The Supreme Court of California rejected the preemption argument and held that the cause of action against the advertising—that it improperly targeted minors—would stand. According to the court, the advertising had apparently been effective in targeting adolescents: Camel cigarettes were chosen by an estimated 0.5 percent of teenage smokers in 1988 (the last full year of sales before the Joe Camel campaign) and by an estimated 25–33 percent in 1992 (as quoted in the decision; other sources cite a substantial, although smaller, increase [CDC 1994b]). In 1992, teenage smokers accounted for about $476 million of Camel sales, a vastly greater amount than the $6 million in sales for 1988 (*Mangini*, p. 1060). The portion of the *Mangini* lawsuit regarding the Joe Camel advertising campaign was settled September 8, 1997, when R.J. Reynolds agreed to cease placing Joe Camel on California billboards, placing Joe Camel materials in magazines and newspapers, and distributing promotional materials through retail mechanisms (*Mangini v. R.J. Reynolds Tobacco Co., cited in* 12.5 TPLR 3.349 [1997]). It also agreed to pay the cities and counties that had joined the action as co-plaintiffs $9 million for a counteradvertising campaign, presumably to dispel the lingering effects of the Joe Camel marketing.

In another state, Washington, a private action using that state's law failed to prohibit advertising using Joe Camel (*Sparks v. R.J. Reynolds Tobacco Co.*, No. C94-783C [W.D. Wa. Dec. 9, 1994], *cited in* 9.6 TPLR 2.171 [1994]). Nonetheless, the decision of the Supreme Court of California indicates that at least in some instances in some jurisdictions, private parties acting as representatives of the general public can bring an action normally brought only under specific federal or state law against cigarette advertising.

Thus, as with a number of other legal issues (see "Litigation Approaches," later in this chapter), the judicial response to aggressive pursuit of legal policy options is still unfolding. Although the process of legally regulating tobacco advertising and promotion has been under way for decades, the extent of such regulation and its ultimate limits are not yet known.

The most significant developments in this area revolved around the release of—and subsequent reaction to—the FDA's August 10, 1995, preliminary determination. The determination accompanied a proposed rule that sought to restrict the availability and marketing of tobacco products to children and adolescents. The FDA's final determination that it had authority to regulate cigarettes and smokeless tobacco products (released on August 28, 1996) is discussed later in this chapter, where the analysis of product regulation focuses on "Further Regulatory Steps."

Arguably the second most important development in this area was the June 20, 1997, proposed agreement that would have settled lawsuits between 41 state attorneys general and the tobacco industry. Because the advertising and promotion provisions of that agreement directly presupposed legislation that would have upheld the FDA's asserted jurisdiction to regulate tobacco products, this key multistate agreement is, like the FDA announcement, discussed later in this chapter, where the analysis of product regulation focuses on "Legislative Developments" and "Master Settlement Agreement."

Product Regulation

Introduction

Cigarette smoke contains approximately 4,000 chemicals, including a number of carcinogens and other toxic chemicals, such as hydrogen cyanide and oxides of nitrogen (USDHHS 1989). Regulating tobacco products requires appropriate assessment of these primary and secondary products of combustion and other substances that may be inhaled. Current tobacco product regulation requires that cigarette advertising disclose levels of "tar" (an all-purpose term for particulate-phase constituents of tobacco smoke, many of which are carcinogenic or otherwise toxic) and nicotine (the psychoactive drug in tobacco products that causes addiction [USDHHS 1988]) in the smoke of manufactured cigarettes and that warning labels appear on packages and on some (but not all) advertising for manufactured cigarettes and smokeless tobacco;[2] the current federal

[2] In California, a state suit against tobacco manufacturers for failure to comply with the state's Safe Drinking Water and Toxic Substances Enforcement Act of 1986 led to an agreement requiring that a warning about the possibility of reproductive harm and cancer appear on packages not covered by federal requirements (USDHHS 1989).

laws preempt, in part, states and localities from imposing other labeling regulations on cigarettes and smokeless tobacco (see the previous major section, "Advertising and Promotion").

Since the mid-1980s, federal law has required makers of manufactured cigarettes and of smokeless tobacco products to submit lists of additives to the tobaccos (but not to filters or papers) in their products to the Secretary of Health and Human Services (Comprehensive Smoking Education Act, Public Law 98-474, sec. 5; Comprehensive Smokeless Tobacco Health Education Act of 1986, Public Law 99-252, sec. 4). Information about the quantity of additives used and their placement in specific brands is not required, and the Secretary is bound by law to safeguard the lists from public disclosure. In 1994, attorneys for six manufacturers released to the public the list of ingredients added to tobacco in 1993.

Tobacco products are explicitly protected from regulation in various federal consumer safety laws (USDHHS 1989). Although regulation requires public reporting of some constituents in cigarette smoke, cigarette manufacturers are not required to report to a governmental body (or to include on product labels for consumers) brand-specific information about the nicotine content or any other property (e.g., nitrosamine levels, ammonia level, pesticide residues, heavy metals [lead, cadmium, mercury, or chromium], pH, or sugar content) of the material that forms the tobacco rod of their products. At the very least, knowledge of the upper bound of nicotine in the tobacco rod of cigarettes is important because actual smoking may produce constituent levels that vary considerably from that in smoke delivery yields reported to the FTC (USDHHS 1988; see also "Compensatory Smoking," later in this chapter). Those measurements were conducted by the Tobacco Institute Testing Laboratory.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 requires smokeless tobacco manufacturers to report the total nicotine content of their products to the Secretary of Health and Human Services (Public Law 99-252, sec. 4), but the Secretary may not release the data to the public. A uniform protocol implementing this provision was published in the March 23, 1999, *Federal Register*. No federal public health laws or regulations apply to cigars, pipe tobaccos, or fine-cut cigarette tobaccos (for "roll-your-own" cigarettes) in any manner other than prohibiting the advertising of small cigars through electronic media (USDHHS 1989).

The Constituents of Smoke From Manufactured Cigarettes

Since 1967, the FTC has regularly published tables of tar and nicotine delivery of smoke from manufactured cigarettes. Since 1980, the tables have also included a measurement for carbon monoxide delivery. The data are based on results of a standardized, machine-driven test procedure (Pillsbury et al. 1969) that provides a basis of comparison among various brands of cigarettes. Manufacturers are not required to print these values on the product package, but "ultra low" cigarette brands often include tar and nicotine deliveries on the package, presumably to differentiate these brands (Davis et al. 1990). No brand having a tar yield above 11 mg prints this information on the package. Carbon monoxide deliveries are not listed either on packages or in advertising (USDHHS 1989).

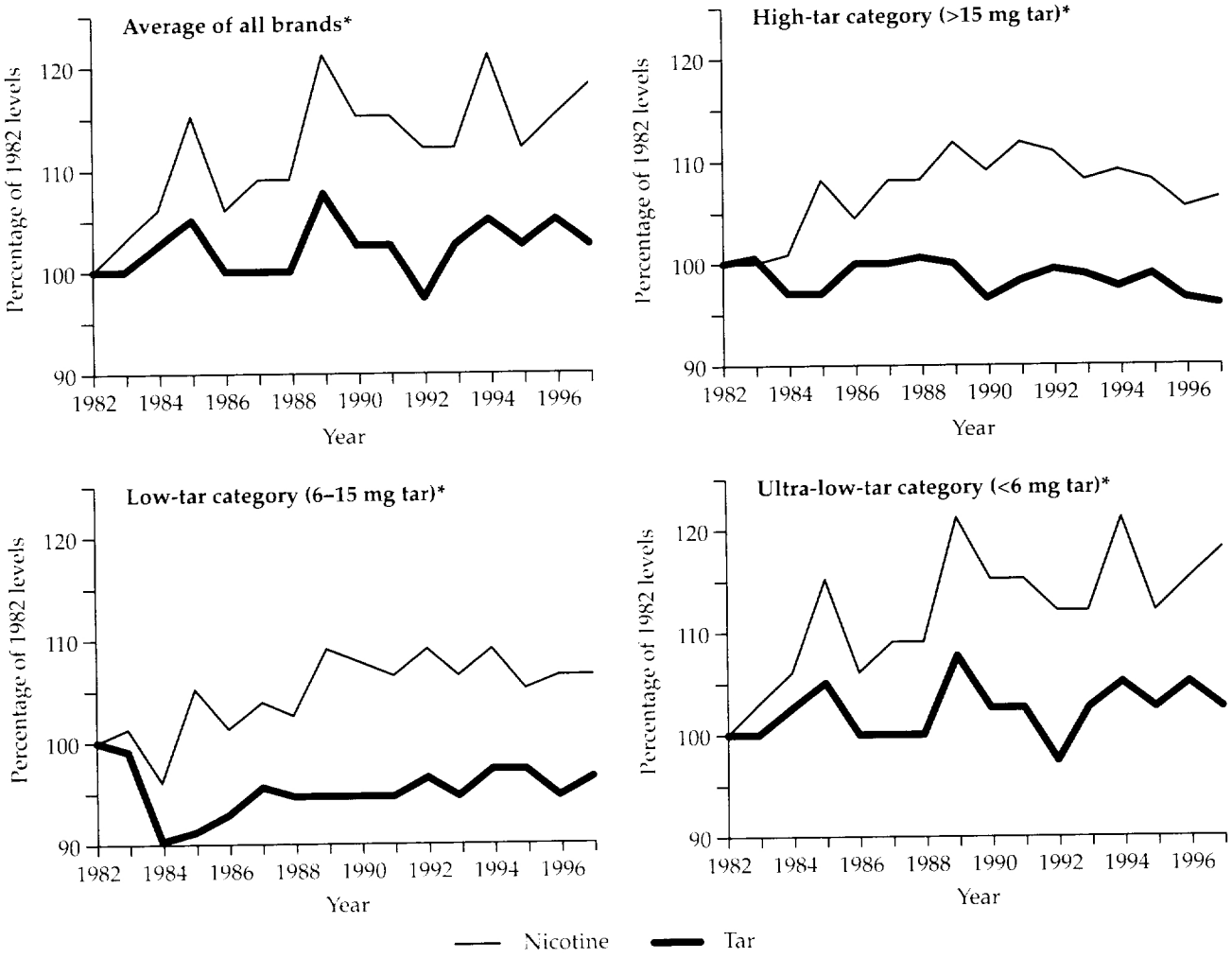
Regulation by Tar Levels

The FTC's tables of tar levels have provided some jurisdictions with criteria for regulating tar content by levying taxes on higher-tar cigarettes or, in the case of countries in the European Union, by altogether banning high-tar cigarettes. The apparent assumption behind such actions—that discouraging or banning consumption of higher-tar cigarettes will result in reduced morbidity and mortality from smoking-related diseases—has been questioned, as is discussed in the section "Compensatory Smoking," later in this chapter.

Tar content has in several instances served as the basis for cigarette taxation, on the presumption that the taxing structure would provide a competitive advantage to low-tar brands—an advantage of interest, for supposed public health reasons, to the jurisdiction levying the tax. For several years beginning in 1971, New York City taxed cigarettes that had either tar yields over 17 mg or nicotine yields over 1.1 mg an additional 3 cents per pack and cigarettes that exceeded both thresholds, 4 cents (*Long Island Tobacco Co., Inc. v. Lindsay*, 74 Misc. 2d 445, 343 N.Y.S.2d 759 [N.Y. 1973]). Although the levy was upheld by the courts, the law seems to have been repealed because of allegations that unequal taxation across political boundaries was fostering smuggling (Ranzal 1973). There are no reports on the effects this tax may have had on consumption patterns.

In 1978, the British government imposed a supplementary tax on cigarettes having a measured tar yield greater than 20 mg (Gray and Daube 1980

Figure 5.1. Sales-weighted nicotine and tar levels in smoke as percentage of 1982 levels



*By Federal Trade Commission method.
Source: Kessler 1994b; Federal Trade Commission, unpublished data, 1998.

[note misprint in this publication: on page 93, line 3, "more" should have been "less"; correction furnished by Michael Daube, February 13, 1996]). Within three months of the imposition of the tax, the market share of such brands fell from 15 to 3 percent (Michael M. Daube, letter to John Slade, February 24, 1995). A similar tax was used in Sweden, but it was repealed to achieve uniformity with tax policies of the European Union (Paul Nordgren, letter to David T. Sweanor, December 23, 1994).

