AD-A284 336

REPORT DOCU

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information ... gathering and maintaining the data needed, and completin ... collection of information, including suggestions for reducin ... Davis Highway, Suite 1204, Arlington, VA 22202-4302, and ... Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	Sep 94	

4. TITLE AND SUBTITLE

Regulation of Enviornmental Tobacco Smoke

5. FUNDING NUMBERS

6. AUTHOR(S)

Kathleen Lynn Nesser

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

AFIT Students Attending:

George Washington University

8. PERFORMING ORGANIZATION REPORT NUMBER

AFIT/CI/CIA

94-127

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

DEPRTMENT OF THE AIR FORCE
AFIT/CI
2950 P STREET
WRIGHT-PATTERSON AFB OH 45433-7765

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for Public Release IAW 190-1
Distribution Unlimited
MICHAEL M. BRICKER, SMSgt, USAF
Chief Administration

12b. DISTRIBUTION CODE

DTIC
ELECTE
SEP 1 5 1994
S F

13. ABSTRACT *(Maximum 200 words)*

DTIC QUALITY INSPECTED 3

14. SUBJECT TERMS

15. NUMBER OF PAGES

73

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

Regulation of Environmental Tobacco Smoke

By

Kathleen Lynn Nesser

B.S. June 1980, Ohio State University
M.B.A. March 1983, Ohio State University
J.D. June 1983, Ohio State University

A Thesis submitted to

The Faculty of

The National Law Center

Of The George Washington University
in partial satisfaction of the requirements
for the degree of Master of Laws

September 30, 1994

Thesis directed by
Arnold Winfred Reitze, Jr.
Professor of Law

Accesion For
NTIS CRA&I ☑
DTIC TAB ☐
Unannounced ☐
Justification
By
Distribution /
Availability Codes
Dist | Avail and/or Special
A-1

94-29901

94 9 14 045

PASSIVE INHALATION OF TOBACCO SMOKE

Introduction.....1

EPA's Authority to Regulate ETS.....5
- Clean Air Act.....5
- Toxic Substances Control Act.....5
- Federal Insecticide, Fungicide, and Rodenticide Act.....6
- Radon Gas and Indoor Air Quality Research Act of 1986 Title IV SARA.....6
- EPA's Authority to Regulate.....7

Other Federal Agencies Authority to Regulate.....8
- Consumer Product Safety Commission.....8
- Department of Health and Human Services.....9
- National Institute for Occupational Safety and Health.....10
- Occupational Safety and Health.....11

Congressional Attempts to Regulate.....15

Case Law.....20

EPA and Other Studies.....28

Government and Business Response to Studies.....44

Industry Response to the EPA Study.....51
- Basis for the Lawsuit.....51
- EPA's Response.....61
- Motions Raised by Third Parties.....66
- Discussion of Probable Court Response.....67

Future of ETS.....68

Conclusion.....72

INTRODUCTION

Environmental Tobacco Smoke (ETS), secondhand smoke and passive smoke are all terms for tobacco smoke a non-smoker inhales. The paramount controversy concerns the extent of health risk to non smokers from ETS. Groups on both sides of the controversy hold extreme views on the degree of risk, especially regarding the risk of contracting cancer. This is a battle where the outcome could result in the collapse of an industry.

The Environmental Protection Agency (EPA) currently regulates many health risks to the American public, but it has only limited regulatory authority over indoor air, including ETS. There are, however, many reasons for regulating in this area. First, most people spend as much as 90 percent of their time indoors.[1] Second, indoor environments contain a complex and varied array of potential sources of air pollution.[2] Third, studies indicate that pollutant levels may be two-five times higher indoors, than outside levels and occasionally more than 100 times higher.[3] Fourth, exposure to indoor air pollutants is believed to have increased due to a variety of factors,

---

[1] Environmental Protection Agency, Targeting Indoor Air Pollution EPA's Approach And Progress (1993); Ken Sexton, *An Inside Look at Air Pollution, in* EPA Journal (1993).

[2] Ken Sexton, *An Inside Look at Air Pollution, in* EPA Journal at 9 (1993).

[3] Environmental Protection Agency, Targeting Indoor Air Pollution EPA's Approach and Progress (1993).

including construction of more tightly sealed buildings and reduced ventilation rates used to save energy.[4] Fifth, the potential health effects pose a serious threat to public health.[5] And sixth, indoor air is estimated to cause significant increases in medical costs and declines in productivity.[6] They are valid reasons to regulate indoor air. But, there are questions about the extent of regulation.

One component of indoor air pollution is environmental tobacco smoke (ETS). According to the EPA, ETS is the largest source of indoor air pollution.[7] A cigarette contains over 4,000 substances, more than 40 of which are known to be carcinogenic and many are strong respiratory irritants.[8]

Indoor levels of particles inhaled(e.g., the "tars" in a cigarette) often exceed the national air quality standard.[9] High levels of carbon monoxide are also a

---

[4] Robert Sussman, Deputy Administrator of the Environmental Protection Agency, Testimony before the Subcommittee on Clean Air and Nuclear Regulations, Committee on Environment and Public Works, United States Senate (May 25, 1993).

[5] H.R. 1530, 101st Cong., 1st Sess. (1989).

[6] *Id.*

[7] Jay Siwek, *Consultation - Dangers of Secondhand Smoke*, Washington Post, Dec. 14, 1993, at Health C15.

[8] Carol M. Browner, *Environmental Tobacco Smoke: EPA's Report, in* EPA Journal at 18 (1993).

[9] *Id.*

serious pollutant from with ETS.[10] The EPA estimates that in adults approximately 3,000 lung cancer deaths are caused by ETS, and in children approximately 150,000 to 300,000 cases of lower respiratory tract infections are attributable to ETS.[11] Also, exposure increases the prevalence of fluid in the middle ear and symptoms of upper respiratory tract irritation.[12] A small, but significant, reduction in lung function occurs.[13] The severity of episodes of asthma in children has increased, and ETS is a risk factor in the development of new cases of asthma.[14]

The EPA has concluded that ETS is a serious and substantial public health risk, and there is sufficient scientific evidence to warrant action to protect the nonsmoker from involuntary exposure.[15] Forty six states currently restrict smoking in public places.[16] Further, many business have restricted smoking beyond that required

---

[10] Browner, *supra* note 8, at 18.

[11] Environmental Protection Agency, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders (1993).

[12] *Id.*

[13] Environmental Protection Agency, *supra* note 11 at 1-1.

[14] Environmental Protection Agency, *supra* note 11 at 1-1.

[15] Environmental Protection Agency, *supra* note 11 at 1-1 and 6-1.

[16] Fran Du Melle, *Laws Protecting Nonsmokers, in* EPA Journal (1993).

by law.[17] These restrictions are important since the Center for Disease Control states that 25.7 percent of all adults in the United States smoke.[18] Therefore, a large percentage of the population are being effected by these restrictions.

This paper will review the EPA's current authority to regulate ETS. It will then discuss other federal agencies authority to regulate ETS. Congress has taken action to pass legislation in the indoor area arena. These attempts will be discussed, and pending legislation reviewed. A discussion of relevant case law will follow. Next, the various studies will be discussed including the major EPA publication on ETS and other independent studies. Government and business responses to studies, regulations, and case law also will be explored. The tobacco industry suit against the EPA's publication, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,* will be discussed along with responses.[19] Finally, the future of ETS will be addressed and recommendations will be

---

[17] Kirstin Downey Grimsley, *More Malls, Stores Curb Smoking Health Legal Issues Spur Retailers to Act,* Washington Post, Jan. 26, 1994, at A01.

[18] *Id.*

[19] Flue Cured Tobacco Cooperative Stabilization Corp; The Council for Burley Tobacco, Inc; Universal Leaf Tobacco Co., Inc; Philip Morris Inc.; R. J. Reynolds Tobacco Co and Gallins Vending Co. v. Environmental Protection Agency and Carol Browner, Administrator, No. 6:93CV370 (Middle District of N.C. U.S.D.C. filed June 22, 1993.

offered on how the federal and state governments should regulate in this area.

EPA'S AUTHORITY TO REGULATE ETS

The EPA has statutory authority to regulate a variety of pollutants that could be used to regulate ETS. EPA could potentially use the following statutes to regulate ETS.

Clean Air Act

The Clean Air Act[20] does not preclude regulation of indoor air, but the EPA's position is that Congress intended the Clean Air Act (CAA) to only address ambient air.[21] Further, the legislative history reveals that Congress was concerned with ambient air and makes no reference to indoor air.[22] Thus, the EPA regulations define ambient air as the air external to buildings and other structures.[23]

It would be very difficult for the EPA to change their interpretation of the CAA and regulate ETS under the CAA. It would take an act of Congress to include regulation of indoor air, including ETS.

Toxic Substances Control Act

This statute gives the EPA authority to regulate chemical substances and mixtures that are an unreasonable

---

[20] 42 U.S.C. § 7401(b) (1990).

[21] Letter from A. James Barnes, *Environmental Protection Agency,* to Honorable George Mitchell, *U.S. Congress Chairman,* (Jun 1, 1987).

[22] H.R. Rep. No. 728, 90th Cong. (1987).

[23] 40 C.F.R. § 50.1(e) (1983).

risk of injury to health and the environment.[24] A limitation in this act prohibits the creation of unnecessary economic barriers to technological innovations.[25] Another limitation restricting the regulation of ETS is the exception to regulation of tobacco in the statute.[26] While it can be argued that regulation of ETS is not regulation of tobacco but a product of smoking tobacco, this argument probably would not succeed.

Federal Insecticide, Fungicide, and Rodenticide Act

This act could only have a limited impact on tobacco since this act limits the distribution, sale or use in any state, of any pesticide not registered to prevent unreasonable adverse effects on the environment.[27] Pesticides are defined to include insecticides, fungicides and rodenticides.[28] Therefore, tobacco could only be regulated to the extend that it contains a pesticide that is not registered. This would be a very small window of opportunity to regulate, if at all.

Radon Gas and Indoor Air Quality Research Act of 1986 Title IV SARA

This act gives the EPA authority in the indoor air

---

[24] 15 U.S.C. § 2601(b)(2) and (c) (1977).

[25] 15 U.S.C. § 2601(b)(3) (1976).

[26] 15 U.S.C. § 2602(2)(B)(iii) (1976).

[27] 7 U.S.C. § 136a(a) (1991).

[28] 7 U.S.C. § 136(u) (1991).

arena to gather data and information on all aspects of indoor air quality, to assess appropriate federal government actions to mitigate environmental and health risks and to make information available to the public.[29] It does not give the EPA authority to regulate indoor air.[30]

The EPA study on ETS, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, was completed under the authority of this act.[31] The EPA is being sued by the tobacco industry claiming among other things that the EPA exceeded its authority under the Radon Gas and Indoor Air Quality Research Act of 1986 Title IV SARA in completing the above publication.[32]

EPA's Authority to Regulate

EPA's authority to regulate ETS is nebulous at best. Attempts by the EPA to regulate are met by great resistance from the tobacco industry. Because Congress believes the EPA does not have authority to regulate indoor air, it has attempted to pass bills to give the EPA broader authority to

---

[29] 42 U.S.C. § 7401 note (1990).

[30] *Id.*

[31] Environmental Protection Agency, *Preface to* Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders (1992).

[32] This lawsuit will be discussed in the section of this paper titled Industry Response to the EPA Study.

regulate in the indoor air arena.[33] These bills will be discussed later.

OTHER FEDERAL AGENCIES AUTHORITY TO REGULATE

Other federal agencies have power to regulate ETS.

Consumer Product Safety Commission

This commission is basically ruled by the Consumer Product Safety Act.[34] It's mandate is to protect the public against unreasonable risks of injury associated with consumer products.[35] To the extent that a product affecting indoor air creates an unreasonable risk of injury, it could be regulated by the Consumer Product Safety Commission.

While indoor air may be regulated, ETS can not. This is because the act explicitly excludes tobacco products.[36] The only way this agency has dealt with cigarettes is as a fire hazard.[37] An example of cigarette involvement would include such things as controlling the contents of a

---

[33] H.R. 3809, 100th Cong., 2nd Sess. (1988); S. 1629, 100th Cong., 2nd Sess. (1988); H.R. 1530, 101th Cong., 1st Sess. (1989); S. 657, 101st Cong., 1st Sess. (1989); H.R. 5155, 101st Cong., 2nd Sess. (1990); S. 455, 101st Cong., 2nd Sess. (1990); S. 656, 103d Cong., 1st Sess. (1993); H.R. 1930 103rd Cong., 1st Sess. (1993); H.R. 2919, 103d Cong., 1st Sess. (1993).

