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Cigarette classification a burning issue

New evidence could lead to 'drug' classification for cigarettes

by Michael S. Burkhardt and M. Allison Despard

Beginning in the early 1960s, the United States Surgeon General began to examine the health consequences of smoking tobacco. In the first major report on smoking and health, the Surgeon General linked smoking with lung cancer. Since that report, thousands of scientific studies exploring the health consequences of smoking have followed. Today there remains absolutely no scientific debate about the harmful effects of smoking tobacco.² There is not one national or international health organization which denies that smoking is a serious health hazard.³

As early as 1964, the Advisory Committee to the Surgeon General published a report concluding that cigarette smoking is a cause of lung cancer in men and a suspected cause in women.⁴ In that same year, the American Medical Association called smoking a serious health hazard. By 1966, health warnings appeared on cigarette packages.⁵ In 1967, the Surgeon General concluded that smoking is the primary cause of lung cancer.⁶ In 1986, the Surgeon General's report concentrated on the harmful effects of involuntary smoking.⁷ Cigarette smoking is responsible for more than 300,000 deaths each year in the United States alone.⁸ Smoking related diseases include cancer of the mouth, lungs, liver, and pancreas, emphysema, chronic obstructive pulmonary diseases, heart problems, strokes, and many others.⁹

Throughout the past several decades, Congress has enacted a number of statutes specifically designed to protect consumers from harmful substances. The well-known damaging effects of tobacco and cigarette smoke make cigarettes a prime target for regulation by a number of these existing statutes. Despite the obvious deleterious effects of

[C]igarette smoking remains the largest single preventable cause of death and disability for the U.S. population.¹

—C. Everett Koop
U.S. Surgeon General

tobacco, however, cigarettes have remained relatively unregulated. United States Representative Henry Waxman commented:

They [the tobacco industry] are now unregulated. They are treated very differently, in a very special way, than any other industry in this country.... They have no review of their activities by any level of government.¹⁰

Outside of taxation,¹¹ cigarettes are meaningfully regulated in only two ways. First, cigarette manufacturers must locate a warning statement conspicuously on each package of cigarettes and on printed advertisements.¹² Second, Congress bans all cigarette advertising from broadcast media, which includes television and radio.¹³

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There are three important statutes that could and should regulate cigarettes in order to protect consumers and the public—at-large from the harmful effects of cigarettes: the Hazardous Substances Act,¹⁴ the Toxic Substances Control Act,¹⁵ and the Food, Drug, and Cosmetic Act.¹⁶

Both the Hazardous Substances Act and the Toxic Substances Control Act are potentially suited to regulate smoke generated from cigarettes. The Hazardous Substances Act defines a substance as hazardous "if such substance...may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use..."¹⁷

Cigarettes contain a number of different substances. Twenty one known or suspected carcinogens, co-carcinogens, or tumor promoters have been identified in cigarette smoke. The toxic substances found in smoke, commonly referred to as Environmental Tobacco Smoke (ETS), include nicotine, carbon monoxide, carbonyl sulfide, hydrogen cyanide, and nitrogen oxides. Carcinogens found in ETS include benzene, formaldehyde, hydrazine, tar, o-toluidine, 2-naphthylamine, nickel, cadmium, and quinoline.¹⁸ Not only are these chemicals harmful in themselves, but also the Environmental Protection Agency (EPA) has classified environmental tobacco smoke as a Group A carcinogen, a category reserved for compounds with the strongest causal relationship to injury.¹⁹

In addition to regulating toxins, the Hazardous Substances Act also regulates chemical irritants. Besides containing toxins, cigarette smoke is also an irritant. As early as 1972, the Surgeon General noted the discomfort caused to those exposed to cigarette smoke.²⁰ Tissue in the eyes is most vulnerable to irritation, but smoke also affects the mucous membrane of the nose, throat, and lungs.²¹

Any use of a product containing this many damaging substances clearly will

result in personal injury or substantial illness as defined in the Hazardous Substances Act. Cigarette use has already been linked to numerous painful and deadly diseases. Therefore, the plain language of the definition of a "hazardous substance" includes cigarette smoke. It seems illogical, then, that cigarette smoke is excluded from regulation.