Among countries in the European Union, a fixed ceiling on tar content has been used as a regulatory method. The European Union has imposed a graduated decline in the upper limit of tar deliveries permitted for cigarettes sold in member countries. Beginning January 1, 1993, the ceiling was 15 mg tar delivery per cigarette; after December 31, 1997, the ceiling was 12 mg (Council Directive 90/239/EEC 1990 O.J. [L 137]).

Implications of Nicotine Levels

The FTC's tables on nicotine levels have revealed a recent change in the ratio of tar to nicotine in cigarettes. Kessler (1994b) has reported that for 1982–1991, the ratio of average sales-weighted nicotine yield to

tar yield[3] in cigarette smoke has risen steadily for each of three major tar-yield categories and for the overall market (Figure 5.1). Given the addictive properties of nicotine and its contribution to cardiovascular disease (USDHHS 1988), this change may have important public health implications. Moreover, "low-yield" and "ultra low-yield" cigarettes in the same period had higher nicotine yield to tar ratios than did brands in the high tar-yield categories. Consumers who pay more heed to the "numbers" for tar levels than to the much smaller (but no less important) numbers for nicotine levels may be under the illusion that they are reducing their health risks and increasing their chances of quitting by smoking "low-tar" cigarettes. (This illusion is further discussed in "The Low-Tar 'Alternative,' " later in this chapter.)

A manufactured cigarette generally contains 8–10 mg of nicotine (USDHHS 1988), regardless of the machine-measured nicotine delivery in the smoke. Under usual smoking conditions, consumers absorb about 10–30 percent of the nicotine contained in the tobacco rod of the cigarette (USDHHS 1988; Benowitz and Henningfield 1994). Some thought has recently been given to systematically lowering the nicotine content of tobacco products to levels that would not pose a threat of addiction (Benowitz and Henningfield 1994; Douglas 1994). Benowitz and Henningfield (1994) have suggested that addiction is unlikely to be sustained below a nicotine dose of about 5 mg per day. This dose is about one-fourth the daily dose commonly ingested by tobacco users. To achieve such a ceiling for cigarettes, the nicotine content of the tobacco rod would have to be 0.5 mg or less, assuming that the smoker consumes about 30 cigarettes per day and receives 30 percent of the nicotine available. However, cigarettes with such low levels of nicotine may not be popular (Campbell 1994). The experience of Philip Morris Companies Inc. in trying to sell a low-nicotine-content cigarette, "Next," illustrates this point; the company judged the test-marketing of this cigarette a failure. Such failure provides indirect support for the importance of nicotine addiction to the tobacco industry.

Mandating the reduction of nicotine for the purpose of weaning smokers from tobacco products was contemplated as a strategy available to the FDA in legislation proposed to enable the multistate settlement agreement with the tobacco companies (see "Legislative Developments" and "Master Settlement Agreement," later in this chapter). A similar strategy is used in some voluntary stop-smoking programs (e.g., Gahagan 1987). But this strategy cannot work unless accurate measures are available of the actual nicotine uptake that smokers and other tobacco users receive.

In 1994, the NCI convened an ad hoc expert committee to determine the adequacy of the standard, smoking-machine-based, FTC protocol for determining the tar and nicotine content of cigarettes. The committee concluded that "the FTC test protocol was based on cursory observations of human smoking behavior. Actual human smoking behavior is characterized by wide variations in smoking patterns, which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behavior, which may negate potential health benefits" (NCI 1996, p. vi).

In 1996, Massachusetts enacted a law designed to obtain reports of brand-specific nicotine levels that more closely approximate the uptake by actual smokers of these brands. The statute instructs the state Department of Public Health to establish standards for nicotine yield ratings that "accurately predict nicotine intake for average consumers" (Mass. Gen. Laws ch. 94, sec. 307B). Each cigarette and smokeless tobacco manufacturer must then report, in a manner consistent with these standards, the nicotine yield rating of each brand of tobacco products it produces. These reports become public records.

Other Constituents in Cigarette Smoke

Tar and nicotine measurements have traditionally been used as surrogate measures for other toxic constituents in cigarette smoke, because changes in tar and nicotine levels presumably are predictive of changes in the levels of most other particulates. Studies suggest otherwise. For example, tar level as measured by smoking machines is not a good predictor of benzo[a]pyrene level (Kaiserman and Rickert 1992). In general, declared tar values are not predictive of tobacco-specific nitrosamine levels (Fischer et al. 1990, 1991b). Similarly, tar delivery is a poor predictor of the delivery of gas-phase constituents, such as carbon monoxide, hydrogen cyanide, and acrolein (Young et al. 1981).

In Canada, the Department of National Health and Welfare (Health Canada) has undertaken a program to develop methods for collecting and analyzing toxic constituents, other than tar, nicotine, and carbon monoxide, in tobacco smoke. Methods have been developed to measure the levels of benzo[a]pyrene, the

[3] Average sales-weighted nicotine-to-tar yield means that the average amount reported here was calculated by taking the yield from all brands of cigarettes and weighting each yield by its sales figures. Thus, the yield for a popular cigarette would "count" more in the average of all brands than the yield for a less popular brand.

tobacco-specific nitrosamines, hydrogen cyanide, benzene, formaldehyde, 4-amino-biphenyl, and heavy metals such as lead and cadmium (Health Canada 1995a). The Department of National Health and Welfare intends to require manufacturers to use these test methods to provide quantitative reports on these chemicals in tobacco smoke or, in the case of heavy metals, in the tobacco itself (Health Canada 1995a).

Rickert (1994) has described the presence of the potent bladder carcinogen 4-amino-biphenyl in the sidestream smoke from all 10 brands of cigarettes tested in a study for Health Canada. Under occupational safety regulations, the permissible level of exposure to 4-amino-biphenyl is zero. Applying these standards to cigarette smoke would require either that this material be absent from cigarette smoke entirely or that cigarette smoke not be permitted in spaces subject to regulation.

An important development indicating a possible design flaw in the manufacture of cigarettes has been the report that cellulose acetate fibers are shed from cigarette filters. Such fibers, coated with tar, have been observed in the lungs of smokers; this observation suggests that these fibers may be long-lived in human tissue and may be associated with disease (Pauly et al. 1995).

Additives to Tobacco Products

Hundreds of ingredients besides tobacco are used in the manufacture of tobacco products. Additives make cigarettes more acceptable to the consumer; they can make smoke seem milder (and easier to inhale), prolong shelf life, prolong burning, and improve taste. These additives may be a single chemical used as a humectant or a complex mix of chemicals used as a flavorant.

Cigarette Additives

The six major cigarette manufacturers reported a pooled list of 599 ingredients that were added to the tobacco of manufactured cigarettes as of 1994 (R.J. Reynolds Tobacco Company 1994). The list is annotated with references to which materials are approved for use as food additives by the FDA (under the category "Generally Recognized as Safe") and are thought to be safe by the Flavor and Extract Manufacturers Association of the United States. However, that a material is regarded as safe when ingested in foods provides no assurance of its safety in a tobacco product, where it will be combined with other substances, heated to high temperatures, and may be inhaled into the lungs.

The American Health Foundation (1990) has pointed out the toxic potential of numerous cigarette tobacco additives under expected conditions of use. Heating and burning may lead to the formation of carcinogens from some of the additives used. For instance, amino acids used as additives are known to form compounds of various elements, including genotoxic agents (known to damage DNA) and experimental carcinogens, during heating. Licorice root extract contains glycyrrhizin, and both are used as additives in cigarettes; glycyrrhizin produces carcinogenic by-products when burned. The leukemia-producing agent benzene is a component of cigarette smoke that may be formed from the combustion of many cigarette additives. Because the Federal Food, Drug, and Cosmetic Act requires that a food additive "be safe under the conditions of its intended use" (sec. 321), tobacco additives in manufactured cigarettes may not fulfill the specifications of the law were the law applied to tobacco.

The use of additives may reinforce cigarette smoking by strengthening the addictive effects of nicotine. At least one major domestic cigarette maker uses some additives to boost the absorption of nicotine in cigarette smoke (Kessler 1994c). Ammonia compounds alter the pH of nicotine in tobacco, converting it from the protonated, bound form (various nicotine salts) to the unprotonated, freebase form. Freebase nicotine more readily enters the smoke stream and has been predicted to cross lung and oral cavity membranes more quickly than nicotine salts do (Henningfield et al. 1995). The broader issue of enhancing the delivery of nicotine is discussed in the introductory section of "Further Regulatory Steps," later in this chapter.

Several European countries regulate cigarette additives, but only to a modest extent. In France, the total percentage of the cigarette that consists of additives is listed on the side of the package. Among representative brands manufactured in the United States but sold in France (e.g., Camel, Kent, Marlboro, and Winston), the cigarette labels indicate that between 6.2 and 10.0 percent of each cigarette is composed of additives. The British government maintains a list of "permitted" or "approved" additives for smoking tobacco and cigarette paper (Lewis and Davis 1994, p. 206). The list, which had 474 ingredients in 1988, specifies the maximum level permitted for each specific additive (Lewis and Davis 1994). In Canada, the Tobacco Products Control Act (sec. 10; Department of National Health and Welfare 1989) requires manufacturers to report a quarterly list of ingredients used in their products. Canadian producers use far fewer additives—about 50 in all—than do American manufacturers.

Massachusetts, Minnesota, and Texas have enacted laws to require the disclosure of nontobacco ingredients in tobacco products (Mass. Gen. Laws ch. 94, sec. 307B; Minn. Laws ch. 227 [1997]; Vernon's Texas Statutes and Codes Annotated ch. 161, sec. 161.252 [1997]). Health officials in the Canadian province of British Columbia have announced their intention of taking similar steps there.

The Massachusetts law, applicable to cigarettes and smokeless tobacco, requires the manufacturer to report, in descending order by weight, measure, or numerical count, the identity of each brand's added constituents other than tobacco, reconstituted tobacco sheet, or water. Ingredients that are recognized as safe when burned and inhaled are exempted. The Department of Public Health is then instructed to disclose the reported information to the public to the extent that "there is a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health" (Mass. Gen. Laws ch. 94, sec. 307B).

The tobacco industry challenged the statute in court on both preemption and trade secret grounds. The Federal District Court ruled that nothing in federal law preempted Massachusetts from taking this action, and the court of appeals affirmed (*Philip Morris Inc. v. Harshbarger*, 122 F.3d 58 [1st Cir. 1997]). However, the same Federal District Court thereafter issued a preliminary injunction that prevented the state from enforcing the ingredient disclosure provision of the statute; the court ruled that doing so would expose the trade secrets of the manufacturers (*Philip Morris Inc. v. Harshbarger*, Civil Action No. 96-11599-GAO, Civil Action No. 96-11619-GAO, 1997 U.S. Dist. LEXIS 21012 [D. Mass. Dec. 10, 1997]). That ruling is currently under appeal. Texas has adopted a similar statute requiring the tobacco industry to submit a list of ingredients and nicotine yield ratings to the Texas Department of Health by December 1998 (Vernon's Texas Statutes and Codes Annotated ch. 161, secs. 161.252, 161.254, 161.255).

The Minnesota statute requires manufacturers of tobacco products to publicly disclose, for each brand, whether the product contains detectable levels—in either its unburned or its burned states—of ammonia or ammonia compounds, arsenic, cadmium, formaldehyde, or lead. The industry filed suit in Federal District Court to enjoin the enforcement of the statute but agreed to drop the suit as part of its May 1998 settlement of the state's Medicaid reimbursement lawsuit (discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter) (*Minnesota v. Philip Morris Inc., cited in* 13.2 TPLR 3.39, 3.45 [1998]).

Most recently, British Columbia health officials announced plans to require cigarette manufacturers to disclose to the government all ingredients, including additives used to treat the papers and filters. Manufacturers would also have to test and report on 44 poisons that the health officials claim are contained in cigarette smoke (Reuters 1998).

