



Cigarette Company Lawsuits Against 1992 EPA Study Dismissed

In a 1992 report, the U.S. Environmental Protection Agency (EPA) outlined a number of the serious diseases and health risks caused by secondhand smoke.¹ In response to tobacco industry legal challenges, in August 1998 a U.S. District Court in North Carolina struck down the report's finding that secondhand smoke is a "Class A" carcinogen (i.e., a carcinogen with no safe level of exposure for humans), saying that EPA had not followed certain required procedures and that the evidence -- in 1992 -- did not support its finding.² On December 11, 2002, however, the United States Court of Appeals for the Fourth Circuit vacated the judgment of the lower court, ruling that the EPA report was not a reviewable agency action under the Administrative Procedures Act and dismissed the case brought by the tobacco industry.³ In addition, numerous studies since 1992 and since the EPA finding have firmly established that secondhand smoke is not only a carcinogen but also causes heart disease, and numerous other serious health problems among nonsmokers, especially children, and kills thousands of people each year.

Nevertheless, those opposing new smoke-free laws still wrongly claim that the courts have invalidated the EPA's finding that secondhand smoke is a Class A carcinogen. In fact, that finding has been confirmed by the Appellate court's rejection of the initial lower court ruling – and the cigarette companies have not even appealed the ruling against them and in favor of EPA. Moreover, even if the lower court's ruling had not been overturned, it did not establish that secondhand smoke is not a Class A carcinogen – and did not say anything at all to contradict solid research findings regarding the many other harms and diseases caused by secondhand smoke.

What Were the Major Conclusions of the 1992 EPA Rule?

For adults, the report concluded that, "ETS [environmental tobacco smoke] is a human lung carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers" and the report found that secondhand has a statistically significant effect on the respiratory health (e.g., reduced lung function) of non-smoking adults. ⁴

For children, the report concluded that, "ETS exposure is causally associated with an increased risk of lower respiratory tract infections (LRIs) such as bronchitis and pneumonia; increased prevalence of fluid in the middle ear, symptoms of upper respiratory tract irritation, and a small but significant reduction in lung function, and; additional episodes and increased severity of symptoms in children of asthma, with ETS exposure a risk factor for new cases of asthma in children who have not previously displayed symptoms."⁵

While it is also well established that secondhand smoke also causes many other diseases and health problems, the EPA report was "limited to an analysis of respiratory effects, primarily lung cancer in non-smoking adults and non-cancer respiratory illness in children."⁶

What Did the Lower Court Actually Do in 1998?

The District Court did not dispute EPA's conclusion that secondhand smoke causes lung disease, asthma, and other chronic respiratory disorders among nonsmokers, and especially children; and the Court said nothing about passive smoke's firmly established role in causing heart disease, sudden infant death syndrome, and a variety of other health problems.⁷

The Court did not even rule that secondhand smoke is not a carcinogen -- but only that the EPA's report had not, by itself, established *in 1992* that secondhand smoke was a "Class A" carcinogen. In fact, the Court only evaluated the data and research that EPA actually considered prior to making its 1992 findings -- with the judge taking it upon himself to make scientific analyses and medical determinations in the place of qualified scientists and medical researchers. Whether or not the judge's conclusions based on the 1992 evidence were valid, the enormous amount of additional scientific proof that had been published since 1992 clearly confirms that secondhand smoke causes cancer and merits the "Class A Carcinogen" designation. In another 1998 case, for example, a different federal judge, who was able to consider all the evidence up to that point, found that "It is beyond dispute that secondhand smoke is a carcinogen."⁸

The EPA appealed the 1998 Court ruling at it was overturned by the Fourth Circuit Court of Appeals on December 11, 2002.⁹ With all doubts about the EPA's case now erased, the facts are clearer than ever that exposure to secondhand smoke poses major health risks to adults and children, and the Fourth Circuit's ruling regarding EPA's 1992 study on reconfirms the facts as we know them today.

Scientific Findings on the Health Harms and Risks Caused By Secondhand Smoke

- *International Agency for Research on Cancer* (June 2002) – According to the IARC, "involuntary smoking (exposure to secondhand or 'environmental' tobacco smoke) is carcinogenic to humans (Group 1)." ¹⁰ Further, the IARC concluded that there is a "statistically significant and consistent association between lung cancer risk in spouses of smokers and exposure to secondhand tobacco smoke from the spouse who smokes. The excess risk is on the order of 20% for women and 30% for men."

In addition, the IARC found that "epidemiological studies have demonstrated that exposure to secondhand tobacco smoke is causally associated with coronary heart disease" and they estimated that "involuntary smoking increases the risk of an acute coronary heart disease event by 25-35%." Further, the IARC noted that, for adults, "the strongest evidence for a causal relation exists for chronic respiratory symptoms."