A second statute, the Toxic Substances Control Act, also focuses on health and safety and should reasonably apply to tobacco.²² The purpose of the statute is to require manufacturers of chemical substances to collect data on the effect of their products on health and the environment.²³ Further, the Act grants authority to regulate substances that pose an unreasonable risk of injury to health or the environment to the Administrator of the EPA.²⁴ The EPA has authority to regulate a substance when it fits within the definition of a "chemical substance," defined by the Act as "any organic or inorganic substance of a particular molecular identity including...substances...occurring in nature" (emphasis added).²⁵

In order for a substance to be tested, the EPA must find in part that its use "may present an unreasonable risk of injury to health or the environment."²⁶ It would not be difficult to reach this conclusion. The number of toxins and carcinogens found in tobacco and cigarette smoke has been discussed earlier. Overwhelming medical evidence shows links between tobacco and cancer, heart disease, and respiratory ailments.²⁷

The Toxic Substances Control Act explicitly excluded cigarettes from regulation.²⁸ In 1990, the Equal Treatment For Cigarettes Act was introduced in Congress to repeal the tobacco exemption from the Toxic Substances Control Act, but the bill failed.

The tobacco industry continues to deny the serious health risks of smoking tobacco. After releasing a once-secret list of over 600 ingredients found in cigarettes, the tobacco industry claimed that every ingredient was reviewed by

an independent panel of expert toxicologists and found safe for use in the amount present in a cigarette.²⁹ Further, the tobacco industry still maintains that the link between cigarette smoking and lung cancer is in dispute in the biomedical community.³⁰ These claims directly contradict widely disseminated and researched medical information.³¹ It is this attitude, and the lobbying power possessed by a multi-million dollar industry, that has helped cigarettes escape much of the regulatory scheme established by Congress to protect public health.

The tobacco industry is an important economic force. The \$50 billion a year industry employs 48,800 people in the manufacturing process alone.³² Tobacco is grown in 23 states and in Puerto Rico. It is the nation's seventh largest cash crop, responsible for \$3 billion and 136,000 farms.³³

Recently, the special protection granted to tobacco has come under fire. On May 18, 1993, U.S. Representative Mike Synar (D-Okla.) introduced an amendment to the Federal Food, Drug, and Cosmetic Act.³⁴ The amendment, the Fairness in Tobacco and Nicotine Regulation Bill, proposes to develop regulations concerning the manufacture, sale, labeling, advertising, and promotion of tobacco. The amendment bars the Food and Drug Administration (FDA) Commissioner from outlawing the sale and distribution of tobacco merely because it causes disease.

The amendment would establish a Tobacco and Nicotine Products Advisory Committee in the FDA that would review (1) the scientific data of tobacco's effects on human health, (2) the tobacco manufacturing process, (3) nicotine's role in the smoking habit, (4) the manufacturers' marketing and promotional methods, and (5) current laws regulating tobacco at the local, state, and federal level. The bill is currently pending.³⁵

The amendment has floundered in Congress for some time and it appears

the FDA has decided to force the issue. The current FDA Commissioner, Dr. David Kessler, supported regulating cigarettes under the Federal Food, Drug and Cosmetic Act while testifying before Congress on March 25, 1994. Previous FDA Commissioners have refused to regulate tobacco, claiming that cigarettes did not fall within the statutory definition of a drug or device.

The tobacco industry undoubtedly will challenge any attempt by the FDA to regulate cigarettes. The Federal Food, Drug, and Cosmetic Act does not specifically exclude tobacco from its reach.

The plain-language definition of "hazardous substance" includes cigarette smoke. Why, then, is cigarette smoke exempt from regulation?

