself, who expect NIH funds to be spent on finding ways to cure and prevent diseases, have to pay for the assassination of their own character. I have been able to get the attention of NIH Director Elias Zerhouni on this matter.

Aspect 4) Glantz's May 24, 2005 *Circulation* special report on ETS

Glantz has just published a 15-page special report in the May 24, 2005 issue of *Circulation*, entitled "Cardiovascular Effects of Secondhand Smoke: Nearly as Large as Smoking" (<http://circ.ahajournals.org/cgi/reprint/111/20/2684>). Glantz found "The pooled relative risk computed with a random-effects model (computed with Stata Version 7) was 1.31 (95% CI, 1.21 to 1.41), similar to the estimates of earlier meta-analyses." However, he omitted the two largest studies from his analysis relating ETS and coronary heart disease (CHD). The largest study, published in 1995 by Drs. Maurice LeVois and Maxwell Layard (<http://legacy.library.ucsf.edu/tid/sph32d00>), was omitted without comment and was not even cited. The second largest study (my 2003 *BMJ* study) was omitted with the claim that had "serious misclassification bias." Based on their statistical weight, these two studies represent about 75% of the US evidence and 65% of the world-wide evidence. Yet Glantz dismissed them without any evidence that they differ in any material way from the other US cohort studies. All these studies examined never smokers classified by the smoking status of their spouse and the subjects in all these studies were alive as of 1959. Inclusion of these two studies would reduce the pooled relative risk to about 1.05. And there is no dose-response relationship as a function of spousal smoking level. Contrary to the title of Glantz's report, the effect of ETS is much smaller than the effect of active smoking on cardiovascular mortality.

A fair evaluation of all published epidemiologic evidence on ETS and CHD shows there is a great difference between the US evidence, where the relative risk is about 1.05 depending on how the exposure categories are compared, and the non-US evidence, where the relative risk is

about 1.4-1.5 depending on how the studies are combined. It is not clear why the difference is so large, but most of the US evidence is based on cohort studies, whereas most of the non-US evidence is based on case-control studies. The distinction between the US and non-US evidence deserves proper explanation. If Glantz cannot objectively evaluate all studies in his own new review of ETS, then how can he objectively evaluate the evidence on ETS in the CARB report?

Conclusions

Epidemiology is replete with examples where the evidence on associations changes over time. Just consider the recent controversy about obesity discussed in the April 20, 2005 *JAMA* (<http://jama.ama-assn.org/cgi/reprint/293/11/1861.pdf>). Two groups of investigators from CDC have come to vastly different conclusions about the number of deaths attributable to obesity, but their differences have been dealt with professionally. The controversy about the health effects of ETS and the various epidemiologic studies on this subject should be handled the same way. The unprofessional tactics used by Glantz against honest scientists like me and Dr. Kabat should not be tolerated by the SRP. Given all the evidence presented above, it should be clear that Glantz is not objective on the subject of ETS. Thus, I feel he should be removed as a member of the SRP.

Finally, I request the opportunity to meet with at least one member of the SRP (other than Glantz) shortly before or after the SRP holds its June 24, 2005 meeting at UCLA. I would like to present additional evidence, not discussed above, that I feel is of great importance to the CARB report on ETS. This evidence may more fully explain why Glantz has been conducting a two-year campaign designed to discredit me and my research. This evidence will contribute to more accurately describing the health effects of ETS in California and to improving the quality of the CARB report on ETS.