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Introduction

Efforts to regulate the use of tobacco date back to its introduction to European colonists of North America (see Chapter 2). As noted, these early movements to restrict tobacco use were motivated less by health concerns than by complex political, economic, and social factors. With the appearance in the 1950s of substantial scientific evidence on specific health risks of smoking, and with subsequent dissemination of that information in the 1960s, general support for a government regulatory response emerged.

As noted in Chapter 1, such regulatory activities do not necessarily fit the traditional concept of "intervention," but their effect is to change the way people use tobacco. Because advertising and promotion are perhaps the chief social force for continued tobacco use, their regulation—or the failure to regulate them—can have substantial effects on smoking prevalence. The manner in which the product is manufactured, packaged, and distributed can similarly influence people's decision to smoke. Regulation of smoking in public places provides an opportunity to reduce the quantity of tobacco used, the prevalence of smoking, and the exposure of nonsmokers to environmental tobacco smoke. The regulation of minors' access to cigarettes has considerable potential for postponing or preventing the uptake of smoking, thereby making a long-term impact on the smoking epidemic. Finally, personal litigation and the tort system can influence the policies and practices of the tobacco industry and can have an impact on social perceptions of smoking.

Thus, if a broad definition of intervention can be entertained, each of these regulatory processes can be assessed for the nature of its influence on the use of tobacco. Unlike assessments of more traditional interventions (see Chapters 3 and 4), evaluation of regulatory processes must invoke a different set of measurement tools that are less quantitative but not necessarily less compelling (see Chapter 1).

Several key developments in the mid-to-late 1990s have propelled tobacco regulation in new directions and into new forums. Three key events have catalyzed these changes. They are discussed briefly in the next sections and in greater detail later in this chapter in "Further Regulatory Steps" and "Litigation Approaches."

Food and Drug Administration (FDA) Regulations

First, on August 28, 1996, after receiving public comment on a proposed rule, the FDA issued final regulations restricting the sale, distribution, advertising, and promotion of cigarettes and smokeless tobacco (*Federal Register* 1996). Several tobacco companies, retailers, and advertisers sued the FDA to block the implementation of the regulations, arguing that the agency lacked the jurisdiction or authority to regulate these products and that the proposed advertising restrictions violated the First Amendment of the United States Constitution (*Coyne Beahm, Inc. v. Food and Drug Administration*, No. 2:95CV00591 [N.C. Aug. 10, 1995], *cited in* 10.5 *Tobacco Products Litigation Reporter* [TPLR] 3.379 [1995]).

On April 25, 1997, the federal district court in Greensboro, North Carolina, ruled that the FDA had the authority to regulate cigarettes and smokeless tobacco products, as drug delivery devices, under the Federal Food, Drug, and Cosmetic Act (*Coyne Beahm, Inc. v. U.S. Food & Drug Administration*, 966 F. Supp. 1374 [M.D.N.C. 1997]). The court upheld all of the FDA's 1996 restrictions involving youth access to tobacco products and regulating product labeling. However, the court "stayed," or temporarily blocked, implementation of most of these provisions. The only FDA regulations that escaped this stay were the prohibition on sales of cigarettes and smokeless tobacco to minors and the requirement that retailers check photo identification of customers who appear to be under 27 years of age. These provisions went into effect on February 28, 1997. The age and identification provisions remained in force until the Supreme Court's March 21, 2000, decision.

Most notably, the court invalidated the FDA's restrictions on the advertising and promotion of cigarettes and smokeless tobacco. Both sides in the FDA case appealed the decision to the Fourth Circuit of the United States Court of Appeals in Richmond, Virginia. A three-member panel of the court overturned the lower court's decision and ruled that the FDA lacked the authority to regulate tobacco products. The full Fourth Circuit Court of Appeals declined to review

this reversal. The government petitioned the United States Supreme Court for review, and the 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 FDA continued to enforce the age and photo identification provisions while the case was appealed to the United States Supreme Court. On March 21, 2000, the Supreme Court ruled that although premature deaths from tobacco use present "one of the most troubling health problems facing our nation today" (*Food and Drug Administration v. Brown & Williamson*, 529 U.S. _____ [2000], 120 S. Ct. 1291), the FDA lacks the authority to issue and enforce its tobacco regulations.

These developments, central to most of the regulatory efforts covered in this chapter, are discussed in detail in the major section "Product Regulation," later in this chapter.

Initial Attempts at Multistate Settlement and Federal Legislation

Second, on June 20, 1997, a group of 41 state attorneys general presented a tobacco settlement proposal to the American public (*Tobacco Products Litigation Reporter* 1997a; see "Legislative Developments" and "Master Settlement Agreement," later in this chapter). In essence, the proposal was intended to settle all pending lawsuits against the tobacco industry brought by states and other governmental entities as well as all pending class action lawsuits. Although the settlement did not include 9 of the 50 states, its scope was inherently national: to enact its stipulated regulations of the tobacco industry, the settlement presumed the passage of congressional legislation that would necessarily affect the legal rights of all Americans. The settlement included provisions for FDA authority, new warning labels, advertising restrictions, youth access prohibitions, rules to reduce public exposure to environmental tobacco smoke, and a provision designed to provide financial incentives for tobacco manufacturers to reduce sales to underaged consumers.

Despite its intuitive appeal—that the slow, and largely unsuccessful, course of change possible through individual lawsuits would be retired for a sweeping, national, unified policy that dealt with the tobacco problem—the settlement raised concerns from the start. Public health advocates recognized that given the settlement's national scope, it was taking on the role of being the chief public health policy tool for reducing tobacco use. These critics feared that the settlement (and moreover the legislation it presumed) would fail in this role. In particular, by limiting future lawsuits against the tobacco industry, the settlement might in the end benefit the industry more than the public.

A number of bills filed in Congress in 1997 and 1998 intended to codify the terms of the proposed national settlement. One of the bills, S. 1415 (National Tobacco Policy and Youth Smoking Reduction Act, 105th Cong., 2nd Sess., S. 1415, *Congressional Record*, 144:S5034–S5084), which ultimately departed from the settlement proposal in a number of areas, was debated on the Senate floor for several weeks. It was vehemently opposed by the tobacco industry and rejected by the Senate almost one year to the day after the attorneys general announced the proposed national settlement. The regulatory implications of the national settlement proposal are discussed together with the FDA rules, primarily in the "Product Regulation" section of this chapter.

Ultimately, this activity served as prologue to a Master Settlement Agreement that was negotiated in November 1998. On November 23, 1998, the agreement was reached between state attorneys general and major U.S. tobacco companies to settle pending and prospective lawsuits by states to recover Medicaid expenditures incurred as a result of tobacco use. Forty-six states signed the agreement, pending the required ratification in state courts (four states settled separate, individual lawsuits with the industry). The agreement requires tobacco companies to pay $246 billion to states over 25 years and to adhere to specified restrictions on tobacco advertising and promotion. Some provisions are also made for improved disclosure of tobacco industry documents released in litigation. A separate, parallel agreement with the United States Tobacco Company was negotiated for smokeless tobacco products.

Public and Private Litigation

Third, throughout 1997 and 1998, while federal legislation was being filed and debated, the states of Mississippi, Florida, Texas, and Minnesota settled their lawsuits against the tobacco industry. Besides producing sizable settlement funds for the individual states, these settlements (in all but Mississippi) feature provisions akin to public health regulations. For example, the Florida settlement (*Florida v. American Tobacco Co.*, Civil Action No. 95-1466 AH, secs. II.A.1 and II.A.2 [Fla., Palm Beach Cty. Aug. 25, 1997]) was the first to incorporate a ban on outdoor advertising and to call for statewide restrictions on vending machines. The

Minnesota settlement (*Minnesota v. Philip Morris Inc.*, No. C1-94-8565 [Minn., Ramsey Cty. May 8, 1998], *cited in* 13.2 TPLR 3.39 [1998]), which followed a trial and the release of thousands of incriminating internal documents from the tobacco industry, contains an even wider array of public health restrictions, including a ban on promotional items and a national prohibition on commercial placement of tobacco products in movies.

Settlements of other private suits against the industry in the late 1990s have also resulted in important regulatory measures. For example, in a class action lawsuit alleging that flight attendants were injured by exposure to environmental tobacco smoke (*Broin v. Philip Morris Inc.*, No. 91-49738 CA [22] [Fla., Dade Cty. Oct. 9, 1997], *cited in* 12.6 TPLR 3.397 [1997]), the tobacco industry agreed to support legislation banning smoking on all airlines departing from or landing in the United States. In a California case, R.J. Reynolds Tobacco Company agreed to accept advertising restrictions and to fund counteradvertising programs for teens. The latter provision was based on a claim that the company was violating the California consumer protection law by using their Joe Camel advertising campaign to target minors (*Mangini v. R.J. Reynolds Tobacco Co.*, No. 939359 [Calif. Sept. 8, 1997], *cited in* 12.5 TPLR 3.349 [1997]).

As of September 1998, these nonnational litigations against the tobacco industry had had a greater and more immediate impact on tobacco regulation than the delayed FDA rules, proposed national settlement, and defeated federal legislation. Regulation through litigation is a new tool for reducing tobacco use. Specific regulatory measures contained in these smaller-scope settlements are discussed in relevant sections of this chapter.

Advertising and Promotion

Introduction

Industries use various marketing tools and strategies to influence consumer preference, thereby increasing market share and attracting new consumers. The tobacco industry is among the most intense in its efforts; among U.S. manufacturers, only the automobile industry markets its products more heavily (Centers for Disease Control [CDC] 1990a). It may be assumed that cigarette manufacturers, like other industrial entities, direct their money and marketing efforts in ways that will reach consumers they believe are most likely to purchase their products. The ensuing discussion focuses on direct product marketing and excludes other promotional and public relations efforts that are not product specific.

The potential influence of cigarette advertising and promotion on smoking prevalence has been a subject of concern and debate for many years (U.S. Department of Health and Human Services [USDHHS] 1994).[1] Much of the concern has focused on whether consumers know about the adverse health effects of smoking and can make informed choices; whether children and adolescents are exposed to and are affected by tobacco advertising and promotion; and whether tobacco companies inappropriately target advertising and promotion to specific consumer groups. A contentious debate has persisted about whether marketing induces demand and what the appropriate role of government is in protecting the consumer. Although some of these issues are not fully settled, they provide the background for considering the reduction of smoking through regulating cigarette advertising, promotion, product availability, and product presentation.

In May 1981, a Federal Trade Commission (FTC) staff report (see "A Midcourse Assessment," later in this chapter) concluded that consumer knowledge about the health effects of cigarette smoking was generally inadequate (Myers et al. 1981). Since then, adult smoking prevalence has declined substantially (from 33.5 percent in 1980 [Giovino et al. 1994] to 24.7 percent in 1995 [CDC 1997a]), and the general population's knowledge about the adverse health effects of tobacco use has improved (in recent years, 80–90 percent of

[1] In the following discussion, *advertising* refers to company-funded advertisements that appear in paid media (e.g., broadcasts, magazines, newspapers, outdoor advertising, and transit advertising), whereas *promotion* includes all company-sponsored nonmedia activity (e.g., direct-mail promotion, allowances, coupons, premiums, point-of-purchase displays, and entertainment sponsorships).

the general population has known that smoking is a health hazard [USDHHS 1989, 1998b]). During the same period, revenue devoted to advertising and promotion by the tobacco companies has increased from $1.24 billion in 1980 to a high of $6.03 billion in 1993 (FTC 1999) and $5.10 billion in 1996 (FTC 1999). Tobacco companies spent $5.66 billion on advertising and promotion in 1997 (FTC 1999). The relationship among these three events is not straightforward, and considerable ancillary information is needed for proper interpretation. In particular, the effects that both knowledge and advertising and promotion have on smoking prevalence are complex. For example, the increase in smoking uptake among women beginning in 1967 was associated with the marketing of specific cigarette brands for women (Pierce et al. 1994a). Similarly, an increase in smoking initiation among adolescents during 1985–1989 has been ecologically associated with considerable increases in promotion expenditures, as exemplified by the Joe Camel campaign (see "A Critical Example: Joe Camel," later in this chapter) (CDC 1995b). Regardless of how these associations are interpreted, the actions of the tobacco industry bespeak the industry's belief in corporate benefit from a major investment in advertising and promotion—an investment that may be interpreted as even exceeding an economically optimal level (see Chapter 6).

The tobacco industry has argued that its main purpose in advertising is to maintain brand loyalty and to capture a greater market share of current smokers (USDHHS 1994). Intensive review of the available data, however, suggests a positive correlation between level of advertising and overall tobacco consumption—that is, as advertising funds increase, the amount of tobacco products purchased by consumers also increases (USDHHS 1989, 1994; Smee 1992; Pierce and Gilpin 1995; also see Chapter 6). Furthermore, several judicial opinions (reviewed in "Constitutionality of Regulating Tobacco Advertising," later in this chapter) have questioned whether the enormous investment in advertising serves only brand loyalty. It has also been argued that a significant part of the expanding budget for tobacco marketing is for promotion to specific market segments (Hollie 1985). Other observers have suggested that marketing campaigns heavily target cultural and ethnic minorities through product development, packaging, pricing, and brand promotion (Warner et al. 1986; Ernster 1993).

Underlying these observations is awareness of a basic commercial principle: to continue to be successful, a product must not only retain consumers but also, over time, gain new consumers. Gaining new consumers is necessarily of particular concern to the tobacco industry. Advocates for reducing tobacco use have pointed out that if the tobacco industry is to maintain current consumption or even slow the ongoing decline in smoking, the industry must aggressively seek replacement smokers for the estimated 3,500 Americans who quit smoking each day and for the additional 1,200 tobacco customers and former customers who die each day of smoking-related illnesses (CDC 1993b, 1997b).

The facts about uptake of tobacco use strongly suggest where the industry's replacement smokers will come from. Epidemiologic studies show that nearly all first use of tobacco occurs before high school graduation (USDHHS 1994). Whether tobacco companies deliberately market their products to preadults is difficult to ascertain. Nonetheless, indirect evidence of the importance of advertising and promotion to the tobacco industry is provided by surveys that suggest that most adolescents can recall certain tobacco advertisements, logos, or brand insignia; these surveys correlate such recall with smoking intent, initiation, or level of consumption (Alexander et al. 1983; Goldstein et al. 1987; Pierce et al. 1991; Evans et al. 1995).

The American Medical Association (Utah Delegation 1989), together with a broad range of public health organizations, has called for stricter regulation of cigarette advertisements and even for a complete ban—resolutions that were reiterated in 1995 (American Medical Association House of Delegates 1995). Many public health and smoking prevention groups specifically seek government regulation to address what they consider discriminatory practices of tobacco manufacturers in targeting members of minority groups (Warner et al. 1986). These groups claim that advertisements overwhelm smoking prevention messages and increase the number of people who smoke each year beyond the number that would smoke if advertising and promotion affected only market share. Industry officials deny targeting and argue that because most of the population is now aware of the risks associated with tobacco products, citizens can make informed decisions for themselves. More important, the tobacco industry claims its First Amendment constitutional right to promote its products (Cotton 1990; Tollison and Wagner 1992; see the discussion in "Constitutionality of Regulating Tobacco Advertising," later in this chapter).

Such arguments and counterarguments have been at the heart of a 30-year endeavor to regulate advertising and promotion in the tobacco industry. A review of this effort, with some specific examples from the United States and other countries, provides insight

into the strengths and weaknesses of both sides of the argument and suggests several areas for policy development.

Attempts to Regulate Tobacco Advertising and Packaging

Regulatory efforts to restrict the advertising and promotion of cigarettes were among the earliest responses to the 1964 landmark report of the Surgeon General's Advisory Committee, which set forth overwhelming scientific evidence on the health hazards of cigarette smoking. A week after the January 11, 1964, release of the report, the FTC filed a Notice of Rule-Making Proceeding (January 17, 1964) that appeared in the January 22, 1964, *Federal Register*. The notice set forth the agency's tentative views of how the requirements of the Federal Trade Commission Act (Public Law 96-252) would apply to the advertising and labeling of cigarettes in light of the Advisory Committee's report (*Federal Register* 1964). In a pertinent part, section 5 of the Federal Trade Commission Act states that "unfair or deceptive acts or practices [are] declared unlawful" and that the commission has the power to proceed against them as an administrative agency.

In its notice of rulemaking, the FTC stated its concern with "two ways in which cigarette advertising may be unlawfully misrepresenting or concealing the health hazards of smoking. First, the Commission has reason to believe that many current advertisements falsely state, or give the false impression, that cigarette smoking promotes health or physical well-being or is not a health hazard, or that smoking the advertised brand is less of a health hazard than smoking other brands of cigarettes" (*Federal Register* 1964, p. 530). The FTC also stated that much cigarette advertising then current portrayed cigarette smoking as pleasurable, desirable, compatible with physical fitness, or indispensable to full personal development and social success—all without informing the consumer of the health hazards of cigarette smoking.

The FTC posited that the dangers to health from cigarette smoking are so serious that knowledge and appreciation of them would be a material factor in influencing a person's decision to smoke cigarettes or to smoke a particular brand. (This point is considered in detail in "Tobacco Packaging and Informed Choice," later in this chapter.) Affirmative disclosures of these health hazards might thus be necessary in cigarette advertising that could cloud or obscure public consciousness of these health hazards. After receiving written comments and materials from interested parties and after conducting hearings in March 1964 on the proposed rule (see the text box "Response From the Tobacco Industry—1964"), the FTC issued on June 22, 1964, the "Statement of Basis and Purpose" regarding its proposed Trade Regulation Rule. (A Trade Regulation Rule is, in effect, an administrative statute with the force of law.) In this document, the commission announced that it would require warnings on cigarette packages and in advertisements for cigarettes that cigarette smoking is dangerous to human health.

Cigarette Warning Labels

After participating in hearings before the U.S. House of Representatives Committee on Interstate and Foreign Commerce on cigarette labeling and FTC rules, the commission postponed until 1965 the implementation of any Trade Regulation Rule. In that year, the Federal Cigarette Labeling and Advertising Act of 1965 (Public Law 89-92) required that the warning "Caution: Cigarette Smoking May Be Hazardous to Your Health" (Federal Cigarette Labeling and Advertising Act, sec. 4) be placed in small print on one of the side panels of each cigarette package. The act permitted no additional labeling requirement under any federal, state, or local law, thus effectively preempting any other health messages on cigarette packages. The act also suspended for three years the FTC's authority to require health warnings on cigarette advertising.

This preemption was strongly opposed in the minority view of Representative John E. Moss (D-CA), who presented the argument as follows:

> I most strongly object to sections 6 and 7 of this bill. Section 6 would prevent the Federal Trade Commission, the Food and Drug Administration, and the U.S. Public Health Service in administering their respective laws from imposing any additional requirement with regard to the labeling of cigarettes involving a health warning. The bill would also preclude State and local health authorities from imposing such requirements.
>
> Section 7, the preemption provision of the bill, provides that no cautionary statement with respect to smoking and health other than specified in this legislation shall be required on any package; and that no such statement with respect to smoking and health shall be required in advertising for cigarettes packaged in conformity with the labeling provisions of this legislation.

> The Secretary of Health, Education, and Welfare has said that preventing any regulatory agency from imposing a label warning requirement other than that prescribed in the bill is "a position which we consider too inflexible."
>
> The National Interagency Council on Smoking and Health submitted a petition to the committee asking us "not to approve any legislation which will prevent the Federal Trade Commission from carrying out its reaffirmed intention of requiring health warnings in cigarette advertising" (Moss 1965, pp. 2365–6).

Representative Moss concluded his minority report with a strong condemnation:

> In summary, I am strongly opposed to those features of this legislation which would preclude the imposition of more stringent labeling requirements or the imposition of health warnings in advertisements which Federal, State, or local health authorities may deem necessary in the future in the proper exercise of their respective powers. We must face the facts as presented to us by the Surgeon General, American Cancer Society, American Medical Association, American Heart Association, and the National Tuberculosis Association. We must first concern ourselves with public health and welfare, not legislate to the whims of a special interest (Moss 1965, p. 2367).

In commenting on the 1965 labeling law, the Secretary of the Department of Health, Education, and Welfare outlined an alternative view of effective health warnings on cigarette packages (Celebrezze 1965). Secretary Anthony J. Celebrezze recommended that the warning appear in large type on the main faces of the package. He commented:

> The statute should require the warning to be prominent and conspicuous but should leave the precise location and size of the warning on the label, and related matters, to regulation in the light of the expertise and experience of the regulatory agency. . . . [Ten]-point type, which is 2 points smaller than the type size used in typing this letter, is hardly calculated to invite the consumer's attention. . . .
>
> If the required warning is in effect negated or disclaimed on the label or in accompanying literature by words, statements, designs, or other graphic material, the warning requirement shall be deemed

Response From the Tobacco Industry—1964

In April 1964, in rapid response to the Surgeon General's report, the tobacco industry published a voluntary code for advertising and marketing practices (Gray 1964). The stated purpose of the code was "to establish uniform standards for cigarette advertising and to provide means whereby compliance with this code can be ascertained promptly and fairly and on a consistent basis" (p. 141). The code was designed to restrict cigarette advertisements aimed at young people, to limit implied or direct health claims to those that could be medically and scientifically proved, and to curb the so-called virility theme in cigarette advertisements. The code specifically prohibited advertising that suggested that cigarette smoking was essential to "sexual attraction," "success," sophistication, athletic abilities, physical stamina, and "social prominence" (p. 143)—images that the industry recognized as influencing smoking by young people.