[34] 15 U.S.C. § 2051(b) (1990).

[35] *Id.*

[36] 15 U.S.C. § 2052(a)(1)(B) (1990).

[37] Telephone interview with Ken Jiles, Consumer Products Safety Commission (May 24, 1994).

mattress so that it would not create a fire hazard if a cigarette was dropped on the mattress.[38]

Department of Health and Human Services

While the Department of Health and Human Services (DHHS) does not regulate ETS, it is involved in assisting States in this area.[39] A tobacco control program gives grants to States to run public information programs to increase the public's awareness of tobacco and its health risks including ETS.[40] DHHS also coordinates with other federal agencies. For example, it held an interagency meeting in June 1993 concerning the effects of ETS in the workplace.[41] This meeting in which the future of ETS was discussed involved many federal agencies.[42]

The Food and Drug Administration (FDA), a part of the Department of Health and Human Services, is considering regulation of cigarettes as a drug, because of their nicotine content.[43] This regulation would be based on: the addictive nature of nicotine, the tobacco industries'

---

[38] *Id.*

[39] Telephone interview with Gala Walter, Department of Health and Human Services (May 24, 1994).

[40] *Id.*

[41] Telephone interview with Gala Walter, *supra* note 39.

[42] Telephone interview with Gala Walter, *supra* note 39.

[43] David A. Kessler, M.D., Commissioner of Food and Drugs, Statement on Nicotine-Containing Cigarettes, Address Before the House Subcommittee on Health and the Environment (Mar. 25, 1994).

ability to control the level of nicotine in cigarettes and the similarities of the tobacco industry to the pharmaceutical industry.[44] Such regulation, while aimed at cigarettes, would have indirect implications for ETS if regulation of cigarettes caused a decrease in smoking and, therefore, the amount of ETS.

National Institute for Occupational Safety and Health (NIOSH)

NIOSH has no regulatory authority for the control of ETS[45] One of their basic mandates is to respond to complaints about unsafe working conditions from an employer, employee or union. A team will be sent to the site to evaluate the situation and make recommendations. The most common complaint NIOSH receives concerns indoor air quality, and ETS is considered a subset of indoor air.[46]

If the NIOSH team believes there is an immediate danger to life or health it will immediately report to the Occupation Safety and Health Administration which may take regulatory action. The determination of immediate danger to life or health is based on established concentration levels

---

[44] *Id.*

[45] Telephone interview with Dave Vota, National Institute for Occupational Safety and Health (May 25, 1994).

[46] Telephone interview with Dave Vota, *supra* note 45.

for chemicals, but ETS has no set standard.[47] NIOSH has classified ETS as a potential occupational carcinogen. (This classification is different than the EPA's classification of ETS as a Group A carcinogen, which will be discussed later.) But, this classification does not mean there are standards for a minimum or maximum exposure. It does not give the inspector direction in deciding when there is too much exposure and, therefore, an immediate danger to life or health.

Occupational Safety and Health (OSHA)

The OSHA has the power to ensure safe and healthful working conditions so that no employee will suffer diminished health, functional capacity or life expectancy as a result of his/her work experience.[48] To comply with this mandate, it sets permissible exposure limits (PELs). The OSHA promogated 428 PELs for indoor air issues, but they were challenged and the court invalidated them based on invalid procedures in promogating the rules.[49] Currently, OSHA does not have any standards or PELs for ETS.[50] It considered setting standards a few years ago, but it

---

[47] Telephone interview with Dave Vota, *supra* note 45.

[48] 29 U.S.C. § 651 (1970).

[49] American Federation of Labor and Congress of Industrial Organizations v. Occupational Safety and Health Administration, 965 F.2d 962 (11th Cir 1992).

[50] Telephone interview with Debra James, Occupational Safety and Health (May 24, 1994).

determined the subject was too complicated, given the number of chemicals involved (4,000 in the smoke stream) and the fact that no single chemical was an accurate indicator of the concentration of the other chemicals.[51]

But this decision changed, and on April 5, 1994 a proposed rule making concerning indoor air was published by OSHA.[52] It was prompted by three public interest groups petitioning OSHA in May 1987 for an Emergency Temporary Standard for ETS under the Occupational Safety and Health Act.[53] OSHA determined that the available data, with respect to exposure to ETS, was not sufficient to meet the "grave danger requirement" under the statute.[54] OSHA was sued, but the court denied relief to the plaintiffs.[55] OSHA then requested information to determine if it was feasible and appropriate to pursue regulatory action.[56] OSHA concluded regulation was appropriate, based on the following:

> OSHA believes that data submitted to the record, and other evidence, support the conclusion that air contaminants and other air quality factors can

---

[51] *Id.*

[52] Indoor Air Quality; Proposed Rule, 59 Fed. Reg. 15,968 (1994) (to be codified at 29 C.F.R. §§ 1910, 1915, 1926 and 1928).

[53] *Id.*

[54] Indoor Air Quality; Proposed Rule, *supra* note 52.

[55] Indoor Air Quality; Proposed Rule, *supra* note 52.

[56] Indoor Air Quality; Proposed Rule, *supra* note 52.

> act to present a significant risk of material impairment to employees working in indoor environments. Adverse health effects associated with poor IAQ (indoor air quality) may include sensory irritation, respiratory allergies, asthma, nosocomial infections, humidifier fever, hypersensitivity pneumonitis, Legionnaires' disease, and the signs and symptoms characteristic of exposure to chemical or biologic substances such as carbon monoxide, formaldehyde, pesticides, endotoxin, and mycotoxins.
>
> The Agency believes that available data support proposing regulation of IAQ, including exposure to ETS. Further stimulus for this determination was provided by conclusions reached in a report published in December, 1992 by the Environmental Protection Agency, addressing hazards associated with exposure to ETS. In that study, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders (Ex. 4-311), EPA concluded that exposure to ETS presents an excess risk of induction of cancer in humans.[57]

The proposed rule involves regulation of indoor air, included ETS. The basic provisions of this proposed rule will apply to all indoor nonindustrial work environments. For ETS worksites coverage is expanded to include both industrial and nonindustrial worksites.[58] Employers are required to develop a written indoor air quality compliance plan and to implement the plan actions such as inspection and maintenance of the building systems that influence indoor air quality.[59] Provisions under the proposed rule also require employers to implement controls for specific

---

[57] Indoor Air Quality; Proposed Rule, *supra* note 52, at 15,969.

[58] Indoor Air Quality; Proposed Rule, *supra* note 52, at 15,968.

[59] Indoor Air Quality; Proposed Rule, *supra* note 52.

contaminants, which includes ETS. The rule states that "designated smoking areas which are to be separate, enclosed rooms exhausted directly to the outside are proposed to be required in buildings where the smoking of tobacco products is not prohibited."[60] Thus, there must be a separately exhausted room or no smoking. There are other provisions requiring information and training of the building's systems maintenance and operation workers and other employees.[61] Finally, there are record keeping requirements, which would increase compliance, since records could be used to prove a violation.[62]

This rule making's comment period ends on June 29, 1994, but there have been numerous requests for an extension. OSHA normally grants such extensions, and probably will grant it in this case.[63]. Most of the comments to date have concerned ETS. The Secretary of Labor stated that he hopes the final rule will be out in two years.[64] Even if the rule is promulgated in a timely manner the industry will probably sue and try to delay regulation of ETS.

---

[60] Indoor Air Quality; Proposed Rule, *supra* note 52.

[61] Indoor Air Quality; Proposed Rule, *supra* note 52.

[62] Indoor Air Quality; Proposed Rule, *supra* note 52.

[63] Telephone interview with Debra James, Occupation Safety and Health (May 24, 1994).

[64] *Id.*

CONGRESSIONAL ATTEMPTS TO REGULATE

Congress has considered passing an Indoor Air Quality Act on various occasions. The first attempt was in 1987.[65] In 1989 both the House and Senate again initiated Indoor Air Quality Act bills.[66] Again, in 1990 both Houses initiated bills.[67] None of these bills would have given the EPA the authority to regulate. For the most part, they gave the EPA power to continue research in the indoor air area. It can be argued that the EPA had this authority in the Radon Gas and Indoor Air Quality Research Act of 1986, Title IV SARA.[68]

In 1993, three bills were introduced, two in the House and one in the Senate.[69] H.R. 2919 would give the EPA authority to regulate by allowing it to promulgate guidelines covering the operation and maintenance of existing buildings, design and construction of new buildings, building renovation and sources of indoor air

---

[65] H.R. 3809, 100th Cong., 2nd Sess. (1987), S. 1629, 100th Cong., 2nd Sess. (1987).

[66] H.R. 1530, 101st Cong., 1st Sess. (1989); S. 657, 101st Cong., 1st Sess. (1989).

[67] H.R. 5155, 101st Cong., 2nd Sess. (1990); S. 455, 101st Cong., 2nd Sess. (1990).

[68] 42 U.S.C. § 9604(a)(1) (1992).

[69] H.R. 1930, 103d Cong., 1st Sess. (1993); H.R. 2919, 103d Cong., 1st Session (1993); S. 656 103d Cong., 1st Sess. (1993). H.R. 1930 was basically replaced by H.R. 2919. While this bill is still in committee it does not officially die until the end of the Congressional session.

pollution and such other guidelines as necessary to identify, eliminate or prevent indoor air hazards that are listed in the act.[70] One important aspect of these guidelines is that they are voluntary, unless the EPA Administrator requires compliance.[71] The proposed Act requires the EPA to coordinate and establish a national campaign to increase public awareness concerning the health risks of, and to encourage action to reduce exposure to, indoor air pollutants.[72] The EPA is also required to coordinate with other federal agencies to establish a program to identify, eliminate and prevent indoor air hazards in federal facilities.[73] It is to develop a program with state and local governments, and to provides grants for such programs.[74] It is also to conduct studies, provide financial and other assistance for others to conduct studies.[75]

The Subcommittee on Health and Environment, of the House Committee on Energy and Commerce, held a hearing on

---

[70] H.R. 2919, 103d Cong., 1st Sess., § 2702 (1993).

[71] H.R. 2919, 103d Cong., 1st Sess., § 2702 (1993).

[72] H.R. 2919, 103d Cong., 1st Sess. § 2704 (1993).

[73] H.R. 2919, 103d Cong., 1st Sess. § 2705 (1993).

[74] H.R. 2919, 103d Cong., 1st Sess. § 2707 (1993).

[75] H.R. 2919, 103d Cong., 1st Sess. § 2708 (1993).

November 1, 1993.[76] At this hearing the EPA generally supported the bill as a constructive augmentation to the existing agency programs.[77] It liked the voluntary guidelines approach for reducing or eliminating hazards and desired to work with the subcommittee to clarify the scope of their authority and the circumstances when it would be necessary to make guidelines mandatory.[78] EPA expressed concern about the bill's short deadlines because: 1) it would require them to rely on limited existing data in looking at the potential for adverse health effects at low levels and 2) of the potential ramifications of the requirement to set action levels for health advisory pollutants that are required to be set by the act.[79] EPA concluded:

> The Indoor Air Act builds successfully on the approaches EPA has taken in the establishment and implementation of its current programs. Administrator Browner and I support the Act and remain steadfast in our desire to work with this committee to ensure that the indoor air quality of

---

[76] Telephone interview with representative on the Subcommittee on Health and Environment (May 24, 1994).

[77] Robert Sussman, Deputy Administrator of the Environmental Protection Agency, Testimony before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives (Nov. 1, 1993).

[78] Sussman, *supra* note 86.

[79] Sussman, *supra* note 77.

our Nation is improved.[80]

The Senate bill, which has passed in the Senate, has different provisions than the pending House bill.[81] One of the stated reasons for the bill is that federal agencies are not making adequate efforts to conduct research, identify health effects, develop control techniques, provide education programs and offer other methods to decrease human exposure.[82]

The Senate bill requires the EPA to develop and coordinate, with other departments and agencies of the United States, a comprehensive program of research and development; to make information available to the public; to give grants; to enter into cooperative agreements; to develop methods for prevention, detection and correction; to hold conferences; to acquire processes, data, licenses, etc. and to conduct research and development through nonprofit organizations.[83] It is required to have a technology demonstration program, study schools and child care facilities and prepare a healthy building baseline

---

[80] Sussman, *supra* note 77, at 20.