Smokeless Tobacco Additives

In 1994, ten manufacturers of smokeless tobacco products released a list of additives used in their products (Patton, Boggs & Blow 1994). As with the additive list for cigarette tobacco, the smokeless tobacco list notes which of the 562 materials listed have been approved for use in foods by the FDA and also notes which are regarded as safe by the Federal Emergency Management Agency. As with cigarette tobacco, applying these safety standards to nonfood substances is problematic; however, smokeless tobacco used in an unaltered (unburned) state lessens some of the concern over the possible hazards of additives.

The list of additives to smokeless tobacco includes sodium carbonate and ammonium carbonate, which are alkalinizing agents that increase the level of "free" (chemically uncombined) nicotine in moist snuff by raising the pH level (Slade 1995). A division of the Swedish Tobacco Company has stated that sodium carbonate is added to its moist snuff brands to alkalinize the tobacco and thus enhance nicotine absorption (Kronquist 1994). The pH of moist snuff products—which is not reported to consumers—varies from acidic to alkaline, providing a wide range of free-nicotine levels in various products (Djordjevic et al. 1995; Henningfield et al. 1995). Products for persons entering the market (such as those that have easy-to-use unit dosages) are acidic (thus reducing absorption) and have very low levels of free nicotine, whereas products for more experienced users (such as the Copenhagen brand) are alkaline and have high levels of free nicotine. The epidemiology of moist snuff use among teenagers and young adults indicates that most novices start with brands having low levels of free nicotine and then graduate to brands with higher levels (Tomar and Henningfield 1992; Tomar et al. 1995). These patterns are consistent with the industry's marketing strategies as reflected in their advertising and marketing activities and their internal documents (Connolly 1995).

Sweeteners and flavorings, such as cherry juice concentrate, apple juice, chocolate liqueur, and honey, are used in various smokeless tobacco products, and dominant flavors are often mentioned in the product

name (e.g., the Skoal Cherry Long Cut brand). As with manufactured cigarettes, these additives increase palatability and may intensify use of smokeless tobacco, at least among novices (Freedman 1994).

The Low-Tar "Alternative"

As the health hazards of smoking have been increasingly documented, the production of lower-tar cigarettes has increased. The FTC's tables on average sales-weighted tar levels for cigarettes on the U.S. market from 1968 through 1987 reflect this shift toward lower-tar cigarette brands (USDHHS 1981, 1989).[4] The public health implications of this shift merit closer inspection.

Compensatory Smoking

Considerations of product regulation must take into account the variability in toxic exposure attributable to specific smoking practices. The overall evidence suggests that many smokers compensate when smoking low-delivery cigarettes by inhaling more tar and nicotine than are measured by smoking machines under standard conditions. Any potential health benefit implied by machine measurements of lower tar and nicotine yields may thus be mitigated by such compensatory smoking.

Studies have shown that as consumers switched to lower-yield cigarettes in Great Britain, they tended to smoke more cigarettes each day (Ferris 1984), apparently to compensate for the lower nicotine yield per cigarette. Similar compensatory measures may have occurred in the United States. For example, smokers in Cancer Prevention Study I, conducted during the 1960s when lower-yield brands were rare, smoked fewer cigarettes per day than smokers in Cancer Prevention Study II, which was conducted during the 1980s, by which time most smokers used lower-yield brands (Thun et al. 1997). Strong evidence suggests that smokers increase the number of cigarettes consumed as nicotine availability is reduced, and vice versa (USDHHS 1988; Kaufman et al. 1989; Palmer et al. 1989; Stellman and Garfinkel 1989; Negri et al. 1993; Thun et al. 1997). In addition, lower nicotine delivery in the FTC test is associated with smoking a greater number of cigarettes (USDHHS 1988). This compensatory effect has been confirmed in other studies (Benowitz et al. 1983; Bridges et al. 1990; Höfer et al. 1991; Woodward and Tunstall-Pedoe 1992; Coultas et al. 1993); only one published study found no such effect (Rosa et al. 1992). In an abstract, Byrd and colleagues (1994) reported no compensatory effect, but their small study population may not have been representative of all smokers; for instance, the nicotine intake seen among the group that smoked the ultra low-delivery cigarettes was smaller than that observed by others.

Health Risks From Low-Tar Cigarettes

Even when compensatory smoking is not accounted for and calculations are derived from machine-rated tar levels, the risk of lung cancer is only slightly lower from using low-tar cigarettes than from using high-tar cigarettes, and reduced tar level has little if any impact on the occurrence of other cigarette-caused lung disease or of heart disease (USDHHS 1981, 1989; Parish et al. 1995; Wannamethee et al. 1995).

Giovino and colleagues (1996) have examined results from several national surveys of tobacco use for attitudes and behaviors related to the use of low-tar cigarettes. In these surveys, current smokers of low-tar brands were found to be more likely than smokers of high-tar brands to acknowledge the health risks of smoking, to express concerns about these risks, to report that they had been advised by a physician to stop, and to report that they had experienced negative health consequences from smoking. These smokers were also more likely, however, to believe that smoking a low-tar brand reduced those risks. For example, in the 1987 National Health Interview Survey, 44 percent of smokers reported that they had switched to a low-tar cigarette to reduce their health risk, and 48 percent of low-tar brand users thought their brand was less hazardous than most other brands (Giovino et al. 1996). These attitudes were confirmed by a 1993 Gallup poll in which 49 percent of respondents stated that they believed that the advertising message in terms such as "low tar," "low nicotine," or "lower yield" was that the "brand [was] safer"; only 4 percent believed that the advertisements were "false/misleading" (Gallup Organization, Inc. 1993, p. 23).

The analysis by Giovino and colleagues (1996) also suggested that many smokers of low-tar cigarettes may have used these brands instead of quitting. Low-tar users were more likely than high-tar users to have tried unsuccessfully to stop smoking. Similarly, a greater proportion of people who had successfully quit smoking had been high-tar cigarette users. This latter

[4] Some reports have included data from 1957 to 1967 (e.g., USDHHS 1989, p. 88). However, those data are unpublished and first appeared in a chart attributed to a personal communication from Dr. Helmut Wakeham, then a research scientist with Philip Morris Companies Inc. (Wynder and Hecht 1976, p. 151).

observation has been confirmed in another survey: those who had stopped smoking tended to have been higher-tar cigarette smokers (Cohen 1996). As was previously suggested (Kessler 1994b), the higher ratios of nicotine yield to tar yield in lower-tar cigarettes than in higher-tar cigarettes could impede efforts to quit among persons who smoke lower-tar cigarettes.

Assessment of consumer attitudes, as well as epidemiologic consideration of health risks from lower-yield cigarettes, has raised concerns about the reporting of FTC test results (Henningfield et al. 1994). An ad hoc committee of the President's Cancer Panel, convened in December 1994 (Jenks 1995), concluded that consumers misunderstand the FTC test results and should be given a range of values for smoke deliveries (reflecting the way cigarettes are actually smoked) and that these values should be included on each package and in all advertisements (NCI 1996). The committee also concluded that terms such as "light" and "ultra light" are in fact health claims that mislead consumers.

Nicotine Replacement Products

The "safe cigarette," long sought, has not been found (Gori and Bock 1980; USDHHS 1981, 1989; Slade 1989, 1993), and the axiom that no tobacco product is safe when used as intended remains true (USDHHS 1989). As long as tobacco products are sold, some people will be unable to stop using nicotine (Kozlowski 1987). Novel nicotine delivery devices have been tried in test markets (R.J. Reynolds Tobacco Company 1988; Slade 1993; Hilts 1994), and several tobacco companies have patents for various designs (David A. Kessler, letter to Scott D. Ballin, February 25, 1994; Slade 1994; Hwang 1995b). All designs share the ability to deliver nicotine for inhalation with a minimum of, or no, tar—thereby avoiding the smoking-associated increased risk of cancer (although not the nicotine-associated increased risk of cardiovascular disease) (USDHHS 1988).

Nicotine replacement products have been developed and marketed by pharmaceutical companies as adjuncts to help people stop smoking (Jarvik and Henningfield 1993). As was discussed in Chapter 4 (see "Pharmacologic Interventions"), concerns over possible intentional or unintentional misuse of these products have been weighed against the health benefits resulting from their effectiveness as a cessation aid. Nicotine gum and nicotine patches, previously approved by the FDA as prescription drugs for brief use (months), were approved in 1996 for over-the-counter use, concluding an intense examination of the issues of nicotine availability. Both a nicotine nasal spray and a nicotine inhaler were approved for prescription use. The Drug Abuse Advisory Committee (1994) of the FDA has expressed concern about the potential abuse liability of the spray and the inhaler, because the pharmacokinetics of their delivered dose of nicotine comes closer than the gum or patch to what occurs through using tobacco products. Benowitz and Pinney (1998) concluded that the benefits from over-the-counter availability of the gum and patch would outweigh the risks. In December 1996, the FDA's Drug Abuse Advisory Committee recommended approval of the nicotine inhaler for prescription use (FDA Drug Abuse Advisory Committee, draft minutes of December 13, 1996, meeting).

Nicotine maintenance is not an approved therapeutic approach, but some observers have called for a coordinated clinical and public health program to explore this option (Slade et al. 1992). A useful program not only must substantially reduce health risks and satisfy addicted individuals who cannot otherwise stop using tobacco products but also must include realistic safeguards to prevent the new onset of nicotine dependence among the young, to prevent relapse among those who have already stopped, and to further reduce overall smoking prevalence.

The elements of such a program would include research to (1) fully characterize the population that would benefit from nicotine maintenance, (2) identify potential delivery devices for nicotine or an appropriate analogue, (3) explore fully the safety of these devices as well as the safety of nicotine or the chosen analogue (including assessments of potential cardiovascular, fetal, cognitive, and performance problems consequent to use of the drug, as well as other potential health effects), and (4) design a drug distribution system that would be acceptable to intended users but that would substantially limit access by novices to tobacco use and by those who have already been successful at achieving abstinence from nicotine (Slade et al. 1992).

Product Regulations for Consumer Education

The previous discussion of product regulation centered on the contents of the tobacco product itself. Another critical focus for product regulation is packaging, a promising field for public information and education on smoking and health. Government actions in this area have included product packaging to convey health messages (see "Attempts to Regulate

Tobacco Advertising and Packaging," earlier in this chapter). The goal of this packaging strategy, as discussed in the following section, is to help ensure that the purchase of tobacco products occurs only as a transaction involving informed consumer choice. Also discussed is a related, more complex goal for this strategy: to help ensure a situation of informed consumer consent rather than simply choice.

Tobacco Packaging and Informed Choice

The current required warning labels on U.S. tobacco packages are but a single, narrow means by which package-based messages can promote informed choice among consumers. The vast amount of information available on the adverse health effects of tobacco use constitutes a wide range of messages that can be presented this way (USDHHS 1989). This information can appear on packages in many ways, given the numerous variables such as size, wording, placement, colors, graphics, typefaces, and package inserts.

The potential public education value of package-based health messages is inherent in their exceptionally large rate of exposure to consumer view. In the United States, about 478 billion cigarettes were consumed in 1997 (Tobacco Institute 1998). Each of these cigarettes will be removed from a package that could be viewed by many cigarette users at exactly the time they are preparing to engage in the activity such messages are intended to prevent. These messages can be seen not only immediately before use but also at the point of sale or at any time the package is in the possession of the user. The messages do not have to be directed only at tobacco users; any exposed package can be viewed by, and can provide information equally germane to, users and nonusers alike.

An example of the potential inherent in package messages is provided from Canada. In legislation supplementing the Tobacco Products Control Act (sec. 9), the federal government of Canada not only increased the number of rotating messages from four to eight but also made new stipulations regarding the messages' size, location, and color (Department of National Health and Welfare 1993; for details on these changes, see "Examples of Product Labeling in Other Countries," earlier in this chapter). These changes followed studies undertaken to determine the existing messages' legibility, readability, believability, and ease of understanding. These studies had indicated that health warnings were read about 1.4 times per day (women, 1.8 times; men, 1.2 times) and that cigarette packs were a primary source of tobacco-related health information for 55 percent of smokers, second only to television (59 percent) and well ahead of newspapers (17 percent) (Tandemar Research Inc. 1992; Kaiserman 1993).