At hearings before the House Interstate and Foreign Commerce Committee on June 25, 1964, Bowman Gray, Chairman of the Board of R.J. Reynolds Tobacco Company, speaking on behalf of the industry, told Congress, "This advertising code represents a sincere effort by the industry to respond to criticism of the industry's advertising which has been voiced in some quarters. It is an earnest effort at industry self-regulation. I hope the industry will be given reasonable opportunity to implement this code" (Gray 1964, p. 141).

The code was to be enforced by an independent administrator. All advertisements were to be precleared, and violations of the code were subject to a fine of $100,000. Enforcement provisions of the code were dropped shortly after passage of the Federal Cigarette Labeling and Advertising Act in 1965.

> not to have been met. . . . [Congress should consider giving the department] specific authority to prohibit or regulate the use of statements that while not clearly negating the warning and while literally true or at least not demonstrably false, may give the consumer the misleading impression that a given cigarette is safer than others (Celebrezze 1965, p. 2359).

These recommendations predate by three decades similar implementation of warnings in other countries (described in "Examples of Product Labeling in Other Countries," later in this chapter); such an approach, however, has not been taken in this country.

The 1965 law also required that the FTC annually transmit to Congress a report on the effectiveness of cigarette labeling, on current cigarette advertising and promotion practices, and on recommendations for legislation. In June 1967, in its first report to Congress, the FTC recommended that the package label be changed to "Warning: Cigarette Smoking Is Dangerous to Health and May Cause Death from Cancer and Other Diseases" (FTC 1967, p. 30).

Broadcast Advertising Ban

In 1969 Congress passed the Public Health Cigarette Smoking Act (Public Law 91-222), which prohibited cigarette advertising on all media subject to Federal Communications Commission (FCC) regulation, especially radio and television broadcasting, and required that each cigarette package contain the label "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health" (Public Health Cigarette Smoking Act, sec. 4). This new law also preempted any other health warning requirements for cigarette packages. The prohibition on broadcast media advertising became effective on January 2, 1971. The FTC issued complaints against the cigarette companies that eventually led to a consent decree requiring the companies to add the statutory label warning to their advertising in magazines, newspapers, and outdoor displays (*Trade Regulation Reporter* 1973).

The prohibition on television and radio advertising was challenged—not by the cigarette companies, but by a group of broadcasters—in *Capital Broadcasting Co. v. Mitchell* (333 F. Supp. 582 [D.D.C. 1971]). That case upheld the constitutionality of the congressional prohibition by a 2 to 1 vote. Despite this victory, a sobering note was struck in the dissenting opinion of Judge J. Skelly Wright. Far from casting his vote against smoking prevention, Judge Wright was concerned that upholding the act, and thus upholding the prohibition on broadcast advertising, would actually aid the tobacco industry. His reasoning—which proved correct—was that the ban would put an end not only to tobacco advertising but also to the cost-free counteradvertising that had been running in the electronic media since 1969, when the FCC's Fairness Doctrine was first held applicable to cigarette advertising.

The Fairness Doctrine, which was put forth in 1949 (and ceased applying to tobacco in 1971 after cigarette advertising on radio and television ended), required that whenever material covering "'a controversial issue of public importance'" (*Banzhaf v. FCC*, 405 F.2d 1082, 1086 [D.C. Cir. 1968], *cert. denied*, 396 U.S. 842, 90 S. Ct. 50 [1969]) was aired, the broadcaster had an obligation to present, to some degree, both sides of the issue. Although the Fairness Doctrine had not previously been interpreted to apply to advertising, in *Banzhaf* the Federal Circuit Court of Appeals ruled that the FCC had the authority, through the Fairness Doctrine, to require that radio and television stations carrying cigarette advertising devote (i.e., without charging advertising fees) a significant amount of broadcast time to presenting the case against smoking. (For more on the plaintiff, John F. Banzhaf, see "The Attack on Advertising" in Chapter 2.) In the court's ruling, Chief Judge David Bazelon observed that "if we are to adopt [the tobacco industry's] analysis [of Congress' intention in enacting the Federal Cigarette Labeling and Advertising Act], we must conclude that Congress legislated to curtail the potential flow of information lest the public learn too much about the hazards of smoking for the good of the tobacco industry and the economy. We are loathe to impute such a purpose to Congress absent a clear expression" (*Banzhaf*, p. 1089).

However, three years later, in *Capital Broadcasting Co. v. Acting Attorney General* (405 U.S. 1000 [1972], *aff'd sub nom. Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 [D.D.C. 1971]), it was Judge Wright's view that the television and radio counteradvertising that had arisen from the Fairness Doctrine was so effective that the tobacco companies actually favored the challenged ban. There is some support for this view. Per capita cigarette consumption in the United States, which had declined (with some fluctuation) generally since the 1964 report to the Surgeon General on the health effects of smoking, had leveled off and then increased after cigarette advertising was removed in 1971 from radio and television. Some analysts have asserted that these changes indicate that the cost-free counteradvertisements opposing cigarette use, which along with the commercials promoting cigarettes,

largely disappeared from the airwaves except for a relatively few public service announcements, were more effective in discouraging consumption than cigarette commercials were in encouraging consumption (Warner 1979). Moreover, the prohibition of cigarette advertising on broadcast stations has allowed the tobacco companies to avoid the significant expense of advertising on national television and to devote their promotional dollars to other media.

A Midcourse Assessment

A decade after the broadcast ban, the FTC issued a staff report in May 1981 on cigarette advertising (Myers et al. 1981). This report asserted that "the dominant themes of cigarette advertising are that smoking is associated with youthful vigor, good health, good looks and personal, social and professional acceptance and success, and that it is compatible with a wide range of athletic and healthful activities" (p. 2-13). Although such advertising included the required general warning about the health hazards of cigarette smoking and listed the cigarette's tar and nicotine contents (as determined by FTC testing methods), the advertisements otherwise made no mention of the adverse health consequences of smoking cigarettes. The overriding message of cigarette advertising was thus that smoking is a positive, desirable experience.

Details from a nonpublic version of the FTC report revealed, for example, that a primary theme for the marketing of Salem cigarettes was the association of the cigarette with the lifestyle of young adult males who were (in the words of the company's campaign notes) "masculine, contemporary, confident, self-assured, daring/adventurous, mature" (Banzhaf 1982, p. 260). The report quoted from a Doral cigarette campaign that sought to project the image of "an independent, self-reliant, self-confident, take-charge kind of person" (p. 260) and a campaign that depicted a "Winston man" as "a man's man who is strong, vigorous, confident, experienced, mature" (p. 260). Taking another tack, the Eve cigarette campaign sought to portray the smoker as a "sophisticated, up-to-date, youthful and active woman who seems to have distinct ideas about what she wants" (p. 261). The campaign for the Lark brand was designed to position it as a "youthful, contemporary brand that satisfies the lifestyles of the modern smoking public" (p. 260) and emphasizes "moments of post-tension and relaxation" (pp. 260–1).

The nonpublic version of the FTC report also detailed and quoted from the conclusion of a marketing and research firm that had conducted focus group interviews to help Ted Bates and Company, Inc., develop a marketable image for Viceroy cigarettes. The report, summarizing the results of the research, asserted that many smokers perceived the smoking habit as a dirty and dangerous one engaged in only by "very stupid people" (Banzhaf 1982, p. 262). The report concluded: "Thus, the smokers have to face the fact that they are illogical, irrational and stupid. People find it hard to go throughout life with such negative presentation and evaluation of self. The saviors are the rationalization and repression that end up and result in a defense mechanism that, as many of the defense mechanisms we use, has its own logic, its own rationale" (p. 262).

This marketing analysis went on to state that because there "are not any real, absolute, positive qualities or attributes in a cigarette" (Banzhaf 1982, p. 262), the most effective advertising is designed to "reduce objections" (p. 262) to the product by presenting a picture or situation ambiguous enough to provide smokers with a rationale for their behavior and a means of repressing their health concerns about smoking. The advertisement must thus project the image that cigarettes have clearly beneficial functions, such as improving the smoker's self-image and self-acceptance or serving as a stimulant or tranquilizer that offers an acceptable means of self-reward. Accordingly, the analysis recommended that advertisers should start from "the basic assumption that cigarette smoking is dangerous to your health" (p. 263) and then try to circumvent the problem rather than fight what would be a losing battle.

A particularly notable element of the report was how to persuade young people to smoke:

> For the young smoker, the cigarette is not yet an integral part of life, of day-to-day life, in spite of the fact that [young smokers] try to project the image of a regular, run-of-the-mill smoker. For them, a cigarette, and the whole smoking process, is part of the illicit pleasure category. . . . In the young smoker's mind a cigarette falls into the same category with wine, beer, shaving, wearing a bra (or *purposely* not wearing one), declaration of independence and striving for self-identity. For the young starter, a cigarette is associated with introduction to sex life, with courtship, with smoking "pot" and keeping late studying hours (Banzhaf 1982, p. 263).

The survey then recommended a strategy for attracting young people to start cigarette smoking: present the cigarette as one of a few initiations into the adult world and show the cigarette as part of the illicit pleasure category of products and activities. To the

degree possible under legal constraints, the strategy advised relating the pleasure of smoking cigarettes to the pleasures of adult or illicit activities, such as drinking alcohol, smoking marijuana, or having sex (Myers et al. 1981). Brown & Williamson Tobacco Corporation stated that these proposals were never implemented and did not represent their policy.

In sum, the marketing and research firm recommended that successful cigarette advertising must either consciously or unconsciously deal with smoking and health issues by repressing the health concerns of the consumers of the product and providing a rationalization for consumption. The 1981 FTC report also concluded that the federally mandated health warning had little impact on the public's level of knowledge and attitudes about smoking. The report further observed that the warning was outworn, abstract, difficult to remember, and not perceived as personally relevant (Myers et al. 1981). These concerns contributed to Congress' enactment of the Comprehensive Smoking Education Act of 1984 (Public Law 98-474), which required four specific, rotating health warnings on all cigarette packages and advertisements (Comprehensive Smoking Education Act, sec. 4):

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
>
> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

The Comprehensive Smoking Education Act of 1984 thus amended the Federal Cigarette Labeling and Advertising Act and required warnings to be placed on advertisements as well as on cigarette packages. The act preempts state and federal attempts to place additional warnings on packages, but it preempts only state action with regard to advertising. The FTC retains such jurisdiction under section 5.

From the first, the exact appearance of warning labels (wording, layout, and positioning on packages and advertisements) has represented compromises between the recommendations of the FTC and smoking prevention advocates and those of the tobacco industry. In 1969, for example, the FTC recommended a warning on cigarette packages that specifically mentioned death, cancer, heart disease, chronic bronchitis, and emphysema. The resulting legislation required the legend to provide the general warning only that smoking is "dangerous" to one's health (Public Health Cigarette Smoking Act of 1969, sec. 4). Similarly, in its 1981 report on cigarette advertising, the FTC recommended that new warning labels use a "circle-and-arrow" format that would be more effective than the traditional rectangular format, but Congress did not take this approach in the Comprehensive Smoking Education Act of 1984. Also, the new labels did not incorporate the FTC's recommendations to contain specific references to addiction, miscarriage, and death and to disclose the brand's yields of tar, nicotine, and carbon monoxide.

Smokeless Tobacco Warning Labels

Requirements for warning labels on smokeless tobacco products lagged behind those on cigarettes by more than 20 years. By the mid-1980s, the strong evidence that smokeless tobacco causes oral cancer, nicotine addiction, and other health problems and that its use was increasing among boys led Massachusetts to adopt legislation requiring warning labels on packages of snuff and caused 25 other states to consider similar legislation (USDHHS 1989).

The Massachusetts law was preempted, before it could take effect, by the federal Comprehensive Smokeless Tobacco Health Education Act of 1986 (Public Law 99-252). This law not only required three rotating warning labels on smokeless tobacco packaging and in all advertising (except billboards) but also stipulated that the labels have the circle-and-arrow format that the FTC had recommended earlier for cigarette warnings. The three rotating labels read as follows (Comprehensive Smokeless Tobacco Health Education Act of 1986, sec. 3):

> WARNING: This product may cause mouth cancer.
>
> WARNING: This product may cause gum disease and tooth loss.
>
> WARNING: This product is not a safe alternative to cigarettes.

Initially, the FTC excluded utilitarian items—such as hats, T-shirts, lighters, and jackets—bearing the name or logo of smokeless tobacco products. A consortium

of Public Citizen and several prominent health organizations sued the FTC, arguing that this exclusion was contrary to the provisions of the act, which sought a comprehensive rather than a narrow use of health warnings (*Public Citizen v. Federal Trade Commission*, 869 F.2d 1541 [D.C. Cir. 1989]). The Court of Appeals for the District of Columbia ruled for the plaintiff, stating that the act was intended to cover utilitarian items, since those were among the smokeless tobacco industry's most effective means of promoting its products to adolescents. The court elaborated its point, saying that adolescents were less likely than adults to read magazines and newspapers and thereby less likely to encounter the mandated warnings there. Adolescents were also likely to have passed the critical moment of decision by the time they obtained the product itself and encountered its warning label. Accordingly, in 1991, the FTC issued a final rule requiring health warnings to be displayed on utilitarian items and providing for the manner in which the warnings were displayed.

All advertising of smokeless tobacco products is also banned on any medium of electronic communication subject to the jurisdiction of the FTC. Under this act, federal agencies and state and local governments are preempted from imposing additional health warnings on smokeless tobacco products and advertisements (except for billboards, which were excluded from this act). Furthermore, instead of stipulating where the labels must be positioned, the act required only "conspicuous and prominent" placement (Comprehensive Smokeless Tobacco Health Education Act of 1986, sec. 3). Implementation was left to the FTC, which enacted enabling regulations on November 4, 1994.

Regulation of Tobacco Packaging

Package size of tobacco products has been another area of public health concern and action. Evidence that levels of tobacco consumption reflect the affordability of tobacco products (see Chapter 6) has raised concern about selling cigarettes in packs containing fewer than the usual 20 cigarettes. In many countries, cigarettes are sold in packages of 15, 10, or 5 cigarettes. These smaller package formats have been dubbed "kiddie" packs in Canada by smoking prevention activists (Chrétien 1994). Research has shown that young people account for many sales of smaller cigarette packages (Wilson et al. 1987; Nova Scotia Council on Smoking and Health 1991; IMPACT Research 1993), probably because of their low price and ease of concealment.

These findings have led some jurisdictions to prohibit the marketing of packages containing fewer than 20 cigarettes. An Australian state legislature has also passed such a ban (the Western Australia Tobacco Control Act of 1990). In Canada, several provinces have banned small package sizes, and the revised federal Tobacco Sales to Young Persons Act of 1993 nationally banned packages of fewer than 20 cigarettes.

Another issue of concern regarding tobacco packaging is the use of potentially misleading descriptive words in the labeling of some tobacco products (Davis et al. 1990). A recent Gallup poll found that words such as "slim," "low tar," and "light" conveyed messages viewed as healthful (Gallup Organization, Inc. 1993, pp. 23, 25). Cohen (1992) reported that tobacco companies have long known that their customers equate the marketing term "low tar" (p. 85) with health benefits. Chapman and colleagues (1986) reported that smokers tend to systematically underestimate the actual tar deliveries of their particular brands, and Gori (1990) found that one-half of smokers interviewed in the United States and Europe assume that the lower the tar rating, the lower the brand's propensity to cause disease. The Coalition on Smoking OR Health (1988) has further analyzed how promoting cigarette brands as having low tar and low nicotine content communicates a message to consumers that these brands have health benefits.

The use of such descriptive words in cigarette brand names has been called into question because variations in the way cigarettes are actually smoked may mean that the actual yield of toxic constituents from cigarettes differs from the levels determined by currently accepted testing procedures (Henningfield et al. 1994; see "Compensatory Smoking," later in this chapter). For example, smokers of reduced-tar cigarettes may (deliberately or not) inhale harder to draw more smoke through the denser filter and deep into the lungs and may smoke the cigarette down closer to the filter, thereby inhaling greater concentrations of toxins. This concern led to the appointment of an ad hoc committee of the President's Cancer Panel of the National Cancer Institute (NCI) to evaluate the current FTC protocol for testing tar, nicotine, and carbon monoxide. One of the conclusions of this panel was that "brand names and brand classifications such as 'light' and 'ultra light' represent health claims and should be regulated and accompanied, in fair balance, with an appropriate disclaimer" (NCI 1996, p. vii). This recommendation has not yet been carried out.

A further aspect of tobacco packaging that is currently receiving significant attention, although primarily outside the United States, is the possibility of

legislated plain (or "generic") packaging for tobacco products. This initiative is partly motivated by the belief that removing much of the brand image of tobacco products would not only make the product less attractive but also weaken the connection with—and thus lessen the effect of—visual and verbal image-linked efforts to promote particular brands (Mahood 1995). There is evidence that young people find plain packaging less attractive (Beede and Lawson 1992; Centre for Health Promotion 1993) and that plain packaging makes health messages more noticeable (Centre for Behavioural Research in Cancer 1992). In Canada, the federal government has considered using plain packaging for tobacco products (Standing Committee on Health 1994; Health Canada 1995b), and the province of Ontario, in enacting the Tobacco Products Control Act in 1994, authorized the requirement for plain packaging on all cigarettes sold in Ontario. Such packaging reforms have not yet been enacted in any jurisdiction.

Examples of Product Labeling in Other Countries

In recent years, many countries have taken significant action on specifying packaging and warning labels for tobacco products. All countries of the European Union must comply with a May 15, 1992, directive (Council Directive 92/41/EEC 1992 O.J. [L 158]) that requires stipulated health warnings on each of the main package panels. In Thailand, pursuant to its Tobacco Products Control Act, which was based on principles developed in Canadian regulations (discussed later in this section), prominent black-and-white health messages are required on the front of the package. South Africa and New Zealand require detailed health messages on the main package panels; the messages are based largely on Australian packaging.

The messages appearing on Australian cigarette packages are based on the work of the Centre for Behavioural Research in Cancer (1992). These messages were required as of January 1, 1995, and were incorporated into a broad effort "to inform smokers of the long-term health effects of tobacco use" (Lawrence 1994, p. 1). The Australian system uses six rotating messages covering 25 percent of the front of the cigarette packets. One side of the packet is entirely given to the labeling of dangerous constituents, and all the labels must be in black and white. Thirty-three percent of the rear main packet panel must be covered by the same health message given on the front of the pack and followed by an elaboration of that message (Chapman 1995).

Of special interest are the package regulations currently in place in Canada. The Canadian health messages were established by regulatory power granted under the 1988 federal Tobacco Products Control Act, which came into effect on January 1, 1989. This legislation gives broad regulatory powers over tobacco product packaging. It also gives regulatory authority to require package inserts, although this power has not yet been acted on. By eventually delegating formulation of the precise warnings to administrative regulation, this legislation took the approach that had been recommended 25 years earlier by the U.S. Department of Health, Education, and Welfare (Celebrezze 1965; see also "Cigarette Warning Labels," earlier in this chapter). This law also makes clear that the various provinces of Canada can require additional messages and that the provision of federal messages does not preempt other messages. The first set of regulations following this law required that four specific rotating health messages be placed on the two main panels of cigarette packages and be printed in a large typeface; this set of regulations stipulated that the messages must be "prominently displayed in contrasting colours" (Department of National Health and Welfare 1989, p. 64) and cover at least 20 percent of the panel face.

When the mandated Canadian health messages started appearing on tobacco products in 1989, it was clear to many public health workers that the language of the regulations had left the tobacco companies too much room for interpretation and had resulted in less prominence and contrast than the regulations had intended. Minister of National Health and Welfare Henry Perrin Beatty commented, "It's very clear that, when you look at [the health warning on cigarette packs], it's not designed to stand out. If our experts [at the Department of National Defence] knew as much about camouflage as the tobacco company did, nobody'd ever find our fellows" (*Spectator* 1989). This situation gained more attention when it was revealed that a prominent tobacco lobbyist had apparently influenced development of the regulations (Fraser 1989). Health advocates subsequently campaigned to attain more prominent messages through revising the regulations (Mahood 1995).

New legislation was enacted on August 11, 1993 (Department of National Health and Welfare 1993), and all packaging for tobacco products destined for sale in Canada had to comply by September 11, 1994. Among these precedent-setting regulations (Mahood 1995) were the following requirements:

- The message must cover at least 25 percent of the top of each main panel.

- The message must be framed by a stipulated border (on many packs, this border yields a total message area that uses over 40 percent of the surface).
- Each of eight rotating messages must be presented one-half of the time in black on a white background with a black border. The other one-half of the time, the messages must be white on a black background surrounded by a white border.
- One entire side panel must be used to present information on the toxic constituents.
- Every side panel of tobacco cartons must display a black-on-white message covering 25 percent of the panel area and stating "Cigarettes are addictive and cause lung cancer, emphysema, and heart disease" (Department of National Health and Welfare 1993, p. 3278).
- The message must bear no attributions.

One ironic result of these requirements was that cigarettes manufactured in the United States for the Canadian market were produced, albeit only for export, with health messages that conform with the recommendations provided in 1965 by the U.S. Department of Health, Education, and Welfare.