The purpose of the Act is to safeguard health and protect consumers from misleading claims and adulterated food, drugs, and cosmetics,³⁶ and the statute should be read broadly to effectuate this purpose.³⁷ The statute on its face is designed to prevent the introduction or sale into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.³⁸ The battle between the FDA and the tobacco industry will center around whether nicotine contained in cigarettes can be classified as a drug or device under the statutory definition. A drug is defined in relevant part as:

The term "drug" means... (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals....³⁹

A device is defined as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . (3) intended to

affect the structure or any function of the body of man or other animals.⁴⁰

In 1952, the courts first considered whether cigarettes were a drug under an identical definition of that term found in the Federal Trade Commission Act.⁴¹ In *FTC v. Liggett & Myers Tobacco Co.*,⁴² the Federal Trade Commission attempted to exercise jurisdiction over cigarettes and enjoin dissemination of allegedly false cigarette advertising. The term "drug" had the same definition as the one in the Food, Drug, and Cosmetic Act and, therefore, the court examined

the legislative history of the Act to determine whether cigarettes could be considered a drug.⁴³

The court found that products included in the definition of the word drug, such as "slenderizers," had decided effects upon the structure of the body, and people consumed the products to bring about those effects.⁴⁴ The court decided that cigarettes could not be described in that way and, therefore, they were not drugs under the FDA definition.⁴⁵

In line with this reasoning, courts have classified tobacco as a drug in only two cases. In the first case, the manufacturer of Fairfax cigarettes distributed a leaflet with its product lauding the benefits of its cigarettes.⁴⁶ The leaflets suggested that Fairfax cigarettes were "effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps..." and were harmless to those suffering from heart conditions, high blood pressure, or circulatory diseases.⁴⁷ Because the cigarettes were advertised as having an effect on the functioning of the body, the court concluded that these particular cigarettes were drugs.

In the second case, the manufacturer of "Trim Reducing-Aid Cigarettes" made various claims about how its prod-

uct would help consumers lose weight.⁴⁸ When asked to produce medical evidence of this claim, the manufacturer did supply medical opinions of a few doctors, but stated that some of its ads contained "metaphors or figures of speech, not to be taken literally."⁴⁹

The next court case considering whether cigarettes are a drug was in 1980 in *Action on Smoking and Health v. Harris*.⁵⁰ The Action on Smoking and Health Organization challenged the FDA to assert jurisdiction over cigarettes as a drug or device and asked the FDA Commissioner to restrict their sale to pharmacies. The Commissioner refused to exercise jurisdiction over cigarettes and the Action on Smoking and Health Organization filed a claim challenging that decision.⁵¹ The case was dismissed and on appeal the court found that the Commissioner's refusal to assert jurisdiction over cigarettes was not arbitrary, capricious, or contrary to law.⁵² Similarly to *Liggett & Myers*, the *Harris* court examined whether cigarettes were a drug or device under the statutory definition and concluded that cigarettes were not intended to affect the functioning of the body.⁵³

Liggett & Myers and *Harris* may have been properly decided at the time, but today there is concrete scientific evidence that cigarettes have a pronounced effect on the structure and function of the body and that nicotine in cigarettes is physically addictive. The effects of cigarette smoking were completely unknown in 1952 and the facts about nicotine addiction were not officially acknowledged until 1986. Consequently, there is a strong argument that cigarettes should now be considered a drug or device by the FDA.

In *Harris*, the court stated, "the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising and any other relevant source."⁵⁴ The tobacco industry will certainly not come right out and state that they intend their ciga-

rettes to affect the structure or function of the human body. Consumers must therefore look to other sources of information to discover whether the tobacco industry actually intends their products to affect the function of the human body.