Tobacco Use and Informed Consent

Although many discussions of tobacco use invoke "free choice," the more rigorous legal concept is "informed consent." As applied to tobacco use, informed consent would obtain only when potential purchasers of tobacco products could make fully informed purchase decisions after carefully weighing the health risks of using those products. Thus, like patients considering whether to undergo potentially harmful medical procedures, consumers considering whether to use tobacco would have to know which health problems are caused by the product's use, what increases in personal risk of these various problems occur through this use, what the prognosis is should any of these problems arise, and what effect ending or adjusting the use could have on these problems. Courts of law in this country and elsewhere have articulated the duty of product manufacturers to warn consumers about product hazards. A particularly clear statement of the principles involved in informed consent is found in an Ontario Court of Appeal decision concerning oral contraceptives:

> Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question (*Buchan v. Ortho Pharmaceutical [Canada] Ltd.*, [1986] 54 O.R.2d 101 [Ct. App.] [Can.]).

Similarly, a U.S. court has described an adequate product warning in the following way:

> In order for a warning to be adequate, it must provide "a complete disclosure of the existence and extent of the risk involved" (*Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330 [5th Cir. 1984]) citing *Alman Brothers Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc.*, 437 F.2d 1295, p. 1303 [5th Cir. 1971]). . . . A warning must (1) be designed so it

> can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk (*Pavlides*, p. 338).

At issue, then, is whether consumers have received adequate warning for informed consent to apply to tobacco use. Although public knowledge about the health effects of tobacco use has improved over the past 15 years (FTC 1984; USDHHS 1989), evidence persists of gaps in understanding. An American Cancer Society (ACS) study showed respondents a list of selected causes of death and asked which was responsible for the greatest number of deaths (Marttila & Kiley, Inc. 1993). The study found that only one in five Americans could correctly identify cigarette smoking as the listed cause associated with the most deaths. Similar studies in other countries (Hill and Gray 1984; Gallup Canada, Inc. 1988; Environics Research Group Limited 1991; Health and Welfare Canada 1992 [unpublished data]) have found a similar lack of knowledge.

These studies indicate that the public continues to underestimate the magnitude of the risks arising from tobacco use. The resulting inability of consumers to make fully informed decisions about tobacco use could be interpreted as a failure on the part of the manufacturer to achieve informed consent from users of the product. To date, this issue has not been legally addressed, and the previously discussed notion of informed choice, which carries clearer legal implications, is generally invoked.

Further Regulatory Steps

Although some of the aforementioned product regulations address the chemical constituents of tobacco use, none directly broaches the issue of whether tobacco, as a nicotine delivery system, should be subject to federal regulation as an addictive product. In March 1994, the Coalition on Smoking OR Health ([CSH] composed of the American Heart Association, the American Lung Association, and the American Cancer Society) filed a petition with the FDA to declare all cigarette products to be drugs under section 201 of the Federal Food, Drug, and Cosmetic Act (CSH 1994a). This petition followed an earlier one by the same coalition requesting the classification of low-tar and low-nicotine cigarettes as drugs and similarly classifying the proposed new R.J. Reynolds Tobacco Company "smokeless cigarette" as a drug (CSH 1988).

A few weeks earlier, the FDA had made public that it was investigating whether it might assert jurisdiction over tobacco products (Kessler 1994a). The legal basis for such a move requires demonstrating that the manufacturers of tobacco products intend to affect the structure or function of their customers' bodies (21 U.S.C. section 321 [g] [1]). The Commissioner of the Food and Drug Administration, David A. Kessler, M.D., had indicated in testimony before Congress that there was evidence that pointed to this conclusion (Kessler 1994b,c).

The FDA has concluded that words used by tobacco companies to describe some effects of smoking (e.g., "satisfaction," "strength," and "impact") are euphemisms that actually describe pharmacologic effects of nicotine (Kessler 1994b, p. 150). Dr. Kessler has noted that cigarettes are sophisticated, carefully designed devices. Industry patents disclose a detailed knowledge of nicotine pharmacology and describe as desirable those product refinements that increase the efficiency of nicotine delivery. One company has patented a series of nicotine analogues having desired pharmacologic effects, much as a conventional pharmaceutical company might develop a new drug that produces effects similar to those of an existing drug.

The FDA has disclosed several specific examples of product manipulation to adjust the delivered dose of nicotine in cigarettes (Kessler 1994c). The Brown & Williamson Tobacco Corporation has used in cigarettes sold in the United States a strain of tobacco (Y-1) that had been genetically engineered to have a high nicotine content. According to a major American tobacco company's handbook on leaf blending and product development, ammonia compounds can be used as additives to boost the delivery of nicotine in smoke to enhance the "impact" and "satisfaction" from smoke (Kessler 1994c, p. 365). In an official prosecution memorandum to the U.S. Attorney General, Representative Martin T. Meehan (D-MA) has asserted that product manipulation of Eclipse brand cigarettes has taken place. Meehan cites the addition of high-nicotine-content tobacco near the filter and the addition of potassium carbonate to change the pH of the tobacco (or to enhance absorption through the mucous membranes) (Meehan 1994; see "Criminal Proceedings," later in this chapter). Moreover, information obtained from internal industry documents suggests that at least some tobacco companies have long had an accurate and detailed knowledge of nicotine pharmacology. Dr. Kessler told Congress that "such research would be of interest to the industry only if the industry were concerned with the physiological and pharmacological effects of nicotine. Certainly, this is

not consistent with the industry's representation that nicotine is of interest to it only because of flavour and taste" (Kessler 1994c, p. 367).

Following his testimony before Congress, in a speech at Columbia University School of Law, Dr. Kessler emphasized the importance of preventing nicotine dependence among children and teenagers. Calling it "a pediatric disease" (David A. Kessler. Remarks. Presented at the Samuel Rubin Program, Columbia University School of Law, New York City, March 8, 1995, unpublished), he outlined a number of specific priorities for public health action:

> A comprehensive and meaningful approach to preventing future generations of young people from becoming addicted to nicotine in tobacco is needed. Any such approach should: First, reduce the many avenues of easy access to tobacco products available to children and teenagers; second, get the message to our young people that nicotine is addictive, and that tobacco products pose serious health hazards—and not just for someone else; and third, reduce the powerful imagery in tobacco advertising and promotion that encourages young people to begin using tobacco products (p. 19).

On August 10, 1995, the FDA announced the result of its investigation. The agency stated that evidence appears to indicate that "nicotine in cigarettes and smokeless tobacco products is a drug and [that] these products are nicotine delivery devices under the Federal Food, Drug, and Cosmetic Act" (*Federal Register* 1995a). In August 1995, the FDA issued in the *Federal Register* (1) a proposed rule of regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents and (2) an analysis of the FDA's jurisdiction over cigarettes and smokeless tobacco. The FDA requested comments on its proposed regulations and analysis of its jurisdiction, and indicated that it would give serious consideration to comments filed with the agency concerning the evidence amassed during its investigation. The Clinton administration also suggested that Congress could eliminate the need for this rulemaking by passing new legislation to affirm the FDA's authority over tobacco products and address the issue of tobacco use among minors.

In its legal analysis of its proposed jurisdiction over tobacco products, the FDA argued that cigarettes and tobacco products "affect the structure or any function of the body" (key language for invoking the agency's authorizing legislation) and that it is the intent of tobacco manufacturers that their products have addictive effects (*Federal Register* 1995a). The argument was presented as a logical chain of inference: the addictive properties of tobacco are "widely known and foreseeable" by tobacco manufacturers; consumers use the product to satisfy their addiction; and tobacco manufacturers know of the addiction, know of consumers' use, and have facilitated that use (*Federal Register* 1995a). An extensive analysis, including internal documents from tobacco companies, was used to elucidate these assertions (*Federal Register* 1995a). The FDA presented a further legal discussion of whether the cigarette is a device and postulates that the cigarette is "a consciously engineered instrument . . . to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed" (*Federal Register* 1995a).

The proposed regulations centered on restricting the availability and appeal of tobacco products to children and adolescents and consisted of the following provisions:

- The tobacco industry would be required to spend at least $150 million per year to support smoking prevention education for children.
- Tobacco sales would be prohibited to those under 18 years of age, and vendors would be required to see photo identification as proof of age.
- Vending machines, self-service displays, and mail-order sales would be prohibited, as would the sale of individual cigarettes or packs of fewer than 20 cigarettes.
- The sale or gift of promotional items bearing brand names, logos, or other brand identity would be prohibited.
- Free samples would be banned.
- Only black-and-white text advertising for cigarette products would be permitted in publications for which more than 15 percent of the readership is under age 18 and in publications with more than 2 million young readers.
- Outdoor tobacco advertising would be prohibited within 1,000 feet of schools and playgrounds. All other outdoor tobacco advertising would have to be in black-and-white text.
- Sponsorship of sporting or entertainment events using specific brand names or product identification would be prohibited, although the use of company names would not.

The proposed regulations stirred immediate action from the tobacco industry. Four lawsuits were filed immediately after the *Federal Register* announcement. A lawsuit filed by tobacco companies in federal court in Greensboro, North Carolina, asserted that the FDA had no jurisdiction over cigarettes. The plaintiffs were Brown & Williamson Tobacco Corporation, Liggett Group Inc., Lorillard Tobacco Company, Philip Morris, and R.J. Reynolds Tobacco Company (*Wall Street Journal* 1995). Parts of the advertising industry, which has a large stake in the outcome of the proposed regulations, also filed suit on the grounds of infringement of First Amendment rights (*American Advertising Federation v. Kessler*, Civil Action No. 2:95CV00593 [M.D.N.C. Aug. 10, 1995], *cited in* 10.5 TPLR 3.401 [1995]). In addition, a smokeless tobacco company (*United States Tobacco Co. v. Food and Drug Administration*, Civil Action No. 6:95CV00665 [M.D.N.C. Sept. 19, 1995]) and a trade group representing convenience stores (*National Association of Convenience Stores v. Kessler*, Civil Action No. 2:95CV00706 [M.D.N.C. Oct. 4, 1995]) filed suit.

By the January 2, 1996, close of the public comment period on the proposed rules, the FDA had received more than 95,000 individual comments, the largest outpouring of public response in the agency's history. From March 18 to April 19, 1996, the FDA reopened the comment period for the limited purpose of seeking comments on the statements of three former Philip Morris employees about that company's alleged manipulation of nicotine in the design and production of cigarettes and to seek comments on further explanations of certain provisions in the proposed rule.

The review process culminated in a Rose Garden ceremony at the White House on August 23, 1996, in which President Clinton announced the publication of the final FDA rules. To emphasize that the FDA's central intent was to reduce tobacco use among young people, these final rules essentially regrouped the regulations from the original announcement into two categories: reducing minors' access to tobacco products and reducing the appeal of tobacco products to minors. The only notable changes to the former rules were that the ban on mail-order sales was eliminated and the ban on vending machines and self-service displays was relaxed to allow exceptions for certain nightclub and other "adults-only" facilities totally inaccessible to persons under the age of 18. Similarly, the limitation to black-and-white text for in-store advertising excepted adults-only facilities if the advertising was not visible from the outside.

In place of its original regulation requiring the tobacco industry to spend at least $150 million each year to support tobacco prevention education for children, the final rules were less explicit. The FDA proposed to require the six tobacco companies with a significant share of sales to minors to educate that population about the health risks of using tobacco products. This action would be pursued under processes dictated by section 518(a) of the Federal Food, Drug, and Cosmetic Act (FDCA). Under the act, the FDA may require manufacturers to inform the consumer about unreasonable health risks of their products.

The various provisions were to be phased in between six months and two years from August 28, 1996, the date of publication in the *Federal Register*. Two principal hurdles to quick and full implementation of the FDA regulations soon emerged. First, as noted above, several tobacco companies, retailers, and advertisers had sued the FDA to block implementation of the regulations. Second, various legislative proposals, which began circulating in Congress both before and after publication of the FDA's final rule, threatened to alter or bar the FDA's regulation of tobacco products.

Judicial Developments and the Status of FDA Regulations

Three briefs filed on October 15, 1996, on behalf of the plaintiffs in these suits moved for summary judgment, arguing that the proposed regulations exceed the agency's jurisdiction and are contrary to congressional intent, that tobacco products are not "drugs" or "devices" within the agency's statutory grant of authority, and that the advertising restrictions are a violation of the First Amendment (*Mealey's Litigation Reports: Tobacco* 1996b).