The Canadian regulations were reversed in 1995, when the Supreme Court of Canada held that the country's complete ban on overt tobacco advertisements (another key component of the 1993 regulations) and its requirement of unattributed health warnings on packages were in violation of the tobacco industry's freedom of expression and the *Canadian Charter of Rights and Freedoms* (*RJR-MacDonald Inc. v. Attorney General of Canada*, File Nos. 23460, 23490 [Can. Nov. 29–30, 1994, Sept. 21, 1995], *cited in* 10.6 TPLR 2.167 [1995]). These central elements of Canada's Tobacco Products Control Act fell because the Canadian government did not meet its constitutional obligation of proving that the approach taken was the least drastic means of achieving a public health objective. These narrow evidentiary grounds on which the decision was made left room for the Canadian government to counter. The government offered a new proposal, called *Tobacco Control: A Blueprint to Protect the Health of Canadians*, that reinstated the advertising ban, imposed restrictions on brand-name promotion and sponsorship, instituted controls over packaging and labeling, and increased product regulation and reporting requirements.

In creating a new legal framework, the Canadian government would make tobacco a de facto illegal product whose sale could be permitted but would be subject to specific conditions. This reversal of the burden of proof gives constitutional allowance to the advertising restrictions in Canada. Following the unveiling of the *Blueprint*, the tobacco industry brought forward a voluntary proposal to restrict advertising. Subsequent resumption of advertising has been controversial, and the industry has been accused of breaching its own code (LeGresley 1996).

Tobacco Advertising, Commercial Speech, and the First Amendment

Regulation of tobacco advertising in the United States is legally problematic. Although protections afforded by the First Amendment to the U.S. Constitution may be modified for commercial speech, including advertising, such modification is an area of intensive legal debate. The two decades of lawsuits described in this section make it clear that a concerted and persistent government interest is essential if such restriction of free speech is to be upheld in courts. To satisfy legal scrutiny, the government's efforts must clearly show that any restrictions directly and materially advance its asserted interest—protecting the health of the American people.

The United States Supreme Court has defined commercial speech as "expression related solely to the economic interests of the speaker and its audience" (*Central Hudson Gas & Electric v. Public Service Commission of New York*, 447 U.S. 557 [1980]). Commercial speech thus includes advertisements by cigarette manufacturers that invite consumers to buy their product. As the Supreme Court has observed, "For most of this Nation's history, purely commercial advertising was not considered to implicate the constitutional protection of the First Amendment" (*United States v. Edge Broadcasting Co.*, 113 S. Ct. 2696, 2703 [1993]). Restrictions on commercial speech were viewed as being similar to economic regulation and were routinely upheld. A midcentury example key to later efforts to restrict tobacco advertising occurred when the Supreme Court, in *Valentine v. Chrestensen* (316 U.S. 52 [2d Cir. 1942], *rev'd*), held that the state could prohibit the street distribution of handbills containing commercial advertising matter (see also *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 [1980]). Such precedents enabled the courts to uphold the 1972 congressional ban on tobacco advertising on radio and television (*Capital Broadcasting Co.*, 405 U.S. 1000). Subsequent legal scrutiny, however, has acted to reverse this trend.

Constitutionality of Regulating Advertising

In 1975, the United States Supreme Court held for the first time that commercial advertising in general was entitled to protection under the First Amendment. In *Bigelow v. Virginia* (421 U.S. 809 [1975]), the Court struck down a state statute banning commercial advertisements for abortion referral services. The Court found that "the relationship of speech to the marketplace of products or services does not make [commercial advertising] valueless in the marketplace of ideas" (p. 826). However, the Court emphasized that it was defending not merely commercial speech, but speech that contained "material of clear 'public interest' " (p. 822).

The Court also defended commercial speech in a case involving advertising of the price of pharmaceuticals. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.* (425 U.S. 748 [1976]), the Court found that the constitutional protection afforded to advertisements of the price of pharmaceuticals was shared by advertisers and recipients of the information. The Court noted the importance of information to consumers: "As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate" (p. 763). The Court pointed out that advertising is disseminating information to the consumer about who is producing the product, for what reason, and at what price, even if it does not "editorialize on any subject, cultural, philosophical, or political" (p. 761).

In that same ruling, however, the Supreme Court emphasized that commercial speech would not be afforded the same level of protection as other forms of speech and therefore that the state can regulate advertising if such regulation is in conformity to a valid public interest. These interests include avoiding deceptive and misleading claims; preventing unlawful activities, such as the sale of alcoholic beverages to minors; and protecting public health. "The First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely" (*Virginia State Board of Pharmacy*, pp. 771–2).

Most cases involving regulated advertising are assessed through a four-pronged test to determine whether the regulations violate the First Amendment. This test was set forth in *Central Hudson* (447 U.S. 557). First, the speech being suppressed must have forfeited its First Amendment protection by being unlawful or deceptive or fraudulent: "The First Amendment's concern for commercial speech is based on the informational function of advertising. . . . Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it" (p. 563). Second, the government must assert a substantial interest in regulating the speech. Third, regulating commercial speech must directly and materially benefit this government interest. Fourth, the government must show that the means chosen to benefit its interest are no more extensive than necessary. (This four-pronged test is discussed more fully in "Constitutionality of Regulating Tobacco Advertising," later in this chapter.)

The level of deference the Supreme Court gives to legislatures in meeting these four requirements seems to vary. In some cases, the Court defers to the legislative judgment that the speech restriction will be effective (*Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*, 478 U.S. 328 [1986]; *Edge Broadcasting*), while in other cases the Court demands more empirical support for the legislature's assumptions and conclusions (*Rubin v. Coors Brewing Co.*, 514 U.S. 476, 115 S. Ct. 1585 [1995]; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 116 S. Ct. 1495 [1996]).

In *Posadas de Puerto Rico*, the Supreme Court upheld a statute that prohibited advertising legal gambling casinos to residents. The Court found that even though nonfraudulent advertising that concerned a legal activity deserved First Amendment protection, the commonwealth's legislature could take steps to regulate it. The government has a substantial interest in protecting the health, safety, and welfare of its citizens, and this interest includes reducing the demand for gambling among residents through the regulation of advertising. The Court accepted the argument by the commonwealth that resident gambling would disrupt moral and cultural patterns, cause an increase in crime, foster prostitution, and develop corruption. In *Board of Trustees of the State University of New York v. Fox* (492 U.S. 469 [1989]) (also known as *Fox III*), the Court deferred to the legislature and refused to set aside a State University of New York statute that prohibited private commercial enterprises from operating on campus. In *Edge Broadcasting* (113 S. Ct. 2696), the Court upheld a federal statute that prohibited the broadcast of lottery advertisements generally but permitted advertisements of state-run lotteries on stations licensed to a state that conducts lotteries. The Court held that "the State [has] 'a strong interest in adopting and enforcing rules of conduct designed to protect the public' " (p. 2706). Citing *Fox III* with approval, the

Court said, "Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments" (p. 2707).

In contrast, in *44 Liquormart*, the Supreme Court looked closely at the logic of the Rhode Island government in the ban it imposed on liquor price advertising. The Court considered that the Rhode Island restriction was a total prohibition and that there was too weak a connection between banning speech regarding prices and the state's assertion that this restriction would reduce liquor consumption. Furthermore, the Court was aware of the concern that the legislature had been captured by one group of economic competitors (small liquor stores that could not otherwise compete in price wars) and that the law was then drafted at the expense of the disfavored economic competitor (larger liquor chains). In the *44 Liquormart* decision citing the dissent in *Rhode Island Liquor Stores Association v. Evening Call Pub. Co.* (497 A.2d 331 [R.I. 1985]), it was "suggested that the advertising ban was motivated, at least in part, by an interest in protecting small retailers from price competition" (p. 491, FN4).

In *Coors Brewing Co.*, the Supreme Court struck down a regulation restricting the printing of alcohol strength on beer labels. The Court found that the restriction did little to advance the government interest in preventing "strength wars" between competing beer manufacturers, particularly when other types of alcohol were required to list the alcohol potency on their labels. Finding that the speech restriction lacked a logical foundation, the Court viewed the regulation skeptically.

The pattern that emerges from these legal judgments is that where a law restricting commercial speech has a solid grounding in logic and empirical data, the Court will uphold it. If the regulatory system has a faulty connection between its goal and its method, the law will fail the third prong of the *Central Hudson* test and be struck down. In *44 Liquormart*, Justice John Paul Stevens' plurality opinion required that the social science evidence supporting the legislative rationale directly and materially tie the government's goal (reducing liquor consumption) to its methodology (restricting liquor price advertising); the government failed to meet this legal requirement. Furthermore, the Court views harshly laws that impose a total ban on speech and thus paternalistically deprive consumers of information because the government perceives that the ban is "for their own good."

Constitutionality of Regulating Tobacco Advertising

Government regulations of tobacco product advertising can withstand legal scrutiny if they are carefully crafted and are not overbroad (*Edge Broadcasting*, p. 2705 [citing *Fox III*, p. 480]). Courts have found state and local regulations of tobacco advertising to be preempted by the Federal Cigarette Labeling and Advertising Act when they conclude that the regulation is based on "smoking and health." If the regulation is not preempted, then it must pass the four-pronged test advanced in *Central Hudson*. Reasonable regulations on tobacco advertising are likely to be upheld.

Preemption and the Federal Cigarette Labeling and Advertising Act

The Federal Cigarette Labeling and Advertising Act preempts a "requirement or prohibition based on smoking and health . . . imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter" (15 U.S.C. [United States Code] 1334[b]). In *Cipollone v. Liggett Group Inc.* (505 U.S. 504, 112 S. Ct. 2608 [1992]), the Supreme Court interpreted that language narrowly, allowing Cipollone to sue the tobacco industry if the claim were not based on a failure to warn about smoking and health issues in product advertising or promotion. The claim would not be preempted if it were based on more generalized state interests, such as preventing intentional fraud or enforcing manufacturer warranties. In *Mangini v. R.J. Reynolds Tobacco Co.* (22 Cal. App. 4th 628 [1993]), the California Court of Appeals restated the *Cipollone* holding by declaring that regulations are preempted only if they demand a "requirement or prohibition based on smoking and health. . . . imposed under State law with respect to. . . . advertising or promotion." If one of these elements is missing, the state law is not preempted.

State and local governments can still regulate tobacco advertising if they justify the law with a valid rationale not related to health. For example, Baltimore asserted that its ordinance restricting tobacco advertising on billboards was a reasonable and necessary measure for reducing illegal consumption of cigarettes by minors (*Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 862 F. Supp. 1402 [Md. 1994]). The city claimed that the focus of the ordinance was not on protecting the health of young people; the language of the ordinance was instead exclusively related to preventing youth from engaging in illegal transactions. (This assertion was made even though Baltimore does not criminalize youth purchase or

possession of tobacco products; Baltimore criminalizes the sale of tobacco to minors.) The district court accepted this stated intent of the ordinance. Even when legislators who supported the ordinance made certain health-related comments, the court discounted these as not necessarily being representative of the motives of the city council as a whole.

On appeal by the advertising company that was the plaintiff in the case, the Fourth Circuit Court of Appeals further held that the Baltimore ordinance was not preempted by the Federal Cigarette Labeling and Advertising Act because it did not relate to the content of advertising, but rather to billboard location (*Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 63 F.3d 1318 [4th Cir. 1995]). The court interpreted the ordinance as a limited physical restriction in a limited media, for Baltimore allows such billboards in parts of the city zoned for commercial and industrial use. The court also observed that the Baltimore ordinance did not restrict tobacco industry advertising in other media, such as newspapers and magazines. State or local governments that cannot separate such ordinances from health-related issues, however, will have difficulty passing the preemption test. In Minnesota, for example, the court struck down a municipal statute that restricted tobacco advertising explicitly to protect health (*Chiglo v. City of Preston*, 909 F. Supp. 675 [D. Minn. 1995]).

The Four-Pronged Test

Is the Advertising Unlawful or Misleading?

A central justification for affording constitutional protection to advertising is the consumer's interest in the free flow of information (*Central Hudson*). Public health and smoking prevention groups often question whether attractive images that portray smoking as a socially acceptable, sexual, and athletic activity have any informational use to the consumer (Lowenstein 1988). Despite the emotive, noninformative character of cigarette advertising, the tobacco industry might argue that restricting such advertising should fail the first prong of the *Central Hudson* test because the product being advertised is lawful for adults and its promotion is not directly deceptive or fraudulent.

Certainly, advertisements that use images to connect health, vitality, and the good life with cigarette smoking distort the truth (Law 1992). Yet the United States Supreme Court's definition of "inherently misleading" refers to advertisements that promote fraud, represent overreaching, or create consumer confusion (*Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 462 [1978]). Proscriptions against misleading advertising have not traditionally extended to "puffery" or imagery alone (*Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 [1985]). For example, courts have held that advertisements for alcoholic beverages that project images of drinkers as successful and fun-loving and do not warn of the dangers of alcohol abuse are not legally "misleading" (*Oklahoma Telecasters Association v. Crisp*, 699 F.2d 490, 500 [10th Cir. 1983], *rev'd on other grounds sub nom.; Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 [1984]). By analogy, courts may not find that promotions are directly misleading simply because they project images of smokers as glamorous people and do not mention the associated dangers of smoking.

A cigarette advertisement would be found to be misleading, however, if it included unsubstantiated health claims. Advertisements could not assert that cigarette smoking poses little or no risk to health or does not affect breathing. For example, the FTC challenged as false and misleading a newspaper advertisement (or advertorial), paid for by R.J. Reynolds Tobacco Company, that claimed smoking is not as hazardous to health as the public has been led to believe. Although the tobacco company initially stated that the statement was not commercial speech because it did not invite the public to purchase a particular product, the parties entered into a consent decree under which R.J. Reynolds agreed to stop the advertisement and to avoid future misrepresentation of scientific studies (Bureau of National Affairs, Inc. 1990).

Some proponents of restricting tobacco advertising argue that courts in the future could find the visual images projected in cigarette advertisements to be inherently deceptive or misleading. A legal opinion for the American Medical Association concluded, "Given what the cigarette advertising does portray, what it fails to say, and the vast public ignorance of the dangers and addictive quality of smoking, particularly among young persons, it is plain to us that this kind of advertising can be proscribed as deceptive or misleading" (Blasi and Monaghan 1986, p. 506). Analogously, the Supreme Court has construed the preemptive provisions of the cigarette labeling act to permit tort actions against cigarette manufacturers in the instance of fraudulent misrepresentation or conspiracy to misrepresent or conceal material facts (*Cipollone*).

Furthermore, to the extent that recent documents from the tobacco industry show that the industry purposefully marketed to minors, the courts may find this to be a deceptive advertising practice that leads to an illegal act. There is no constitutional speech protection for proposing illegal transactions, such as sales of cigarettes to minors. The tobacco company Liggett

Group Inc. has admitted that the entire tobacco industry conspired to market cigarettes to children (*Settlement Agreement Between Settling States and Brooke Group LTD, Liggett & Myers, Inc. and Liggett Group, Inc.*, *cited in* 13.1 TPLR 3.11 [1998]), and documents obtained in litigation from the other tobacco companies and recently made public confirm that tobacco companies have purposefully marketed to children as young as 14 years old (Coughlin et al. 1999). Regulation of some tobacco advertising may thus pass the first prong of the *Central Hudson* test (see the discussion of the *Mangini* case in "A Critical Example: Joe Camel," later in this chapter).

Is the Government's Interest Substantial?

Appellate courts have consistently found that states have a substantial interest in limiting tobacco advertisements (see, for example, *Penn Advertising*; *Oklahoma Telecasters*; and *Dunagin v. City of Oxford*, 718 F.2d 738 [5th Cir. 1983], *cert. denied*, 467 U.S. 1259 [1984]). Because of the strong epidemiologic evidence associating smoking with lung cancer, heart disease, and other causes of morbidity and mortality (USDHHS 1989), no court would deny that the federal government has a compelling interest in reducing smoking. As evidence mounts concerning the health hazards of environmental exposure to cigarette smoke (Environmental Protection Agency [EPA] 1992; Leary 1993; Reynolds 1993; Bero et al. 1994; California EPA 1997), the federal government may also exercise its police powers to protect nonsmokers.

The Federal Cigarette Labeling and Advertising Act preempts state and local governments from regulating cigarette advertising based on "smoking and health." Instead, as noted, many governments (such as those of Baltimore and New York City) are asserting an interest in preventing minors from being involved in illegal transactions. Additional nonhealth rationales include avoiding deceptive advertising and providing economic (as opposed to health-based) consumer protection.

Does the Regulation Directly Benefit the Public Interest?

The third prong of the *Central Hudson* test requires that governmental regulation of commercial speech must advance the government interest. The Supreme Court has not yet given clear direction as to what level of evidence is required to show that such regulation directly advances the government interest, but the Court is beginning to demand some scientific or statistical evidence of efficacy. In *Florida Bar v. Went For It, Inc.* (515 U.S. 618, 632 [1995]), the Court was satisfied with a general assertion by the state that common sense dictated that restricting attorneys from advertising by direct mail would reduce ethical violations by attorneys and have a positive effect on the public's opinion of attorneys. Limited social science evidence was presented, yet the restriction was upheld. On the other hand, in *44 Liquormart*, Justice Stevens' plurality opinion stated that one reason the Rhode Island statute was struck down was that the state had not produced evidence that its speech restriction would directly and materially produce the results desired to advance the government interest.

Even if the courts require empirical support of efficacy, tobacco advertising restrictions can still satisfy the third prong of the *Central Hudson* test. There is extensive social science research regarding the effect of tobacco advertising on the purchasing habits of teen smokers and on the positive imagery with which children regard and recognize tobacco advertising images. After R.J. Reynolds Tobacco Company introduced the Joe Camel advertising campaign in the late 1980s, the market share of Camel cigarettes among teenagers increased at least 20-fold; from the same point in time, the previous decline in overall teenage smoking prevalence was reversed (CDC 1994b). An association between a rise in young girls' smoking habits and the tobacco industry's decision to target marketing to adolescent girls has also been documented (Pierce et al. 1994a).

Some relevant legal judgments suggest that although the courts tend to require more than a commonsense assertion of the government's interest in restricting commercial speech, something less than empirical evidence may suffice. For example, although Justice Stevens in *44 Liquormart* demanded empirical evidence, he also recognized there is "some room for the exercise of legislative judgment" (p. 508). The Supreme Court in *Edenfield v. Fane* (113 S. Ct. 1792 [1993]) suggested the need for a scientific validation of a connection between regulation and the achievement of a substantial state interest: the Court stated that the government "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree" (p. 1800).

In cases involving advertising restrictions for alcoholic beverages, the courts have consistently accepted—even in the absence of objective scientific studies—the reasonable legislative belief that such restrictions would lower consumption. The Tenth Circuit Court of Appeals found it not "constitutionally unreasonable for the State of Oklahoma to believe that advertising will not only increase sales of particular brands of alcoholic beverages but also of alcoholic beverages generally" (*Oklahoma Telecasters*, p. 501).

Similarly, the Ohio Supreme Court found that the advertising of drink prices would encourage and stimulate consumption of alcoholic beverages (*Queensgate Investment Co. v. Liquor Control Commission*, 433 N.E.2d 138, 142, 69 Ohio St. 2d 361 [Ohio 1982]). The advertising prohibition was thought to be closely connected to the state's interest in preventing consumption.

Courts have found a direct relationship between advertising and consumption or abuse in other dangerous products and activities (see, for example, *Williams v. Spencer,* 622 F.2d 1200 [4th Cir. 1980]; *Capital Broadcasting*). In *Central Hudson*, the Supreme Court found an immediate connection between advertising and the demand for electricity. The Court in *Metromedia, Inc. v. City of San Diego* (453 U.S. 490 [1981]) similarly found a link between billboard advertisements and traffic safety. The Court stated that this link is established by the "accumulated, common-sense judgments of local lawmakers" (p. 509).

Claims made on behalf of the tobacco and advertising industries that tobacco advertising is designed not to increase consumption but only to develop brand loyalty and gain an increased market share (Boddewyn 1989) may be unpersuasive to the courts (Chetwynd et al. 1989; Joossens 1989). Although some of the studies showing that advertising increases tobacco consumption have methodologies that are controversial—such as econometric (Lewit et al. 1981; Schneider et al. 1981; Seldon and Doroodian 1989), cross-cultural (Hamilton 1976; Reuijl 1982), and advertising recognition (Goldstein et al. 1987; DiFranza et al. 1991; Fischer et al. 1991a)—the courts would likely accept the legislature's reasonable belief that what the studies show is true. For example, the Ninth Circuit, in a 1997 opinion after *44 Liquormart*, maintained that "common sense suggests that advertising increases participation" (*Valley Broadcasting Co. v. United States*, 107 F.3d 1328, 1344 [9th Cir. 1997]). This portion of *Posadas de Puerto Rico* has survived *44 Liquormart*.

In an analogous situation, alcohol industry arguments against the relationship between advertising and consumption were rejected by the Fifth Circuit Court of Appeals, which held that Mississippi's ban on intrastate liquor advertising directly promoted the state's interests in the health and safety of its citizens. The court said that it did not ". . . believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors. . . . we hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban, whether or not 'concrete scientific evidence' exists to that effect" (*Dunagin*, p. 750). Because the tobacco industry spends six times as much as the liquor industry on advertising and promotion (FTC 1995), because smoking remains the leading cause of avoidable death in America (McGinnis and Foege 1993), and because about 50 million Americans still smoke, even small reductions in smoking behavior—whether consumption or uptake—resulting from reduced advertising could achieve significant health benefits.