- In 1997, the National Cancer Institute (NCI) issued its 10th Monograph, *Health Effects of Exposure to Environmental Tobacco Smoke*, which evaluated the available scientific research and concluded that secondhand smoke exposure is causally associated with a number of negative health effects in adults and children.
 - For children, the NCI estimated that exposure to secondhand smoke resulted in more than 10,000 annual cases of low birthweight, more than 2,000 cases of SIDS,

more than 8,000 new cases of asthma, and as many as 1 million cases of exacerbated asthma.

- For adults, the NCI estimated that each year secondhand smoke causes 3,000 deaths from lung cancer and 35,000 to 62,000 deaths associated with ischemic heart disease.¹¹
- *U.S. Surgeon General (1986)* – In 1986, the Surgeon General concluded the following regarding exposure to secondhand smoke:
 - “Involuntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers.
 - The children of parents who smoke, compared with the children of nonsmoking parents, have an increased frequency of respiratory infections, increased respiratory symptoms, and slightly smaller rates of increase in lung function as the lung matures.
 - Simple separation of smokers and nonsmokers within the same air space may reduce, but does not eliminate, exposure of nonsmokers to environmental tobacco smoke.”¹²
- In 2000, the American College of Occupational and Environmental Medicine issued the following summary of current knowledge on health harms from workplace exposure to secondhand smoke:

“Environmental tobacco smoke (ETS) contains numerous toxins. Robust epidemiologic evidence implicates ETS as a cause of lung cancer and as a primary cause and a source of exacerbation of excess respiratory disease. There is also increasing evidence that ETS may be associated with other outcomes, including heart disease. There is currently little doubt that ETS is an important and avoidable health hazard. Unfortunately, ETS is frequently encountered in the workplace - where it is no safer than in other environments and where it presents hazards to exposed workers and others. A unique aspect of workplace ETS is that exposure is rarely an outcome of essential manufacturing, extraction, or service delivery process.”¹³

- In December 2002, the U.S. Public Health Service's National Toxicology Program issued its *10th Report on Carcinogens*, which unambiguously states, based on a thorough review of the available scientific and medical evidence, that:

“Environmental tobacco smoke (ETS) is *known to be a human carcinogen* based on sufficient evidence of carcinogenicity from studies in humans that indicate a causal relationship between passive exposure to tobacco smoke and human lung cancer (IARC 1986, EPA 1992, CEPA 1997). Studies also support an association of ETS with cancers of the nasal sinus (CEPA 1997). Evidence for an increased cancer risk from ETS stems from studies examining nonsmoking spouses living with individuals who smoke cigarettes, exposures of nonsmokers to ETS in occupational settings, and exposure to parents’ smoking during childhood. Many studies, including recent large population-based case control studies, have demonstrated increased risks of approximately 20% for developing lung cancer following prolonged exposure to ETS, with some studies suggesting higher risks with higher exposures. Exposure to ETS from spousal smoking or exposure in an occupational setting appears most strongly related to increased risk.”¹⁴

- There has also been an enormous amount of new published scientific research on the health risks from exposure to secondhand smoke since the original EPA report was released, including (but not limited to) the following:
 - A 1997 analysis of 37 epidemiological studies of lung cancer and secondhand smoke, published in the *Journal of the National Cancer Institute*, found that lifelong nonsmokers living with smokers had, on average, a 24 percent higher chance of contracting lung cancer than those living with nonsmokers, and that those exposed to the heaviest smokers for the longest time had the highest risks.¹⁵ Subsequent research studies have made similar findings.¹⁶
 - A 1997 *British Medical Journal* meta-analysis of 19 published studies found that "Breathing other people's smoke is an important and avoidable cause of ischaemic heart disease, increasing a person's risk by a quarter."¹⁷
 - A June 2001 study published in the journal *Pediatrics* found that exposure to secondhand smoke through the mother in utero was associated with increased rates of hospitalization in infants with non-smoking mothers, and that use of tobacco products by household members has an "enormous adverse impact" on the health of children.¹⁸
 - A July 2001 study in the *Journal of the American Medical Association* concluded that exposure to secondhand smoke "substantially reduced" coronary circulation in healthy non-smokers, providing "direct evidence" that exposure to secondhand smoke causes coronary circulatory dysfunction in non-smokers.¹⁹
 - A December 2001 study published in *The Lancet* found that exposure to secondhand smoke "increased the likelihood of experiencing [adverse] respiratory symptoms and was associated with increased [adverse] bronchial responsiveness." Specifically, the study found that exposure to secondhand smoke was "significantly associated" with nighttime chest tightness and breathlessness after physical activity, and that exposure to secondhand smoke in the workplace was significantly associated with all types of respiratory symptoms and current asthma.²⁰
 - A January 2002 study in the *British Medical Journal* found that maternal smoking during pregnancy represents a "true risk factor for early adult onset of diabetes." In addition, the study found that in utero exposures due to smoking during pregnancy "may increase the risk of both diabetes and obesity" possibly due to fetal malnutrition or toxicity.²¹
- While there have been some studies published that question the harmfulness of secondhand smoke, a study in the *Journal of the American Medical Association*, found that the only way to predict whether a medical journal article on secondhand smoke would conclude that it was not hazardous was to determine whether the author had received tobacco industry funding.²²