Evidence of consumer intent can be a relevant source of information where the evidence is strong enough to justify an inference as to the manufacturer's or seller's intent.⁵⁵ In order to infer the requisite statutory intent from the actions of consumers, those consumers must use the product almost exclusively with the appropriate intent: to affect the structure or function of their bodies.⁵⁶ Logically, if consumers use a particular product almost exclusively for a certain purpose then sellers of that product will intend that their product satisfy consumer expectations so that consumers continue to buy their product. Thus, we must examine why people continue to buy and smoke cigarettes.

The origin of tobacco smoking is unknown, but it seems fair to say that the appeal for tobacco did not originate with fancy advertisements or promotional gifts. So what has sustained a demand for tobacco that leads to millions of dollars in profits for tobacco companies each year? RJR Nabisco contends that smokers use cigarettes as a psychological tool for "enjoyment, performance enhancement and/or anxiety reduction."⁵⁷ There is no doubt that tobacco companies spend large sums of money on advertisements and promotions each year which help to sell their products. However, with all the negative media coverage about smoking and the volume of information about its harmful effects, continued tobacco use cannot be attributed simply to ad campaigns, peer pressure, or stress relief.

People continue to smoke, even though they know it could cause any number of deadly diseases, because smoking is addictive.⁵⁸ Nicotine has a powerful effect on the central nervous system, and the cigarette is a diabolically effective delivery system. When a

smoker inhales, nicotine first goes into the lungs and bloodstream. Within seven to 10 seconds, a significant portion of the nicotine travels through the blood stream directly to the brain.⁵⁹

An average cigarette contains about 10 mg of nicotine, of which between one and two milligrams reach the lungs. The actual amount absorbed into the bloodstream depends on several factors such as the number of inhalations and the depth and duration of inhalations.⁶⁰ Inhaling nicotine allows it to reach the brain twice as fast as intravenous drugs and three times as fast as alcohol.⁶¹

Nicotine simultaneously relaxes and stimulates the body. Once nicotine reaches the brain it acts like adrenaline, a hormone, and acetylcholine, a neurotransmitter. Both substances affect the nervous system.⁶² After a few puffs, the increased level of nicotine causes the heart to beat faster and blood pressure to rise resulting in increased alertness and possibly increased mental acuteness.⁶³ Nicotine can also affect hormone release from the pituitary gland and the adrenal gland.⁶⁴ While stimulating hormone release and heart rate, nicotine also triggers the release of natural opiates called beta-endorphins, causing muscles to relax.⁶⁵ Nicotine further causes the release of a chemical substance called dopamine which affects mood, emotions, and muscular movements.⁶⁶ As scientist Dr. Neil Grunberg explained: "We know that nicotine increases dopamine, a fact that may explain why smokers report feeling good when they light up."⁶⁷

There is overwhelming scientific evidence that nicotine from tobacco is addictive and that smokers quickly become addicted to this drug.⁶⁸ Former United States Surgeon General, C. Everett Koop, concluded in a 618-page report, called "The Health Conse-

quences of Smoking: Nicotine Addiction," that nicotine found in cigarettes and other forms of tobacco is addictive in the same manner as illegal drugs such as heroin and cocaine.

Other major health organizations also have recognized nicotine as an addictive substance including the World Health Organization, the American Medical Association, the American Psychiatric Association,⁶⁹ and the American Psychological Association.⁷⁰ While these organizations define addictive substances differently, common components of the definitions include (1) compulsive use despite knowledge of the harmful qualities of a substance, (2) a psychoactive or chemical effect on the brain, and (3) reinforcing behavior that develops continued use.⁷¹

Nicotine meets these three common elements of addictive substances. Nicotine's addictive power is evidenced by the fact that 51 million Americans still smoke despite the overwhelming evidence linking smoking to numerous

With all the negative media coverage of smoking, and the volume of information about its harmful effects, continued tobacco use cannot be attributed simply to ad campaigns, peer pressure, or stress relief.