Cases trying to restrict alcohol advertising have also, however, set precedents that may stand in the way of comparable cases involving tobacco advertising. Most notably, in *44 Liquormart, Inc. v. Racine* (829 F. Supp. 543 [R.I. 1993]), the Rhode Island District Court judge found that the state's specific statute banning liquor price advertising had had "no significant impact on levels of alcohol consumption" (p. 549). Justice Stevens, in his plurality opinion, found that the statute could not survive without social science evidence because "speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends" (*44 Liquormart, Inc. v. Rhode Island*, p. 507).

Yet the Fourth Circuit Court of Appeals, the highest court to rule on tobacco advertising restrictions, has twice upheld Baltimore's limitation on tobacco advertising. The Fourth Circuit noted several differences between the liquor price advertising prohibition in *44 Liquormart, Inc. v. Rhode Island* and the limited restrictions in the Baltimore ordinance. *44 Liquormart* dealt with a total ban on speech directed to adults, whereas the Baltimore ordinance was a partial restriction of speech that targeted children as consumers of an adult product. The Fourth Circuit Court also held there was a close connection between the government's goal of preventing teen participation in illegal transactions and the limited speech restriction intended to support that goal (*Penn Advertising*, 63 F.3d 1318; *Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 101 F.3d 332 [4th Cir. 1996]). By contrast, a notable reason for the Supreme Court's rejection of advertising restrictions in *44 Liquormart* was that the government had not proved a clear tie between its interest and the restrictions supposedly supporting that interest.

The Fourth Circuit reaffirmed its decision in *Penn Advertising* after the Supreme Court had asked it to review the decision in light of *44 Liquormart*. The Fourth Circuit specifically stated, "We have read the opinion in *44 Liquormart* and have considered its impact on the judgment in this case . . . we conclude that *44 Liquormart* does not require us to change our decision" in this case (*Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 101 F.3d 332 [4th Cir. 1996], *cert. denied*, 117 S. Ct. 1569 [1997]).

Because a restriction like that upheld in *Penn Advertising* cannot constitutionally be a complete ban on all advertising of the product, some minors will be exposed to some level of adult tobacco advertising. This limit in scope does not constitute serious grounds for an appeal. A recent decision involving liquor regulation notes that the "Supreme Court has made it clear in the commercial speech context that underinclusiveness of regulation will not necessarily defeat a claim that a state interest has been materially advanced" (*Bad Frog Brewery, Inc. v. New York State Liquor Authority*, 134 F.3d 87, 99 [2d Cir. 1998]). In sum, the regulation need not cure all ills but it does need to advance the state interest in a demonstrably significant, rather than a small or otherwise circumstantial, way.

Is the Regulation of Advertising a Reasonable Fit?

The Supreme Court has made it clear that this standard is not to be confused with the "least restrictive means" test. In *Edge Broadcasting* (p. 2705), the Court said that the "requirement of narrow tailoring was met if 'the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation,' provided that it did not burden substantially more speech than necessary to further the government's legitimate interests." The existence of less restrictive methods of achieving the government's goals does not automatically defeat the legislation as it would in political speech cases. Instead the Court looks to see if the restriction does not sweep more broadly than necessary. In *Florida Bar* the Court stated,

> In *Fox*, we made clear that the "least restrictive means" test has no role in the commercial speech context . . . "What our decisions require," instead, "is a 'fit' between the legislature's ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served,' that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective" (citations omitted) (p. 632).

In practical terms, the decision implies that restrictions on tobacco advertising that target areas where children gather, such as schools and playgrounds, do not create a total ban, because the tobacco industry will still have many alternative channels to communicate with its adult customers. Adults can still receive information on price, quality, comparative product features, and any other information to help them make an informed decision on tobacco products. Even if the tobacco industry were limited to communicating in tombstone format (black letters on a white background), the government would not have prohibited the flow of information.

For a similar reason, *44 Liquormart, Inc. v. Rhode Island* does not change this analysis. The rationale the Supreme Court used there in overturning Rhode Island's alcohol advertising restriction—that the statute was a paternalistic ban on the free flow of truthful information—does not apply in tobacco advertising regulations like those upheld in *Penn Advertising*, because the tobacco industry would still have many avenues of communication open to it and could communicate all aspects of information.

Justice Stevens in *44 Liquormart* also generally rejected a vice exception to commercial speech restrictions. In *Posadas de Puerto Rico*, the Court was willing to allow the legislature broad deference to curb speech that promoted "vice" activities such as gambling. Justice Stevens rejected this approach that allowed legislatures to ban speech rather than the vice itself. He stated, however, that "a 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity" (*44 Liquormart, Inc. v. Rhode Island*, p. 514). In the case of restricting tobacco advertising aimed at children, the restriction matches the prohibition. It is illegal to sell tobacco products to minors, and therefore the legislature has a principled reason to prevent commercial speech in the limited area where it has already prohibited the commercial activity. This is in accord with Justice Clarence Thomas' view that a jurisdiction "may not restrict advertising regarding commercial transactions except to the extent that it outlaws or otherwise directly restricts the same transactions within its own borders" (p. 525).

In *44 Liquormart*, Justice Sandra Day O'Connor's concurrence set out the guideposts she would use to judge commercial speech restrictions. "The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. If alternative channels permit communication of the restricted speech, the regulation is more likely to be considered reasonable" (*44 Liquormart, Inc. v. Rhode Island*, pp. 529–30 [internal citations omitted]). The ruling presupposes that other less restrictive alternatives, such as price increases and access restrictions, have been tried (if enacted) and have not completely solved the problem. It is reasonable for a legislature

to conclude that limited restrictions on commercial speech aimed at youth must be a component of an overall plan to limit youth involvement with tobacco products. At the same time, the tobacco industry will have alternative channels to communicate to adults all the information in which adults are interested, including price, tar and nicotine levels, and taste. In the context of alcohol advertisements, courts have asserted that "the state's concern is not that the public is unaware of the dangers of alcohol. . . . The concern instead is that advertising will unduly promote alcohol consumption despite known dangers" (*Dunagin*, *cert. denied*, 467 U.S. 1259).

The preceding review of relevant cases suggests that carefully designed, reasonable government restriction of cigarette advertising would likely meet the Supreme Court's four criteria for restricting commercial speech and would therefore be found constitutional.

A Critical Example: Joe Camel

Perhaps the most discussed tobacco promotion of the 1990s—and one that brings together many of the issues discussed in the preceding section—is the advertising campaign for Camel cigarettes that features a cartoon camel character called Old Joe (often referred to as Joe Camel). Assertions have been made that this campaign improperly targeted minors, seeking to attract them to cigarette smoking. These concerns were heightened in the wake of the 1994 Surgeon General's report on smoking and health, which focused on adolescents (USDHHS 1994). That report's major conclusions included the following: those who smoke usually begin by age 18; most adolescent smokers become addicted to nicotine; tobacco addiction is associated with the later development of other drug addiction; tobacco use is related to psychosocial risk factors; and some cigarette advertising appears to be particularly effective on adolescents.

Critics argue that the cartoon character of Joe Camel, which has been used by R.J. Reynolds Tobacco Company in its advertising campaign for Camel cigarettes since 1988, has had substantial impact on smoking among underaged youth (DiFranza et al. 1991; Fischer et al. 1991a; Breo 1993; CDC 1994b). The character appears in print advertising and on promotional products disseminated by the company, such as mugs, matchbooks, store exit signs, and soft drink can holders. After a staff investigation, in 1994 the FTC declined, by a 3 to 2 vote, to issue a complaint charging that advertising using the Joe Camel character violated section 5 of the Federal Trade Commission Act by inducing minors to smoke. Subsequently, the FTC did bring a complaint against R.J. Reynolds on May 28, 1997, alleging that "the purpose of the Joe Camel campaign was to reposition the Camel brand to make it attractive to younger smokers. . . . The Joe Camel campaign induced many of these children and adolescents under the age of 18 to smoke Camel cigarettes or increased the risk that they would do so. . . . R.J. Reynolds' actions . . . have caused or were likely to cause substantial and ongoing injury to the health and safety of children and adolescents under the age of 18 that is not offset by any countervailing benefits and is not reasonably avoidable by these consumers" (*In re R.J. Reynolds Tobacco Co.*, Docket No. 9285 [FTC, May 28, 1997], *cited in* 12.3 TPLR 8.1, 8.2 [1997]). As late as the spring of 1998, Joe Camel memorabilia were still being offered for sale in R.J. Reynolds catalogs. The FTC ultimately dismissed its complaint as no longer necessary after the November 23, 1998, Master Settlement Agreement banned the use of all cartoon characters, including Joe Camel, in the advertising, promotion, packaging, and labeling of any tobacco product.

The Federal Trade Commission Act grants no private right of enforcement (*Holloway v. Bristol-Myers Corp*., 485 F.2d 986 [D.C. Cir. 1973]). However, the California Unfair Competition Law authorizes actions for injunctive relief (a measure sought to prevent a given course of action) not only by specified state and local officers but also by persons acting for the interest of themselves or the general public. A private action was brought in California state court by Janet Mangini, who asserted that R.J. Reynolds' advertising practices in the Joe Camel campaign violated the Federal Trade Commission Act and the California statutory law of unfair competition (*Mangini v. R.J. Reynolds Tobacco Co.*, 7 Cal. 4th 1057, 875 P.2d 73 [Cal. 1994], *cert. denied*, 1994 U.S. LEXIS 8361 [Nov. 28, 1994]). Unfair competition is defined to include "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising" (California Business & Professions Code, sec. 17200). R.J. Reynolds, in contesting Mangini's action, asserted that federal law preempted any action in the state courts. The Federal Cigarette Labeling and Advertising Act, as amended by the Public Health Cigarette Smoking Act of 1969, provides that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provision of this Act" (Public Health Cigarette Smoking Act of 1969, sec. 5[b]).

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).

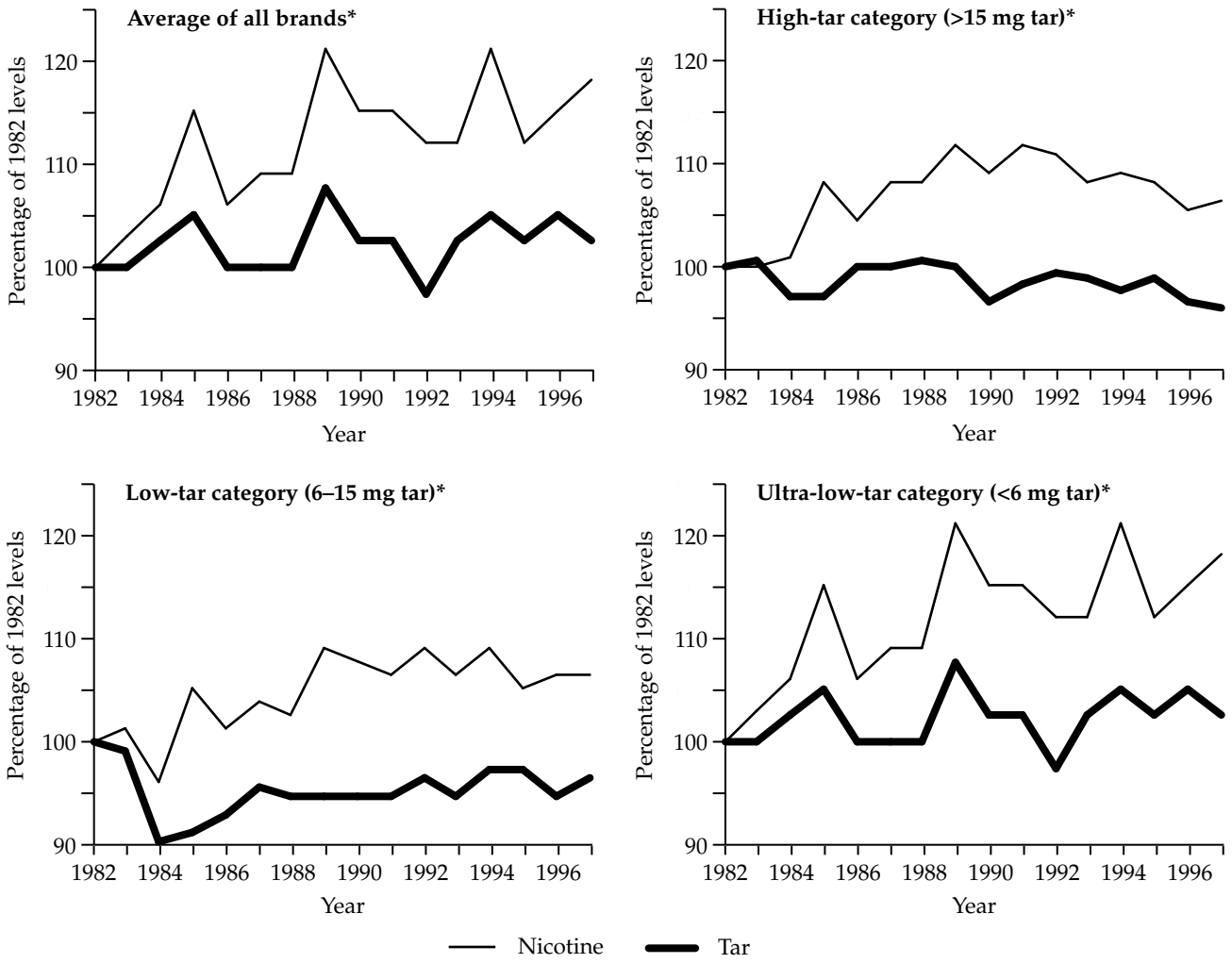
Regulation by Tar Levels

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 non-government 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

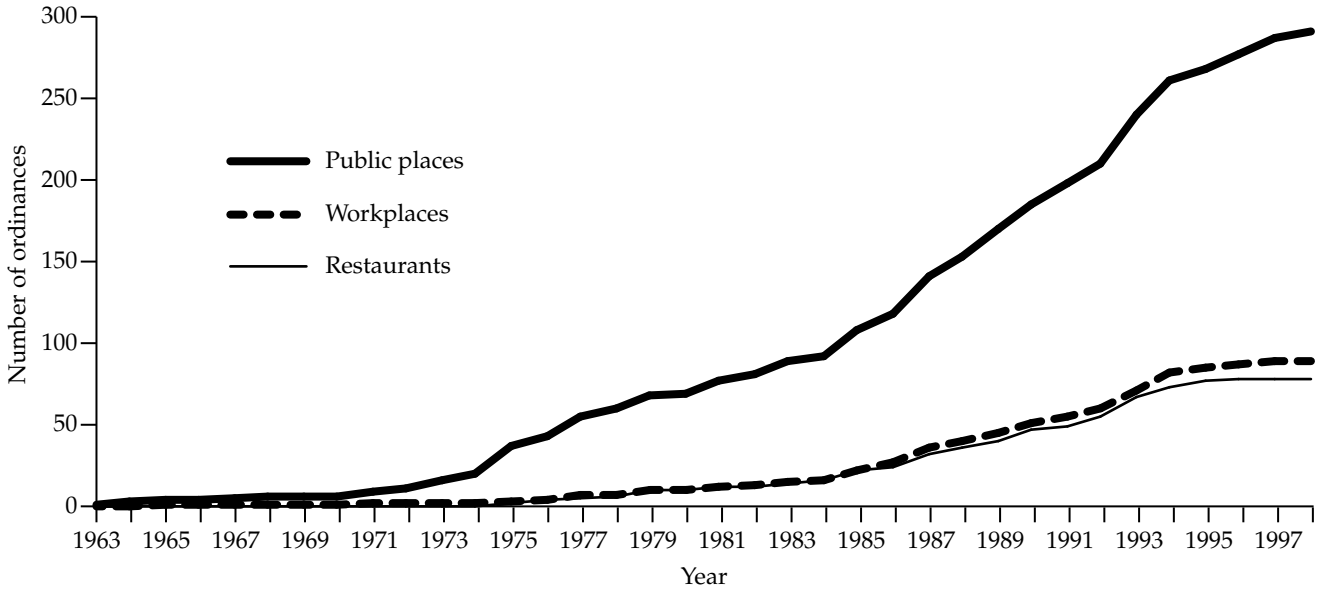
The most notable federal regulation of ETS is the requirement that domestic airline flights be smoke free. The regulation was first enacted in 1988 for domestic flights lasting two hours or less and was renewed in 1989 for domestic flights lasting six hours or less (Table 5.1). Since the early 1970s, 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

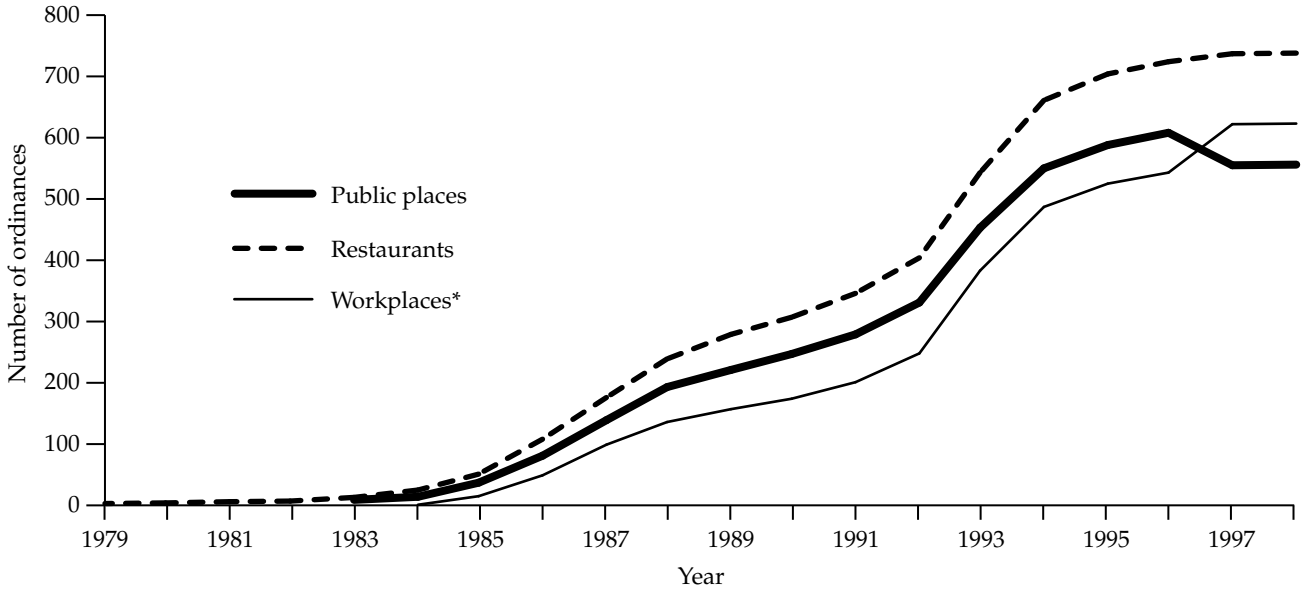
Although it is generally accepted that regulatory changes influence nonsmokers' exposure to ETS and smokers' behavior, relatively few evaluation studies quantify these effects over time. Evaluating such changes is hampered by the complex interaction of social forces that shape behavior, by the decline 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.

In measuring the impact of a statewide law for clean indoor air, researchers in Missouri examined self-reported data on ETS exposure from 1990 through 1993 (Brownson et al. 1995a). Nonsmokers' exposure to ETS in the workplace declined slightly the year the law was passed and substantially more after the law went into effect. Exposure to ETS in the home remained constant over the study period; this finding suggests that the declining workplace exposure was more likely linked to the smoking regulations than to the overall declining smoking prevalence observed during the study period. Despite improvements over time, ETS exposure in the workplace remained at 35 percent in the final year of the study (1993). Other data from California indicate that nonsmokers employed in workplaces with no policy or a policy not covering their part of the workplace were eight times more likely to be exposed to ETS (at work) than those employed in smoke-free workplaces (Borland et al. 1992).

Attitudes Toward Restrictions and Bans

Studies of awareness and attitudes toward workplace smoking restrictions and bans have been conducted in cross-sectional samples of the general population and among employees affected by bans. In a 1989 survey of 10 U.S. communities, most respondents favored smoking restrictions or smoke-free environments in all locations, including workplaces, government buildings, restaurants, hospitals, and bars (CDC 1991). Although support for smoking restrictions was higher among nonsmokers, across the 10 communities, 82–100 percent of smokers favored restrictions on smoking in public places. Support was highest for smoking bans in indoor sports arenas, hospitals, and doctors' offices. A 1993 survey from eight states showed greater support for ending smoking in fast-food restaurants and at indoor sporting events than in traditional restaurants and indoor shopping malls (CDC 1994a).

Support for proposed changes may differ from support for actual, implemented changes. Yet in studies of smoke-free hospitals, patients, employees, and physicians have overwhelmingly supported the policy (Rigotti et al. 1986; Becker et al. 1989; Hudzinski and Frohlich 1990; Baile et al. 1991; Offord et al. 1992). In some instances, a majority of smokers support a smoke-free hospital (Becker et al. 1989). Studies of smoking restrictions and bans in other industries also have found that nonsmokers overwhelmingly favor smoke-free workplaces (Petersen et al. 1988; Borland et al. 1990b; Gottlieb et al. 1990; Sorensen et al. 1991b). Time—and consequent habituation—can make changes more acceptable. In a prospective study of a smoking ban in a large workplace, Borland and colleagues (1990b) found that attitudes of both nonsmokers and smokers toward the smoke-free workplace were more favorable six months after such a policy was implemented. Although most smokers reported being inconvenienced, they also reported that they recognized the overall benefits of the policy. Two studies from Massachusetts found that one and two years after two local laws for clean indoor air were enacted, 65 percent of the businesses surveyed favored the law (Rigotti et al. 1992, 1994). The authors concluded that a self-enforcement approach achieved high levels of awareness (about 75 percent) and intermediate levels of compliance (about 50 percent) (Rigotti et al. 1994).