On April 25, 1997, the federal district court in Greensboro, North Carolina, ruled that the FDA possessed the authority to regulate cigarettes and smokeless tobacco products as drug delivery devices under the FDCA (*Coyne Beahm, Inc. v. U.S. Food & Drug Administration*, 966 F. Supp. 1374 [M.D.N.C. 1997]). The ruling, however, marked a considerably qualified victory for the FDA. Although the court upheld all of the agency's restrictions involving youth access and labeling, the court temporarily blocked implementation of most of these provisions. Only the FDA's prohibition on sales of cigarettes and smokeless tobacco to minors and the requirement that retailers check photo identification of customers who are under 27 years of age escaped the court's stay. These provisions went into effect on February 28, 1997, and remained in force until March 21, 2000, the date of the Supreme Court decision.

Notably, the court invalidated the FDA's restrictions on advertising and promotion of cigarettes and smokeless tobacco on the basis that they exceeded the agency's statutory jurisdiction. The pertinent federal statute, 21 U.S.C. section 360j(e), provides, in part, that the government may "require that a device be restricted to sale, distribution or use . . . upon such other conditions as the Secretary may prescribe." The FDA had argued that it was authorized to restrict the "sale, distribution or use" of tobacco products pursuant to section 360j(e) and that its advertising and promotion restrictions were valid because advertising and promotion constitutes an "offer of sale" (*Coyne Beahm*, p. 1398). Judge William L. Osteen Sr. disagreed. The court reasoned that the word "sale" as employed in the statute did not encompass the advertising or promotion of a product. The court also ruled that the "section's grant of authority to FDA to impose 'other conditions' on the sale, distribution, or use of restricted devices [does] not authorize FDA to restrict advertising and promotion" (p. 1398). Furthermore, because the court ruled that the FDA was not authorized to restrict advertising and promotion, the court did not reach or discuss arguments that these provisions violated the First Amendment to the United States Constitution.

Most important, however, Judge Osteen agreed with the FDA's contention that tobacco products fall within the "drug" and "device" definitions of the FDCA. To position its authority within these definitions, the FDA had to have demonstrated that tobacco products are "intended to affect the structure or any function of the body" (21 U.S.C. section 321 [g][1][C]). Judge Osteen ruled that the effects of tobacco products are "intended" within the meaning of the FDCA and that tobacco products affect the structure or function of the body within the meaning of that act. The court also ruled that pursuant to its "device authorities," the FDA could regulate tobacco products as medical devices.

Both sides in the case appealed the decision to the Fourth Circuit of the United States Court of Appeals in Richmond, Virginia. The government and the tobacco companies presented oral arguments to a three-member panel of this court on August 11, 1997. The case became inactive following the death of one of the panel judges on February 22, 1998. A new judge was appointed, and on June 9, 1998, the three-member panel conducted a second hearing on the appeal.

The Court of Appeals Ruling on FDA Authority

On August 14, 1998, the Fourth Circuit Court of Appeals overturned the lower court decision and ruled in a 2 to 1 decision that the FDA lacks the authority to regulate tobacco products (*Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, No. 97-1604 [4th Cir. 1998]). The majority opinion (Judge H. Emory Widener Jr.) found that the FDA had based its determination of authority solely on literal interpretations of "drug" and "device" in the FDCA but did not consider statutory language as a whole, the legislative history, and the history of evolving congressional regulation in the area, including consideration of other relevant statutes. Judge Widener held that there is an internal inconsistency in the FDA's claim of authority to regulate tobacco under the FDCA, since a declaration that cigarettes are unsafe (the basis of the FDA's claim) necessitates a ban on cigarette sales—an action that would be opposed by powerful economic and political forces. Widener reasoned that although the FDA would have the authority to grant exemptions to the ban because potential public health benefits might outweigh harms, such exemptions would undermine the agency's essential view that cigarettes are unsafe. The only exemption open to the FDA would thus be based on social and economic rather than health-related considerations. A well-known catch would then come into play: social and economic considerations are within the purview of Congress, not the FDA. Judge Widener pointed out that Congress had been aware for decades that the FDA lacked the authority to regulate tobacco on social and economic grounds, had rejected attempts to give the FDA such authority, and had enacted numerous pieces of legislation that did not grant such authority.

The dissenting opinion (Judge Kenneth K. Hall) took the position that the intrinsic contradiction in the FDA's authority under the FDCA is irrelevant: ". . . whether the regulations contravene the statute is a question wholly apart from whether any regulations could be issued. . . . It is no argument to say that the FDA can do nothing because it could have done more" (*Brown & Williamson*, p. 48). The opinion proposed that the FDA's current position is a response to "the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the addictive effect of tobacco products" (p. 50). Judge Hall stated that precedents in administrative law clearly indicate latitude for an agency to change its approach in the light of new information. He further asserted that earlier congressional action did not have the benefit of the level

of evidence gathered by the FDA in forming its current position. Finally, he pointed out that the term "sale, distribution and use" (p. 58) is not fully defined in the FDCA and is therefore subject to agency interpretation. This term "can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home" (p. 58). Thus, the judge reasoned, the authority to regulate tobacco promotion should be upheld. The full Fourth Circuit Court of Appeals declined to review this reversal. The government petitioned the United States Supreme Court for review, and the United States Supreme Court accepted the case in April 1999. Oral argument was held December 1999, and the Court, in a 5 to 4 decision, upheld the Fourth Circuit's decision on March 21, 2000.

The U.S. Supreme Court Ruling on FDA Authority

On March 21, 2000, by a 5 to 4 vote, the United States Supreme Court affirmed the Fourth Circuit decision and overturned the FDA's assertion of jurisdiction over cigarettes and smokeless tobacco products (*Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. _____ [2000], 120 S. Ct. 1291). As a result, the FDA no longer has regulatory authority to enforce the final rule it issued in 1996.

Justice Sandra Day O'Connor wrote the majority opinion for the Court. In ruling against the FDA, she noted that "The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States" (p. 1315). Nevertheless, the majority ruled that Congress had precluded the FDA from asserting jurisdiction over tobacco products as customarily marketed because "Such authority is inconsistent with the intent that Congress has expressed" (p. 1297) in the Federal Food, Drug, and Cosmetic Act and other tobacco-specific statutes.

Justice O'Connor noted the unusual nature of both the case the Court was deciding and the role of tobacco in the United States. She wrote:

> Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area (p. 1315).

Justice Stephen Breyer wrote the dissenting opinion. He disagreed with the majority view that Congress never intended the FDA to have the authority to assert jurisdiction over tobacco products. In summarizing why the four justices in the dissent believed the FDA had acted lawfully, Justice Breyer wrote:

> The upshot is that the Court today holds that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the Court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify (p. 1331).

Legislative Developments

In an effort to clarify the public health perspective on potential legislation, on September 17, 1997, President Clinton outlined the principles he believed must be at the heart of any national tobacco legislation (Hohler 1997):

- A comprehensive plan to reduce youth smoking, including tough penalties if targets are not met.
- Full authority for the FDA to regulate tobacco products.
- An end to the tobacco industry's practice of marketing and promoting tobacco to children.
- Broad document disclosure (especially of those documents relating to marketing tobacco to children).
- Progress toward other public health goals, such as reducing environmental tobacco smoke (ETS), expanding smoking cessation programs, strengthening international efforts to control tobacco, and providing funds for health research.
- Protection for tobacco farmers and their communities.

A number of bills intended to enable the enactment of the June 20, 1997, multistate settlement agreement were introduced into the U.S. Senate in late 1997 and early 1998. In March 1998, the Senate Commerce Committee bill introduced by Senator John McCain (R-AZ) became the focus of all settlement-related legislative activity in the Senate. The Commerce Committee endorsed a preliminary version of a substitute bill, S. 1415, on March 30, 1998, by a vote of 19 to 1. On May 1, 1998, the Commerce Committee's version of the bill—S. 1415.RS (the "McCain Committee

Bill")—was reported by Senator McCain to the full Senate. Among other things, the McCain Committee Bill would have done the following:

- Required the tobacco industry to pay $516 billion ($147.5 billion more than was specified in the June 20th multistate settlement agreement) over 25 years to help states and the federal government bear the medical costs of smoking-related illness.
- Raised cigarette taxes by $1.10 per pack over five years.
- Preserved the FDA's ability to regulate the tobacco industry in ways that the June 20th agreement did not.
- Drastically reduced cigarette marketing, advertising, and promotion (Kelder 1998).

In addition, the Floor Manager's Amendment to the bill would have established a detailed regulatory scheme to be administered by the FDA (S. 1415.RS [Floor Manager's Amendment of May 18, 1998, 105th Cong., 2nd Sess.]). First, the FDA could designate demonstrably safer products as "reduced risk tobacco products" (sec. 913[a][2][A]). Second, the FDA would have the authority to promulgate performance standards, including "the reduction or elimination of nicotine yields" (sec. 907[a][2][A][I]) and "the reduction or elimination of other constituents or harmful components of the product" (sec. 907[a][2][A][ii]). The agency would follow normal administrative procedures, unless it sought to eliminate "all cigarettes, all smokeless tobacco products, or any similar class of tobacco products" (sec. 907[b][3][A]) or to require "the reduction of nicotine yields of a tobacco product to zero" (sec. 907[b][3][B]). In that event, the amendment stipulated, "the standard may not take effect before a date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued" (sec. 907[b][3][B]). Third, the Floor Manager's Amendment would have required that the FDA be given the additive information specified in the settlement agreement within six months of enactment (sec. 904[a][3]).

The amendment would also have required that manufacturers share with the FDA "all documents . . . relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) to the health, behavioral, or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives" (sec. 904[a][4]) or "to marketing research involving the use of tobacco products" (sec. 904[a][5]). Tobacco product advertising would be required to include a "brief statement of the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications" (sec. 903[a][8][B][i]). Furthermore, the FDA would be given explicit power to impose "restrictions on the access to, and the advertising and promotion of, the tobacco product" (sec. 906[d][1]).

Senate bill 1415 was vehemently opposed by the tobacco industry. On April 8, 1998—nine days after the Commerce Committee endorsed the preliminary version of the McCain Committee Bill—Steven F. Goldstone, RJR Nabisco's chief executive officer, announced that his company was pulling out of the congressional process for developing comprehensive tobacco legislation. Blaming Congress for failing to stick to the terms of the June 20th agreement, Mr. Goldstone, speaking to the National Press Club in Washington, DC, declared his company's intention not to sign the consent decrees to voluntarily limit advertising that were part of the McCain Committee Bill. Philip Morris, Brown & Williamson, United States Tobacco, and Lorillard made similar announcements shortly after Mr. Goldstone's speech.

In retrospect, one can conclude that this tobacco company brinkmanship—when paired with a widely disseminated, industry-sponsored advertising campaign that portrayed the McCain Committee Bill as a vast "tax-and-spend" proposal—was a major force in scuttling the proposed legislation. Emboldened by the effect that the industry-sponsored advertising campaign had on public opinion, the tobacco industry's Senate allies greatly altered the McCain Committee Bill, culminating in the Floor Manager's Amendment on May 18, 1998. Some of these amendments would have increased the bill's potential harmful impact on public health. For example, in this final form, the bill had been shorn of almost all of its funds for initiatives to fund tobacco use reduction, and the tobacco industry had been given a potential means of immunity in the form of caps on plaintiffs' attorneys' fees (Kelder 1998).

On June 17, 1998, the McCain Committee Bill died after four weeks of intense debate and political maneuvering. In the absence of congressional action to enact the proposed settlement, individual state lawsuits proceeded. Four states—Mississippi, Florida, Texas, and Minnesota—have settled their suits with the tobacco industry. Because these settlements involve the recovery of Medicaid payments made by the states, they are discussed with other such litigation approaches, later in this chapter (see "Recovery Claims by Third-Party Health Care Payers").

