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# NIOSH

## Posthearing Brief to DOL

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POSTHEARING BRIEF OF THE  
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
ON THE  
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION  
PROPOSED RULE ON INDOOR AIR QUALITY

29 CFR Parts 1910, 1915, 1926, 1928  
Docket No. H-122

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

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| 15. Supplementary Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                  |                                                |                              |  |  |
| <p>16. Abstract (Limit: 200 words) This posthearing brief contained a summary of the results of the largest study to date of 353,180 female and 126,500 male never smokers enrolled in 1982 in the American Cancer Society's Cancer Prevention Study-II. Ten percent of married men, and 28% of married women were married to currently smoking spouses. There was a 22% higher coronary heart disease (CHD) mortality among never smoking men married to currently smoking women compared to those married to wives who had never smoked, after controlling for cardiovascular risk factors. Never smokers living with former smokers showed no increased risk. However, a different analysis of the data indicated that there was no increased CHD risk for those exposed to ETS from a spouse. Data from an additional study of heart disease connected to lung cancer and spousal smoking was also reviewed, and the selection criteria were called into question. The selection strategy for controls resulted in controls who were less likely than cases to die of any chronic diseases. Also of concern was the quality of data available on decedent's smoking status and on ETS exposure in this study. NIOSH recommends that little weight or no weight at all be given to analyses of spousal smoking and ETS exposure based on this study.</p> |                                  |                                                |                              |  |  |
| 17. Document Analysis a. Descriptors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                  |                                                |                              |  |  |
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| c. COSATI Field/Group                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                  |                                                |                              |  |  |
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The following posthearing brief is submitted by the National Institute for Occupational Safety and Health (NIOSH) in response to the Occupational Safety and Health Administration (OSHA) proposed rule on indoor air quality.

## **ENVIRONMENTAL TOBACCO SMOKE (ETS) AND HEART DISEASE**

- 1) A NIOSH investigator has recently collaborated with American Cancer Society investigators to study environmental tobacco smoke (ETS) and coronary heart disease (CHD) among never-smokers. This is the largest study to date, a prospective study of 353,180 female and 126,500 male never-smokers enrolled in 1982 in the American Cancer Society's (ACS) Cancer Prevention Study-II (CPS-II) and followed through 1989. It has been submitted for publication. A summary of results are presented here. Analyses focused on sub-cohorts of 309,599 married pairs and of 135,237 subjects concordant for self-reported exposure and exposure reported by their spouse. Over 2,800 CHD deaths (ICD 410-414) occurred among married pairs; 10% of married men and 28% of married women were married to currently smoking spouses, while 10% and 32%, respectively, were married to former smokers. After controlling for many cardiovascular risk factors, investigators found 22% higher CHD mortality (rate ratio=1.22, 95% CI 1.07-1.40) among never-smoking men married to currently smoking wives compared to those married to wives who had never smoked. The corresponding rate ratio for women was 1.10 (0.96-1.27). Never-smokers living with former smokers showed no increased risk. When analyses were restricted to subjects whose ETS exposure was classified via both their own self-report and a spouse's report, the rate ratio was 1.23 (1.03-1.47) for currently exposed men and 1.19 (0.97-1.45) for women. These results are consistent with prior reports that never-smokers currently exposed to ETS have about 20% higher CHD death rates. However, the data did not show consistent dose-response trends and the possibility remains that they are subject to confounding by unmeasured risk factors.

These same American Cancer Society CPS-II data were also obtained and analyzed recently by Levois and Layard (Reg Toxicol Pharmacol 21: 184-191,1995) as part of a larger analysis of alleged publication bias in this field. A draft of this publication had been previously submitted to OSHA as part of the IAQ hearings in comments by Maurice Levois (Aug. 12, 1994). Levois and Layard, in their analysis of the American Cancer Society CPS-II data, analyzed ETS exposure from a spouse using a data set with approximately 18,000 more women and 2,000 more men than did NIOSH-ACS investigators; the larger cohort may be due to different definitions of "known" spousal smoking data. These authors reported finding no increased CHD risk for those exposed to ETS from a spouse, an interpretation with which the authors of the NIOSH-ACS study disagree. Levois and Layard emphasized the results for "any" spousal exposure to ETS, which dilutes the effects among current smokers by including former smokers. They did not report "current" as a separate single category, although they did report results for current smokers by categories of

amount smoked. They also did not use any of the data on self-reported exposure to ETS, or consider data in which self-reported current exposure to ETS at home was concordant with spousal reports of current smoking. These last data are those which are likely to be the least misclassified, and therefore the most accurate. As indicated above, these data show a 20% increased risk for heart disease due to ETS exposure for both male and female never-smokers.

- 2) NIOSH also has reviewed a submission to the OSHA record by Maurice Levois (comments on Aug. 12, 1994), which consisted in part of a manuscript by Maxwell Layard. The Layard manuscript was entitled "Ischemic Heart Disease, Lung Cancer, and Spousal Smoking in the National Mortality Followback Survey." This study was a case-control study of 1986 decedents from the National Mortality Followback Study. The lung cancer subjects were too few in number (21 male and 39 female) to make the lung cancer results meaningful. The heart disease sample was larger, consisting of 475 men and 914 women.

Regarding heart disease, cases were ever-married never-smokers who died of ischemic heart disease, while controls were selected from those ever-married never-smokers who died of diseases not thought to be related to smoking (presumably on the assumption that they would not be related, likewise, to ETS exposure). This selection strategy for controls resulted in controls who were less likely than cases to die of any chronic disease; controls were on the average 9 years younger when they died than cases. This age difference would be expected to have an important effect on whether the spouses of decedent cases smoked; the younger controls would be expected to be more likely to have had smoking spouses, biasing results negatively. Analytic control over age may not have been sufficient to overcome this bias.

However, more importantly, the quality of data available on decedent's smoking status and on ETS exposure in this study is quite limited. Never-smoking status of the decedent and any spouse (not necessarily the most recent spouse) was reported by next-of-kin (81.3% were first-degree relatives; only 35.9% were themselves spouses). The decedent or spouse was considered a smoker if the next-of-kin reported they ever smoked more than 100 cigarettes. The next-of-kin may not have had good knowledge of the decedent's smoking habits, so that, for example, ex-smokers may have been classified as never-smokers. Even more likely, the next-of-kin may not have had good knowledge of the spouse's smoking habits. The spouse reported on by the next-of-kin might not have been currently married to the decedent. Even if the spouse reported on was currently married to the decedent, the data do not permit knowing whether, if the spouse were a smoker, he or she was a current or former smoker. For example, a smoking spouse might have smoked for one year, 30 years prior to the death of the decedent, possibly prior to even marrying the decedent. This would result in the decedent being considered exposed to ETS while he or she might have been minimally exposed far in the past, or not exposed at all. Many studies report that the primary effect of ETS

on the heart appears to be an acute effect, which might be only apparent in those exposed to currently smoking spouses, but such an analysis would not be possible in this study.

The quality of the data on decedent and spousal smoking in the 1986 National Followback study does not appear adequate to analyze with any precision a relationship between ETS exposure from a spouse and heart disease among never-smokers. Therefore, NIOSH would recommend either giving little weight or disregarding entirely any analyses of spousal smoking and ETS exposure based on these data.

**Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office (513/533-8450).**