Effects of Restrictions and Bans on Nonsmokers' Exposure to ETS

As has been found in population-based research, studies conducted in individual workplaces have found that smoke-free workplaces have been effective in reducing nonsmokers' exposure to ETS. Effectiveness has been measured by the perceived change in air quality in the workplace after a smoke-free policy was instituted (Biener et al. 1989; Gottlieb et al. 1990) and by measurement of nicotine vapor before and after such a policy (Stillman et al. 1990). Conversely, workplace policies that allow smoking in designated areas without separate ventilation result in substantial exposure to ETS for nonsmokers (Repace 1994).

An analysis of the effects of a smoke-free workplace in The Johns Hopkins Medical Institutions found that concentrations of nicotine vapor had declined in all areas except restrooms at one to eight months after the ban (Stillman et al. 1990). In most areas, nicotine concentrations after the ban were below the detectable level of 0.24 $\mu g/m^3$.

Effects of Restrictions on Smoking Behavior

An additional benefit from regulations for clean indoor air may be a reduction in smoking prevalence among workers and the general public. For example, in a multivariate analysis, moderate or extensive laws for clean indoor air were associated with a lower smoking prevalence and a higher proportion of quitters (Emont et al. 1993). Another study also found an association between local smoking restrictions and smoking prevalence (Rigotti and Pashos 1991).

Table 5.2. Summary of studies on the effects of a smoke-free workplace on smoking behavior

Authors/year	Location	Industry	Sample size
Andrews 1983	Boston, Massachusetts	Hospital	965
Rigotti et al. 1986	Boston, Massachusetts	Hospital pediatric unit	93
Rosenstock et al. 1986	Puget Sound, Washington	Health maintenance organization	447
Petersen et al. 1988	Connecticut	Insurance company	1,210
Becker et al. 1989	Baltimore, Maryland	Children's hospital	704
Biener et al. 1989	Providence, Rhode Island	Hospital	535
Scott and Gerberich 1989	Midwestern United States	Insurance company	452
Borland et al. 1990b	Australia	Public service	2,113
Centers for Disease Control 1990c	Pueblo, Colorado	Psychiatric hospital	1,032
Gottlieb et al. 1990	Texas	Government agency	1,158
Hudzinski and Frohlich 1990	New Orleans, Louisiana	Hospital	1,946
Stillman et al. 1990	Baltimore, Maryland	Hospital	2,877
Baile et al. 1991	Tampa, Florida	Hospital	349
Borland et al. 1991	Australia	Telecommunications company	620
Sorensen et al. 1991a	New England	Telephone company	1,120
Brenner and Mielck 1992	Germany	National random sample	439
Goldstein et al. 1992	Augusta, Georgia	Hospital	1,997
Offord et al. 1992	Rochester, Minnesota	Hospital	10,579
Wakefield et al. 1992b	Australia	Representative sample	1,929
Jeffery et al. 1994	Minneapolis-St. Paul, Minnesota	Diverse worksites	32 worksites; total number of individuals not reported

Change in individual or overall smokers' consumption	Change in prevalence
Not reported	–8.5% at 20 months follow-up
–2.3 cigarettes per shift (P < 0.01) at 12 months follow-up; no change in overall consumption	No significant change
–2.0 cigarettes per day (P < 0.003) at 4 months follow-up	No significant change
–5.6 cigarettes per day at 12 months follow-up	1.6% at 12 months follow-up
No change at 6 months follow-up	–1.2% at 6 months follow-up
–3.9 cigarettes per day at work at 12 months follow-up	No significant change
22.5% of smokers decreased consumption at 7 months follow-up	–5.1% at 7 months follow-up
–7.9 cigarettes per day in smokers of 25 or more cigarettes per day at 6 months follow-up	–1.0% at 6 months follow-up
–3.5 cigarettes per day at work at 13 months follow-up; –1.8 cigarettes per day over 24 hours	–4.0% at 13 months follow-up
12.0% reduction in consumption of 15 or more cigarettes per day at work at 6 months follow-up (P < 0.001)	–3.4% at 6 months follow-up
25% of smokers no longer smoked at work at 12 months follow-up	Not reported
–3.3 cigarettes per day at 6 months follow-up (P = 0.0001)	–5.5% at 6 months follow-up
40% of smokers decreased consumption at 4 months follow-up	–1.5% at 4 months follow-up
–3.5 cigarettes per day at 18 months follow-up (P < 0.05)	–3.1% at 18 months follow-up
Not reported	21% of smokers quit at 20 months follow-up
–1.8 cigarettes per day in men, –1.4 cigarettes per day in women	Cessation proportion of 30%
57% of smokers reported they had cut down on number of cigarettes smoked	9% of smokers stated they had quit because of the ban
Not reported	–2.9% at 30 months follow-up
–5 cigarettes per day on workdays vs. leisure days	Not reported
–1.2 cigarettes per day	–2% at 24 months follow-up

In recent years, researchers have increasingly recognized the role of the environment[5] in influencing individual smoking behavior through perceived cues (NCI 1991; McKinlay 1993; Brownson et al. 1995b), many of which have their origins in generally held rules about acceptable behaviors (i.e., social norms) (Robertson 1977). Smokers frequently respond to environmental cues when deciding whether to smoke at a given time (NCI 1991). For example, a smoker may receive a personal, habit-derived cue to smoke after a meal or on a work break, but this cue may be weakened (and eventually even canceled) by a social, policy-derived cue not to smoke if the person is in a smoke-free restaurant or worksite (Brownson et al. 1995b).

Numerous studies have assessed the potential effects of workplace smoking bans on employee smoking behavior (Table 5.2). These studies have been conducted in health care settings (Andrews 1983; Rigotti et al. 1986; Rosenstock et al. 1986; Becker et al. 1989; Biener et al. 1989; CDC 1990c; Hudzinski and Frohlich 1990; Stillman et al. 1990; Baile et al. 1991; Goldstein et al. 1992; Offord et al. 1992), government agencies (Gottlieb et al. 1990), insurance companies (Petersen et al. 1988; Scott and Gerberich 1989), and telecommunications companies (Borland et al. 1991; Sorensen et al. 1991a) and among random samples of the working population (Brenner and Mielck 1992; Wakefield et al. 1992b). Most of the studies based in hospitals or health maintenance organizations that banned smoking found a decrease in the average number of cigarettes smoked per day. Several of the hospital studies found significant declines in the overall prevalence of smoking among employees at 6–20 months follow-up (Andrews 1983; Stillman et al. 1990). Studies of smoking behavior in other industries have found similar results; in most settings, daily consumption, overall smoking prevalence, or both had decreased at 6–20 months after workplaces were made smoke free.

In a population-based study of California residents, the prevalence of smoking was 14 percent in smoke-free workplaces and 21 percent in workplaces with no smoking restrictions (Woodruff et al. 1993). Consumption among continuing smokers was also lower in smoke-free workplaces, and the percentage of smokers contemplating quitting was higher. In 1992, Patten and colleagues (1995a) followed up a large sample of persons (first interviewed in 1990) to determine the influences a change in worksite setting might have had on smoking. These researchers observed a statistically nonsignificant increase in smoking prevalence among the group that changed from a smoke-free workplace to one at which smoking was permitted. The prevalence of smoking among other groups was unchanged or had declined. Although these results are tentative, particularly in view of sampling difficulties during the follow-up interview, they signal the potential impact workplace policies can have on smoking behavior.

[5] The term "environment" is defined broadly to include the legal, social, economic, and physical environment (Cheadle et al. 1992).

Case Studies of State and Local Smoking Restrictions

Recent reviews have presented case studies on the passage of state and local laws for clean indoor air (Samuels and Glantz 1991; Fourkas 1992; Jacobson et al. 1992; Traynor et al. 1993). These studies describe the issues that states and local communities dealt with in enacting smoking restrictions in public places.

In a case study of six states, the ability of key legislators to support legislation and the existence of an organized smoking prevention coalition were key determinants of whether statewide legislation was enacted for clean indoor air (Jacobson et al. 1992). Although the enactment of such legislation was not guaranteed when these factors were favorable, enactment was unlikely when they were unfavorable. Two other factors were cited as key in enacting legislation in the six states studied: an active executive branch that pressured the legislature to act, especially by making such legislation an executive policy priority, and existing local ordinances that created a policy environment favorable to the enactment of statewide smoking restrictions.

The study found that coalitions that succeeded in enacting legislation to restrict smoking in public places featured organized commitment, including both a full-time staff and a professional lobbyist. Successful coalitions also had established close working relationships with key legislative sponsors to develop appropriate policy alternatives and to coordinate legislative strategy. Finally, effective coalitions used media and grassroots campaigns to mobilize public support for smoking restrictions.

Another important component in the legislative debate was how the issue of smoking restrictions was framed. In all six states reviewed, the tobacco industry tried to shift the focus from the credibility of the scientific evidence on the health hazards of ETS to the controversial social issue of personal freedom; specifically, the industry lobbied extensively for including nondiscrimination clauses in legislation to restrict smoking (Malouff et al. 1993). Another common strategy that

the tobacco industry has used is to support the passage of state laws that preempt more stringent local ordinances (Brownson et al. 1995b).

Because of the possible countereffect of preemptive legislation and because of the difficulty in enacting statewide legislation, public health advocates have suggested that advocates for reducing tobacco use should devote more resources to enacting local ordinances (Samuels and Glantz 1991; Fourkas 1992; Jacobson et al. 1992). A local strategy can usually impose more stringent smoking restrictions than statewide legislation does. Like the study of Jacobson and colleagues (1992) on statewide initiatives, a study of local initiatives found that two key ingredients for success were the presence of a strong smoking prevention coalition and sympathetic political leadership within the elected body (Samuels and Glantz 1991).

Minors' Access to Tobacco

Introduction

Minors' access to tobacco products is an area of regulation relatively free from the social and legal debate that often arises from other regulatory efforts. Even the staunchest opponents of reducing tobacco use concede that tobacco use should be limited to adults and that retailers should not sell tobacco products to children and adolescents. Yet as was discussed in detail in the Surgeon General's report on smoking among young people, a significant number of minors use tobacco, and a significant number of them obtain their tobacco through retail and promotional transactions, just as adults do (USDHHS 1994; CDC 1996a,b; Kann et al. 1998). Whether intended exclusively for adults or not, these commercial transactions are supported by vast resources. The multibillion-dollar tobacco industry spends a large proportion of its marketing dollars to support a vast network of wholesale and retail activity. In 1997, cigarette makers spent $2.44 billion on promotional allowances to the wholesale and retail trade and an additional $1.52 billion on coupons and retail value-added promotions (FTC 1999). These figures were 42 percent and 26 percent, respectively, of the entire $5.1 billion spent on advertising and promoting cigarettes in the United States that year.

In general, the availability of cigarettes to the adult population has not been a regulatory issue since the first quarter of the 20th century (see Chapter 2), although recent FDA statements about nicotine levels in cigarettes have raised the possibility of some regulation of adult use (see "Further Regulatory Steps," earlier in this chapter). The primary regulatory focus for cigarette access has been on reducing the sale of tobacco products to minors (Forster et al. 1989; Hoppock and Houston 1990; Thomson and Toffler 1990; Altman et al. 1992; CDC 1992a; Cummings et al. 1992; *Federal Register* 1993, 1996). Broad-based public support for limiting minors' access to tobacco has developed in the relatively brief time (since the mid-1980s) that this issue has been in the public eye (DiFranza et al. 1987, 1996; CDC 1990a,b,c, 1993a, 1994a, 1996a,d; Jason et al. 1991; Hinds 1992; Keay et al. 1993; Landrine et al. 1994, 1996; USDHHS 1994).

Reducing the commercial availability of tobacco to minors is a potential avenue for reducing adolescent use. Growing evidence suggests that tobacco products are widely available to minors. Uniformly, surveys find that teenagers believe they can easily obtain cigarettes (see, for example, Forster et al. 1989; Johnston et al. 1992; CDC 1996a; Cummings et al. 1998; University of Michigan 1999). As noted, this access is by no means confined to borrowing cigarettes from peers or adults or stealing them at home or from stores; purchase from commercial outlets is an important source for minors who use tobacco. An estimated 255 million packs of cigarettes were illegally sold to minors in 1991 (Cummings et al. 1994), and daily smokers aged 12–17 years smoked an estimated 924 million packs of cigarettes in 1997 (DiFranza and Librett 1999). Between 20 and 70 percent of teenagers who smoke report purchasing their own tobacco; the proportion varies by age, social class, amount smoked, and factors related to availability (Forster et al. 1989; Response Research, Incorporated 1989; CDC 1992a, 1996a,d; Cummings et al. 1992, 1998; Cummings and Coogan 1992–93; Mark Wolfson, Ami J. Claxton, David M. Murray, and Jean L. Forster, Socioeconomic status and adolescent tobacco use: the role of differential availability, unpublished data). In a review of 13 local

over-the-counter access studies published between 1987 and 1993, illegal sales to minors ranged from 32 to 87 percent with an approximate weighted-average of 67 percent. Several local studies published in 1996 and 1997 found somewhat lower over-the-counter sales rates to minors: 22 percent (Klonoff et al. 1997) and 29 percent (CDC 1996) in two separate studies in California and 33 percent in Massachusetts (DiFranza et al. 1996). Nine studies of vending machine sales to minors published between 1989 and 1992 found illegal vending machine sales ranging from 82 to 100 percent with an approximate weighted-average of 88 percent (USDHHS 1994). Comparison of the results of these research studies with the results of later statewide Synar surveys (see below) is problematic for four reasons: (1) the research studies were generally local surveys of a town, city, or county, whereas the Synar surveys are based on statewide samples; (2) the sampling methods vary across the research studies; (3) store inspection methodologies vary; and (4) some of the research studies contain results of several surveys, often pre- and post-intervention (USDHHS 1998a).

Several factors suggest that widespread reduction in commercial availability may result in reduced prevalence or delayed onset of tobacco use by young people: the reported importance of commercial sources to minors, the easy commercial availability that has been demonstrated, and the reductions in commercial availability demonstrated when legal restrictions have been tightened, as outlined below (Jason et al. 1991; DiFranza et al. 1992; Hinds 1992; Forster et al. 1998). One psychological study supports the potential impact of limiting minors' access to cigarettes (Robinson et al. 1997). In this investigation of 6,967 seventh graders of mixed ethnicity, the best predictor of experimentation with cigarettes was the perception of easy availability. Regular smoking was heavily influenced by cost (see Chapter 6).

Direct studies of factors that influence minors' access have produced mixed results, however. Several investigators found that state laws on minimum age for purchasing tobacco products did not by themselves have a significant effect on cigarette smoking among youth (Wasserman et al. 1991; Chaloupka and Grossman 1996). Other studies have provided evidence in single communities (without comparison groups) that compliance with youth access regulations does lead to reductions in regular smoking by adolescents (Jason et al. 1991; DiFranza et al. 1992). In a nonrandomized, controlled community trial (three intervention and three control communities), Rigotti and colleagues (1997) found that although illegal sales rates to minors decreased significantly more in the control communities than in the intervention communities, there was no difference between control and intervention communities in either self-reported access to tobacco from commercial sources or in smoking behavior among youth. The authors suggest that illegal sales rates were not reduced sufficiently in the intervention communities to cause a decrease in commercial access that was substantial enough to impact youth smoking. Noting that these studies were limited by their scope or sample size, Chaloupka and Pacula (1998) analyzed data from the 1994 Monitoring the Future surveys on 37,217 youths. Using personal and ecologic variables in a two-part multivariate model to estimate cigarette demand by youth and average daily cigarette consumption, the investigators found that adolescents are less likely to smoke and that those who smoke consume fewer cigarettes in the following settings: where prices are higher, in states that use cigarette excise tax revenues for tobacco control activities, where there are stronger restrictions on smoking in public places, and in states that have adopted comprehensive approaches to measuring retailer compliance with youth access laws. The authors concluded that comprehensive approaches, including enforcement of minors' access laws, will lead to a reduction in youth smoking. A large, community-based clinical trial—seven intervention and seven control communities—also found an intervention effect (Forster et al. 1998). In this study, communities that developed new ordinances, changes in merchant policies and practices, and changes in enforcement practices experienced a significantly smaller increase in adolescent smoking than did the control communities. Further exploration of this issue may be required to substantiate the impact of the enforcement of minors' access laws.

As commercial sales to minors are decreased, there is evidence that minors may shift their attempts to obtain cigarettes to "social" sources, e.g., other adolescents, parents, or older friends (Hinds 1992; Forster et al. 1998). One study found that adult smokers aged 18 and 19 years were the most likely group of adults to be asked by a minor for cigarettes (Ribisl 1999). This study did not assess how frequently minors asked other minors for tobacco. There is also evidence, however, that minors who provide tobacco to other minors are more likely to purchase tobacco than other minors who smoke (Wolfson 1997), and in any event, some of the cigarettes provided by minors to other minors were initially purchased from commercial sources (Forster et al. 1997). Whether the source is social or commercial, it is clear that a comprehensive approach to reducing minors' access is needed; smokers of all ages

in addition to tobacco retailers must avoid provision of tobacco to minors.

Efforts to Promote Adoption and Enforcement of Minors' Access Laws

Public organizations at the federal, state, and local levels have become active in encouraging state and local jurisdictions to adopt and enforce minors' access laws. The NCI-ACS collaboration known as ASSIST (American Stop Smoking Intervention Study) has identified reducing minors' access to tobacco products as one of its goals for its 17 demonstration states. The Robert Wood Johnson Foundation's SmokeLess States program also encourages funded states to address minors' access. The USDHHS has widely distributed a model state law as a result of an investigation by the Office of Inspector General (OIG) reporting little or no enforcement of state laws on minimum ages for tobacco sales (OIG 1990; USDHHS 1990). *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youth*, a report from the Institute of Medicine (IOM), includes an extensive study of minors' access and a series of recommendations about state and local laws in this area (Lynch and Bonnie 1994). A group of 25 state attorneys general formed a working group on the issue and released a set of recommendations regarding retail sales practices and legislation aimed at reducing tobacco sales to minors (Working Group of State Attorneys General 1994).

Efforts to curb illegal sales to minors have also occurred at the federal level. The former FDA program (see description in Chapter 7) was a major effort for several years. Probably the most sustained and widespread attention to the issue of minors' access laws and their enforcement was precipitated by the U.S. Congress, which in 1992 adopted the Synar Amendment as part of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (Public Law 102-321, sec. 1926), which amended the Public Health Service Act. This provision requires states (at the risk of forfeiting federal block grant funds for substance abuse prevention and treatment) to adopt laws establishing minimum ages for tobacco sales, to enforce the law, and to show progressive reductions in the retail availability of tobacco products to minors. The implementation of the Synar Amendment, which initially was to go into effect during fiscal year 1994, was delayed because regulations about how states were to implement the statute had not yet been finalized. During the considerable lag between passage of the amendment and the issuance of final regulations, advocates for Synar-like restriction of youth smoking and those opposed to the Synar approach used the draft regulations to encourage states to adopt laws that in these parties' differing views were the minimum necessary for states to comply with the Synar Amendment (*Federal Register* 1993; DiFranza 1994c; DiFranza and Godshall 1994). These anticipatory responses, together with the opinions and concerns they elicited, were analyzed in a study conducted in 1995 by Downey and Gardiner (1996). An interim report from the OIG in 1995 indicated that states were finding the implementation process difficult. Although 85 percent of states performed some inspections, the majority did not use a rigorous sampling scheme. Fifty-six percent reported no statewide enforcement activity (OIG 1995).

The draft regulations were finalized in early 1996 after a review of comments from the health community, state agencies, and the tobacco industry. Responsibility for implementation was placed with the Substance Abuse and Mental Health Services Administration (SAMHSA), which in the course of 1996 conducted two technical assistance meetings with states and issued three separate guidance documents. Under these regulations, the Synar Amendment requires the 50 states, the District of Columbia, and U.S. jurisdictions to do the following:

- Have in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any person under the age of 18.
- Enforce such laws in a manner that can be reasonably expected to reduce the extent to which tobacco products are available to persons under the age of 18.
- Conduct annual random, unannounced inspections to ensure compliance with the law; inspections are to be conducted to provide a valid sampling of outlets accessible to underaged youth.
- Develop a strategy and time frame for achieving an inspection failure rate of less than 20 percent among outlets accessible to underaged youth.
- Submit an annual report detailing the state's activities in enforcing the law, the success achieved, methods used, and plans for future enforcement.

In the event of noncompliance with these regulations, the Secretary of Health and Human Services is directed by statute (42 U.S.C. section 300X-26[c]) to make reductions of from 10 percent (for the first applicable fiscal year) to 40 percent (for the fourth

applicable fiscal year) in the noncompliant state's federal block grant for substance abuse programs. Although no additional monies have been appropriated to offset the costs of complying with these regulations, states may use block grant funds for certain Synar-related administrative activities, such as developing and maintaining a list of retail outlets, designing the sampling methodology, conducting Synar survey inspections, and analyzing the survey results.