painful and deadly diseases like cancer and emphysema.⁷² As discussed above, nicotine's effect on the brain and nervous system is medically unchallenged. Because nicotine actually changes the way our cells normally function, continued exposure to nicotine leads to a physical dependence.⁷³ Forced to function with the presence of nicotine, cells adapt as a matter of course, creating a biological dependence. Most smokers maintain a relatively constant level of nicotine in their blood, usually supplied by at least ten cigarettes daily.⁷⁴

Surveys indicate that 90 percent of smokers would like to quit and that 85 percent of those who tried to quit relapsed within three months.⁷⁵ These figures convincingly demonstrate that smokers continue because of the physical addiction to nicotine. Moreover, smokers who attempt to quit experience withdrawal symptoms typical of an addictive drug.⁷⁶ Withdrawal from nicotine is not as dramatic as that from alcohol, but it resembles withdrawal from central nervous system stimulants such as cocaine and amphetamines.⁷⁷ The critical factor to creating nicotine dependence is exposure.

Even if nicotine were not physically addictive, it nonetheless affects the body: the enjoyment caused by smoking results from increased alertness and relaxation caused by nicotine.⁷⁸ If cigarettes created no pleasant physical sensations, people would not buy them and tobacco manufacturers would be out of business. This is especially true in today's climate where smokers are increasingly becoming outcasts in workplaces and public buildings and where there is a wealth of information available that smoking kills smokers. Thus, for the tobacco industry to claim that they do not intend cigarettes to affect the function of the human body—for nicotine to create a pleasurable physical sensation—is like saying they do not care if their products sell.

Conclusion

Nicotine affects the body and is addictive. The addiction and long term effects of nicotine result in many health disabilities and death. Congress has enacted statutes to protect consumer health and safety. Without heavy political pressure against regulation by the Tobacco Institute, and without other significant economic considerations, there would be no logical reason for these statutes to exempt tobacco. However, there is a tide in the affairs of tobacco, and it is ebbing. Under the

plain language of the Federal Food, Drug and Cosmetic Act, cigarettes should be regulated. Further, the specific exemptions found in the Hazardous Substances Act and the Toxic Substances Act should be repealed and these Acts should regulate cigarette smoke along with other harmful substances.

ENDNOTES

¹OFFICE ON SMOKING AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING 5-6 (1986) [hereinafter 1986 SURGEON GENERAL REPORT].

²CATHY BECKER POPESCU & J.M. CAREY, AMERICAN COUNCIL ON SCIENCE AND HEALTH, SMOKING OR HEALTH...IT'S YOUR CHOICE (1992), available in LEXIS, NEWS library, NWLTRS file.

³*Id.*

⁴OFFICE ON SMOKING AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, SIGNIFICANT DEVELOPMENTS RELATED TO SMOKING AND HEALTH 1964-1993 1 (1994).

⁵*Id.*

⁶*Id.*

⁷*Id.* at 4.

⁸POPESCU & CAREY, *supra* note 2; H. Thomas Milhorn Jr., *Nicotine Dependence*, 39 AMERICAN FAMILY PHYSICIAN 214 (March 1989); Christine Gorman, *Why It's So Hard to Quit Smoking; A New Report Declares that Tobacco, Like Heroin, is Addictive*, TIME, May 30, 1988, at 57.

⁹POPESCU & CAREY, *supra* note 2.

¹⁰News Conference on Tobacco Companies and Nicotine Spiking with Representative Henry Waxman (D-CA) House Radio TV Gallery Washington D.C., April 13, 1994, available in LEXIS, LEGIS library, FEDNWS file [hereinafter "Waxman"].

¹¹Over \$13 billion in taxes are collected at the federal, state, and local levels. John Dillin, *Sharp Criticism Puts Tobacco Industry on the Political Ropes*, THE CHRISTIAN SCIENCE MONITOR, April 18, 1994, at 24.