Cigarette Company Efforts to Mislead the Public About Secondhand Smoke

- According to a former director of applied research at Philip Morris (makers of Marlboro), the tobacco industry's own private, unpublished research determined as early as the 1970s that exposed nonsmokers were at significant risk of contracting lung cancer just from sidestream smoke (the smoke and chemicals released by cigarettes between puffs).²³

- Prior to the Court ruling against the EPA, the tobacco industry paid thousands of dollars to more than a dozen scientists to send letters attacking the 1992 EPA finding to various medical journals and other publications.²⁴
- In the late 1980s, Philip Morris began "Operation Whitecoat," through which it took steps to "recruit" scientists (whitecoats) throughout Europe and beyond through direct financial payments and other support in order to infiltrate scientific and policy organizations and research journals and promote the idea the secondhand smoke was not as harmful as other, untainted research indicated and "keep the controversy alive."²⁵
- Today, the cigarette companies continue to deny that secondhand smoke is a serious health hazard. For example, the Brown & Williamson Tobacco Company states on its website that while "smoking can be annoying and irritating to nonsmokers," it does not believe that "the scientific evidence, taken as a whole, is sufficient to establish that environmental tobacco smoke (ETS) is a cause of disease."²⁶ Similarly, as part of their efforts to strike down a Florida ballot question to make the state's workplaces smoke free before the voters even get a chance to vote on it, the Lorillard and RJ Reynolds tobacco companies have argued that secondhand smoke is not a public health hazard.²⁷
- On its website, the Philip Morris cigarette company focuses on the procedural objections to the EPA's 1992 carcinogen finding, stating that the Court "rejected the EPA assessment, largely based on findings that the agency did not adhere to applicable legal requirements and failed to adequately explain its results." The Philip Morris website even acknowledges the growing scientific evidence that secondhand smoke is a serious health hazard, and even admits that there is "an impressive accumulating body of evidence that confirms and strengthens the EPA findings" in its 1992 report; but the cigarette company continues to oppose state and local efforts to pass smoke-free workplace or restaurant laws and pushes a discredited ventilation option, instead.²⁸

Footnotes:

¹ U.S. Environmental Protection Agency (EPA), Office of Research and Development & Office of Air and Radiation, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, EPA/600/6-90/006F, December 1992.

² Memorandum Opinion, *Flue Cured Tobacco Cooperative Stabilization Corp. v. EPA*, U.S. District Court for the Middle District of North Carolina, Winston-Salem Division, July 17, 1998.

³ *Flue Cured Tobacco Cooperative v. EPA*, Appeals from the United States District Court for the Middle District of North Carolina, at Winston-Salem. William L. Osteen, District Judge. (CA-93-370-6), Argued: June 7, 1999, Decided: December 11, 2002, <http://pacer.ca4.uscourts.gov/opinion.pdf/982407.P.pdf>.

⁴ EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, December 1992.

⁵ EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, December 1992.

⁶ EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, December 1992.

⁷ Memorandum Opinion, *Flue Cured Tobacco Cooperative Stabilization Corp. v. EPA*, July 17, 1998. EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, December 1992. See also, e.g., National Cancer Institute (NCI), *Health Effects of Exposure to Environmental Tobacco Smoke: The Report of the California Environmental Protection Agency*, Smoking and Tobacco Control Monograph No. 10, NIH Pub. No. 99-4645, 1999, http://cancercontrol.cancer.gov/tcrb/nci_monographs/MONO10/MONO10.HTM, as well as research cited below.

⁸ Memorandum of Decision and Order, *Sayville Inn v. County of Suffolk*, United States District Court for the Eastern District of New York, August 3, 1998.