[81] Interview with a representative from the Office of Legislative Information (May 24, 1994); S. 656, 103d Cong., 1st Sess. (1993).

[82] S. 656, 103d Cong., 1st Sess. § 2 (1993).

[83] S. 656, 103d Cong., 1st Sess. § 5 (1993).

assessment.[84] The EPA must set up a management practice program, a voluntary partnership program and ventilation standards.[85] It is required to set up a national indoor air quality response plan, federal building response plan and demonstration program.[86] Finally, it is to set up an Office of Radiation and Indoor Air, the Council on Indoor Air Quality and the Indoor Air Quality Clearinghouse for disseminating information.[87] It is not given the authority to regulate ETS or indoor air under this bill.

On May 25, 1993, Robert Sussman, Deputy Administrator of the EPA, spoke before Senate Committees concerning this bill. While the EPA had some reservations on portions of the bill, generally it supports the legislation.[88]

Since the provisions in both bills vary greatly, it will require significant compromise work in committee to get a bill that would be accepted by both the House and the Senate. The major difference in the two bills is the authority of the EPA to regulate.

If the final version includes authority to regulate

---

[84] *Id.*

[85] S. 656, 103d Cong., 1st Sess. § 6 (1993).

[86] S. 656, 103d Cong., 1st Sess. §§ 8 and 9 (1993).

[87] S. 656, 103d Cong., 1st Sess. §§ 11-14 (1993).

[88] Robert Sussman, Deputy Administrator of the EPA, Testimony before the Subcommittee on Clean Air and Nuclear Regulation, Committee on Environment and Public Works, United States Senate (May 25, 1993).

indoor air, the prior discussion on EPA's authority to regulate indoor air will become moot, since they will have direct authority under the Indoor Air Quality Act of 199X. Statutes, such as the Clean Air Act, will not have to be relied on to regulate ETS.

CASE LAW

While statutes and regulations are important, case law effects ETS. Applicable case law involves prisoner rights, employee rights and others who have been exposed to ETS. There have been suits by smokers and the tobacco industry claiming it is illegal to limit the areas where smoking is permitted.

There have been many lawsuits, by prisoners, claiming that exposure to ETS has violated their constitutional rights.[89] While the prisoners raised many claims, the courts focused on the Eighth Amendment claims. The circuit

---

[89] Helling v. McKinney, 113 S. Ct. 2475, 125 L. Ed. 2d 22, 61 USLW 4648 (1993); Avery v. Powell, 695 F. Supp. 632 (D. New Hampshire 1988); Caldwell v. Quinlan, 729 F. Supp. 4 (D.D.C. 1990); West v. Wright, 747 F. Supp. 329 (E.D. Virginia 1990); Wilson v. Lynaugh 878 F.2d 846 (5th Cir 1989); Gorman v. Moody, 710 F. Supp. 1256 (N.D. Indiana 1989); Clemmons v. Bohannon, 956 F 2d 1523 (10th Cir 1992); Doughty v. Board of County Commissioners for the County of Weld, State of Colorado, 731 F. Supp. 423 (D. Colorado 1989); Washington v. Tinsley v. Klevenhagen, 809 F. Supp. 504 (S.D. Texas 1992); Mott v. State of Indiana, 793 F. Supp. 178 (N.D. Indiana 1991); Steading v. Thompson, 942 F.2d 498 (7th Cir 1991); Murphy v. Dowd, 975 F.2d 435 (8th Cir 1992); Grass v. Sargent, 903 F.2d 1206 (8th Cir 1990); Stanfield v. Hay, 849 S.W. 2d 551 (Ky. Ct. App. 1992); Hunt v. Reynolds, 974 F.2d 734 (6th Cir 1992); Steele v. Trigg, 978 F.2d 1261 (7th Cir 1992); Wood v. Goldschmidt, 962 F.2d 16 (9th Cir 1992); Frye v Hamilton, 862 F.2d 869 (4th Cir 1988).

courts were divided in determining that exposure to ETS is cruel and unusual punishment under the Eighth Amendment.[90] In 1993 the U.S. Supreme Court settled this issue.[91] The U.S. Supreme Court ruled that exposure to ETS could violate the Eighth Amendment. There is a two part test to determine if the Eighth Amendment has been violated. First, there is an objective standard which deals with exposure to ETS and next there is a subjective standard which deals with "deliberate indifference" of prison officials. The objective standard is defined by the court as follows:

> ... with respect to the objective factor, determining whether McKinney's conditions of confinement violate the Eight Amendment requires more than a scientific and statistical inquiry into the seriousness of the potential harm and the likelihood that such injury to health will actually be caused by exposure to ETS. It also requires a court to assess whether society considers the risk that the prisoner complains of to be so grave that it violates contemporary standards of decency to expose anyone unwillingly to such a risk. In other words, the prisoner must show that the risk of which he complains is not

---

[90] McKinney v. Anderson, 924 F.2d 1500 (9th Cir 1990); Avery v Powell, 695 F. Supp. 632 (D. Hew Hampshire 1988); Caldwell v. Quinlan, 729 F. Supp. 4 (D.D.C. 1990); West v. Wright, 747 F. Supp. 329 (E.D. Virginia 1990); Wilson v. Lynaugh, 878 F.2d 846 (5th Cir 1989); Gorman v. Moody, 710 F. Supp. 1256 (N.D. Indiana 1989); Clemmons v. Bohannon, 956 F.2d 1523 (10th Cir 1992); Doughty v. Board of County Commissioners for the County of Weld, State of Colorado, 731 F. Supp. 423 (D. Colorado 1989); Steeding v. Thompson, 941 F.2d 498 (7th Cir 1991); Hunt v. Reynolds, 974 F.2d 734 (6th Cir 1992).

[91] Helling v. McKinney, 113 S. Ct. 2475, 125 L. Ed. 2d 22, 61 USLW 4648 (1993).

one that today's society chooses to tolerate.[92]

The court found that exposure to ETS could be a violation of the Eighth Amendment since there is a possibility of future harm to health. The subjective element must also be met to have a violation of the Eighth Amendment. This standard requires the prisoner to show that the prison officials were deliberately indifferent to the hazards of ETS. This is to be determined in light of the officials' current attitudes and conduct.[93] Therefore, exposure to ETS is not enough to have a valid cause of action under the Eighth Amendment, but it is a start.

Prisoners have also claimed that smoking bans are cruel and unusual punishment, but the courts have uniformly held that such bans are not unconstitutional.[94] When the issue of nicotine withdrawal was raised, a court stated that nicotine withdrawal was not disproportionate to the good achieved by the ban and therefore was not unconstitutional.[95]

---

[92] Helling v. McKinney, supra note 91, at 2481.

[93] *Id.*

[94] Grass v. Sargent, 903 F.2d 1206 (8th Cir 1990); Stanfield v. Hay, 849 S.W. 2d 551 (Ky. Ct. App. 1992); Washington v. Tinsley v. Klevenhagen, 809 F. Supp. 504 (S.D. Texas 1992); Doughty v. Board of County Commissioners for the County of Weld, State of Colorado, 731 F. Supp. 423 (D. Colorado 1989).

[95] Washington v. Tinsley v. Klevenhagen, 809 F. Supp. 504 (S.D. Texas 1992).

These two types of cases show the direction of court rulings on ETS is to limit smoking and to protect the rights of nonsmokers. Since 90 percent of the population in prisons are smokers, ten percent of the prison population is controlling prison policy when smoking is an issue.[96]

Many employees have also sued based on exposure to ETS.[97] Some cases were requests for unemployment compensation for employees who voluntarily terminated their employment because of policies concerning smoking.[98] In Lapham v. Commonwealth of Pennsylvania Unemployment Compensation Board of Review (Lapham) the plaintiff quit a job based on allergic bronchitis due to exposure to

---

[96] N.Y. Times, July 9, 1990 at A10, col. 5.

[97] Palmer v. Del Webb's High Sierra, 838 P.2d 435 (Supreme Court of Nevada 1992); Lapham v. Commonwealth of Pennsylvania Unemployment Compensation Board of Review, 103 Pa Cmwlth 144, 519 A 2d 1101 (Pa. Commw. Ct. 1987); Bompane v. Enzolabs Inc, 608 N.Y.S. 2d 989 (Supreme Court Suffolk County 1994); Pechan v. Dynapro Inc, 622 N.E. 2d 108 (Ill. App Ct., 2nd Dist. 1993); Bernard v. Cameron and Colby Co. Inc, 397 Mass. 320, 491 N.E. 2d 604 (Supreme Judicial Court of Mass. 1986); Quinn, Gent, Buseck and Leemhuis, Inc. v. Unemployment Compensation Board of Review, 147 Pa. Cmwlth. 141, 606 A.2d 1300 (Pa. Commw. Ct. 1992); McCarthy v. Dept of Social and Health Services, 110 Wash.2d 812, 759 P.2d 351 (Supreme Court of Wash. 1988); Shimp v. New Jersey Bell Telephone Co., 145 N.J. Super 516, 368 A.2d 408 (N. J. Super. Ct, N. J. Ch. 1976); Kensell v. State of Oklahoma, 716 F.2d 1350 (10th Cir 1983); Gordon v. Raven Systems and Research Inc., 462 A.2d 10 (D.C. Cir 1983); Smith v. Western Electric Company, 643 S.W. 2d 10 (Mo. Ct. App. 1982).

[98] Lapham v. Commonwealth of Pennsylvania Unemployment Compensation Board of Review, 103 Pa. Cmwlth. 144, 519 A.2d 1101 (Pa. Commu. Ct. 1987), Quinn, Gent, Buseck and Leemhuis, Inc v. Unemployment Compensation Board of Review, 147 Pa. Cmwlth. 141, 606 A.2d 1300 (Pa. Commw. Ct. 1992).

cigarette smoke. In Quinn, Gent, Buseck and Leemhuis, Inc v. Unemployment Compensation Board of Review (Quinn) the employee quit her job due to a total ban of smoking in the workplace. Lapman was given compensation while the employee in the Quinn case was not. Such a result can be explained by the trend by the courts to rule against smoking.

Many cases involve an employee's attempts to obtain a smoke free environment.[99] These cases involve both requests for injunctive relief and money damages. Injunctive relief was granted in some jurisdictions, or at least the circuit allowed the case to go forward since there was a valid cause of action.[100] Other districts have not permitted injunctive relief, but permitted damages to be awarded.[101] One case said that "common law does not impose a duty on the employer to provide a smoke-free

---

[99] Pechan v. Dynapro Inc, 622 N.E. 2d 108 (Ill. App. Ct. 2nd Dist. 1993); Bernard v. Cameron and Colby Co Inc., 397 Mass. 320, 491 N.E. 2d 604 (Supreme Judicial Court of Mass. 1986); McCarthy v. Dept of Social and Health Services, 110 Wash.2d 812, 759 P.2d 351 (Supreme Court of Wash. 1988); Shimp v. New Jersey Bell Telephone Co., 145 N.J. Super. 516, 368 A.2d 408 (N. J. Super. Ct., N. J. Ch. 1976); Kensell v. State of Oklahoma, 716 F.2d 1350 (10th Cir 1983); Smith v. Western Electric Company, 643 S.W. 2d 10 (Mo. Ct. App. 1982).

[100] Shimp v. New Jersey Bell Telephone Co., 145 N.J. Super. 516, 368 A.2d 408 (N. J. Super. Ct., N. J. Ch. 1976); Smith v. Western Electric Company, 643 S.W. 2d 10 (Mo. Ct. App. 1982).

[101] Pechan v. Dynapro Inc., 622 N.E. 2d 108 (Ill. App. Ct., 2nd Dist. 1993), McCarthy v. Dept of Social and Health Services, 110 Wash.2d 812, 759 P.2d 351 (Supreme Court of Wash. 1988).

environment for a particular employee with special sensitivity to tobacco smoke."[102] Other districts did not allow recovery for failure to provide a smoke free environment.[103] Jurisdictions are divided on how to handle employee exposure to ETS. This may be a problem for companies establishing smoking policies in multiple jurisdictions. The best way for these companies to protect themselves would be to limit smoking, because smokers have not successfully sued employers for the right to smoke.