¹²15 U.S.C. § 1333 (1994). The act provides four options for manufacturers, such as "SURGEON GENERAL'S WARNING: Cigarette smoking contains carbon monoxide."

¹³*Id.*

¹⁴15 U.S.C. §§ 1261-1277 (1988 & Supp. 1993).

¹⁵15 U.S.C. §§ 2601-2629 (1988 & Supp. 1993).

¹⁶21 U.S.C. §§ 301-395 (1988 & Supp. 1992).

¹⁷15 U.S.C. § 1261(f)(1)(A) (1982).

¹⁸NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, CURRENT INTELLIGENCE BULLETIN No. 54, ENVIRONMENTAL TOBACCO SMOKE IN THE WORKPLACE 12 (1991).

¹⁹Hearings before the Subcommittee on Clean Air and Nuclear Regulation of the Senate Committee on Environment and Public Works, 103rd Cong., 2nd Sess. (May 11, 1994) (testimony of Carol M. Browner, Administrator, EPA), available in WESTLAW, USTESTIMONY database, document number 1994 WL 232971 (F.D.C.H.) at *4.

²⁰Hearings Before the Subcommittee on Clean Air and Nuclear Regulation of the Senate Environment and Public Works Committee, 103rd Cong., 2nd Sess. (May 11, 1994) (testimony of Aubrey E. Taylor, Ph.D.), available in WESTLAW, USTESTIMONY database, document number 1994 WL 232960 (F.D.C.H.) at *5.

²¹1986 SURGEON GENERAL REPORT, *supra* note 1, at 15.

²²15 U.S.C. §§ 2601-2629 (1988 & Supp. 1992).

²³15 U.S.C. § 2601(b)(1) (1982).

²⁴15 U.S.C. § 2601(b)(2) (1982).

²⁵15 U.S.C. § 2602(2)(A) (1982).

²⁶15 U.S.C. § 2603(a)(1)(A)(i) (1982).

²⁷POPESCU & CAREY, *supra* note 2.

²⁸See 15 U.S.C. §§ 2601(b)(1), 2602(2)(B)(iii) (1982).

²⁹Waxman, *supra* note 10.

³⁰Hearings Before the Subcommittee on Health and Environment of the House Committee on Energy and Commerce, 103rd Cong., 2nd Sess. (April 14, 1994) (testimony of William Johnston, Chief Executive Officer of R. J. Reynolds Tobacco Co.), available in WESTLAW, USTESTIMONY database, document number 1994 WL 229319 (F.D.C.H.) at *9.

³¹POPESCU & CAREY, *supra* note 2.

³²Dillin, *supra* note 11.

³³*Id.*

³⁴139 CONG. REC. 2522 (1993).

³⁵H.R. No. 2147, 103rd Cong., 1st Sess. (1994).

³⁶See *United States v. Article Consisting of 216 Cartoned Bottles*, 288 F.Supp 29, 38 (D.C.N.Y. 1968); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914).

³⁷Numerous cases state this proposition as far back as the early 1900s. See *International Nutrition, Inc. v. United States Dep't of Health and Human Services*, 676 F.2d 338, 341 (8th Cir. 1982); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 246 (2d Cir. 1977).

³⁸21 U.S.C. § 331(a) (1972 & Supp. 1994).

³⁹21 U.S.C. § 321(g)(1) (Supp. 1994). The definition of the term "drug" is to be given a liberal construction to aid in protecting the public. See *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 336 (2d Cir. 1977).

⁴⁰21 U.S.C. § 321(h) (Supp. 1994).

⁴¹15 U.S.C. § 15(c) (1973 & Supp. 1994).

⁴²*Federal Trade Comm'n v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952).

⁴³*Id.* at 576.

⁴⁴*Id.*

⁴⁵*Id.* at 577.

⁴⁶*United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953).

⁴⁷*Id.* at 337.