- ⁹ EPA Press Release, September 15, 1998, <http://www.epa.gov/iaq/ets/etsappea.html>. *Flue Cured Tobacco Cooperative v. EPA*, December 11, 2002, <http://pacer.ca4.uscourts.gov/opinion.pdf/982407.P.pdf>.
- ¹⁰ International Agency for Research on Cancer, *Volume 83: Tobacco Smoke and Involuntary Smoking Summary of Data Reported and Evaluation, June 2002*, <http://www.iarc.fr/>.
- ¹¹ NCI, *Health Effects of Exposure to Environmental Tobacco Smoke: The Report of the California Environmental Protection Agency*, 1999, http://cancercontrol.cancer.gov/tcrb/nci_monographs/MONO10/MONO10.HTM.
- ¹² The Health Consequences of Involuntary Smoking: A Report of the Surgeon General (1986), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health, Rockville, MD 20857, http://www.cdc.gov/tobacco/sgr/sgr_1986/SGR1986-PrefaceAndForward.PDF.
- ¹³ American College of Occupational & Environmental Medicine, *Epidemiological Basis for an Occupational and Environmental Policy on Environmental Tobacco Smoke*, www.acoem.org/paprguid/papers/etspaper.htm, July 30, 2000.
- ¹⁴ National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services (HHS), *10th Report on Carcinogens: Revised December 2002*, December 2002, <http://ehp.niehs.nih.gov/roc/tenth/profiles/s176toba.pdf>.
- ¹⁵ Hackshaw, AK et al, "The Accumulated Evidence on Lung Cancer and Environmental Tobacco Smoke," *British Medical Journal* vol. 315 980-988, October 18, 1997.
- ¹⁶ Boffetta, P, et al., "Multicenter Case-Control Study of Exposure to Environmental Tobacco Smoke and Lung Cancer in Europe," *Journal of the National Cancer Institute* 90: 1440-50, October 7, 1998. See, also, NCI, *Health Effects of Exposure to Environmental Tobacco Smoke: The Report of the California Environmental Protection Agency*, 1999, http://cancercontrol.cancer.gov/tcrb/nci_monographs/MONO10/MONO10.HTM.
- ¹⁷ Law, M. R., et al., "Environmental Tobacco Smoke Exposure and Ischaemic Heart Disease: An Evaluation of the Evidence," *British Medical Journal* 315: 973-979, October 18, 1997. See, also, He, J., et al, "Passive Smoking and the Risk of Coronary Heart Disease -- A Meta-Analysis of Epidemiologic studies," *New England Journal of Medicine* 340(12): 920-26, March 25, 1999.
- ¹⁸ Lam, Tai-Hing, et al, "The Effects of Environmental Tobacco Smoke on Health Services Utilization in the First Eighteen Months of Life," *Pediatrics* 107(6), June 2001. See, also, Anderson, HR & DG Cook, "Passive Smoking and Sudden Infant Death Syndrome: Review of the Epidemiological Evidence," *Thorax* 52: 1003-1009, November, 1997.
- ¹⁹ Otsuka, Ryo, et al, "Acute Effects of Passive Smoking on the Coronary Circulation in Healthy Young Adults," *Journal of the American Medical Association* 286(4), July 25, 2001.
- ²⁰ Janson, Christer, et al, "Effect of passive smoking on respiratory symptoms, bronchial responsiveness, lung function, and total serum IgE in the European Community Respiratory Health Survey: a cross-sectional study," *The Lancet* v.358, December 22/29, 2001.
- ²¹ Montgomery, S. & A. Ekbom, "Smoking during pregnancy and diabetes mellitus in a British longitudinal birth cohort," *British Medical Journal*, 324: 26-27, January 5, 2002.
- ²² D. E. Barnes & L. A. Bero, "Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions," *JAMA* 279(19): 1566-1570, May 20, 1998.
- ²³ Farone, WA, "Toxic Gas for the Masses," personal document, July 13, 1998. See, also, Headden, S, "Secondhand Smokescreen: Tobacco Firms Worried for Years About Risks of Passive Smoke," *U.S. News and World Report*, August 3, 1998.
- ²⁴ See, e.g., Hanners, D, "Scientists Were Paid To Write Letters – Tobacco Industry Sought to Discredit EPA Report," *Pioneer Planet/St. Paul Press*, August 4, 1998.
- ²⁵ See, e.g., website of ASH-UK (Action on Smoking and Health), "Philip Morris & Passive Smoking," which includes internal tobacco industry documents on Operation Whitecoat , www.ash.org.uk/html/conduct/html/pmorris1.html.
- ²⁶ Brown and Williamson website accessed on January 4, 2002, http://www.bw.com/Index_sub2.cfm?ID=6.
- ²⁷ Brief of Lorillard Tobacco Company, R.J. Reynolds Tobacco Company, et al., *In Re: Advisory Opinion to the Attorney General Re: Protect People from the Health Hazards of Second-Hand tobacco Smoke by Prohibiting Workplace Smoking*, Supreme Court of Florida, Filed November 28, 2001.
- ²⁸ See, e.g., Philip Morris's "Options" website, <http://www.pmoptions.com/>; Campaign Fact Sheet, *Ventilation Technology Does Not Protect People from Secondhand Tobacco Smoke*, www.tobaccofreekids.org