Other lawsuits involving ETS exposure include a class action suit by approximately 60,000 flight attendants who sued tobacco manufacturers for damages under theories of strict tort liability, breach of implied warranty, negligence, fraud, misrepresentation and conspiracy to commit fraud.[104] This case was heard by the appellate court based on the issue of the appropriateness of the class action. The court held that the class was appropriate and sent it back to the trial court to hear the case. If plaintiffs win, it would be a major victory for the non-smokers who want to limit smoking areas but this may be mooted since these limitations are already taking place.

---

[102] Gordon v. Raven Systems and Research Inc, 462 A 2d 10 (D.C. Cir. 1983).

[103] Kensell v. State of Oklahoma, 716 F.2d 1350 (10th Cir 1983).

[104] Broin v. Philip Morrison Company, 1994 WL 81712 (Fla. Dist. App. 3rd District 1994).

In another case, a nonsmoking passenger sued American Airlines for injury from ETS exposure due to negligence by the airlines.[105] The trial court granted summary judgement for the defendant, which the appellate court reversed holding summary judgement inappropriate in this case as there may be a valid issue.[106]

A prisoner has sued the manufacturer of cigarettes, claiming injury resulting from second-hand smoke.[107] The court held that there was no merit in his claim.

There is no uniformity among the jurisdictions concerning the few ETS cases. As the number of cases increase this may create forum shopping issues for the plaintiffs.

ETS has also been raised in child custody disputes.[108] In one case the court ordered the custodial parent not to smoke in the presence of her asthmatic daughter.[109] When she did not stop smoking, the judge gave temporary custody to the grandmother, ruling that

---

[105] Ricci v. American Airlines, 226 N.J. Super 377, 544 A.2d 428 (N. J. Super. Ct. App. Div. 1988).

[106] *Id.*

[107] Schultz v. American Tobacco Co, 8 F.3d 29 (9th Cir 1993).

[108] Thomas Harvey Holt, *Pets' Attacks on Smoking Threatens Individual Freedoms*, Insights, Oct. 18, 1993, at 30, Andrea Sachs, *Home Smoke-Free Home*, Time, Oct. 25 1993, at 56(1).

[109] Andrea Sachs, *Home Smoke-Free Home*, Time, Oct 25, 1993, at 56(1).

smoking endangered her daughter's health. Eleven states have dealt with this issue always siding with the non-smoking parent.[110]

While most of the lawsuits are by the nonsmokers, smokers and tobacco companies have sued to limit government designated nonsmoking areas.[111] Industry has attacked the validity of regulations and smoking bans, winning two of the three cases, but the laws could be changed to avoid the courts reasons for finding the regulation unlawful.[112] Because the challenges were based on the state agency exceeding its authority to promulgate the regulation any win is probably short lived.

A smoker sued the Civil Aeronautics Board because no seats were available in the smoking section.[113] The court said there was no private right of action, and denying a passenger the right to smoke does not constitute discrimination.

---

[110] *Id.*

[111] National Association of Motor Bus Owners v. United States, 370 F. Supp. 408 (D.C.C. 1974); Diefenthal v. Civil Aeronautics Board, 681 F.2d 1039 (5th Cir 1982); Boreali v. Axelrod, 71 N.Y. 2d 1, 517 N. E. 2d 1350, 523 N.Y.S. 2d 464 (Court of Appeals of N.Y. 1987); Boreali v. Axelrod, 130 A.D. 2d 107, 518 N.Y.S. 2d 440 (N.Y. App. Div. 1987).

[112] Boreali v. Axelrod, 71 N.Y. 2d 1, 517 N.E. 2d 1350, 523 N.Y.S. 2d 464 (Court of Appeals of N.Y. 1987); Boreali v. Axelrod, 130 A.D. 2d 107, 518 N.Y.S. 2d 440 (N.Y. App. Div. 1987).

[113] Diefenthal v. Civil Aeronautics Board, 681 F.2d 1039 (5th Cir 1982).

ETS has become an issue in many different types of lawsuits and will likely continue to be a basis of lawsuits. If more studies are published saying that exposure to ETS causes health risks, and more individuals litigate, it is likely nonsmokers will obtain injunctions and/or monetary damages. Many courts now support smoke-free areas and this trend will probably increase.

EPA AND OTHER STUDIES

There have been many studies on ETS and its health effects.[114] The most controversial has been the December 1992 EPA study correlating epidemiological studies[115] on

---

[114] Akiba, S, Kato, H., Blot, W.J. *Passive Smoking and Lung Cancer Among Japanese Women* in 46 Cancer Res. 4804-4807 (1986); Arundel A., Sterling, T., Wenikam, J. *Never-smoker Lung Cancer Risks from Exposure to Particulate Tobacco Smoke* in 13 Environ. Intl. 443-452 (1987); Bergman, A.B., Wiesner, B.A. *Relationship of Passive Cigarette Smoking to Sudden Infant Death Syndrome* in 58 Pediatrics 665-668 (1976); Breese-Hall, C., Hall, J.H., Gala, C.L. MaGill, F.B., Leddy, J.P. *Long-term Prospective Study in Children After Respiratory Syncytial Virus Infection* in 105 J. Pediatr. 358-364 (1984); Chen, Y., Li, W., Yu, S. *Influence of Passive Smoking on Admissions for Respiratory Illness in Early Childhood* in 293 Br. Med. J. 303-306 (1986); Dodge, R. *The Effects of Indoor Pollution on Arizona Children* in 37 Arch. Environ Health 151-155 (1982).

[115] Epidemiology is the study of the occurrence of a disease in human populations. Investigators observe patterns of the disease occurrences and attempt to statistically correlate the occurrence of the disease with a potential cause. This is done by comparing the incidence rates between two groups. One of which is exposed to the factor or potential cause and one group is not exposed which is the control group.

the health effects of ETS.[116] The study covered illnesses such as lung cancer, acute respiratory illnesses, middle ear diseases, chronic respiratory symptoms, asthma, sudden infant death syndrome (SIDS), heart disease and lung function impairments, but only the studies involving lung cancer will be discussed.[117]

Lung cancer is the health issue of greatest controversy. The tobacco industry has challenged claims of ETS causing lung cancer in a pending lawsuit discussed below. They challenge the EPA's analysis that resulted in the classification of ETS as a group A carcinogen, but they did not challenge the EPA's analysis concerning ETS causing other illnesses.

In reviewing the EPA's analysis one must assess the factors that could create errors in the final conclusion. There are numerous factors that can effect the results of an epidemiologic study. Among these factors are bias, confounding, relative risk, the statistical significance of the study, consistency of results, the dose-trend relationship and the meta-analysis. Each of these will be discussed to provide a basic understanding of the factors and how they apply to the EPA study.

There are multiple forms of bias which include:

---

[116] Environmental Protection Agency, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, EPA/600/6-90/006F (1992). Hereinafter Report.

[117] Report, *supra* note 116, at 7-2.

interviewer bias, selection bias, bias arising from misclassification of exposure status and disease diagnosis and respondent bias.[118] Interviewer bias is created when the interviewer asks questions and records answers and ask questions in a way that affects the result. Selection bias is caused by the researcher who selects subjects that are not representative of the population. Misclassification of exposure status and disease diagnosis can produce conclusions not be based on true exposures or diseases. Respondent bias comes from the respondent answering questions inaccurately or untruthfully.

Multiple forms of bias can occur. If the respondent reports he has never had asthma, and did have asthma in his past, this would be misclassification of disease diagnosis and respondent bias.

The amount of bias in any study is not fixed. A study could have no bias or be so biased as to be useless. It is difficult to determine the extent and type of bias. When reviewing any study the possibility of bias slanting the results must be considered.

The EPA's ETS study determined that there was a chance

---

[118] Maxwell Layard, An Address to the Proceeding of the International Symposium at McGill University 1989, on Environmental Tobacco Smoke and Cancer: The Epidemiologic Evidence, *reprinted in* Environmental Tobacco Smoke, Proceedings of the International Symposium at McGill University 1989, at 99 (1989). Hereinafter Address.

of bias in the studies reviewed.[119] This bias was in smoker misclassification. The misclassification would be by former smokers misrepresenting themselves as never-smokers. EPA felt that an adjustment in the results of the studies could account for this misrepresentation and, accordingly they made an adjustment in the relative risk number (this will be discussed later). An across the board adjustment such as this would probably not be valid for each study, but when studies are grouped, errors would tend to cancel themselves out.

There are biases the EPA did not adjust that possibly effected the study's conclusions. This includes an exposure bias and the estimate as to dose and recall bias. It is difficult to determine the level of exposure an individual receives because the individual usually has no accurate idea of how often and when he or she is exposed. It is too expensive and/or difficult to measure the actual dose. Because many studies have to rely on questionnaires to determine past exposures and because it is difficult to for a person to recall how they were exposed -- recollection creates a bias in and of itself. A person who has lung cancer is likely to remember more exposures than would a person who is not ill. Failure to adjust for these biases, if it is possible to adjust for them, reduces the validity of the study results.

---

[119] Report, *supra* 126, at 5-22.

Confounding factors are important in epidemiologic studies because they are derived from the characteristics of the sample population.[120] Confounding factors are factors that contribute to or cause the illness that an individual comes into contact with during their lifetime.[121] Therefore, while we are exposed to ETS we are also exposed to other air pollutants, foods we eat, our exercise regime, and other factors that may have caused the disease being studied. If a population is chosen that has had an exposure to A which caused the disease, but another effect, B, is looked at in the study, the study may erroneously conclude that effect B is the cause of the illness when effect A is the real cause.

In the EPA study a number causes of lung cancer were reviewed as potential confounding factors.[122] These included history of lung disease, family history of lung disease, heat sources for cooking and heating, cooking with oil, occupation and dietary factors. The EPA concluded that:

> ...an examination of six non-ETS factors that may affect lung cancer risk finds none that explains the association between lung cancer and ETS exposure as observed by independent investigators across several countries that vary in social and cultural behavior, diet, and other characteristics. On the other hand, the high

---

[120] Report, *supra* note 116, at 5-49.

[121] Address, *supra* note 118, at 104.

[122] Report, *supra* note 116, at 5-51.

> levels of indoor air pollution from other sources (e.g., smoky coal) that occur in some parts of China and show statistical associations with lung cancer in the studies ... (3 studies have this effect) ... may mask any ETS effects in those studies.[123]

In other words, the EPA concluded that there are no confounding factors that effect the results of the studies, outside of the China studies. The China studies did have a statistical association of other indoor air pollutants and lung cancer, which could have caused the lung cancer in the ETS subjects.

Relative risk is used to review the strength of the association between the cause and effect. The weaker or smaller the relative risk the less confidence there is in the association.[124] There is no precise definition of a "weak" association, but relative risks less than 2.0 are generally considered to be weak.[125]

In the EPA study the relative risks range from 1.38 to 3.11, with an average of 1.81 for the highest exposure category, after adjustment for misclassification bias.[126] (The highest exposure category is the one with the most exposure of ETS in any given study, i.e. more cigarettes smoked in the presence of the non-smoker.) The average

---

[123] Report, *supra* note 116, at 5-60.

[124] Address, *supra* note 118, at 102.

[125] Address, *supra* note 118, at 102.

[126] Report, *supra* note 116, at 5-38 and 5-39.

relative risks for the various studies as a whole range from .58 to 2.55.[127] The EPA acknowledges that this is a weak association, but notes this is expected due to the dilute nature of ETS.[128] The EPA believes that while the association is weak, the studies show an important association with results that are consistent across the studies. This association is part of the basis the EPA used in determining whether there is a cause and effect relationship with ETS and lung cancer.[129]

There always is a chance that the results of a study will erroneously show a relationship that does not exist. Statistical significance is an estimate of the probability that chance produced a study's result.[130] A statistically significant result does not prove that the difference is real or that there is a real relationship, it still could be as a result of chance.[131] A result that is not statistically significant does not say that there is no cause and effect relationship.[132] It does infer that

---

[127] Report, *supra* note 116, at 5-28 - 5-29.

[128] Report, *supra* note 116, at 5-37.

[129] Report, *supra* note 116, at 5-68 and 5-38.