Master Settlement Agreement

On November 23, 1998, 11 tobacco companies executed a legal settlement with 46 states, the District of Columbia, and five commonwealths and territories. The plaintiffs had sued the tobacco industry to recoup Medicaid costs for the care of persons injured by tobacco use. The suit alleged that the companies had violated antitrust and consumer protection laws, had conspired to withhold information about adverse health effects of tobacco, had manipulated nicotine levels to maintain smoking addiction, and had conspired to withhold lower-risk products from the market.

In the settlement, the companies agreed to pay states $246 billion over 25 years. But in addition, the settlement agreement contained a number of important public health provisions (see the text box). The agreement placed significant marketing restrictions on the industry by prohibiting direct advertising and promotion aimed at young people, by limiting brand name sponsorship at events that might be frequented by youth, by requiring the removal of street advertising without restrictions on counteradvertising, by placing substantial restrictions on lobbying and on the suppression of research findings, and by requiring major contributions from the industry to cessation and prevention activities (Wilson 1999). In addition, the agreement dealt with such issues as legal fees, court supervision, civil liabilities restrictions, and public disclosure. Unlike the 1997 settlement, the 1998 settlement contained no provisions regarding FDA authority.

The agreement raised a number of issues for states, but foremost among these has been the competition between tobacco control efforts and other state spending priorities. The National Governors Association issued a policy statement that reaffirmed states' entitlement and asserted that the federal government had no legitimate claim to settlement funds. The association committed to spending "a significant portion of the settlement funds on smoking cessation programs, health care, education, and programs benefitting children" but reserved the right to make funding decisions tailored to states' individual needs (National Governors Association 1999). By mid-1999, 27 states had allocated their first and second settlement payments. Of these, 23 had specified some portion of the money for public health activities, and 16 had specifically designated spending for tobacco control and prevention efforts. Specific issues related to the allocation of Master Settlement Agreement funds to tobacco control efforts in states are discussed in Chapter 7.

Clean Indoor Air Regulation

Introduction

If the regulation of tobacco products themselves has been characterized by slow and incremental advances, the regulation of where and how tobacco products are used—that is, the regulation of exposure, particularly of nonsmokers, to ETS—has encountered comparatively little resistance. Public and private steps to regulate ETS have become both more common and more restrictive over the past several decades.

There are various reasons for this broad and rapid implementation. One reason is that the public health necessity of regulating ETS exposure is manifest: ETS is known to cause acute and chronic diseases in nonsmokers (National Academy of Sciences 1986; USDHHS 1986; National Institute for Occupational Safety and Health 1991; EPA 1992; California EPA 1997). Moreover, this demonstrated health threat is unentangled with legal or ethical issues of "informed choice" or "informed consent" (see "Product Regulation," earlier in this chapter)—hence a popular name for this exposure, *passive* smoking. Regulating ETS exposure also has important implications for reducing smoking: studies have shown that restricting smoking in public settings increases the likelihood that smokers in these settings smoke fewer cigarettes or quit smoking entirely (Petersen et al. 1988; Borland et al. 1990a; Stillman et al. 1990; Sorensen et al. 1991a; Woodruff et al. 1993). It has been estimated that the combined effect of general smoking cessation and smoking reduction in public settings could decrease total cigarette consumption by as much as 40 percent (Woodruff et al. 1993), although this conclusion may be questioned based on assessment of worksite interventions (see "Worksite Programs" in Chapter 4). A second reason for the expansion of ETS regulations is that their public support, a key marker for successful

Major Provisions of the Master Settlement Agreement

In addition to the monetary payments from the tobacco industry to states, the settlement provided for other requirements and restrictions:

Youth Access

- No free samples except in an enclosed area where operator ensures that no underage persons are present.
- No gifts to youth in exchange for buying tobacco products.
- No gifts through the mail without proof of age.
- Prohibits sale, manufacture, or distribution of cigarettes in packages of fewer than 20 until December 31, 2001.

Marketing

- No brand name sponsorship of concerts, team sporting events, or events with a significant youth audience.
- No sponsorship of events in which paid participants are underage.
- Bans use of tobacco brand names in stadiums and arenas.
- Bans use of cartoon characters in tobacco advertising, packaging, and promotions.
- Bans payments to promote tobacco products in entertainment settings, such as movies.
- Bans distribution and sale of merchandise with brand name tobacco logos.

Lobbying

- Prohibits industry from supporting diversion of settlement funds to nonhealth uses.
- Restricts industry from lobbying against restrictions of advertising on or in school grounds.
- Prohibits new challenges by the industry to state and local tobacco control laws enacted before June 1, 1998.

Outdoor Advertising

- Bans transit and outdoor advertising, including billboards.
- Tobacco billboards and transit ads to be removed.
- At industry expense, states could substitute advertising discouraging youth smoking.

Cessation and Prevention

- The tobacco industry will contribute $25 million annually for 10 years to support a charitable foundation established by the National Association of Attorneys General to study programs to reduce teen smoking and to prevent diseases associated with tobacco use. The foundation, since named the American Legacy Foundation, is governed by a board and will carry out a sustained national advertising and education program to counter tobacco use by young people and educate consumers about the health hazards of tobacco use. It will also evaluate the effectiveness of counteradvertising campaigns, model classroom educational programs, and cessation programs and will disseminate the results. Other activities include commissioning and funding studies on the factors that influence youth smoking, developing training programs for parents, and monitoring youth smoking to determine the reasons for increases or failures to decrease tobacco use rates.
- The industry will contribute $1.45 billion over five years to support the National Public Education Fund, which will carry out a national sustained advertising and education program to counter youth tobacco use and to educate consumers about tobacco-related diseases. The tobacco industry will continue to contribute $300 million annually to the fund as long as the participating tobacco companies hold 99.05 percent of the market.

implementation, is implicit: national studies suggest that most of the U.S. public experiences discomfort and annoyance from ETS exposure (CDC 1988, 1992b), and smaller-scale surveys have found that the great majority of both nonsmokers and smokers favors smoking restrictions in various public locations, including the workplace, restaurants, and bars (CDC 1991). A third reason is that employers might be expected to support ETS regulations, because prohibiting smoking in the workplace can help employers realize lower maintenance and repair costs of buildings and property, lower insurance costs, and higher productivity among nonsmokers (Mudarri 1994). Employer support, however, may be influenced by other factors (see "Effectiveness of Clean Indoor Air Restrictions," later in this chapter).

Not surprisingly, during the 1980s the tobacco industry identified ETS regulation as the single most important issue confronting the industry's economic future (Chapman et al. 1990). The industry is concerned that the increasing focus on ETS may cause the public and policymakers to view smoking as an environmental issue with broad social consequences instead of as a personal behavior involving individual choice. The tobacco industry is also concerned about legal backlash from possible ETS-related litigation against employers and about revenue losses from possible decreased cigarette consumption due to smoking restrictions (Chapman et al. 1990). An example of the latter concern may be found in California, where workplace restrictions extant in 1990 have reduced consumption by an estimated 148 million packs per year, at a value of $203 million in pretax sales (Woodruff et al. 1993).

Health Consequences of Exposure to ETS

The detrimental health effects of exposure to ETS are well established (National Research Council 1986; USDHHS 1986, 2000b; EPA 1992; California EPA 1997). The most comprehensive review of the respiratory effects of ETS to date is the 1992 report of the EPA, which states that ETS is a human lung carcinogen that annually accounts for approximately 3,000 lung cancer deaths among adult nonsmokers in the United States. Autopsy reviews (Trichopoulos et al. 1992) and studies of ETS metabolites in body fluids (Hecht et al. 1993) provide biologic support for epidemiologic studies linking ETS and lung cancer. ETS also has subtle but significant effects on the respiratory health (including cough, phlegm production, and reduced lung function) of adult nonsmokers.

Among children, ETS has far-reaching health effects. ETS causes bronchitis and pneumonia, accounting for an estimated 150,000–300,000 annual cases in infants and young children, and causes middle ear diseases (infections and effusions). ETS causes additional episodes of asthma and increases its severity, worsening an estimated 400,000–1,000,000 cases annually. As a risk factor for new cases of asthma, ETS may account for 8,000–26,000 annual cases (EPA 1992; California EPA 1997).

In an important ruling, Judge Osteen of the U.S. District Court annulled Chapters 1–6 and the Appendices to the EPA's 1992 report (EPA 1992; *Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency*, 4 F. Supp. 2d 435 [M.D.N.C. 1998]). The decision was a mix of procedural and scientific concerns. Judge Osteen found that the EPA had not complied with the procedural requirements of the Radon Gas and Indoor Air Quality Research Act of 1986, had acted beyond congressional intent, and had violated administrative law procedure by drawing conclusions about ETS prior to concluding a scientifically sound risk-assessment study. The judge was also concerned with the amount of evidence in the record supporting EPA's final basis for its plausibility hypothesis, with some of the animal laboratory tests that he felt were inconclusive but were cited as compelling evidence of the dangers of ETS, and with the EPA's choice of epidemiologic studies to support its findings.

Considerable information appeared after the EPA's 1992 report that supported its general conclusions (Brownson et al. 1992a; Stockwell et al. 1992; Fontham et al. 1994; Cardenas et al. 1997). A recent meta-analysis of workplace ETS exposure and increased risk of lung cancer also provided needed epidemiologic support (Wells 1998). The ninth EPA report on carcinogens was released in the year 2000 and lists ETS as a known carcinogen for the first time (USDHHS 2000).

Since the 1992 EPA report, further evidence linking ETS and heart disease has been assembled as well. (Glantz and Parmley 1995; Steenland et al. 1996; California EPA 1997; Kawachi et al. 1997; Law et al. 1997; Howard et al. 1998; Valkonen and Kuusi 1998; Wells 1998). If ETS is a causal risk factor for coronary heart disease, it likely accounts for many more deaths from heart disease than from lung cancer (EPA 1992; Wells 1994). A review of 12 epidemiologic studies has estimated that ETS accounts for as many as 62,000 annual deaths from coronary heart disease in the United States (Wells 1994). However, because smoking is but one of the many risk factors in the etiology of heart disease,

quantifying the precise relationship between ETS and this disease is difficult.

Strong evidence is also accumulating that ETS is a risk factor for sudden infant death syndrome (Jinot and Bayard 1994; DiFranza and Lew 1995; Klonoff-Cohen et al. 1995; Anderson and Cook 1997; California EPA 1997; Alm et al. 1998; Dybing and Sanner 1999). In a large U.S. study, maternal exposure during pregnancy and postnatal exposure of the newborn to ETS increased the risk of this syndrome (Schoendorf and Kiely 1992).

Other Consequences of ETS

Separate from their concerns about direct health effects, most nonsmokers are annoyed by ETS exposure (CDC 1988; Brownson et al. 1992b). U.S. survey data have suggested that 71 percent of all respondents, including 43 percent of current smokers, are annoyed by ETS (CDC 1988). Similarly, data from urban St. Louis and Kansas City, Missouri, have shown that 66 percent of all respondents and nearly 40 percent of current smokers were annoyed by ETS exposure (Brownson et al. 1992b). The term "annoyance," a seemingly minor attribute, has some nontrivial ramifications. Public attitudes toward smoking, an amalgam of concerns about health and social interactions, have changed in the past decade, as is discussed in greater detail in the section "Effectiveness of Clean Indoor Air Restrictions," later in this chapter. The findings from one survey suggested that the proportion of Americans who favored a total ban on smoking in restaurants and workplaces increased from less than one-fifth in 1983 to almost one-third in 1992 (Gallup Organization, Inc. 1992). The proportion favoring no restrictions fell from as high as 15 percent in 1983 to 5 percent in 1992. Similarly, by 1992, more than 90 percent of respondents favored restrictions or a total ban on smoking in trains and buses as well as in hotels and motels. More than 90 percent "agreed" or "strongly agreed" that ETS is injurious to children, pregnant women, and older adults. Thus, an important consequence of information on ETS has been a changing social norm regarding smoking and an evolving foundation for clean indoor air regulations.

Because of the consequences of ETS, employers are likely to save costs by implementing policies for smoke-free workplaces. Savings include those associated with fire risk, damage to property and furnishings, cleaning costs, workers compensation, disability, retirement, injuries, life insurance, absenteeism, productivity losses, and synergistic occupational risks such as asbestos exposure (Kristein 1989). Such costs were estimated at $1,000 per smoking employee in 1988 dollars. In a recent report on the savings associated with a nationwide, comprehensive policy on clean indoor air, the EPA estimated that such a law would save $4 billion to $8 billion per year in operational and maintenance costs of buildings (Mudarri 1994).