In the several years following the issuance of the final Synar regulation, some significant advances have been made in enforcement of youth access laws. All states have laws prohibiting sale or distribution and they are enforcing those laws (USDHHS 1998a). Further, the median rate at which retailers failed to comply with laws prohibiting tobacco sales to minors in 1998 was 24.4 percent compared with the median rate of 40 percent in 1997 and pre-1997 studies that found violation rates ranging from 60 to 90 percent (USDHHS, in press). In the course of implementing Synar, every state has been required to establish a sampling methodology that measures the statewide retailer violation rate within a known confidence interval and to establish inspection protocols for conducting the statewide survey of tobacco retailers. These protocols include restrictions on the ages of minor inspectors and to establish procedures for recruiting and training of both minor inspectors and adult escorts. Additionally, the random, unannounced inspections conducted by the states in compliance with the Synar regulation provide the largest body of statewide data available on the level of retailer noncompliance.

Twenty-two states and two U.S. jurisdictions modified their youth access laws within a year of implementing Synar inspections. These changes improved the states' ability to enforce the law by clarifying responsibility for enforcement, defining violations, clarifying penalties, restricting vending machine sales, and establishing a list of tobacco vendors through retail licensure or vendor registration (USDHHS, in press).

In spite of these advances in enforcement of youth access laws, states also encountered difficulties while attempting to comply with the Synar mandate. The Synar regulation does not allow for the allocation of federal dollars (e.g., the Substance Abuse Prevention and Treatment Block Grant) to be used for enforcement. For many states, this proved to be a significant problem, because enforcement of youth access laws had not been previously viewed as a priority, and states were unwilling to redirect already limited funds for prevention and treatment services to law enforcement. Some states addressed the problem by earmarking revenue derived from fines, fees, or taxes. Other states implemented collaborative enforcement efforts among several agencies so that the financial burden would be shared. And still other states relied heavily on the use of volunteer youth inspectors and adult escorts (USDHHS 1998a). As the FDA became active in the youth access issue, a few states were able to use FDA funding for enforcement to cover some of the cost of Synar inspections in 1998.

Another obstacle to enforcement involved developing a valid random sample of tobacco outlets in the state when there was no accurate or current list of vendors available. Although a few states addressed this problem by working to pass retailer licensing laws at the state level, states initially had to build lists by relying on information from wholesale tobacco distributors and vending machine distributors and by searching existing lists that inadvertently identify tobacco vendors (e.g., convenience store association membership lists) (USDHHS 1999).

Other less frequently cited obstacles to enforcement included fear of lawsuits from cited vendors, concerns with the liability issues associated with working with youth, and opposition to conducting enforcement from state and local officials, law enforcement, and the general public in regions of the country where the economy is tied to the production of tobacco (USDHHS 1999).

In addition to federal and state efforts targeting illegal tobacco sales to minors, a great amount of local activity has occurred. Many local ordinances have resulted from the work of various groups, particularly in California, Massachusetts, and Minnesota (DiFranza 1994a,b; Kropp 1995; Forster et al. 1996, 1998). These ordinances—which may, for example, prohibit vending machine sales or all self-service sales of tobacco, require the tobacco sellers to be aged 18 years or older, require checking identification before sale, specify civil penalties for violators of the minimum-age law, require posting that law at the point of purchase, and require compliance checks with a specified timetable—permit creative responses at the local level to the minors' access problem. Compared with state officials, local officials deal with fewer retailers and a more limited set of constraints and are freer to tailor their policy to local conditions. Tobacco interests are less influential at the local level, because industry representatives are more likely to be perceived as outsiders, and their campaign contributions are less likely to be important to local officials; moreover, community members and local advocacy groups are often more effective against tobacco interests at this level than they are in statewide policy arenas (Sylvester 1989). Policy implementation

is also likely to be more consistent at the local level, because local advocates can monitor the process and because enforcement officials are more likely to have been a part of the policy's adoption. However, many of the policies at the federal, state, and local levels are interrelated: the federal Synar Amendment is implemented through state laws and has led to enforcement at the state and local level (USDHHS 1998a). The former FDA enforcement program operated through contracts with state agencies or organizations to conduct compliance checks in communities across the states. State agencies often fund local coalitions and projects, and local efforts influence and support efforts at the state level. For example, much of the local activity in California and Massachusetts would not have been possible without actions implemented at the state level, specifically designated funding.

Laws enacted by states pertaining to minors' access to tobacco as of December 31, 1999, have been compiled by the CDC (CDC, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data)(Table 5.3). Dates of enactment or amendment indicate that some legislative change occurred in all but one state from January 1990 to December 1997 (National Cancer Institute, State Cancer Legislative Database, unpublished data, October 6, 1998).

Restrictions on Distribution of Samples

Tobacco product samples provide a low-cost or no-cost initiation to their use and thus encourage experimentation at early ages. Many states or other jurisdictions have laws that prohibit not only sales but also any samples distribution of tobacco to minors, whereas some laws specify exceptions permitting parents or guardians to provide tobacco to their children. All states have a specific restriction on the distribution of free samples to minors, and a few states or local jurisdictions prohibit free distribution altogether because of the difficulty of controlling who receives these samples. A ban on product sample distribution can extend to coupons for free tobacco products. In Minnesota, the attorney general levied a $95,000 civil penalty against the Brown & Williamson Tobacco Corporation for allowing such coupons to be redeemed in the state (Minnesota Attorney General 1994). The reports from both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) recommended a ban on the distribution of free tobacco products. The final FDA rules issued in August 1996 would have prohibited the distribution of free samples (see "Further Regulatory Steps," earlier in this chapter). The proposed multistate settlement presumed congressional legislation that would uphold those rules (see "Legislative Developments" and "Master Settlement Agreement," earlier in this chapter).

Regulation of Means of Sale

How tobacco can be sold may also be regulated to make it more difficult for minors to purchase it. Historically, the first such restrictions adopted have been regulations of cigarette vending machines, which are an important source of cigarettes for younger smokers (Response Research, Incorporated 1989; Cummings et al. 1992, 1998; CDC 1996d). These regulations have taken the form of total bans, restrictions on placement (e.g., being within view of an employee instead of in coatrooms or entrances, or not being near candy or soda machines), restrictions on the types of businesses where vending machines may be located (e.g., limited to liquor-licensed businesses, private businesses, or businesses where minors are not permitted), and restrictions on characteristics of the machines themselves (e.g., requiring electronic locking devices or coin slugs purchased over a sales counter) (Forster et al. 1992a; DiFranza et al. 1996). The final FDA rules would have prohibited vending machines except in certain nightclubs and other adults-only facilities totally inaccessible to persons under age 18. The proposed multistate settlement anticipated legislation supporting this prohibition.

Forty-one states and the District of Columbia have laws that restrict minors' access to vending machines, including two states, Idaho and Vermont, that have enacted legislation totally banning vending machines. However, many of the state vending machine laws are weak. For example, 21 states and the District of Columbia do not restrict placement if the machine is supervised, and New Jersey bans vending machines in schools only (CDC, Office on Smoking and Health, unpublished data, 2000). However, more than 290 local jurisdictions, including New York City, have been able to adopt and enforce outright bans on cigarette vending machines or to severely restrict them to locations, such as taverns, where minors are often excluded (American Nonsmokers' Rights Foundation, unpublished data, 2000).

Representatives of tobacco manufacturers and retailers have strongly opposed bans on cigarette vending machines and have argued instead for weaker restrictions, if any, especially for what they term "adult" locations (Minnesota Automatic Merchandising Council 1987; Adkins 1989; Parsons 1989; Grow 1990; Moylan 1990; Pace 1990; Gitlin 1991). Many of these locations, including bars and other liquor-licensed

Table 5.3. Provisions of state laws relating to minors' access to tobacco as of December 31, 1999

State	Minimum age for tobacco sales	Tobacco license required	Vending machine restrictions	Enforcement authority	Sign-posting requirements*	Prohibits purchase, possession, and/or use by minors
Alabama	19	yes	no	yes	no	yes
Alaska	19	yes†	yes	no	yes	yes‡
Arizona	18	no	yes	no	no	yes
Arkansas	18	yes	yes	yes	yes	yes
California§	18	no	yes	no	yes	yes
Colorado	18	no	yes	yes	yes	yes
Connecticut§	18	yes†	yes	yes	yes	yes
Delaware§	18	yes	yes	yes	yes	yes
District of Columbia	18	yes†	yes	no	yes	no
Florida§	18	yes	yes	yes	yes	yes
Georgia	18	yes	yes	yes	yes	yes
Hawaii	18	no	yes	no	yes	yes
Idaho	18	no	yes△	yes	no	yes
Illinois§	18	no	yes	yes	no¶	yes
Indiana§	18	no	yes	yes	yes	yes
Iowa§	18	yes†	yes△	yes	no	yes
Kansas	18	yes†	yes	no	yes	yes
Kentucky§	18	yes†	yes	yes	yes	yes
Louisiana§	18	yes	yes	yes	yes	yes**
Maine	18	yes	yes	yes	yes	yes
Maryland	18	yes†	no	no	no	yes
Massachusetts§	18	yes	no	no	yes	no
Michigan§	18	yes	yes	no	yes	yes††
Minnesota	18	yes	yes	yes	no	yes
Mississippi§	18	yes	yes	yes	yes	yes§§

*Refers to the requirement to post the minimum age for purchase of tobacco products.
†Excludes chewing tobacco or snuff.
‡Except minors at adult correctional facilities.
§Some or all tobacco control legislation includes preemption.
△Requires businesses that have vending machines to ensure that minors do not have access to the machines; however, the law does not specify the type of restriction, such as limited placement, locking device, or supervision.
¶Signage required for sale of tobacco accessories, but not for tobacco.
**Except persons who are accompanied by a parent, spouse, or legal guardian 21 years of age or older or in a private residence.
††A pupil may not possess tobacco on school property.
Source: Centers for Disease Control and Prevention, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data.

Table 5.3. Continued

State	Minimum age for tobacco sales	Tobacco license required	Vending machine restrictions	Enforcement authority	Sign-posting requirements	Prohibits purchase, possession, and/or use by minors
Missouri	18	no	no	no	yes	no
Montana[§]	18	yes	yes	yes	yes	yes[‡‡]
Nebraska	18	yes[§§]	yes	no	no	yes
Nevada[§]	18	yes [§§]	yes	yes	no	no
New Hampshire	18	yes	yes	yes	yes	yes
New Jersey[§]	18	yes[†]	yes	yes	yes	no
New Mexico[§]	18	no	yes	yes	yes	yes
New York[§]	18	yes	yes	yes	yes	no
North Carolina[§]	18	no[†§§ΔΔ]	yes	no	yes	yes
North Dakota	18	yes[§§]	yes	no	no	yes
Ohio	18	yes[†]	yes	no	yes	no
Oklahoma[§]	18	yes[†]	yes	yes	yes	yes
Oregon[§]	18	no	yes	yes	yes	yes
Pennsylvania[§]	18	yes[†]	no	no	no	no[‡‡]
Rhode Island	18	yes[†]	yes	yes	yes	yes[¶¶]
South Carolina[§]	18	yes	no	no	no	no
South Dakota[§]	18	no	yes	yes	no	yes
Tennessee[§]	18	no	yes	yes	yes	yes
Texas	18	yes	yes	yes	yes	yes
Utah[§]	18	yes	yes	yes	no	yes
Vermont	18	yes	yes	yes	yes	yes
Virginia[§]	18	no	yes	yes	yes	yes
Washington[§]	18	yes[†]	yes	yes	yes	yes
West Virginia[§]	18	no	no	yes	no	yes
Wisconsin[§]	18	yes	yes	no	yes	yes
Wyoming[§]	18	no	yes	no	yes	yes
Total	51	35	44	33	36	42

[‡‡]A pupil may not possess or use tobacco on school property.
[§§]Except vending machines.
[ΔΔ]A retail license exists for those retailers who manufacture their own tobacco products or deal in nonpaid tobacco products.
[¶¶]On any public street, place, or resort.

businesses, do not prohibit minors' entry and have been shown to be readily accessible to underaged buyers (Forster et al. 1992b; Wakefield et al. 1992a; Cismoski and Sheridan 1993). Because less-restrictive measures must be consistently implemented to be effective, and because such implementation is difficult, the USDHHS (1994) and the IOM (Lynch and Bonnie 1994) recommend a total ban on cigarette vending machines. The 1996 FDA rules would have excluded locations that are inaccessible to minors, but the multistate settlement proposed a total ban.

Restrictions on vending machines are a category of regulation of self-service cigarette sales. A general ban on self-service would require that tobacco be physically obtained from a salesperson and be stored so that products are not directly accessible to customers. In one study of 489 over-the-counter purchase attempts, minors were successful at purchasing in 33 percent of locations where cigarettes were behind the counter and 45 percent of locations where cigarettes were openly available (Forster et al. 1995). In another study, stores that did not give customers access to tobacco products were less likely to sell to minors (12.8 percent) than stores that permitted direct contact with tobacco products (30.6 percent)(Wildey et al. 1995a). Finally, data suggest that shoplifting is an important commercial source of tobacco to underaged youth (Cummings et al. 1992, 1995; Cismoski and Sheridan 1994; Lynch and Bonnie 1994; Forster et al. 1995; Wildey et al. 1995b; CDC 1996d; Roswell Park Cancer Institute 1997). Shoplifting may be deterred by regulations that specify that until the moment of purchase, single packs, any amount less than a carton, or all tobacco products must be physically handled by an employee only (Cismoski 1994; Wildey et al. 1995a; Caldwell et al. 1996).

Several states have addressed the issue of self-service sales of tobacco products. For example, Idaho and Minnesota restrict self-service sales to only those stores that do not allow minors to enter and that obtain most of their sales from tobacco. Texas prohibits self-service sales in any location accessible to minors. Three hundred and ten localities have chosen to restrict tobacco sales by prohibiting self-service displays (American Nonsmokers' Rights Foundation, unpublished data, 2000). Opposition to this measure is generally organized by tobacco distributors and retailers, who fear the loss of slotting fees—payments (often substantial) to retailers for advantageous placement of tobacco products and for point-of-purchase advertising in their business (Gersten 1994; Thomas A. Briant, letter to Litchfield Tobacco Retailers, February 16, 1995; Caldwell et al. 1996). The IOM recommends a ban on self-service displays (Lynch and Bonnie 1994), and the Working Group of State Attorneys General (1994) recommends to tobacco retailers that they eliminate such displays. That this recommendation is not unreasonably burdensome has been demonstrated by one study in which 28 percent of retailers in 14 communities complied voluntarily (Forster et al. 1995) and by another study involving 15 cities in northern California (Kropp 1995). The 1996 FDA rules would also have prohibited self-service displays except in certain adults-only facilities; the proposed national settlement further stipulated that in non-adults-only facilities, tobacco products must be out of reach or otherwise inaccessible or invisible to consumers.

Anecdotal reports have suggested that single or loose cigarettes are sold in some locations. Such sales are often prohibited by state or local law, at least implicitly because single cigarettes do not display the required state tax stamp or federal warning. Frequently, single cigarettes are kept out of sight and are available only by request. Researchers in California found that even after a state law explicitly banned the sale of single cigarettes, almost one-half of tobacco retailers sold them to their customers (Klonoff et al. 1994). The study found that the stores that made loose cigarettes available sold them to almost twice as many minors as they did to adults. That finding lends support to the argument that single cigarette sales are an important avenue to addiction for some youth. A recent study in Central Harlem has produced similar results: 70 percent of the licensed outlets sold single cigarettes to minors (Gemson et al. 1998). The IOM, the 1996 FDA rules, and the proposed multistate settlement have all recommended that the sale of loose or single cigarettes be explicitly prohibited (Lynch and Bonnie 1994).

Regulation Directed at the Seller

All states now have a law specifying the minimum purchaser's age for legal sale of tobacco products. For all but two states, that age is 18; Alabama and Alaska specify age 19. Almost two-thirds of the states and many local jurisdictions require tobacco retailers to display signs that state the minimum age for sale. Some regulations specify the size, wording, and location of these signs. Other regulations specify the minimum age for salespersons; these regulations recognize the difficulty young sellers may experience in refusing to sell cigarettes to their peers.

Most of these laws define violation either as a criminal offense (e.g., misdemeanor or gross

misdemeanor), with accompanying penalties, or as a civil offense, with specified civil penalties (e.g., fines and license suspension). Civil offense laws are thought to make enforcement easier and are therefore more likely to be carried out, since they do not generally require court appearances. Many state or local laws specify penalties only against the salesperson. Applying penalties to business owners, who generally set hiring, training, supervising, and selling policies, is considered essential to preventing the sale of tobacco to minors, although tobacco retailers have vigorously opposed these measures (Skretny et al. 1990; Feighery et al. 1991; McGrath 1995a,b).

More than one-half of the states and some local jurisdictions require that tobacco retailers obtain licenses for over-the-counter sales, but smokeless tobacco is exempted by 13 of these states (CDC, Office on Smoking and Health, unpublished data). Licensure sometimes is simply a mechanism for collecting taxes or generating revenue; in other states and cities, conditions are attached that relate to minors' access. In addition to civil penalties, retail licensure for tobacco represents another approach for facilitating youth access law enforcement efforts and strengthening sanctions for violators of the law. Retail licensure can facilitate the identification of retailers. The lack of a current and accurate list of tobacco vendors has been cited by many states involved in Synar enforcement as a serious impediment to efficient enforcement (USDHHS 1999). Retail licensure can also create an incentive for retail compliance. License suspensions or revocations could be imposed as penalties for violation of youth access laws, resulting in revenue loss for retailers. Licensure would also provide a source of funds to pay for enforcement and retailer education when licensing fees or fines for violations are earmarked for such education purposes. Finally, retail licensure provides a mechanism for administrative adjudication of youth access law violations. License holders who fail to comply with the law could be held accountable before the licensing authority.

No published empirical research examines the effects of tobacco retail licensure on either enforcement efforts or retail compliance. Studies on policies targeted to increase retail compliance, however, suggest several specific elements of licensure policies that should be present in order to increase the likelihood of positive effects. The points below outline the ways in which licensure policies could be used to enhance retail compliance efforts.

- Licensure laws must explicitly link the privilege of selling tobacco products to retail compliance with youth access laws (Levinson 1999).
- Licensure should cover both retail stores and vending machines (Levinson 1999).
- License holders should be required to renew their license annually (Levinson 1999; USDHHS 1999).
- License holders should be fined for violation of youth access laws (Levinson 1999).
- Fines should be high enough to encourage vendors to comply with youth access laws but not so high as to risk loss of community or judicial support for the imposition of penalties (Lynch and Bonnie 1994).
- Fines should be graduated so that greater consequences are associated with increased number of violations. Repeated violations should lead to license suspension or revocation (CDC 1995a; NCI n.d.).
- License fees should be sufficient to cover the average cost of compliance checks (CDC 1995a).
- The revenue from fines should subsidize the costs of enforcement (Working Group of State Attorneys General 1994).

In addition to these items, several other policy elements have been suggested for incorporation into licensure laws. These licensure policy components should communicate clear and consistent messages about the illegality of tobacco sales to minors and should promote societal norms intolerant of youth access law violations (Kropp 1996). These elements include mandatory posting of warning signs within clear sight of consumers, mandatory checking of age identification, state provision of merchant and clerk education about youth access law requirements (i.e., consequences for violations and techniques for improving merchants' and clerks' skills at detecting underage youth and refusing sales), restrictions or bans on self-service displays, and ensuring that clerks are at or above the legal purchase age.

Without enforcement provisions, however, licensing laws are not effective measures to restrict minors' access. Before 1996, only 16 states with licensing laws specified the agency with enforcement responsibility, despite recommendations (USDHHS 1990; Lynch and Bonnie 1994; Working Group of State Attorneys General 1994) that states adopt a licensing requirement that has civil penalties and a designated

enforcement agent. In its 1998 report, SAMHSA indicates that all but one state requiring licenses have a designated enforcement agency (USDHHS 1998a; see "Enforcement of Laws on Minimum Ages for Tobacco Sales," later in this chapter).

State laws and local ordinances can be a mechanism for increasing retailer awareness of youth access laws and retailer ability to comply with the law. Often referred to as responsible vendor laws, this type of legislation can require retailer education and training as a condition of retail tobacco licensure or simply require education and training for all tobacco vendors. Numerous studies have shown the potential benefit of comprehensive merchant education and training programs in helping to reduce illegal sales to minors (Altman et al. 1989, 1991, 1999; Feighery 1991; Keay 1993; Cummings et al. 1998). In many instances, representatives of tobacco retailers have supported the passage of responsible vendor laws (McGrath 1995a,b; Thomas A. Briant, Letter to Litchfield Tobacco Retailers, February 16, 1995) when these laws also exempt business owners from penalties or specify lower penalties for tobacco sales to minors if owners have trained their employees. Under such conditions, employee training would relieve retailers of responsibility for ongoing supervision and monitoring of employee behavior and likely result in decreasing the impact of youth access laws. It should be noted, however, that as a result of both Synar and FDA attention to the problem of youth access to tobacco, several states have worked to ensure the modification of youth access and/or retail licensure laws to mandate vendor education and training without the incorporation of clauses relieving retailer responsibility (USDHHS 1998a). These efforts recognize that responsible vendor laws have the potential to be an effective way to increase the ability of retailers and clerks to comply with the law by accurately detecting underage purchases and confidently and safely refusing sales.