[130] Sir Austin Bradford Hill, Principles of Medical Statistics (1971).

[131] *Id.*

[132] Hill, *supra* note 130.

chance is not an unlikely reason for the results.[133] Statistical significance is important, but it is not a controlling factor in deciding the validity of a study.[134]

Confidence intervals are used in determining if a study is statistically significant.[135] A confidence interval is a statistical tool. If the results are greater than the confidence interval, then the results are statistically significant.[136]

A 95 percent confidence interval is normally used,[137] but in the EPA study a 90 percent confidence interval was used.[138] If the 95 percent confidence interval was used, only six studies would be statistically significant.[139] By using the 90 percent confidence interval nine of thirty

---

[133] Hill, *supra* note 130.

[134] Report at 5-30, *supra* note 116; Interview with James Weekes, Public Health Dept. at George Washington University, at George Washington University, Washington D.C. (June 2, 1994).

[135] Interview with James Weekes, Public Health Dept. at George Washington University, at George Washington University, Washington D.C. (June 2, 1994); P. Armitage, Statistical Methods in Medical Research (1973).

[136] P. Armitage, Statistical Methods in Medical Research (1973).

[137] Address, *supra* note 118, at 100; P. Armitage, Statistical Methods in Medical Research (1973).

[138] Report, *supra* note 116, at 5-34.

[139] *Id.*

studies were statistically significant.[140]

The EPA stated they used the 90 percent interval to correspond to a right-tailed test hypothesis.[141] In other words, they felt that there was an established relationship between ETS and lung cancer, therefore, statistically this is reflected in the right-tailed 90 percent test.

The EPA's use of the right-tailed 90 percent test to prove a relationship between ETS and lung cancer is biased. (It is similar to proving God exists by starting with the assumption that God exists.) This is not objective science and was probably not needed to get the same end result. A right-tailed test should only be used if it is quite certain that departures are only in one direction.[142] In other words, the EPA must know that ETS causes cancer before using a right-tailed 90 percent test. It should not have used the right-tailed 90 percent confidence interval without a better explanation.

The EPA also reviewed the consistency of results in the studies, which is important when reviewing studies.[143] Consistency is not internal to a given study. It is viewed by comparing the results of various studies on the subject.

---

[140] Report, *supra* note 116, at 5-28 - 5-29.

[141] Report, *supra* note 116, at 5-35.

[142] P. Armitage, Statistical Methods in Medical Research (1973).

[143] Address, *supra* note 118, at 102.

The studies concerning lung cancer the EPA reviewed in it's report have not been consistent.[144] The relative risks, range from no relationship, at .58, to a relatively strong relationship, at 2.55.[145] Some of this can be explained by chance, biases and confounding factors. This inconsistency decreases the confidence of the studies as a whole.

The dose-trend or dose-response relationship is an important consideration. If causation exists, as exposure increases incidence of the outcome increases.[146] For example, the chance of contracting lung cancer should increase as an individual is exposed to more ETS. Lack of a dose-response relationship is an internal inconsistency. Without a dose-response relationship an observed association is likely to be due to bias and/or confounding, rather than an affect of exposure.[147]

The EPA ETS study looked at the dose-response in 24 studies reviewed by the EPA; 12 had a perfect dose-response relationship.[148] As the dose increased so did the relative risk. In the other 12 studies there was a dose-

---

[144] *Id.*

[145] Report, *supra* 126, at 5-28 and 5-29.

[146] Address, *supra* note 118, at 103.

[147] Address, *supra* note 118, at 103.

[148] Report, *supra* note 116, at 5-41 - 5-43.

response relationship, but not a clear linear mutual increase.[149] For example, one study used cigarettes per day as the dose factor. With zero cigarettes per day of exposure the relative risk was 1.0. With one to nine cigarettes per day of exposure the relative risk was 1.15. This linear increase was the type of dose-response relationship that indicates a dose-response exists. When the subjects were exposed to ten to nineteen cigarettes per day the relative risk fell to 1.08, but when the subjects were exposed to twenty or more cigarettes per day the relative risk rose to 2.11.[150] This study shows an overall dose-response relationship, but is inconsistent due to the unexplained drop for subjects exposed to ten to nineteen cigarettes per day. Half of the studies had this type of unexplained drop.

This drop can be explained as being due to confounding factors, but the confounding factors that created the shift are not known. Even with unexplained variations in the dose-response relationship, the basic positive dose-response relationship is used by the EPA as another reason to conclude that ETS is a Group A carcinogen.[151]

The EPA also used a meta-analysis in their study. A meta-analysis combines results from many different studies,

---

[149] *Id.*

[150] Report, *supra* note 116, at 5-41, GARF study.

[151] Report, *supra* note 116, at 5-68.

but meta-analysis bias can create problems.[152] This bias has its genesis in problems such as studies that report a positive result have a better chance of being published. A meta-analysis is counterindicated unless the studies provide comparable estimates of a common quantitative endpoint; in this case, the risk of developing lung cancer among nonsmokers exposed to ETS.[153] A meta-analysis requires reasonably comparable studies regarding: exposure indices, demographic and social characteristics of the study populations, disease diagnosis and other factors.[154] In addition, each study should to be methodologically sound and free from potential biases and confounding factors that distort results.[155]

The EPA performed a meta-analysis in their study and used this analysis as evidence that ETS is a carcinogen.[156] There has been much criticism of using such an analysis for ETS and lung cancer.[157] Many

---

[152] Address, *supra* note 118, at 100.

[153] Address, *supra* note 118, at 100.

[154] Address, *supra* note 118, at 100.

[155] Address, *supra* note 118, at 101.

[156] Report, *supra* note 116, at 5-68.

[157] Address, *supra* note 118, at 101; Interview with James Weekes, Public Health Department of George Washington University, at George Washington University Washington D.C. (June 2, 1994); J. Fleiss at al, *Meta Analysis in Epidemiology, with Special Reference to Studies of the Association Between Exposure to Environmental Tobacco Smoke and Lung Cancer: A Critique,* 44(2) Journal of Clinical

professionals believe that the studies can not be combined because they fail to meet the necessary conditions for accurate analysis.[158] This controversy further weakens the EPA's conclusion.

The EPA's analysis of the epidemiological studies and other information, was used to determine that ETS is a cancer causing substance.

In classifying a substance as a carcinogen, the EPA has five classifications:

> Group A carcinogens consists of known human carcinogens.
>
> Group B carcinogens are probable human carcinogens.
>
> Group C carcinogens are possible human carcinogens.
>
> Group D carcinogens are agents that are unclassifiable as to human carcinogenicity.
>
> Group E are agents that have shown evidence of non-carcinogenicity for humans.[159]

The EPA, in their study, concluded that ETS is a Group A carcinogen.[160] It determined there is a strong causal

---

Epidemiology 127-139 (1991); Alvan Fenstein, *Justice, Science, and the "Bad Guys"*(critique), 20(2) Environmental Tobacco Smoke (1992).

[158] *Id.*

[159] Environmental Protection Agency, Methodology for Evaluating Potential Carcinogenicity in Support of Reportable Quantity Adjustments Pursuant to CERCLA Section 102 13-16 (1988).

[160] Report, *supra* note 116, at 5-68.

association between lung cancer and ETS exposure.[161] These conclusions are based on an analysis of 31 reports, that analyzed the chemical components of ETS and the relationship between a smoker's risk of cancer with those exposed to ETS.[162]

Two studies on the subject have been published since the EPA completed its analysis.[163] The first, reported no overall statistically significant increased risk due to exposure to ETS, but suggested that long-term exposure to ETS increased the risk of lung cancer in women who ever smoked.[164] The second report, found no overall statistically significant increased risk for exposure to ETS. The authors stated their data supported a small but consistent elevation in the risk of lung cancer in nonsmokers due to passive smoking.[165]

---

[161] Report, *supra* note 116, at 1-7.

[162] Report, *supra* note 116, at 5-68.

[163] R.C. Brownson, M. Alavanja, E. Hock, T. Loy, *Passive Smoking and Lung Cancer in Nonsmoking Women*, 82 American Journal of Public Health 1525-1530 (1992); H. Stockwell, A. Goldman, G. Lyman, C. Noss, A. Armstrong, Pinkham, E. Candelora, M. Brusa, *Environmental Tobacco Smoke and Lung Cancer Risk in Nonsmoking Women*, 84 Journal of the National Cancer Institute 1417-1422 (1992).

[164] H. Stockwell, A. Goldman, G. Lyman, C. Noss, A. Armstrong, P. Pinkham, E. Candelora, M. Brusa, *Environmental Tobacco Smoke and Lung Cancer Risk in Nonsmoking Women*, 84 Journal of the National Cancer Institute 1417-1422 (1992).

[165] R. Brownson, M. Alavanja, E. Hock, T. Loy, *Passive Smoking and Lung Cancer in Nonsmoking Women*, 82 American Journal of Public Health 1525-1530 (1992).

The EPA's conclusions, that there is an increased risk of lung cancer, due to ETS exposure, is supported by the studies reviewed by the agency and these two additional studies. The lack of statistical significance does not invalidate the conclusions of these studies. The majority of studies that the EPA used were not statistically significant and, these additional studies do not change the EPA's conclusion.

The studies, as a whole, show increased risk of lung cancer from exposure to ETS. However confounding factors could explain these results. This is a problem with many epidemiologic studies, since people are exposed to many substances during a lifetime. The studies' lack of statistical significance limit their value but the studies, while not conclusive, are the best evidence available.

To support its conclusions the EPA also looked at the physical properties of ETS and mainstream smoke (the cigarette smoke inhaled by smokers.).[166] It determined there are both substantial similarities and differences between the two types of smoke.[167] The EPA went further,

---

[166] Report, *supra* note 116, at 3-2.

[167] Report, *supra* note 116, at 3-3. Other researchers have concluded there are significant differences, while finding the two types of smoke qualitatively similar. Delbert Eatough, Ph.D. with Lee Hansen, Ph.D. and Edwin Lewis Ph.D., Address at the proceedings of the International Symposium at McGill University 1989 on the Chemical Characterization of Environmental Tobacco Smoke, *reprinted in* Environmental Tobacco Smoke, Proceedings of the International Symposium at McGill University 1989 (1989).

by stating that emissions in sidestream smoke are considerably higher than in mainstream smoke.[168] (Sidestream smoke is the smoke that is emitted from the smoldering tobacco between puffs, contaminants emitted into the air during the puff, and contaminants that diffuse through the cigarette paper and mouth end between puffs.)[169] Of the known carcinogens in sidestream smoke, the emissions rate is magnitudes higher than that in mainstream smoke.[170] Thus, exposure to ETS will result in exposure to toxic carcinogenic agents.[171] This exposure is an additional reason the EPA used to concluded that ETS is a Group A carcinogen.[172]

The EPA also looked at the effects of smoking on active smokers.[173] They stated that there was a clear relationship between lung cancer and the amount of exposure.[174] They theorized that exposure to ETS might increase the risk of lung cancer in both smokers and

---

[168] Report, *supra* note 116, at 3-5.

[169] Report, *supra* note 116, at 3-1.

[170] Report, *supra* note 116, at 3-4.

[171] Report, *supra* note 116, at 3-11.

[172] Report, *supra* note 116, at 5-68.

[173] Report, *supra* note 116, at Chapter 4.

[174] Report, *supra* note 116, at 4-1.

nonsmokers based on the relationship of cancer and smokers.[175]

In deciding that ETS is a Group A carcinogen the EPA used the total weight of the evidence including epidemiologic studies, the evaluation of the chemical constituents of ETS, and the accepted causal link between smokers and lung cancer which it applied to ETS exposure..[176]

While the EPA's conclusions may be questionable; it is understandable. The grass roots movement against smoking and ETS exposure is pressuring the EPA to take a stand.[177] While the EPA's conclusion may be questionable science, it's conclusion will probably be upheld in court.

GOVERNMENT AND BUSINESS RESPONSE TO STUDIES

Both government and business have responded to requests for smoke free environments. Responses have varied depending upon who is taking the action.

The federal government has some modest restrictions on smoking in the public and private sectors. For example, smoking is banned on all domestic airline flights, except

---

[175] Report, *supra* note 116, at 4-1.

[176] Report, *supra* note 116, at 1-8.