Prevalence of Exposure to ETS

Exposure to ambient tobacco smoke is widespread. The 1988 National Health Interview Survey reported that an estimated 37 percent of the 79.2 million U.S. nonsmoking workers worked in places that permitted smoking in designated and other areas and that 59 percent of these experienced moderate or great discomfort from ETS exposure in the workplace (National Center for Health Statistics 1989). Since the advent of urinary cotinine screening, firmer documentation of ETS has become available. In a study of 663 nonsmokers attending a cancer screening, Cummings and colleagues (1990) found that 76 percent of participants were exposed to ETS in the four days preceding the interview. The authors concluded that the workplace and the home were the primary sources of ETS exposure among these nonsmokers. The best single predictor of urinary cotinine was the number of smokers among friends and family members seen regularly by the study participant. In a study of 881 nonsmoking volunteers, Marcus and colleagues (1992) found that employees in workplaces that were "least restrictive" (i.e., allowed smoking in numerous locations) were more than four times more likely to have detectable saliva cotinine concentrations than employees from smoke-free workplaces were (p. 45).

The largest study of population exposure to ETS with biochemical markers is the CDC's Third National Health and Nutrition Examination Survey, conducted from 1988 to 1991 on a nationally representative sample of 16,818 persons aged 2 months and older (Pirkle 1996). Serum cotinine was measured in 10,642 participants aged 4 years and older. The data indicate high concordance between reported ETS exposure and serum cotinine level. Among nontobacco users, 87.9 percent had detectable levels of serum cotinine, and the level was significantly and independently associated with both the number of smokers in the household and the number of hours of work exposure. The authors concluded that both the work and the household environments make important contributions to the widespread exposure to ETS experienced by children and adults.

Some improvement in ETS exposure has been noted. A study from California found that nonsmokers' self-reported exposure to ETS at work declined from

29 percent in 1990 to 22 percent in 1993 (Patten et al. 1995b). This decline was not as pronounced, however, among some sociodemographic subgroups, such as African Americans, Asian Americans, and persons with less than a high school education. During the same period, the percentage of employees reporting that they worked in smoke-free workplaces greatly increased (from 35 to 65 percent). Survey data from Missouri in 1993 indicated that 41 percent of the population were exposed to ETS in the workplace and 18 percent in the home environment (Brownson et al. 1995a). Among subgroups, younger persons, men, Hispanics, and persons with less than a high school education had more workplace exposure to ETS. Similarly, data from rural Missouri showed higher prevalence of workplace ETS exposure among younger persons, men, African Americans, and persons with less than a high school education (Brownson et al. 1995a). Emmons and colleagues (1992) analyzed entries in diaries recording ETS exposure among 186 persons who were former smokers or had never smoked. Approximately 50 percent of the daily ETS exposure was attributed to the workplace, and 10 percent was attributed to the home environment. However, for persons who lived with a smoker, more exposure occurred in the home than in the workplace.

Relatively few population-based data that specifically examine the levels of ETS exposure in the workplace have been collected. Such data may be important, because exposure levels likely vary greatly by workplace, and recent studies have indicated that higher levels of ETS (measured by intensity or duration of ETS exposure) increase the risk of lung cancer in nonsmokers (Brownson et al. 1992a; Stockwell et al. 1992; Fontham et al. 1994). In a review of existing studies, Siegel (1993) found that ETS concentrations varied widely by location; mean levels of nicotine measured in the ambient air were 4.1 $\mu g/m^3$ for offices overall, 4.3 $\mu g/m^3$ for residences with at least one smoker, 6.5 $\mu g/m^3$ for restaurants, and 19.7 $\mu g/m^3$ for bars. In a survey of 25 Massachusetts worksites, Hammond and colleagues (1995) found that the type of worksite smoking policy had a great effect on nicotine concentrations. Levels of nicotine ranged from 8.6 $\mu g/m^3$ in open offices that allowed smoking to 0.3 $\mu g/m^3$ in worksites that banned smoking.

Legal Foundation for Regulation of Public Smoking

The legal foundation for regulating public smoking is based on case law pertaining mainly to the protection of the health of workers. Under common law (the body of law based on court decisions rather than government laws or regulations), employers must provide a work environment that is reasonably free of recognized hazards. Courts have ruled that common-law duty requires employers to provide nonsmoking employees protection from the proven health hazards of ETS exposure (Sweda 1994).

Three pioneering cases have demonstrated the basis for this protection. In *Shimp v. New Jersey Bell Telephone Co.* (368 A.2d 408, 145 N.J. Super. 516 [1976]), a secretary who was allergic to cigarette smoke sought an injunction requiring a smoking ban. The court ordered the employer to provide a safe working environment by restricting smoking to a nonwork area. Similarly, in the case of *Smith v. Western Electric Co.* (643 S.W.2d 10 [Mo. App. 1982]), the Missouri Court of Appeals overturned a lower court and forced the employer to "assume its responsibility to eliminate the hazardous conditions caused by tobacco smoke" (p. 13). Finally, in *Lee v. Department of Public Welfare* (No. 15385 [Mass. Mar. 31, 1983], *cited in* 1.2 TPLR 2.82 [1986]), a social worker sued her employer, seeking relief from ETS exposure at work. The Massachusetts Superior Court ruled in favor of the plaintiff and required a smoke-free workplace. Additional protections to employees are extended by federal statute, such as the Americans with Disabilities Act of 1990 (ADA) (Public Law 101-336), and by rulings in workers compensation claims.

Status of Restrictions to Limit Smoking in Public Places

Although the health risks of ETS exposure began to be publicized in the early 1970s (NCI 1991), momentum to regulate public smoking increased only in 1986, when reports by the Surgeon General (USDHHS 1986) and the National Academy of Sciences (1986) concluded that ETS is a cause of lung cancer in nonsmokers. Since then, government and private business policies that limit smoking in public places have become increasingly common and restrictive (Rigotti and Pashos 1991). The designation of ETS as a class A (known human) carcinogen by the EPA (1992) stimulated further restrictions on smoking in public places (Brownson et al. 1995a), but a recent court ruling set aside that report (see "Health Consequences of Exposure to ETS," earlier in the chapter).

Although many of the regulatory efforts discussed herein focus on government's passage of a law or an ordinance, other regulations can be implemented by

Table 5.1. Summary of landmark events in the development of U.S. policies for clean indoor air

Year	Event
1971	The Surgeon General proposes a federal smoking ban in public places.
1972	The first report of the Surgeon General to identify environmental tobacco smoke (ETS) as a health risk is released.
1973	Arizona becomes the first state to restrict smoking in several public places and to reduce ETS exposure because it is a health risk.
	The Civil Aeronautics Board requires no-smoking sections on all commercial airline flights.
1974	Connecticut passes the first state law to apply smoking restrictions to restaurants.
1975	Minnesota passes a comprehensive statewide law for clean indoor air.
1977	Berkeley, California, becomes the first community to limit smoking in restaurants and other public places.
1983	San Francisco passes a law to place private workplaces under smoking restrictions.
1986	A report of the Surgeon General focuses entirely on the health consequences of involuntary smoking; ETS is proclaimed a cause of lung cancer in healthy nonsmokers.
	The National Academy of Sciences issues a report on the health consequences of involuntary smoking.
	Americans for Nonsmokers' Rights becomes a national group; it had originally formed as California GASP (Group to Alleviate Smoking Pollution).
1987	The U.S. Department of Health and Human Services establishes a smoke-free environment in all of its buildings, affecting 120,000 employees nationwide.
	Minnesota passes a law requiring all hospitals in the state to ban smoking by 1990.
	A Gallup poll finds, for the first time, that a majority (55 percent) of all U.S. adults favor a complete ban on smoking in all public places.
1988	A congressionally mandated smoking ban takes effect on all domestic airline flights of two hours or less.
	New York City's ordinance for clean indoor air takes effect, banning or severely limiting smoking in various public places and affecting 7 million people.
	California implements a statewide ban on smoking aboard all intrastate airplane, train, and bus trips.
1990	A congressionally mandated smoking ban takes effect on all domestic airline flights of six hours or less.
	The U.S. Environmental Protection Agency (EPA) issues a draft risk-assessment on ETS.
1991	CDC's National Institute for Occupational Safety and Health issues a bulletin recommending that secondhand smoke be reduced to the lowest feasible concentration in the workplace.
1992	Hospitals applying for accreditation by the Joint Commission on the Accreditation of Healthcare Organizations are required to develop a policy to prohibit smoking by patients, visitors, employees, volunteers, and medical staff.
	The EPA releases its report classifying ETS as a group A (known human) carcinogen, placing ETS in the same category as asbestos, benzene, and radon.

Table 5.1. Continued

Year	Event
1993	Los Angeles passes a ban on smoking in all restaurants.
	The U.S. Postal Service eliminates smoking in all facilities.
	Congress enacts a smoke-free policy for WIC (Special Supplemental Food Program for Women, Infants, and Children) clinics.
	A working group of 16 state attorneys general releases recommendations for establishing smoke-free policies in fast-food restaurants.
	Vermont bans smoking in all public buildings and many private buildings open to the public.
1994	The U.S. Department of Defense prohibits smoking in all indoor military facilities.
	The Occupational Safety and Health Administration proposes a rule that would ban smoking in most U.S. workplaces.
	San Francisco passes a ban on smoking in all restaurants and workplaces.
	The Pro-Children's Act requires persons providing federally funded children's services to prohibit smoking in those facilities.
1995	New York City passes a comprehensive ordinance effectively banning smoking in most workplaces.
	Maryland enacts a smoke-free policy for all workplaces except hotels, bars, restaurants, and private clubs.
	California passes comprehensive legislation that prohibits smoking in most enclosed workplaces.
	Vermont's smoking ban is extended to include restaurants, bars, hotels, and motels, except those holding a cabaret license.
1996	The U.S. Department of Transportation reports that about 80 percent of nonstop scheduled U.S. airline flights between the United States and foreign points will be smoke free by June 1, 1996.
1997	President Clinton signs an executive order establishing a smoke-free environment for federal employees and all members of the public visiting federally owned facilities.
	The California EPA issues a report determining that ETS is a toxic air contaminant.
	Settlement is reached in the class action lawsuit brought by flight attendants exposed to ETS.
1998	The U.S. Senate bans smoking in the Senate's public spaces.
	California law takes effect banning smoking in bars unless a bar has a separately ventilated smoking area.

agencies with special authority. An example of a nongovernment regulatory action is the recent adoption of an accrediting standard that prohibits smoking in hospital buildings (Joint Commission on Accreditation of Healthcare Organizations 1992; Longo et al. 1995).

Government Restrictions

Several of the noteworthy events in clean indoor air regulation are shown in Table 5.1. These events include federal, state, and local activities.