The general availability of tobacco products in retail outlets that have pharmacies has led to some concerns. In the United States, stores that have pharmacies usually sell tobacco products, contrary to a 1971 policy recommendation of the American Pharmaceutical Association (1971) that cited the inconsistency of selling cigarettes with their function as health institutions. A few small chains and a growing number of independent stores with pharmacies are tobacco free, but all large chains and most independent stores sell tobacco products. Pharmacies (and stores that have pharmacies) that sell tobacco products are as likely as other outlets to sell to minors (Brown and DiFranza 1992). On the other hand, a study has shown that pharmacists who work in stores that do not sell tobacco have a better understanding of the dangers of tobacco than do pharmacists who work in stores that sell tobacco, and they also feel more confident that they can help customers who use tobacco stop (Davidson et al. 1988). Two-thirds of pharmacists surveyed in Minnesota believed that members of the profession should not work in stores that sell tobacco products (Martinez et al. 1993), and many felt that the contiguity of tobacco products and pharmaceuticals produces professional dissonance (Taylor 1992; Kamin 1994). Both the Canadian Medical Association and the American Medical Association are opposed to tobacco sales in pharmacies and in stores that have pharmacies (Staver 1987; Sullivan 1989). The Canadian provincial government of Ontario banned such sales in 1994 (An Act to Prevent the Provision of Tobacco to Young Persons and to Regulate its Sale and Use by Others, Statutes of Orleans, ch. 10, sec. 3[6] [1994] [Can.]).

Regulation Directed at the Buyer

State and local jurisdictions are increasingly imposing sanctions against minors who purchase, attempt to purchase, or possess tobacco products (CDC 1996c; Forster et al. 1996). These laws are favored by some law enforcement officials and tobacco retailers because of the potential deterrent value (Parsons 1989; Talbot 1992). Some advocates for reducing tobacco use argue, however, that such laws are part of an effort to deflect responsibility for illegal tobacco sales from retailers to underaged youth; that these laws are not an efficient substitute for laws regulating merchants, because so many more minors than retailers are involved; and that sanctions against minors are more difficult to enforce than those against retailers (Carol 1992; Cismoski 1994; Lynch and Bonnie 1994; Mosher 1995; Wolfson and Hourigan 1997). Other advocates have insisted that some of the responsibility must devolve on the purchaser and that laws prohibiting possession should be vigorously enforced (Talbot 1992). Although not taking a stand on the advisability of purchase and possession laws, the Working Group of State Attorneys General (1994) recommended that such laws should be considered only after effective retail regulations are already in place.

Enforcement of Laws on Minimum Ages for Tobacco Sales

Although laws on the minimum age for tobacco sales have been part of many state statutes for decades, only in the past few years has attention been focused

on enforcing these laws by federal, state, or local agencies (Lynch and Bonnie 1994; *Federal Register* 1996; USDHHS, in press). As more information has become available about the implementation and effects of various minors' access laws, it is becoming clear that organized enforcement efforts are essential to realizing the potential of these laws. Enforcement of minimum-age laws is more likely to occur when enforcement is self-supporting through license fees and revenues from penalties and when the penalty schedule includes civil penalties that are large enough to be effective but are seen as reasonable and simple to administer (Working Group of State Attorneys General 1994). Law enforcement officials have sometimes balked at applying criminal penalties against clerks and retailers for selling tobacco to minors. Enforcement may be more effective if sanctions can be imposed on managers or business owners rather than, or in addition to, salespersons (Working Group of State Attorneys General 1994).

Moreover, the 1992 enactment of the Synar Amendment (Public Law 102-321, sec. 1926, discussed in the introduction to this section) has forcibly brought this issue to the fore, because the amendment requires states to enact and enforce legislation restricting the sale and distribution of tobacco products to minors. As a result, all states have laws prohibiting the sale and distribution of tobacco to minors and all states enforce these laws through a statewide coordinated program. Additionally, all states have now designated a lead agency and all but one have an agency responsible for enforcing their minimum-age law (Table 5.4) (USDHHS, in press). In addition to federal and state enforcement efforts, a number of local jurisdictions around the country have begun actively enforcing the law against tobacco sales to minors, and local ordinances can include a schedule of required compliance checks (Lynch and Bonnie 1994; Working Group of State Attorneys General 1994; Forster et al. 1996; DiFranza et al. 1998).

Compliance checks are most often carried out by having an underaged buyer, under the supervision of a law enforcement officer, licensing official, or some other designated adult, attempt to purchase tobacco. In jurisdictions where the minor is held legally at fault if a purchase is made (and where no exceptions are made for compliance checks), minors participating in compliance checks are sometimes instructed not to complete the purchase even if the salesperson is willing; in these cases, the retailer is considered to be in noncompliance with the youth access law if the purchase is entered into the cash register (Hoppock and Houston 1990; Cummings et al. 1996).

Several innovative civil enforcement approaches have been attempted in California. The district attorneys in Sonoma and Napa Counties have used the California Business and Professions Code section 17200 to file civil lawsuits against store owners whose outlets repeatedly sold tobacco to minors. Civil enforcement has proved to be more efficient than criminal citations and has resulted in fines and penalties as well as reductions in tobacco sales to minors (Kropp and Kuh 1994).

Increased emphasis on enforcement, coupled with passage of laws against possession of tobacco by minors, may result in enforcement resources being selectively funneled to apprehending underaged smokers rather than penalizing the merchants who sell tobacco to these minors. A survey of 222 police chiefs in Minnesota revealed that although more than 90 percent were enforcing the law against minors' possession, 40 percent reported applying penalties to minors, and only 6 percent reported any enforcement against merchants (Forster et al. 1996).

A vigorous and multidimensional campaign has been mounted by the tobacco industry and its allies to prevent or undermine effective enforcement of minors' access laws and to resist the proposal that retailers be held accountable for their stores' compliance. Since 1992, laws sponsored by the tobacco industry but ostensibly intended to bring states into compliance with requirements of the Synar Amendment have been passed in Georgia, Idaho, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Dakota, and Tennessee (DiFranza 1994c; DiFranza and Godshall 1994). Tobacco industry representatives and their allies have lobbied successfully for the inclusion of language such as "knowingly" or "intentionally" in the law prohibiting sale of tobacco to minors; the impact of such language may be to render the law unenforceable. Industry interests have sought to include various restrictions on how, how often, and by whom enforcement or compliance testing can be conducted. Examples of these restrictions include opposing employing teens in compliance testing or requiring that only very young teens can function as buyers, insisting that enforcement be done only by the alcohol control authority or some other state agency, opposing compliance checks carried out by advocacy groups or for public health research, and opposing requirements that compliance checks occur on a specified schedule. The industry has further proposed immediate reentry and confrontation after an illicit sale—a procedure that could compromise collecting evidence. Industry representatives have also consistently maintained that merchants ought not to be responsible for the costs incurred in complying with minimum-age

Table 5.4. Agencies responsible for enforcing state laws on minimum age for tobacco sales as of fiscal year 1998

State/Territory	Lead agency	Enforcement agency
Alabama	Alcoholic Beverage Control Board	Alcoholic Beverage Control Board
Alaska	Department of Health and Social Services, Division of Alcoholism and Drug Abuse	Attorney General's Office
Arizona	Department of Health Services, Office of Substance Abuse and General Mental Health	Department of Health Services, Office of Substance Abuse and General Mental Health
Arkansas	Department of Health, Bureau of Alcohol and Drug Abuse Prevention	Tobacco Control Board
California	Department of Health Services	Department of Health Services
Colorado	Department of Human Services, Alcohol and Drug Abuse Division	State and local law enforcement
Connecticut	Department of Mental Health and Social Services, Office of Addiction Services	Department of Revenue Services
Delaware	Department of Public Safety, Alcoholic Beverage Control Commission	Department of Public Safety, Alcoholic Beverage Control Commission
District of Columbia	Department of Human Services, Addiction Prevention and Recovery Administration	Department of Consumer and Regulatory Affairs and the Metropolitan Police Department
Florida	Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco	Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco
Georgia	Department of Public Safety	Department of Public Safety
Hawaii	Department of Health, Alcohol and Drug Abuse Division	Department of Health with Department of the Attorney General
Idaho	Department of Health and Welfare, FACS Division, Bureau of Mental Health and Substance Services	Department of Health and Welfare, FACS Division, Bureau of Mental Health and Substance Services
Illinois	Liquor Control Commission	No one agency responsible for enforcement
Indiana	Family and Social Services Administration, Division of Mental Health	Indiana Alcoholic Beverage Commission Excise Police
Iowa	Department of Public Health, Division of Substance Abuse and Health Promotion	Department of Public Health, Division of Substance Abuse and Health Promotion
Kansas	Department of Social and Rehabilitation Services, Alcohol and Drug Abuse Services	Department of Revenue, Alcoholic Beverage Control Board
Kentucky	Department of Alcoholic Beverage Control	Department of Agriculture (specified state law) with the Department of Alcoholic Beverage Control (appointed)

Source: U.S. Department of Health and Human Services, in press.

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency
Louisiana	Department of Revenue and Taxation, Office of Alcoholic Beverage and Tobacco Control	Department of Revenue and Taxation, Office of Alcoholic Beverage and Tobacco Control
Maine	Department of Mental Health and Mental Retardation, Office of Substance Abuse	Department of Mental Health and Mental Retardation, Office of Substance Abuse
Maryland	Department of Health and Mental Hygiene, Alcohol and Drug Abuse Administration	State Comptroller's Office
Massachusetts	Department of Public Health, Bureau of Substance Abuse Services	Department of Public Health, Tobacco Control Program with the Attorney General's Office
Michigan	Department of Community Health, Bureau of Substance Abuse Services	Department of Community Health, Bureau of Substance Abuse Services
Minnesota	Department of Human Services, Chemical Dependency Program Division	Department of Human Services, Chemical Dependency Program Division
Mississippi	Department of Mental Health, Division of Alcohol and Drug Abuse	Office of Attorney General
Missouri	Department of Mental Health, Division of Alcohol and Drug Abuse	Department of Mental Health, Division of Alcohol and Drug Abuse
Montana	Department of Public Health and Human Services, Division of Addictive and Mental Disorders	Department of Public Health and Human Services, Division of Addictive and Mental Disorders
Nebraska	Department of Health and Human Services	Nebraska State Patrol
Nevada	Attorney General of the State of Nevada	State Attorney General
New Hampshire	Department of Health and Human Services, Bureau of Substance Abuse Services	Department of Health and Human Services, Bureau of Substance Abuse Services
New Jersey	Department of Health and Senior Services	Department of Health and Senior Services with local health agencies
New Mexico	Department of Regulation and Licensing, Alcohol and Gaming Division	Department of Regulation and Licensing, Alcohol and Gaming Division (statutory), Department of Health and Department of Public Safety (by executive order)
New York	Department of Health, Office of Alcoholism and Substance Abuse Services	37 local county health units and 10 district offices of the state's Department of Health
North Carolina	Department of Human Resources, Division of Mental Health, Developmental Disabilities and Substance Abuse Services	Local police and sheriff's departments
North Dakota	Department of Human Services, Division of Mental Health and Substance Abuse Services	State and local law enforcement agencies are responsible for enforcing state and local laws prohibiting tobacco sales to minors. The Department of Human Services, Division of Mental Health and Substance Abuse Services, is responsible for conducting compliance surveys.

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency
Ohio	Department of Alcohol and Drug Addiction Services	Department of Alcohol and Drug Addiction Services
Oklahoma	Alcoholic Beverage Law Enforcement Commission	Alcoholic Beverage Law Enforcement Commission
Oregon	Department of Human Resources, Office of Alcohol and Drug Abuse Programs	Oregon State Police
Pennsylvania	Department of Health, Office of Alcohol and Drug Abuse Programs	Department of Health, Office of Alcohol and Drug Abuse Programs
Rhode Island	Department of Health, Division of Substance Abuse	Department of Health, Division of Substance Abuse (The Division of Substance Abuse transferred from the Rhode Island Department of Health to the Department of Mental Health, Retardation, and Hospitals on September 1, 1998.)
South Carolina	Department of Alcohol and Other Drug Abuse Services	Department of Revenue and Taxation
South Dakota	Department of Human Services, Division of Alcohol and Drug Abuse	Division of Alcohol and Drug Abuse coordinates enforcement with the Attorney General's Office and 66 county state's attorneys
Tennessee	Department of Agriculture	Department of Agriculture
Texas	Commission on Alcohol and Drug Abuse and Department of Health	State Comptroller
Utah	Department of Human Services, Division of Substance Abuse	Department of Human Services, Division of Substance Abuse
Vermont	Department of Liquor Control	Enforcement and Licensing Division of the Department of Liquor Control
Virginia	Department of Agriculture and Consumer Services	Alcohol Beverage Control Board
Washington	Department of Social and Health Services, Division of Alcohol and Substance Abuse	Liquor Control Board
West Virginia	Department of Health and Human Resources, Division of Alcoholism and Drug Abuse	Alcohol Beverage Administration
Wisconsin	Department of Health and Family Services, Bureau of Substance Abuse Services	Department of Health and Family Services, Bureau of Substance Abuse Services
Wyoming	Department of Health, Division of Behavioral Health and Substance Abuse Program	Local law enforcement agencies
American Samoa	Department of Human and Social Services, Social Services Division	Department of Public Health
Guam	Department of Mental Health and Substance Abuse	Department of Mental Health and Substance Abuse
Marshall Islands	Office of the Attorney General	Chief Prosecutor of the Office of the Police Commissioner

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency
Micronesia	Department of Health	No single agency; enforcement by local police and health departments
Northern Marianas	Department of Public Health	Department of Public Health
Palau	Ministry of Justice, Bureau of Public Safety with Ministry of Commerce and Trade (responsible for licensing)	Bureau of Public Safety
Puerto Rico	Department of Health, Mental Health and Anti-Addiction Services Administration	Department of Treasury
Virgin Islands	Department of Health, Division of Mental Health, Alcoholism and Drug Dependency Services	Department of Licensing and Consumer Affairs

laws, such as the costs of making tobacco inaccessible to minors or of having merchants monitor their own staff (DiFranza 1994c; DiFranza and Godshall 1994). Despite, or in some cases in response to, these industry efforts, many states have successfully strengthened their youth access laws and/or removed industry-inspired loopholes and provisions for affirmative defense. Six states amended state law to permit minors to participate in compliance checks conducted for enforcement purposes. Twenty-three states now have this provision in their minors' access law. Two states passed legislation that will provide a more accurate list of tobacco retailers for compliance checks and three states added provisions that address funding for enforcement and education programs (USDHHS, in press).

The reports from both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) include strong recommendations that active enforcement of minors' access laws be implemented, that merchants be held responsible for sales in their stores, and that access laws supported by the tobacco industry be rejected.

Using another type of enforcement, some private groups and states have conducted lawsuits against commercial outlets that violate minors' access laws. A selection of these cases, one of which also named a tobacco company as a codefendant, is discussed in "Enhancing Prohibitory Regulation by Private Litigation," later in this chapter.

Traditional law enforcement agencies often resist conducting tobacco enforcement for a number of reasons. They believe that tobacco enforcement diverts limited resources from other more pressing crime and that the public does not support the use of officers for such enforcement. They have also argued that the ill-feeling of members of the business community generated by the issuance of citations negatively affects other enforcement efforts. Finally, the officers themselves frequently resist because they do not want to facilitate potential job loss for a clerk for what they perceive to be a "minor" infraction or because they believe that prosecutors and judges will be reluctant to penalize (USDHHS 1999).

Other agencies can be a suitable alternative for the conduct of enforcement. Chief among them are public health departments, which recognize the importance of conducting enforcement, and alcohol beverage control agencies (ABCs), which are highly experienced in conducting undercover compliance checks. ABCs retain a staff of inspectors that are familiar with the protocols that may be employed during retail inspections (i.e., consummated and unconsummated buys). ABCs also tend to recognize a connection between alcohol and tobacco enforcement and accept the importance of conducting tobacco inspection for practical reasons if not for health reasons. This, in turn, results in less of a philosophical resistance to actually issuing citations for violations. Finally, because ABC authorities regularly engage in enforcement directed at retailers, tobacco enforcement conducted by this agency will not likely generate as negative a backlash from retailers and the general public as enforcement conducted by traditional law enforcement (USDHHS 1999).

State Settlements

All four states that settled their lawsuits against the tobacco industry in 1997–1998 won youth access restrictions in their settlement agreements. (The events leading up to these four settlements, along with their implications as a litigational tool for reducing tobacco use nationwide, are discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter.) For example, the tobacco industry defendants in the state of Florida case agreed to support new state laws or regulations to prohibit the sale of cigarettes in vending machines, except in adult-only locations or facilities (*Florida v. American Tobacco Co.*, Civil Action No. 95-1466 AH, sec. II.A.2 [Fla., Palm Beach Cty. Aug. 25, 1997]). The industry also agreed to support new state laws in Florida to increase civil penalties for sales of tobacco products to minors (including retail license suspension or revocation) and to strengthen civil penalties for the possession of tobacco by minors. The Florida settlement (sec. II.B) further requires the tobacco industry to pay $200 million for a two-year pilot program to reduce tobacco use by minors, including enforcement, media, educational, and other youth-directed programs. Youth access provisions of the Texas settlement that pertain to new state laws mirror the terms of the Florida agreement (*Texas v. American Tobacco Co.*, No. 5-96CV-91 [E.D. Tex. Jan. 16, 1998], secs. 7[a–c]).

The state of Minnesota won the most comprehensive array of public health and youth access restrictions to date when it settled its case after a highly publicized trial in 1998 (*Minnesota v. Philip Morris Inc.*, *cited in* 13.2 TPLR 3.39). One provision of the Minnesota settlement forbids tobacco manufacturers from directly or indirectly opposing state statutes or regulations intended to reduce tobacco use by minors. A list of legislative proposals covered by the prohibition is attached to the settlement agreement (Schedule B) and includes the following measures:

- Expansion of self-service restrictions and removal of the current exception for cigars.
- Amendment of the current law for restricting youth access to vending machines to clarify that machines with automatic locks and machines that use tokens are covered.
- "Enhanced or coordinated funding" for enforcement efforts under sales-to-minors provisions of the criminal code or the statute and ordinances involving youth access.
- Laws to "encourage or support the use of technology to increase the effectiveness of age-of-purchase laws" (e.g., programmable scanners or scanners to read drivers' licenses).
- Restrictions on wearing, carrying, or displaying tobacco indicia in school-related settings.
- Establishment or enhancement of nonmonetary incentives for youth not to smoke (e.g., expand community services programs for youth).

Moreover, prohibiting tobacco companies from challenging the enforceability or constitutionality of current Minnesota laws encompasses some key youth access statutes, such as those pertaining to the sale of tobacco to minors (Minnesota Statutes sec. 609.685) and the distribution of samples (Minnesota Statutes sec. 325.77) (*Minnesota v. Philip Morris Inc., cited in* 13.2 TPLR 3.39, sec. IV.A.2). Another injunctive provision, forbidding the tobacco industry from targeting children through advertising, promotion, or marketing, also prohibits the industry from "taking any action the primary purpose of which is to initiate, maintain or increase the incidence of underage smoking in Minnesota" (*Minnesota v. Philip Morris Inc.*, No. C1-94-8565 [Minn., Ramsey Cty. May 8, 1998], *cited in* 13.2 TPLR 2.112, 2.113 [1998]).

The Minnesota settlement also includes a large industry-funded program to reduce teen smoking. The program includes counteradvertising, classroom education, community partnerships, research, advocacy, and prevention components (*Minnesota v. Philip Morris Inc.*, *cited in* 13.2 TPLR 3.39, sec. VIII.A.2).

Although Mississippi (the first state to settle) did not initially secure public health restrictions, it later imported some of those contained in the sweeping Minnesota settlement by exercising the "most favored nation" clause (discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter) in its original settlement agreement (PR Newswire 1998a). Intended to ensure that Mississippi would receive the benefits any later similar settlement might receive, the most favored nation clause also enabled the state to substantially increase the dollar amount of its settlement with the industry. Furthermore, although the revised agreement prohibits Mississippi from gaining any additional monetary benefit based on future state settlements, it does not limit the incorporation of additional public health provisions or financial adjustments in the event that Congress adopts national tobacco legislation.

Preemption of Local Action by State Policy

As noted earlier in this section (see "Efforts to Promote Adoption and Enforcement of Minors' Access Laws"), the initiative to address minors' access, as well as many creative solutions, has come from the local level. In state legislatures, the balance of power between forces for and against reducing tobacco use is most often tipped in favor of tobacco use. The reverse is often true at the local level, where jurisdictions have enacted innovative approaches that have been evaluated by researchers. At the state level, however, tobacco industry representatives have sought to preclude legislative or enforcement authority at the local level by including preemption language, usually attached to weak statewide restrictions.

As of 1998, 30 states had preemptive tobacco control laws, although they vary widely in the kind of restrictions they preempt (CDC 1999). No preemptive tobacco control laws have been enacted since July 1996. The tobacco industry has adopted preemption as a main strategy to undermine, overturn, and prohibit future efforts to adopt local policies to reduce tobacco use (Siegel et al. 1997; Gorovitz et al. 1998). For instance, in 1991 and 1992, the tobacco industry spent more than $2 million to lobby for the repeal of local clean indoor air ordinances (Traynor et al. 1993). In California in one year alone, the industry spent $18.9 million on an initiative to repeal all local ordinances for reducing tobacco use and to eliminate local authority to enact new ordinances (Siegel et al. 1997).