[177] John Schwartz, *Smoking Recast: From Sophistication to Sin Once-Sacrosanct Industry Feels Effects of Grass-Roots Movement,* Washington Post, May 29, 1994 at A01.

flights to and from Alaska and Hawaii.[178] Smoking is also restricted by various other federal regulations.[179] These restrictions would expand substantially under the "Smoke-Free Environment Act of 1993" bill, introduced by Representative Waxman and Senator Lautenberg. Their bill would ban smoking in virtually all non-residential buildings nationwide, including both public and private workplaces, or restrict smoking to specially ventilated smoking rooms.[180]

Individual federal agencies have acted to restrict smoking. The Federal Bureau of Prisons prohibits smoking in areas where "smoking would pose a hazard to health or safety."[181] The Postmaster General on June 3, 1993, ordered a nationwide ban on smoking in all 40,000 Postal Service Facilities.[182] The Senate has banned smoking in

---

[178] 49 U.S.C.A. App. § 1374(d) (1990).

[179] 14 C.F.R. §§ 252.1-.7 (1990) (regulation of restricting smoking on airlines not otherwise banned); 41 C.F.R. § 101-20.105-3 (1990) (controlling smoking in facilities owned by the General Services Administration); 49 C.F.R. § 1061.1 (1988) (limiting smoking on interstate carriers).

[180] H.R. 3434, 103d Cong., 1st Sess (1993).

[181] McKinney v. Anderson, 924 F.2d 1500 (9th Cir 1990).

[182] Bill McAllister, *Postal Workers Face Major Changes Smoking Banned in All Offices Employee Health Coverage Costs Rising*, Washington Post Jan. 11, 1993 at A19; Flue-Cured Tobacco Cooperative Stabilization Cooperation, The Council for Burley Tobacco, Inc., Universal Leaf Tobacco Company, Inc., Philip Morris Incorporated, R.J. Reyonlds Tobacco Company and Gallins Vending Company v. EPA and Carol Browner, No. 6:93CV370 (Middle Dist. of N.C., U.D.S.C. filed June 22, 1993).

all federal buildings, except for designated areas.[183] The Air Force banned smoking in many facilities while setting up smoking areas in or near these facilities. The Navy banned smoking on the Roosevelt Air Craft Carrier and plans to implement a service wide ban on smoking.[184] The Department of Health and Human Services initiated campaigns to limit ETS. They currently distribute a publication available to the public entitled "It's Time to Stop Being a Passive Victim."[185] This document encourages public involvement in establishing smoking bans.

Other federal agencies are considering ETS restrictions. The OSHA has ETS action pending that would effect all workplaces with over one employee.[186] The Food and Drug Administration is considering regulating cigarettes as a drug.[187] Such regulation would indirectly control

---

[183] Helen Dewar, *Short Takes - Senate Passes Smoking Ban*, Washington Post Aug. 4, 1993 at A15.

[184] Phil Gunby, *Despite Tensions of Monitoring World Trouble Spots, Aircraft Carrier Becomes First to Ban Tobacco*, 269 JAMA 2960 June 16, 1993.

[185] U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *It's Time to Stop Being a Passive Victim*.

[186] Indoor Air Quality; Proposed Rule, 59 Fed. Reg. 15,968 (1994) (to be codified at 29 C.F.R. §§ 1910, 1915, 1926 and 1928); Telephone interview with Debra James, Occupational Safety and Health (May 24, 1993).

[187] David A. Kessler, M.D., Commissioner of Food and Drugs, Statement on Nicotine-Containing Cigarettes before the House Subcommittee on Health and the Environment (Mar. 25, 1994).

ETS.

Forty-six states and the District of Columbia have responded to ETS with restrictions on where an individual can smoke.[188] The only states without restrictions are states where the tobacco industry is a major employer -- Mississippi, Alabama, Georgia and Kentucky. No state has totally banned smoking in all public areas.[189]

Many states regulate smoking, but the type of regulation varies. The majority of states have not taken action to protect private worksites.[190] Action has been taken to protect children but it has not been consistent from state to state. A few states have restricted smoking on school property.[191] There is no significant state-level ETS protection for infants and toddlers.[192] Alaska and Michigan are among the very few states prohibiting smoking in day-care facilities. Other states have some restrictions in day-care facilities, but allow smoking in areas and/or times when children are not present. The correction departments in thirteen states have banned or

---

[188] Fran DuMelle, *Laws Protecting Nonsmokers*, EPA Journal Vol 19 Number 4, 21 (October-December 1993).

[189] *Id.*

[190] DuMelle, *supra* note 188.

[191] DuMelle, *supra* note 188.

[192] DuMelle, *supra* note 188.

considered bans of smoking.[193]

Many local governments have regulated ETS by controlling smoking in buildings.[194] More than 397 cities and counties, effecting 22 percent of the population, have enacted smoking laws.[195] Of these municipalities, 297 have mandated adoption of work place smoking policies.[196]

Many private companies have voluntarily acted to limit smoking in their buildings. Hundreds of malls and restaurants have banned or severely restricted smoking.[197] They have offered three explanations for their actions.[198] First, consumer preference for nonsmoking areas. Second, fear of legal liability. And third, the EPA's designation of ETS as a cancer causing substance.

One airline banned in-flight smoking prior to the

---

[193] McKinney v. Anderson, 924 F 2d 1500 (9th Cir 1990).

[194] Frank Swoboda, *Workplace - OSHA's Move Toward Workplace Smoking Rules Has Unions a Bit Worried*, Washington Post, Jan. 16, 1994, at H02; Tom Kenworth and David Brown, *Firms Sue EPA on Cancer Ruling Second Hand Smoke Studies Based on Fudged Data, Industry Alleges*, Washington Post, Jan 23, 1993 at A01.

[195] Indoor Air Quality; Proposed Rule, 59 Fed. Reg 15,968 at 16,007 (1994) (to be codified at 29 C.F.R. §§ 1910, 1915, 1926 and 1928).

[196] *Id.*

[197] Kirstin Downey Grimsley, *More Malls, Stores Curb Smoking Health Legal Issues Spur Retailers to Act*, Washington Post Jan. 26, 1994 at p. A01; Robert G. Hansen and John R. Lott, Jr, *Regulating IAQ: The Economist's View*, EPA Journal Vol 19 Number 4, October-December 1993.

[198] *Id.*

Federal ban.[199] They went out of business. Evidently flying consumers were not ready to support such a ban. This trend has have changed, and businesses are now successfully banning smoking.

Private organizations have formed to oppose smoking. One sued the federal government seeking restrictions on smoking in federal buildings.[200] Another hopes to restrict the use of particular images in tobacco advertising, aimed at women.[201]

According to the tobacco industry, many companies have reviewed their smoking policies, instituted total workplace smoking bans, and/or expanded workplace smoking restrictions based on the EPA report.[202] Further, restaurants and restaurant associations have initiated smoking bans based on the same report.[203]

While banning is one way that businesses have

---

[199] Robert G. Hansen and John R. Lott, Jr, *Regulating IAQ: The Economist's View*, EPA Journal Vol 19 Number 4, 30, October-December 1993.

[200] Federal Employees for Non Smokers Rights v. U.S., 446 F Supp 294 (Minn 1976).

[201] Associated Press, *Secondhand Smoke Can Affect Even the Unborn, Researchers Find*, Washington Post Feb. 23, 1994 at A01.

[202] Flue-Cured Tobacco Cooperative Stabilization Corporation, The Council for Burley Tobacco Inc., Universal Leaf Tobacco Company, Inc., Philip Morris Incorporated, R.J. Reynolds Tobacco Company and Gallins Vending Company v. EPA and Carol Browner, No. 6:93CV370 (Middle District of North Carolina U.S.D.C. filed June 22, 1993).

[203] *Id.*

responded, some have developed some innovative ways to deal with the problem. One German company gives monthly bonuses to workers that do not smoke.[204] Chrysler Corporation is starting to make ashtrays and cigarette lighters an option on their automobiles.[205]

In the mid 1980s only 36 percent of employers had a smoking policy. Today this number has increased to 90 percent.[206] Some of this is due to the requirements of the local laws, and some is due to the employer initiatives.

Government and business have responded to the ETS "threat." The response has grown over the years and it is growing at an exponential rate.

But, the tobacco industry is fighting back. It spent millions of dollars opposing proposed California legislation.[207] It is organizing smokers, as front groups, to conceal its direct involvement, as well as using direct local opposition.[208] It is involved in referendum petition drives to suspend anti-smoking legislation and in

---

[204] Frank Swoboda, *Workplace - OSHA's Move Toward Workplace Smoking Rules Has Unions a Bit Worried*, Washington Post, Jan. 16, 1994 at H02.

[205] *Id.*

[206] Swoboda, *supra* note 204.

[207] Michael Trayner, Michael Begay, Stanton Glantz, *New Tobacco Industry Strategy to Prevent Local Tobacco Control*, 270 JAMA 479, July 20, 1993.

[208] *Id.*

financing election campaigns.[209] It is fighting hard; but it is losing.

INDUSTRY RESPONSE TO THE EPA STUDY

After the EPA published its study on the effects of ETS, the tobacco industry members filed a lawsuit.[210] The lawsuit seeks review of the EPA's decision to classify ETS as a "Group A" (known human) carcinogen and a review of the risk assessment on which that classification was based.[211] The plaintiffs claim that the EPA's actions violate the Radon Gas and Indoor Air Quality Research Act of 1986, the Administrative Procedure Act (APA), and the guarantee of due process of law in the Constitution Amendment V.[212] They are seeking a declaration that the EPA's classification of ETS as a Group A carcinogen and the underlying risk assessment are arbitrary, capricious, violative of the procedures required by law and unconstitutional.[213]

Basis for the Lawsuit

The tobacco industry plaintiffs attacked the risk

---

[209] Trayner, *supra* note 207.

[210] Flue Cured Tobacco Cooperative Stabilization Corp; The Council for Burley Tobacco, Inc; Universal Leaf Tobacco Co., Inc; Philip Morris Inc.; R. J. Reynolds Tobacco Co and Gallins Vending Co. v. Environmental Protection Agency and Carol Browner, Administrator, No. 6:93CV370 (Middle District of North Carolina U.S.D.C., filed June 22, 1993) hereinafter Flue Cured Tobacco.

[211] Flue Cured Tobacco, *supra* note 210, at 2.

[212] Flue Cured Tobacco, *supra* note 210, at 2.

[213] Flue Cured Tobacco, *supra* note 210, at 2.

assessment as exceeding the authority granted to the EPA by the Radon Gas and Indoor Air Quality Research Act of 1986 (Act). The Act gives authority to the EPA to carry out research, development, and related reporting, information dissemination and coordination activities.[214] It does not authorize a regulatory program.[215] The Plaintiffs believe that classification of ETS, as a group A carcinogen, only serves an impermissible regulatory purpose, and therefore, is beyond the EPA's authority.[216]

Under the Act the EPA was required to consult with the Federal Agency Advisory Committee or the Radon Act Advisory Committee when completing the risk assessment.[217] If these groups were consulted membership would include representatives from the states, industry, scientific community and public interest organizations. Since the groups were not consulted, these individuals were precluded from assisting EPA in the manner required by Congress.[218]

The plaintiffs also challenged the classification

---

[214] 42 U.S.C. § 7401 note (1990).

[215] *Id.*

[216] Flue Cured Tobacco, *supra* note 210, at 9.

[217] Flue Cured Tobacco, *supra* note 210, at 9.

[218] While these parties may have been precluded from commenting as part of a Committee, they could have commented during the public comment period when the document was released for comment.

of ETS as a Group A carcinogen as arbitrary and capricious.[219] They stated in their complaint:

> To arrive at its classification of ETS as a Group A carcinogen, EPA deviated from accepted scientific principles of chemistry, epidemiology and toxicology as well as its own guidelines for conducting cancer risk assessments. EPA manipulated and "cherry-picked" scientific data, ignored contrary studies, and employed scientific models, assumptions, and methodologies not accepted by the scientific community, including EPA in other contexts.[220]

Plaintiffs argue that the epidemiology studies concerning ETS and lung cancer do not support a Group A classification.[221] The plaintiffs also argue that the EPA did not follow its guidelines when it made the finding that ETS was a Group A carcinogen.[222]

First, plaintiffs claim that the EPA changed their confidence interval from 95 percent to 90 percent.[223] The

---

[219] Flue Cured Tobacco, *supra* note 210, at 10.