Federal Laws and Regulations

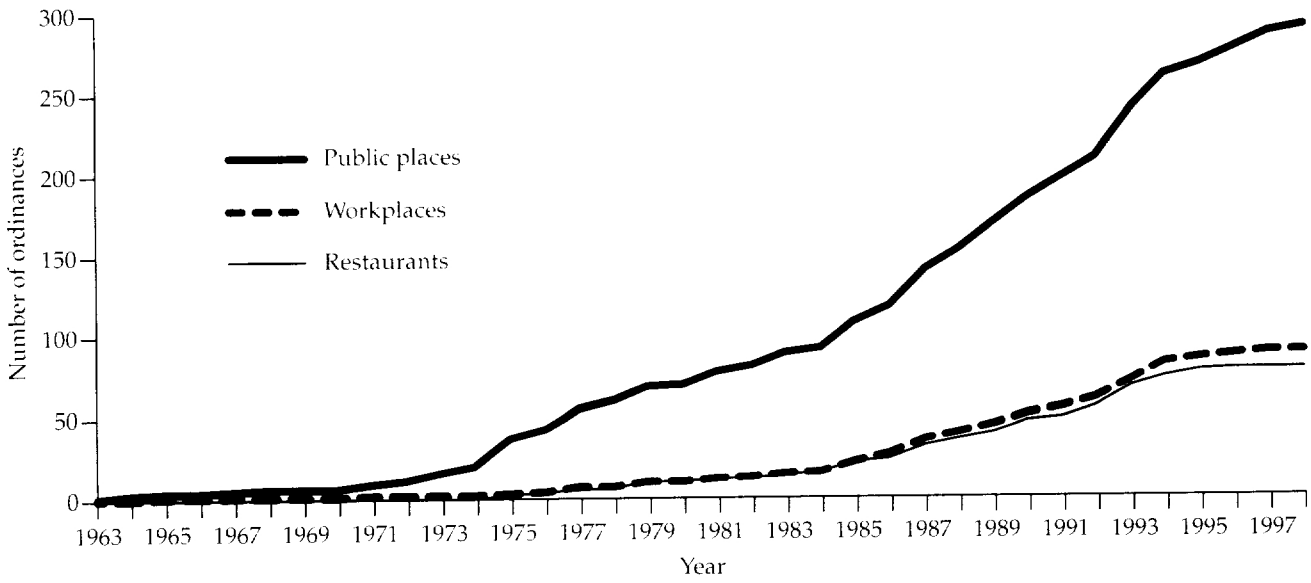
The most notable federal regulation of ETS is the requirement that domestic airline flights be smoke free. The regulation was first enacted in 1988 for domestic flights lasting two hours or less and was renewed in 1989 for domestic flights lasting six hours or less (Table 5.1). Since the early 1970s, the Interstate Commerce Commission (ICC) has required that smoking on interstate buses be confined to the rear of the bus and that smoking sections constitute no more than 10 percent of total seating capacity. Similar ICC regulation for trains was repealed in 1979. In 1987, congressional legislation that threatened to withhold federal funds influenced the State of New York's Metropolitan Transportation Authority to ban smoking on the MTA Long Island Rail Road (USDHHS 1989). Currently, the Occupational Safety and Health Administration is considering regulations that would either prohibit smoking in all workplaces or limit it to separately ventilated areas (*Federal Register* 1994). Furthermore, the federal government has instituted increasingly stringent regulations on smoking in its own facilities, and the Pro-Children's Act of 1994 (Public Law 103-227, secs. 1041–1044) prohibits smoking in facilities in which federally funded children's services are provided on a regular or routine basis.

State Laws and Regulations

As of December 31, 1999, smoke-free indoor air to some degree or in some public places was required by 45 states and the District of Columbia. These restrictions vary widely, from limited restrictions on public transportation to comprehensive restrictions in worksites and public places (CDC, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data). In 1973, Arizona became the first state in which public smoking was regulated in recognition of ETS as a public health hazard (Table 5.1). Five states (Alabama, Kentucky, New Mexico, North Carolina, and Wyoming) have either no legislation or legislation that preempts localities from enacting any law to restrict smoking in public places (see also Figure 5.2).

As of December 31, 1999, laws restricting smoking in government worksites were present in 43 states and the District of Columbia: 29 limit smoking to designated areas, 2 require either no smoking or designated smoking areas with separate ventilation, and 11 prohibit smoking entirely. Twenty-one states have laws restricting smoking in private worksites: 20 limit smoking to designated areas, and 1 (California) requires either no smoking or separate ventilation for smoking areas. Thirty-one states have laws that

Figure 5.2. Cumulative number of state laws and amendments enacted for clean indoor air, 1963–1998



Note: The category "state" includes the District of Columbia.
Source: National Cancer Institute, State Cancer Legislative Database, unpublished data, August 31, 1998.

regulate smoking in restaurants; of these, only Utah and Vermont completely prohibit smoking in restaurants, and California requires either no smoking or separate ventilation for smoking areas (CDC, Office on Smoking and Health, State Tobacco Activities Evaluation System, unpublished data).

In 1994, Maryland proposed a regulation that would prohibit smoking in most workplaces in the state, including restaurants and bars (*Maryland Register* 1994). Despite strong support among both nonsmokers and smokers for restrictions on public smoking in the state (Shopland et al. 1995), this proposal was aggressively challenged by the tobacco industry (Spayd 1994), which questioned the state's legal authority to regulate smoking through administrative rule rather than law. In early 1995, the original regulation was modified by legislative action to permit some exceptions for the hospitality industry, and the rules went into effect. In October 1994, the state of Washington also enacted an extensive indoor workplace ban. In this instance, a temporary injunction was dismissed by the state court, and the ban went into effect without litigation (CSH 1994b).

In North Carolina, legislation was enacted on July 15, 1993 (HB 957), that required that smoking be permitted in at least 20 percent of space in state-controlled buildings but also formally required nonsmoking areas. An important preemption clause prohibited local regulatory boards from enacting more restrictive regulations for public or private buildings after October 15, 1993. During that three-month "window of opportunity," 89 local agencies passed new measures providing some increased protection from ETS. Despite the rush to new restrictions, researchers estimated that by the year 2000, the preemption would prevent 59 percent of private employees in North Carolina from being protected from ETS (Conlisk et al. 1995).

Local Ordinances

The modern era of local ordinances for clean indoor air began in the early 1970s (Pertschuk 1993). In 1977, Berkeley, California, became the first community to limit smoking in restaurants and other public places (Table 5.1). After the release of the 1986 Surgeon General's report on the health consequences of ETS, the rate of passage of local ordinances accelerated (Figure 5.3). By 1988, nearly 400 local ordinances to restrict smoking had been enacted throughout the United States (Pertschuk and Shopland 1989). The trend toward smoke-free local ordinances has accelerated since 1989 (Rigotti and Pashos 1991; Pertschuk 1993). As of June 30, 1998, public smoking was restricted or banned in 820 local ordinances. Of those that specified which agency was responsible for enforcement, 44 percent cited health departments or boards of health, 19 percent named city managers, 5 percent said police departments, and 6 percent identified other agencies (Americans for Nonsmokers' Rights, unpublished data, June 30, 1998). The effectiveness of various enforcement mechanisms and the level of compliance achieved are not known. Data from Wisconsin suggest that implementation may be just as important as legislation in achieving policy goals (Nordstrom and DeStefano 1995).

One study examined the impact a local ordinance had on restaurant receipts (CDC 1995a). Contrary to some prior claims, an analysis of restaurant sales after a ban on smoking in this community (a small suburb of Austin, Texas) showed no adverse economic effect. In a series of ecologic analyses, Glantz and Smith (1994, 1997) analyzed the effect of smoke-free restaurant and bar ordinances on sales tax receipts. Over time, such ordinances had no effect on the fraction of total retail sales that went to eating and drinking places. The authors asserted that claims of economic hardship for restaurants and bars that establish smoke-free policies have not been substantiated.

Private Sector Restrictions on Smoking in Workplaces

Two national data sets are available to ascertain the level of workplace smoking restrictions among private firms in the United States. A survey conducted by the Bureau of National Affairs, Inc. (1991), estimated that 85 percent of large workplaces had policies restricting smoking. The percentage of smoke-free workplaces has increased dramatically, from 2 percent in 1986 to 7 percent in 1987 and to 34 percent in 1991. Similarly, data from the 1992 National Survey of Worksite Health Promotion Activities indicated that 87 percent of workplaces with 50 or more employees regulated smoking in some manner and that 34 percent were smoke free (USDHHS 1993). The 1995 Update of the Business Responds to AIDS Benchmark Survey conducted by CDC also found that 87 percent of worksites with 50 or more employees had a smoking policy of some kind (National Center for Health Statistics 1997).

The prevalence of smoking policies in small workplaces, where the majority of Americans work, is less well studied. A comprehensive examination of workplace smoking policies from the NCI's tobacco use supplement to the Current Population Survey (n = 100,561) indicated that most indoor workers surveyed (81.6 percent) reported that an official policy governed smoking at their workplaces, and nearly half reported that the policy could be classified as

"smoke-free"—that is, that smoking was not permitted either in workplace areas or in common public-use areas (Gerlach 1997). This proportion varied by sex, age, ethnicity, and occupation: blue-collar and service occupations had significantly less access to smoke-free environments. Though data were not specifically reported by workplace size, the range of occupations suggests that the survey included a substantial proportion of persons who work in smaller workplace environments. But for all workplace sizes, the data suggest that access to smoke-free environments could be substantially improved.

Effectiveness of Clean Indoor Air Restrictions

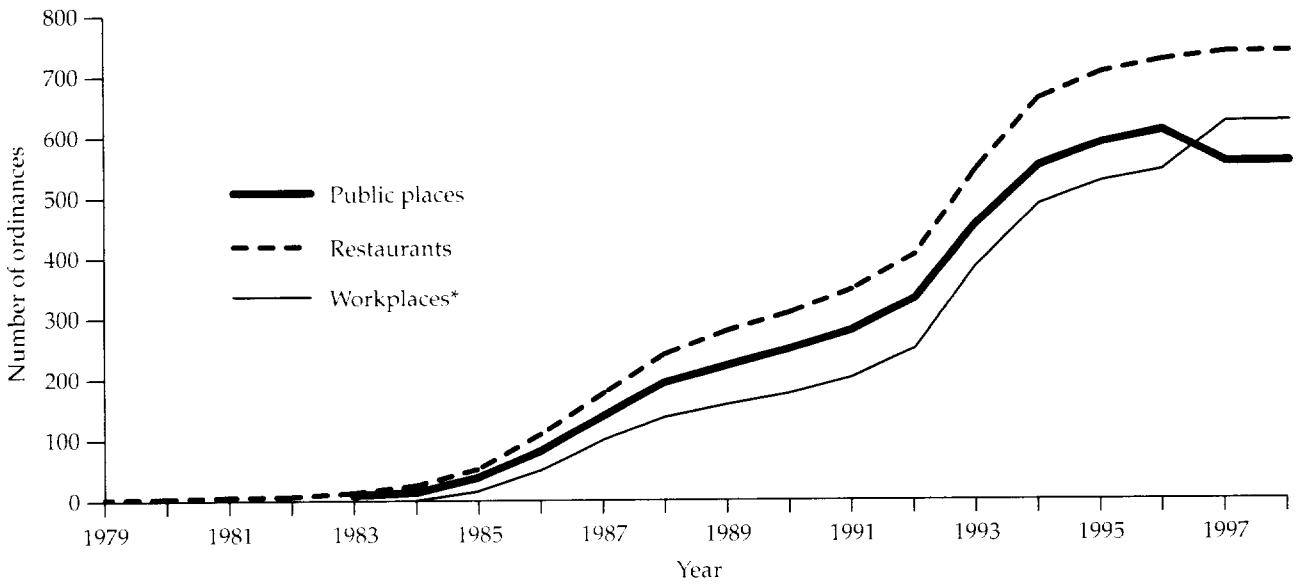
Although it is generally accepted that regulatory changes influence nonsmokers' exposure to ETS and smokers' behavior, relatively few evaluation studies quantify these effects over time. Evaluating such changes is hampered by the complex interaction of social forces that shape behavior, by the decline in smoking and smoke exposure in the overall population, and by the overlapping effects of concomitant regulatory policies (e.g., a new law for clean indoor air passed at or around the time of an increase in the cigarette excise tax). Controlling for such potential confounding factors in studies is difficult.

Population-Based Studies

Effects on Nonsmokers' Exposure to ETS

Despite the widespread implementation of restrictions against public smoking, few population-based studies have examined whether these restrictions have reduced nonsmokers' exposure to ETS. One such study from California used data collected in 1990 and 1991 to examine the association between the strength of local ordinances for clean indoor air and cross-sectional data on nonsmokers' exposure to ETS in the workplace (Pierce et al. 1994b). Exposure to ETS in the workplace ranged from 25 percent of workplaces in areas with a strong local ordinance to 35 percent in areas with no local ordinance.

Figure 5.3. Cumulative number of local laws and amendments enacted for clean indoor air, 1979–1998



Note: Ordinances must specifically mention these locations to be counted. Therefore, other ordinances may cover these areas without being included in these figures.

*Before 1983, there were four workplace ordinances: one passed in 1975, one in 1979, and two in 1980. These are not included in this chart, because data for consecutive years only became available beginning in 1983 for workplaces.

Source: American Nonsmokers' Rights Foundation, unpublished data, June 30, 1998.