⁴⁸*United States v. 354 Bulk Cartons, Trim*

Reducing-Aid Cigarettes, 178 F. Supp. 847, 849 (D.N.J. 1959).

⁴⁹*Id.* at 850.

⁵⁰655 F.2d 236 (D.C. Cir. 1980).

⁵¹*Id.* at 237.

⁵²*Id.* at 240.

⁵³*Id.*

⁵⁴*Id.* at 239.

⁵⁵*Id.*

⁵⁶*Id.* at 240.

⁵⁷Gorman, *supra* note 8.

⁵⁸*Id.*

⁵⁹*Id.*

⁶⁰Milhorn, *supra* note 8, at 214.

⁶¹Gorman, *supra* note 8.

⁶²*Id.*

⁶³*Id.*

⁶⁴Sally Squires, *Smoking: the Evidence Mounts for the first time a Court has Linked Tobacco to a Cancer Death Now Scientists Press Their Case That Nicotine is Addictive*, THE WASHINGTON POST, June 28, 1988, Health Section at 12.

⁶⁵Gorman, *supra* note 8.

⁶⁶Squires, *supra* note 62.

⁶⁷*Id.*

⁶⁸Gorman, *supra* note 8.

⁶⁹"Nicotine dependence" appears in the 1987 revised edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R). Milhorn, *supra* note 8, at 218.

⁷⁰*Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 103rd Cong., 2nd Sess. (March 25, 1994) (testimony of David A. Kessler, M.D., Commissioner of the Food and Drug Administration), available in WESTLAW, USTESTIMONY database, document number 1994 WL 226284 (F.D.C.H.) at *7.

⁷¹*Id.*

⁷²Squires, *supra* note 62.

⁷³*Id.*

⁷⁴AMERICAN LUNG ASSOCIATION, NICOTINE ADDICTION AND CIGARETTES (August 1989), available in LEXIS, NEWS library, NWLTRS file.

⁷⁵POPESCU & CAREY, *supra* note 2.

⁷⁶Milhorn, *supra* note 8, at 217.

⁷⁷*Id.*

⁷⁸Gorman, *supra* note 8.

Announcements

Recent studies examine the effects of product liability suits

Two recent studies of product liability suits challenge conventional views of the effectiveness of such litigation. While one study found that product liability suits help consumers and hinder corporations, the other found that such suits do not place as drastic a financial burden on corporations as was previously believed. Both studies contribute to Congress' tort reform dialogue.

The first study, published by the RAND Institute for Civil Justice in "Product Liability and the Economics of Pharmaceuticals and Medical Devices," suggested that product liability suits both help and hurt consumers. The study's author, economist Steve Garber, concluded that product liability suits as they exist today help consumers because they discourage the marketing of some unsafe products. However, the same suits hurt consumers by undermining corporate willingness to introduce new products into the market and increase the prices of products because of greater litigation risks.

The RAND study also made specific recommendations, like making punitive damage awards more predictable through specific standards which would determine the eligibility and

size of awards; improving procedures for evaluating scientific evidence to determine the cause of injuries; and barring liability in suits alleging defective products or warnings for those defendants who comply with Food and Drug Administration regulations.

The *Wall Street Journal's* study examined how product liability suits affect large corporations. The study suggested that corporations are contributing significantly to the glut of federal lawsuits, and are the winners in an overwhelming majority of all the cases in which they were involved.

Between 1970 and 1991, the period covered by the study, Fortune-1000 companies were the plaintiffs in nearly 123,000 federal court cases of all types. This figure amounts to 27 percent of the total number of suits examined. Furthermore, regardless of whether the Fortune-1000 corporations were plaintiffs or defendants, they usually won the cases in which they were involved. The companies won 79 percent of the cases in which they were plaintiffs, compared to a 65 percent win rate for plaintiffs who are small companies and individuals. More dramatically, the companies won 65 percent of the cases in which they were defendants. This compares to a win rate of only 31 percent for those defendants who are small companies and individuals.