[220] Flue Cured Tobacco, *supra* note 210, at 10.

[221] Epidemiology is the study of the occurrence of a disease in human populations. Investigators observe patterns of the disease occurrences and attempt to statistically correlate the occurrence of the disease with a potential cause. This is done by comparing the incidence rates between two groups. One of which is exposed to the factor or potential cause and one group is not exposed which is the control group.

[222] The EPA has adopted guidelines to help ensure consistency in it methodology when dealing with epidemiologic data. Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33,992 (1986).

[223] The higher the confidence level the less likely the correlation between the cause and the disease is one of chance.

95 percent confidence interval is generally accepted by the scientific community.[224] By changing this interval the EPA changed the results of some of the studies from statistically insignificant to statistically significant. Of the thirty studies reviewed by the EPA 24 did not have statistically significant results at the 95 percent interval.[225] According to the plaintiff, even after the change in the confidence level, over two-thirds of the studies did not have statistically significant results.[226] The plaintiffs concluded that there are a large number of studies which report no overall statistically significant association between ETS and lung cancer and that these studies overwhelm the few studies the EPA claims demonstrate an association.[227] Plaintiffs concluded that given the few studies the EPA used, the EPA's conclusions may simply be based on chance.[228]

Plaintiffs then argued that confounding of data exists. With epidemiologic data it is difficult to disentangle one risk factor from another. Epidemiological studies must be scrutinized closely for confounding before they are relied

---

[224] Flue Cured Tobacco, *supra* note 210, at 13; Address, *supra* note 118, at 100; P. Armitage, Statistical Methods in Medical Research (1973).

[225] Flue Cured Tobacco, *supra* note 210, at 13.

[226] Flue Cured Tobacco, *supra* note 210, at 14.

[227] Flue Cured Tobacco, *supra* note 210, at 15.

[228] Flue Cured Tobacco, *supra* note 210.

upon.[229] The plaintiffs concluded that the EPA's methodology falls well short of its guideline requirements, and therefore, it can not conclude that ETS is a Group A carcinogen.

Plaintiffs also stated that bias is an issue. Plaintiffs defined bias as "any trend in the design, collection, analysis, interpretation or publication of statistical data that causes or may tend to cause a systematic distortion to the true nature of the relationship."[230] The EPA recognized a source of bias in its Risk Assessment -- the tendency of smokers to misrepresent themselves as nonsmokers.[231] The EPA adjusted for this bias by using an unpublished scientific model that, the Plaintiff concluded, contained numerous mathematical and conceptual inconsistencies. Plaintiffs stated that if the EPA had used representative data, the EPA's analysis would not have resulted in statistically significant results.[232]

Plaintiffs next argued that the strength of the data is not high enough to have a statistical association between

---

[229] Flue Cured Tobacco, *supra* note 210, at 16; EPA, *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33,992 (1986).

[230] Flue Cured Tobacco, *supra* note 210, at 17.

[231] Flue Cured Tobacco, *supra* note 210, at 17, EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* at 5-22 (1992).

[232] Flue Cured Tobacco, *supra* note 210, at 17.

ETS and lung cancer.[233] Strength refers to the magnitude of an apparent association between the disease and the causing factor. (Strength in the EPA study was called relative risk.) Plaintiffs stated that associations less than 3.0 are generally considered in the scientific community and by the EPA, to be weak and equivocal.[234] Associations under 2.0 are considered to be extremely weak and there is a greater probability of bias, chance (not statistical significant), or confounding.[235] The overall strength reported by the EPA for the United States studies for ETS is 1.19.[236] Therefore, plaintiffs concluded that the relationship is not strong enough and lung cancer is caused by other factors.

The next attack by plaintiffs involves the dose-response relationship.[237] Plaintiffs stated none of the studies relied on by the EPA show a statistically significant dose-response relationship and, in fact, several

---

[233] Flue Cured Tobacco, *supra* note 210, at 19.

[234] Flue Cured Tobacco, *supra* note 210, at 18.

[235] Flue Cured Tobacco, *supra* note 210, at 18.

[236] Flue Cured Tobacco, *supra* note 210, at 19. While this strength was reported for the average figure for the U.S. studies the number (called relative risk) varied greatly from study to study. Environmental Protection Agency, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* at 5-50 and tables 5-5 to 5-15 (1992).

[237] Flue Cured Tobacco, *supra* note 210, at 20.

studies actually showed a reverse dose-response.[238] That is, as exposure increased there was a decrease in lung cancer.

The issue of consistency was raised by the plaintiffs. This issue looked for consistency across several independent studies. This consistency could prove a causal relationship. Plaintiffs concluded that the epidemiologic studies were remarkably inconsistent.[239] This inconsistency suggested that chance, bias, or confounding has produced the associations reported.

The plaintiffs then attacked the EPA's meta-analysis as not sufficient to provide a basis for a Group A classification.[240] The meta-analysis combined epidemiologic studies that were used to support a Group A classification.[241] The plaintiffs argued that the meta-analysis did nothing to eliminate bias, confounding and methodologic flaws in any individual study, and introduced new and different errors and flaws into the analysis.[242]

Plaintiffs also argued that the EPA's meta-analysis

---

[238] Flue Cured Tobacco, *supra* note 210, at 20. As discussed in the earlier chapter on the EPA study this author disagrees with the Plaintiffs' conclusions on the lack of a dose-response relationship.

[239] Flue Cured Tobacco, *supra* note 210, at 21.

[240] Flue Cured Tobacco, *supra* note 210, at 21.

[241] Flue Cured Tobacco, *supra* note 210, at 21.

[242] Flue Cured Tobacco, *supra* note 210, at 21.

violated accepted scientific methodology, because such studies may only be combined when they are similarly designed, similarly conducted, and the data is pooled with like data.[243] The studies in question do not meet these criteria. They also claim the EPA manipulated, ignored and cherry-picked data for inclusion in the meta-analysis and the EPA failed to adjust adequately for smoking status misclassification bias which effects its meta-analysis.[244] The plaintiffs concluded that the apparent weak association produced by the meta-analysis results are from either failures to account for bias and confounding factors, or from outcome-determinative choices the EPA made when selecting methodology, data and studies to employ.[245]

Plaintiffs attacked the EPA's reliance on a proxy substance to justify the Group A classification.[246] This claim is based on the EPA claiming similarities between ETS and mainstream smoke -- the smoke that is inhaled by a smoker. Plaintiffs argued that ETS is not the equivalent of mainstream smoke because the "general physical and chemical properties of the two smokes, including particle size, ph, constituent-phase distribution and other physicochemical

---

[243] Flue Cured Tobacco, *supra* note 210, at 22.

[244] Flue Cured Tobacco, *supra* note 210, at 22 and 23.

[245] Flue Cured Tobacco, *supra* note 210, at 24.

[246] Flue Cured Tobacco, *supra* note 210, at 25.

traits, differ significantly."[247] They argued that a fair comparison can not be made based on these differences for even if ETS and mainstream smoke are nearly identical the immense quantitative differences precludes reliance on a proxy analyze.[248] Plaintiffs stated that ETS exposure to nonsmokers is only equivalent to smoking one to five cigarettes per year.[249]

Plaintiffs expanded their argument concerning the EPA's failure to follow established risk assessment guidelines.[250] It argued that the EPA failed to ensure that the studies were evaluated according to sound biological and statistical considerations and procedures. Plaintiffs felt the EPA did not use epidemiologic studies that were "sufficient."[251] Nor did they give full consideration to all relevant scientific information. Further, the EPA did not fully present all relevant scientific information in the ETS Risk Assessment. The EPA did not use the most scientifically appropriate interpretation to assess risk. It argued the EPA did not identify the strengths and weaknesses of the ETS Risk Assessment by describing uncertainties, assumptions,

---

[247] Flue Cured Tobacco, *supra* note 210, at 25.

[248] Flue Cured Tobacco, *supra* note 210, at 26.

[249] Flue Cured Tobacco, *supra* note 210, at 27.

[250] Flue Cured Tobacco, *supra* note 210, at 28.

[251] Flue Cured Tobacco, *supra* note 210, at 28.

limitations and the scientific basis and rationale for the assessment. Plaintiffs concluded that if the EPA guidelines were followed, they did not provide for classification of ETS as a Group A carcinogen based upon the epidemiology studies.[252]

Plaintiffs argued that by classifying and publicizing ETS as a Group A carcinogen the EPA expected and intended its action to have a substantial regulatory impact, resulting in restriction of smoking in public and the workplace.[253] This impact exceeds the regulatory authority authorized by Congress.[254]

Plaintiffs raised four counts against the EPA.[255] The counts are that:

> EPA lacked the authority under the Radon Act to classify ETS as a Group A carcinogen and illegally conducted the ETS Risk Assessment.
>
> The classification of ETS as a Group A carcinogen is arbitrary, capricious and otherwise not in accordance with law.
>
> EPA violated the APA by failing to comply with its own guidelines.
>
> EPA violated due process by failing to comply with statutory restrictions, required procedures and its own

---

[252] Flue Cured Tobacco, *supra* note 210, at 32.

[253] Flue Cured Tobacco, *supra* note 210, at 35.

[254] Flue Cured Tobacco, *supra* note 210, at 35.

[255] Flue Cured Tobacco, *supra* note 210, at 40-48.

guidelines.[256]

Plaintiffs sought a declaration that the EPA's classification of ETS as a Group A carcinogen and the ETS Risk Assessment violates the guarantee of due process, a grant of an injunction requiring the EPA to withdrawal its classification of ETS as a Group A carcinogen, and to withdraw the ETS Risk Assessment.[257]

EPA's Response

While this case is pending and the EPA's exact litigation strategy is not known, the EPA indicated its response to the allegations in the lawsuit, through an EPA publication.[258] As to the charge of selecting limited studies, the EPA stated that they included all available lung cancer studies of never-smoking women and ETS which appeared prior to the necessary cutoff date for literature review. The EPA believes that there is a dose-response trend in fourteen of the epidemiology studies that provided data sufficient for dose-response testing. All of the studies had positive trends, and ten of these were statistically significant (this is in contradiction of the tobacco companies' claims). The EPA also stated that it's report examined the total weight of the evidence, not just

---

[256] Flue Cured Tobacco, *supra* note 210, at 40-48.

[257] Flue Cured Tobacco, *supra* note 210, at 47-48.

[258] Steven Bayard and Jennifer Jinot, *Environmental Tobacco Smoke: Industry's Suit*, 19(4) EPA Journal 20 (1993).

the 30 epidemiology studies. It also stated that the similarities of ETS and mainstream smoke is well documented in the Risk Assessment.

The EPA filed a motion to dismiss the complaint for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.[259] They make four arguments.

First, that there has been no "agency action" under the Administrative Procedures Act (APA).[260] Neither the classification of ETS as a known carcinogen or the publication of the report is agency action and therefore, the courts have no jurisdiction to hear the complaint.

The EPA cites to precedent that the publication of a government report is not an agency action within the meaning of the APA.[261] They concluded, that like the listed cases, the ETS report announced no rule and imposed no legal obligation nor authorized the government to seek any civil

---

[259] Filed in Civil Action No. 6:93CV370 supra 205 on July 20, 1993. Hereinafter Motion.

[260] Motion, *supra* note 259, at 11.

[261] Industrial Safety Equipment Association, Inc. v. EPA, 837 F.2d 1115 (D.C.C. 1988); American Trucking Association v. United States, 755 F.2d 1292 (7th Cir 1985); Pharmaceutical Manufacturers Association v. Kennedy, 471 F. Supp. 1224 (D. Md. 1979); Radio-Television News Directors Ass'n v. Federal Communications Comm's, 809 F.2d 860 (D.C.C. 1987); Environmental Waste Control Inc. v. Agency for Toxic Substances and Disease Registry, 763 F. Supp. 1576 (N.D. Ga. 1991).

or criminal enforcement sanctions.[262] There are no requirements for any entity or individual to heed the report's contents, and the report in no way prohibits, restricts or otherwise limits smoking, sale of tobacco or exposure to ETS.[263] EPA concluded that the report only supplied information and is not subject to review under the APA.[264]

For similar reasons they argued that the Group A classification is not reviewable under the APA. It was simply a conclusion in the report with no independent force of its own.[265] They discussed the issue raised by plaintiffs that the classification has a "substantial regulatory impact." They stated that such an impact does not suffice to establish reviewable agency action.[266] They did state that the plaintiffs will have a chance to challenge any regulation of the government restricting smoking, during the public comment period. The EPA concluded that the classification of ETS as a Group A carcinogen is not an activity defined as "agency action" in

---

[262] Motion, *supra* note 259, at 17.

[263] Motion, *supra* note 259, at 17.

[264] Motion, *supra* note 259, at 18.

[265] Motion, *supra* note 259, at 18.

[266] Cabais v. Egger, 690 F.2d 234 (D.C.C. 1982); Industrial Safety Equipment Association, Inc. v. EPA, 837 F.2d 1115 (D.D.C. 1988).

the APA and is beyond the scope of judicial review.[267]

The EPA argued that even if the report and Group A classification were agency action, there was no final agency action subject to review under the APA.[268] Agency action is final, for purpose of judicial review,[269] if it has "the status of law" and "immediate compliance with its terms is expected."[270] The EPA concluded that since no legal consequences flow from the publication of the ETS report, or the classification, the action is not final.

The EPA argued that the issues raised by the plaintiffs are not ripe for review.[271] These issues are factual rather than legal and the EPA concluded that the facts fall on their side. The EPA argued that the report produced no hardship upon the plaintiffs, because it does not have the kind of direct and immediate impact necessary to justify judicial review.

The EPA's final argument was that the plaintiffs presented no justifiable claim that the report, or the

---

[267] Motion, *supra* note 259, at 22.

[268] Motion, *supra* note 259, at 22.

[269] 5 U.S.C. § 704 (1966).

[270] Federal Trade Commission v. Standard Oil Company of California, 449 U.S. 232, 101 S. Ct. 488 (1980).

[271] Motion, *supra* note 259, at 28. Ripeness of agency activity for judicial review depends on two primary factors: "the fitness of the issues for judicial decision and the hardship to the parties from withholding court consideration." Abbott Laboratories v. Gardner, 387 U.S. 136 (1967).

classification, works an unlawful deprivation of property and, is therefore is not unconstitutional.[272] The EPA stated that the plaintiffs contention that they are deprived of property is an impermissible attempt to avoid the restrictions of an APA review by simply recharacterizing the basis of an APA claim as a constitutional violation. It further argued that the allegations of harm do not meet the standards necessary to sustain an action for declaratory and injunctive relief, and therefore, the allegations do not state a claim for relief.

The EPA also said that even if the publication of the report, or the classification, deprived the plaintiffs of a property right, there is no constitutional violation.[273] The EPA stated their responsibility to protect the public health and to inform the public of threats to public health plainly outweigh the injuries alleged by the plaintiff and therefore, there is no taking of a property right.[274]

The EPA requested that the complaint be dismissed for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.[275] The judge has not acted on this motion, but the EPA is hoping for an

---

[272] Motion, *supra* note 259, at 32.

[273] Motion, *supra* note 259, at 35; Mathews v. Eldridge, 424 U.S. 319, 96 S. Ct. 893 (1976).

[274] Motion, *supra* note 259, at 35.

[275] Motion, *supra* note 259, at 35.

action in the near future.[276]

Motions Raised by Third Parties

Private organizations have become involved in this lawsuit. The American Lung Association, American Heart Association, American Cancer Society, American Public Health Association and Public Citizen have requested leave to file a memorandum as amici curiae and also filed a memorandum on the merits.[277] They are seeking to advance two interests: First, an interest in assuring that the public has access to scientific data. Second, that government agencies can issue scientific reports on public health issues without being subjected to lawsuits.[278]

In their motion on the merits, they raised the same issues that the EPA raised in its motion. They requested that the court dismiss the complaint for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.[279]

They raised the issue that the complaint is not

---

[276] Telephone interview of Laura Neuwirth, EPA Office of Counsel (24 May 1994).

[277] Motion filed August 30, 1993 in the Flue Cured Tobacco case, No. 6:93-CV-370 supra 205, filed on July 20, 1993. Hereinafter American Lung Association.

[278] American Lung Association, *supra* note 277, at 3.

[279] American Lung Association, *supra* note 277.

reviewable under the APA.[280] They made the same type of arguments that the EPA raised, but they expanded the argument in looking at the purpose of the report. They stated that:

> These scientific reports are designed to expand the knowledge of scientists and citizens alike. They are vital to the advancement of scientific learning, and those that are controversial generate scientific debate and discussion, thus expanding knowledge about a given topic. Scientific reports on health issues lead to a fuller exploration of the risks faced by the public, thus allowing decisions to be made about where further scientific research is needed, as well as allowing society independently to assess a particular health risk and to decide what steps should be taken to address or minimize those risks.[281]

They also argued that there is no final agency action that is ripe for judicial review.[282] Their arguments are the same as those raised by the EPA in their brief.

Discussion of Probable Court Response

It is likely that the court will rule in favor of the EPA holding the EPA's actions are not the type that would be reviewable under the APA.

While the tobacco industry is "hurt" by the classification, it is ultimately hurt by regulation the use of tobacco, not by the EPA report. Any possible taking or lack of due process would be by those regulating and not by

---

[280] American Lung Association, *supra* note 277, at 7.

[281] American Lung Association, *supra* note 277, at 9.

[282] American Lung Association, *supra* note 277, at 11.

the EPA's report. The tobacco industry can attack the report when they fight any smoking regulation. It will cost the tobacco industry more to fight each law as they are being written, as opposed to fighting the EPA report. But the attack of the report, will most likely fail.

FUTURE OF ETS

ETS is expected to become more regulated. It is likely that businesses will continue to limit smoking. States and municipal governments will continue to expand their regulations. The federal government's role is growing at an exponential rate. The federal role will be discussed as an example of expanding regulation.

There is the Smoke-Free Environment Act bill pending before Congress.[283] This bill imposes a total ban of smoking in virtually all non-residential buildings. This bill recently moved from the Subcommittee on Health and the Environment to the Committee on Energy and Commerce.[284] There changes in the bill, provide exceptions to the ban for bars, restaurants and social clubs.[285]

There are Indoor Air Acts pending before the House and

---

[283] H.R. 3434, 103d Cong., 1st Sess. (1993).

[284] Telephone interview with a Representative from the Subcommittee on Health and Environment on May 26, 1994.

[285] *Id.*

Senate.[286] While there have been Indoor Air Acts, before the House and Senate, for many years (none of them have passed) it is an issue Congress does not drop and eventually a bill will pass. Such a bill may give the EPA power to regulate ETS, as does the one currently before the House.[287]

Even if the EPA never gets authority to regulate indoor air, the OSHA is currently regulating in this area.[288] While the OSHA regulation is limited to protecting employees, a ban on smoking to protect employees would also protect customers.

Finally, the EPA is doing non-regulatory work in this area. It is committed to a pollution prevention approach to indoor air quality.[289] The key elements of this approach are to: "seek to minimize peoples' exposure to all indoor air contaminants to the extent reasonable; transfer existing information to those in a position to improve indoor air quality; and conduct research to develop sound scientific

---

[286] S. 656, 103d Cong., 1st Sess. (1993), H.R. 2919, 103d Cong., 1st Sess. (1993).

[287] H.R. 2919, 103d Cong., 1st Sess. (1993).

[288] Indoor Air Quality; Proposed Rule, 59 Fed. Reg. 15,968 (1994) (to be codified at 29 C.F.R. §§ 1910, 1915, 1926 and 1928.

[289] Robert Sussman, Deputy Administrator of EPA, Testimony before Subcommittee on Clean Air and Nuclear Regulation, Committee on Environment and Public Works, United States Senate (May 25, 1993).

information to fill knowledge gaps."[290] The major thrust of the indoor air program has been to take what is currently known about indoor air problems and solutions and work with experts and outside audiences to produce guidance documents and training materials that address the need for state-of-the-art information.[291] The EPA believes that "significant benefits can be realized by informing key audiences about the prevention and problem solving actions they can undertake voluntarily to improve indoor air quality."[292]

They have set primary objectives in their program. These objects are to:

> Establish effective partnerships with organizations representing the range of target audiences for indoor air quality information to communicate specific guidance and information and promote timely action on indoor air quality issues;
>
> Forge constructive alliances with other Federal agencies to leverage resources and ensure that existing statutory authorities are used most effectively;
>
> Develop practical guidance on indoor air quality issues utilizing a broad-based consensus approach which includes representatives from industry and public interest groups to ensure that information provided is accurate and practical;
>
> Design market-based incentives for industries to lower chemical emissions from their products and provide consumers and other decisions-makers with

---

[290] *Id.*

[291] Sussman, *supra* note 289.

[292] Sussman, *supra* note 289.

information needed to make informed purchasing decisions;

Sharpen the focus of the chemical screening and risk management program under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to ensure that chemicals that pose unreasonable risks indoors are identified and addressed;

Identify and fill research gaps in order to provide information to address outstanding indoor air quality policy issues;

Select appropriate environmental indicators to measure progress in reducing population exposure to indoor air quality problems as the program matures;

Enhance scientific understanding and public awareness of the complex factors affecting indoor air quality; and

Bring about substantial reductions in human exposure to the entire range of indoor air pollutants.[293]

To meet these goals the EPA has published many documents covering indoor air in general and ETS.[294] In addition to working on their own programs, the EPA works closely with other federal agencies in a concerted effort to

---

[293] Environmental Protection Agency, *Targeting Indoor Air Pollution EPA's Approach and Progress,* EPA 400-R-92-012 (1993); Bob Axelrad, *Improving IAQ: EPA's Program*, EPA Journal, Vol. 19, Number 4, October December 1993.

[294] EPA, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* (1992); EPA, *Secondhand Smoke* (1993); EPA, *Targeting Indoor Air Pollution EPA's Approach and Progress* (1993); EPA and CPSC, *The Inside Story A guide to Indoor Air Quality* (1993); EPA, *Introduction to Indoor Air Quality A Self-Paced Learning Module* (1991); EPA, *Introduction to Indoor Air Quality A Reference Manual* (1991).

better understand indoor air and how to reduce risk.[295]

Regulation, in this area, is increasing and will continue to increase in the near future. ETS is a hot topic for the public and the end of the debate is not in sight. Smokers want to maintain the right to light up without restriction, a right they have had for decades, and nonsmokers want the right to breath smoke-free air.

CONCLUSION

Future regulation of ETS is expected although the extent of regulation is in the process of being determined. Currently, the EPA has very limited authority in this area, but acts are pending before Congress to increase this authority. The federal agency with the most authority to regulate is the OSHA, which has pending regulations pending, that would regulate ETS in the workplace. The Food and Drug Administration may soon regulate cigarettes by classifying them as a drug.

Case law is relevant for areas in which ETS is not regulated. Most cases have supported smoking limits or bans. The threat of being sued for allowing exposure is increasing and some companies are taking action based on this threat.

---

[295] Robert Sussman, Deputy Administrator EPA, testimony before the Subcommittee on Clean Air and Nuclear Regulation, Committee on Environment and Public Works, United States Senate (May 25, 1993), Bob Axelrad, *Improving IAQ: EPA's Program*, EPA Journal, Vol. 19, Number 4, October-December 1993.

The EPA ETS study, has created a ripple across America. Many municipal and state governments and businesses have increased the regulation and control of ETS based on this study. The tobacco industry responded by suing the EPA. However, it is likely that the court will rule in favor of the EPA on its motion to dismiss the lawsuit.

While there is doubt about the relationship between ETS and lung cancer, it is clear that ETS is related to other diseases. These diseases, by themselves, are enough to regulate ETS. The ETS-lung cancer relationship is just another nail in the coffin of tobacco.

The future, of ETS, is increased regulation through bans and, possibly, innovative methods. Regulation will continue at federal, state and local levels because of the need to protect the public from possible risks of ETS exposure. Businesses will continue to control exposure to ETS for different reasons. They want to serve their customers, protect themselves from lawsuits and, in some instances, some feel the need to protect the public.

Regulation of ETS is the future. It is appropriate to regulate ETS because it has been linked to numerous illnesses. While there are two sides to this issue, tne tobacco industries side is losing the battle. Ultimately this regulation may be a key factor in the destruction of the tobacco industry.