A memorandum of the 1991 Smokeless Tobacco Council described a strategy to oppose local ordinances and advance statewide antitobacco bills containing preemption clauses (Siegel et al. 1997). In addition, the Tobacco Institute stated that a priority for 1993 was to "encourage and support statewide legislation preempting local laws, including smoking, advertising, sales, and vending restrictions" (Tobacco Institute 1992). This strategy would work against the passage of strong tobacco control laws at the local level and would relieve logistical difficulties of the tobacco industry in devoting resources toward multiple local jurisdictions (Siegel et al. 1997; Gorovitz et al. 1998).

Even when a preemption clause is not specifically included, tobacco industry representatives have argued that state laws that address minors' access are intended to preempt local action, and that argument has been used by at least one court to invalidate more restrictive local ordinances (DiFranza 1993). Both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) recommend that state laws include language specifically stating that they are not meant to preempt stronger local ordinances.

One of the U.S. health objectives for 2000 was to reduce to zero the number of states with preemptive smoke-free indoor air laws (Objective 3.25) (National Center for Health Statistics 1997); an objective proposed for 2010 is to reduce the number of states with any preemptive tobacco control laws to zero (USDHHS 2000a). Most states have preemptive tobacco control laws, and 19 have preemptive provisions for minors' access laws. Thus, achievement of the 2000 objective is unlikely (CDC 1999).

Litigation Approaches

Introduction

Society deploys various regulatory controls to confront risks arising from dangerous products or practices. As has been discussed in previous sections in this chapter, these controls include those intrinsic to the practice itself, such as preventive design and safety procedures built into a product or into the technology of its use, as well as external regulation by government agencies and private parties, such as property owners, employers, or insurers. Certain institutions also absorb and spread losses when a practice does result in injuries, such as relief institutions that assist victims and social and private insurance that compensates the injured. Another regulatory control, introduced here, is private law (referred to generally in this section as litigation and held distinct from the more sweeping legislative scope of public law). In the course of vindicating the claims of injured persons, private law generates, broadcasts, and reinforces safety standards. The various controls are not independent but interact in complex ways. For example, preventive design may stem from the imposition or anticipation either of government regulation or of liability

established through private law; similarly, employers or insurers may institute preventive regulations to limit the cost of remedial measures resulting from private law decisions.

Private Law as a Means of Risk Control

Private law remedies combine existing public standards with a public institution—the courts—that is passive in accepting these standards but is also, accordingly, reactive when the standards change. In private law, the initiative to enforce a change or decision is shifted away from an enterprise or a government to private actors—typically, victims or their surrogates. This diffusion of the enforcement initiative is matched by the decentralized pronouncement of liability standards, which are less often established at a given moment than they are formulated over time, largely by courts responding incrementally to specific cases brought before them. Private law standards are context sensitive, incorporating changing popular values and understandings. In the United States, this incorporation of popular views is accelerated by the use of civil juries.

Tort as a Private Law Control

In the tort system, which applies to actionable wrongful acts other than breach of contract (*tort* is a Middle English word meaning "injury"), information about instances in which injurers (and their insurers) are forced to compensate victims coalesces slowly into a body of knowledge that, acknowledged by other potential injurers, generates various preventive effects (Calabresi 1970). However, because each instance of remedy involves individualized determination of liability and damages, the production of these preventive effects by the tort system is highly inefficient. The process is also very expensive, because a large portion of the money that the tort system extracts from injurers is consumed by the tort process itself (Kakalik and Pace 1986). Nonetheless, although relatively inefficient for compensating specific classes of injuries, the tort system effectively generates overall preventive effects and is flexible and adaptive (American Law Institute 1991; Galanter 1994).

U.S. Reliance on Private Law Controls

Societies differ in the way they deploy this alternative set of controls. The United States has tended to rely more heavily on private law controls than do other industrialized countries (Kagan 1991; Galanter 1994). The expansive U.S. system of private remedy is conjoined with a lesser emphasis on administrative controls and social insurance (Pfennigstorf and Gifford 1991).

Where excessive risks are associated with a product or practice, the U.S. tort system typically acts to shift part of the cost of these risks back to the producers and users. Such litigation campaigns follow a familiar course toward preventing particular risks: after a period of innovation and experimentation, a few successful lawsuits provide a model and incentive for other lawyers and plaintiffs; the threat of a mounting tide of litigation (and occasionally an actual tide) leads to a flow of compensation, modifications in the use or design of the product, and occasionally bankruptcy of the defendant; and eventually the litigation abates as product modifications break the link to risk (McGovern 1986; Galanter 1990; Sanders 1992; Hensler and Peterson 1993; Durkin and Felstiner 1994; Schmit 1994).

Potential Public Health Benefits of Tobacco Litigation

As applied to lawsuits against the tobacco industry, private litigation has the potential to do the following:

- Enlist a new cadre of skilled, resourceful, and relentless advocates on the side of reducing tobacco use—the incentive being the contingency fees plaintiffs' attorneys would receive if they won or settled cases against the industry.
- Force the industry to raise prices dramatically to cover their actual or anticipated liabilities. Studies suggest that such higher costs would lower tobacco consumption—especially among children and teenagers, who are more price-sensitive than adults (Daynard 1988; Hanson and Logue 1998). For example, after Philip Morris raised its wholesale cigarette prices by 10 percent in one year to cover legal settlements with four states, a Wall Street stock analyst estimated that these increases reduced overall consumption of [Philip Morris] cigarettes by nearly 3 percent (Hwang 1998).
- Encourage the manufacture of safer (to the extent possible) products, which have lower liability risks. For instance, a noncarcinogenic nicotine delivery device, though retaining the health risks of nicotine, could create less liability both to individual users and to third-party health care payers.
- Discontinue dishonest practices that increase the risk of liability, especially for punitive damages.

Deterring such "intentional torts" is a main goal of the civil justice system.

- Delegitimize the industry politically by exposing patterns of unsavory practices. For example, many politicians discontinued taking tobacco company contributions in the late 1990s, largely because the discovery process in pending lawsuits revealed industry misconduct (Abramson 1998). Loss of political esteem or loyalty would ease the way for effective tobacco control legislation.
- Educate the public about the risks of tobacco use, since lawsuits attract extensive, free media coverage.
- Compensate injured parties, including smokers, afflicted nonsmokers, their families, and the health care compensation system (Daynard 1988).

The First Two Waves of Tobacco Litigation

Starting in the 1950s, injured smokers tried to use the emergence of product liability to secure remedies from the tobacco companies. During the first two waves of tobacco litigation, hundreds of lawsuits were filed against U.S. tobacco companies by individuals claiming tobacco-related injuries to health. (By one count, 808 cases were filed between 1954 and 1984 [Bernstein Research 1994].) Not one of the claims resulted in any plaintiff, or plaintiff's attorney, receiving any financial compensation.

The First Wave

The first wave of tobacco litigation was launched in 1954, inspired by the appearance in the early 1950s of scientific reports and popular magazine articles that indicated that smoking caused lung cancer. Although convinced that this new information would weigh in as evidence of culpability, the plaintiffs' attorneys were overmatched. The tobacco companies presented a concerted defense in every claim, no matter how small the damages sought, and through all stages of litigation. From the earliest cases, the tobacco companies retained lawyers from the country's most prestigious law firms and directed them to spare no expense in exhausting their adversaries' resources before trial (Rabin 1993). Plaintiffs' attorneys, typically operating from small practices under a contingent fee arrangement with clients who could not afford protracted litigation, found themselves both outnumbered and outspent on all fronts.

Only a handful of the first-wave tobacco cases ever came to trial. Those that did found the courts unwilling to impose strict liability on the tobacco industry. Plaintiffs typically brought suit against tobacco companies under one or both of two theories: negligence and implied warranty. Under a theory of negligence, plaintiffs tried to show that the tobacco companies knew enough about the potential harm of tobacco products to induce them to "engage in [further] research . . . adopt warnings, or, at a minimum, refrain from advertising that suggested the absence of any health concerns" (Rabin 1993, p. 114). However, because plaintiffs' attorneys could offer no evidence at that time that the tobacco industry was aware of the potential harm of their products, this negligence theory met with failure.

Most plaintiffs' cases relied on the theory of implied warranty, which imputes strict liability even in the absence of negligence. The mere marketing of a product that was not of merchantable quality or reasonably fit for use would thus support legal recovery of damages (Rabin 1993). The plaintiff's ability to rely on negligence or implied or express warranty was greatly constrained by two circumstances: since 1965, health warnings had been mandated on tobacco products and on some advertising (see "Cigarette Warning Labels," earlier in this chapter), and the tobacco industry had avoided making direct claims that their products had positive health effects. Since early 1966, then, smokers could no longer argue (or at least not easily) that the tobacco companies had not warned them of the hazards posed in using their products (Schwartz 1993). The doctrine of implied warranty, in particular, thus seemed invalid to plaintiffs who were seeking damages from the tobacco industry.

In general, the courts of that time were unreceptive to strict liability arguments. The courts regarded the manufacturer as "an insurer against foreseeable risks—but not against unknowable risks" (*Lartigue v. R.J. Reynolds Tobacco Co.*, 317 F.2d 19, 37 [5th Cir. 1963], *cert. denied*, 375 U.S. 865 [1963]) or against "the harmful effects of which no developed human skill or foresight can afford" (p. 23). The American Law Institute, a prestigious and influential association of lawyers, judges, and academics, adopted this outlook in its 1973 commentary on section 402A of the Restatement (Second) of Torts, which deals with strict liability for defective products. The nonbinding yet authoritative influence of the restatement sounded "the death knell for the first wave of tobacco litigation" (Rabin 1993, p. 117; Givelber 1998).

The Second Wave

A second wave of tobacco litigation began in 1983, inspired by the success that lawyers had recently achieved in suing asbestos companies: they had not only recovered substantial verdicts (and fees) but also effectively ended the production and use of asbestos in the United States.

As was the case with the first wave of tobacco litigation, in the second wave the "lawyers' litigation strategies rather than their legal arguments . . . constituted the first line of defense" (Rabin 1993, p. 121). The tobacco industry continued to successfully pursue the strategy it had developed during the first wave, taking countless depositions and filing and arguing every motion it could, thus threatening to inflict heavy financial losses on any plaintiff's attorney (Daynard 1994a,b). This strategy was summarized by J. Michael Jordan, an attorney who successfully defended R.J. Reynolds Tobacco Company in the 1980s, in an internal memo to his colleagues: "[T]he aggressive posture we have taken regarding depositions and discovery in general continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers. . . . To paraphrase General Patton, the way we won these cases was not by spending all of [RJR]'s money, but by making that other son of a bitch spend all of his" (*Haines v. Liggett Group, Inc.*, 814 F. Supp. 414, 421 [D.N.J. 1993]).

To try to overcome the disparity of legal resources that had overwhelmed the first-wave cases, plaintiffs' attorneys sometimes pooled resources on a case-by-case basis. The Tobacco Products Liability Project, a nonprofit advocacy group established at Northeastern University in 1984 to encourage lawsuits against the tobacco industry as a public health strategy, served as a clearinghouse of relevant information for attorneys, potential plaintiffs, medical experts, and the media. It began holding annual conferences in 1985, at which participants share information about new legal tactics, as well as solve problems about emerging difficulties.

Besides pooling resources and sharing strategies, plaintiffs' attorneys needed to find an effective legal strategy. To find a new theory, plaintiffs' counsel shifted their focus from implied or express warranty to strict liability, which became a more attractive strategy as courts applied strict liability and comparative fault principles to defective product cases concerning many other products (Edell 1987; Rabin 1993). Smokers' awareness of risks and, accordingly, their "freedom of choice" (Rabin 1993, p. 122) became the linchpins of the tobacco industry's defense against these liability tactics. Though consistently denying the reality of the risks, the tobacco industry paradoxically argued (with great success) that smokers had freely chosen to smoke and had thereby assumed what risks there might be of smoking and had negligently contributed to their own harm. To prove the plaintiff's assumption of risk, counsel for the tobacco industry generally needed to show that the injured smoker, knowing the dangers and risks involved in smoking, chose to smoke anyway. To prove contributory negligence, the tobacco defense typically showed that, by smoking, the injured smoker breached a personal duty to protect himself or herself from injury and thereby contributed to the harm suffered (Kelder and Daynard 1997).

Just as it had aided the tobacco industry in negating charges of negligence and warranty during the first wave of tobacco litigation, the Federal Cigarette Labeling and Advertising Act's imposition of a warning label on cigarette packaging and advertising greatly strengthened the industry's countercharge that plaintiffs had legally assumed their own health risk and were guilty of contributory negligence. As a result, jurors were responsive to the industry's defense. In essence, jurors tended to blame plaintiffs for their disease instead of identifying the tobacco industry as the makers of the product that caused the disease (Daynard 1994a,b). When counsel for plaintiffs pointed to the addictive nature of tobacco, which arguably limited the smoker's ability to make a free choice, defense counsel rebutted by pointing to the large number of former smokers who successfully quit (Rabin 1993).

Taking the freedom-of-choice defense one step further, defense counsel typically drew on, and presented to the jury, information demonstrating that the claimant's lifestyle was overly risky by choice or was even in some way immoral. By presenting this somewhat extraneous material obtained through aggressive pretrial discovery, the defense "appear[ed] to have had considerable success in trying not just the plaintiff's decision to smoke but his or her character more generally" (Rabin 1993, p. 124). The resulting "full-dress morality play" seemed to have effectively negated any jury sympathy for the plaintiff's plight (p. 124).

The case that culminated and best symbolized the uphill battle of second-wave plaintiffs was filed by Rose Cipollone, a dying smoker, in 1983. The case reached the jury in 1988, four years after her death, and the jury awarded the plaintiffs $400,000. But this verdict, subsequently overturned on appeal, was only one moment in a protracted legal battle. As one analyst describes, in *Cipollone v. Liggett Group Inc.*, ". . . over 100 motions were filed, and most of the motions were argued. There were also four interlocutory applications, one resulting in the grant of an appeal and the Third

Circuit's initial decision on preemption, . . . an appeal from the final judgment to the Court of Appeals following a trial of about four months, . . . and two petitions for *certiorari* to the Supreme Court of the United States, one of which was granted resulting in the historic argument before that Court" (Kelder 1994, p. 4).

After nearly a decade, *Cipollone*, the quintessential second-wave case, was sent back to the trial court by the United States Supreme Court. The Court ruled that although the Federal Cigarette Labeling and Advertising Act of 1965 did not invalidate any claims in private litigation, its successor, the Public Health Cigarette Smoking Act of 1969, preempted any claims based on the manufacturers' failure to warn after 1969 in its advertising and promotions (*Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 112 S. Ct. 2608 [1992]). However, the Court left open to the plaintiff the option of proceeding under a wide range of legal theories, including theories of breach of express warranty, defective design, fraudulent misrepresentation, and conspiracy to defraud. But the difficulties of mustering a sufficient showing that such violations by the defendants were the proximate cause of Mrs. Cipollone's injuries (as well as the cause of her death in 1984) persuaded the plaintiff's counsel that there was little likelihood of a significant recovery (Lowell 1992). In 1992, five months after the Supreme Court ruling, the New Jersey federal district court approved the request of the Cipollone estate's lawyer to withdraw from the case.

It had been a lengthy, expensive effort for the plaintiff's counsel: $500,000 in out-of-pocket expenses and approximately $2 million in attorney and paralegal time (Kelder 1994). Posttrial proceedings cost an additional $150,000 in out-of-pocket expenses and $900,000 in attorney and paralegal time. *Time* magazine estimated that the cigarette industry spent at least $75 million defending the *Cipollone* case (Koepp 1988). Michael Pertschuk, co-director of the Advocacy Institute, a public interest group dedicated to reducing tobacco use, has estimated that altogether tobacco companies were spending approximately $600 million per year defending the 50 or so cases pending against them (Stone 1994). Tobacco defendants' reputation for relentless legal battle dissuaded many lawyers from entering the fray. Even formidable litigants such as the asbestos producers refrained from trying to embroil the tobacco manufacturers as being jointly responsible for asbestos injuries (Rabin 1993).

The Aftermath of the First Two Waves

The collapse of the *Cipollone* case was widely viewed as signaling the end of the second wave of tobacco litigation. Commentators advanced various explanations for the failure of tobacco litigation, including superior lawyering resources, coordination, and tactics (Rabin 1993), as well as popular resistance in the form of jury reluctance to award damages to smokers (Schwartz 1993). Many observers concluded that product liability litigation had a limited role to play in the regulation of tobacco. Rabin (1993) found that tobacco presents an instance of "the effective limits of tort law," because "tort law and tort process seem to conspire against any effective role for the tobacco litigant" (p. 127). Schwartz (1993) concurred "that tort law does not have a major role to play in the development of public policy for smoking in the 1990s" (p. 132).

At that juncture, tobacco litigation seemed to illustrate that the incidence and outcome of litigation are influenced by the identity, resources, and status of the parties and by the incentives and strategies of their lawyers. Striking differences have been noted between the large organization with a continuing interest in an area of legal controversy and the individual litigant who typically seeks a remedy only once (Galanter 1974). One-time litigants tend to be represented by lawyers who practice in smaller units that have less capacity for coordination and less capacity to invest strategically in litigation. The monetary stakes—and thus the incentives—are also lower for these smaller litigants than for their corporate opponents, who can extract full benefit from the information and experience generated by litigation expenditures (Galanter 1974; Schwartz 1993).

Nonetheless, at the end of the second wave of tobacco litigation, it was argued that the tobacco industry was not untouchable and that its proud record of never, at that point, having paid a penny to its victims masked a high vulnerability to litigation (Daynard 1988, 1993a,b, 1994a,b; Daynard and Morin 1988). The industry's "scorched earth" litigation tactics (Daynard 1994a) had indeed made suing tobacco companies prohibitively expensive for most plaintiffs and their attorneys. Also, the industry's firm and widely publicized policy of never settling cases further discouraged litigation, because plaintiffs' attorneys, working on contingency fees, realized that they could not expect to be paid unless and until they had succeeded at trial and on subsequent appeals. Furthermore, the low volume of cases in the first and second waves allowed the industry to concentrate its legal resources against the few plaintiffs' attorneys who ventured forth against it.

But a very different scenario was also possible. Although the low-volume litigation environment of the first and second waves favored the defendants, a high-volume environment might favor plaintiffs. As

happened with asbestos litigation, courts facing the problem of clearing large numbers of tobacco cases off their dockets would need to find ways to expedite them. Firm trial deadlines, case consolidations, and class actions would likely be favored; scorched earth defense tactics would no longer be permitted. Defendants would no longer be able to focus all their attention and legal resources on defeating a few plaintiffs. Some cases thus might break through the industry's defenses, and these victories would provide both practical examples and moral support for plaintiffs' attorneys. At some point, the defendants might realize that their nonsettlement policy had ceased to discourage plaintiffs and would begin settling. At that point, the third wave of tobacco litigation—virtually a tidal wave—would have begun (Daynard 1994a).

Given a pre-1994 legal environment characterized by a low volume of tobacco litigation, few lawyers could afford to ignore the highly unfavorable cost/benefit ratio that would likely meet any effort to bring a lawsuit against the tobacco industry. No single lawyer, however motivated, could hope to change this situation through his or her own efforts. The transition from the low-volume to the high-volume scenario would require public events that signaled clearly to lawyers that the environment was changing (Daynard 1994a).

Paradoxically, although the *Cipollone* case was widely viewed as emblematic of why plaintiffs' attorneys were well advised to avoid tobacco litigation, it was also a crucial forerunner for the events that would soon change the litigation environment. Specifically, the Supreme Court's 1992 decision in the case—though of no avail to the resource-depleted plaintiffs' attorneys—presented other plaintiffs' attorneys with a range of potentially devastating legal theories. The trial itself had provided documentary evidence—which, as it turned out, represented the tip of the iceberg—that could be used to help establish the elements of a plaintiff's claims against the cigarette manufacturers (Daynard and Morin 1988; Daynard 1993a,b).

Among the legal theories advanced in the first two waves that remained viable after *Cipollone* were (1) a theory that cigarettes were defective and unnecessarily dangerous, because evidence discovered by plaintiffs' attorneys and antismoking activists strongly suggested that the tobacco industry had known for many years how to make cigarettes that were less likely to cause cancer; (2) a theory that cigarettes were defective, because they contained tobacco adulterated with many nontobacco carcinogenic substances; (3) a theory that cigarettes were defective, because of the dangers inherent to tobacco; (4) a theory of civil conspiracy based on evidence that cigarette manufacturers had joined together beginning in the 1950s to plan and carry out a strategy for marketing cigarettes while concealing the harmful and addictive nature of this product in the face of the developing scientific evidence of their dangers; and (5) a "Good Samaritan" theory, whereby plaintiffs could argue that the tobacco companies, having pledged in 1954 to objectively investigate the possible dangers of smoking, were obliged to carry out their promise and take reasonable action on what they found (Daynard 1988).

Potential support for some or all of these approaches had surfaced during the tortuous process of the *Cipollone* case. Documents uncovered in the case provided evidence that the tobacco industry had fraudulently misrepresented the safety of their product and deliberately concealed knowledge about the harmful and addictive nature of cigarettes. The evidence suggested that the tobacco industry had conspired to defraud the American public by pretending that it was conducting good-faith efforts to uncover the links between smoking and health and by falsely assuring the public that the results were negative or inconclusive (Daynard and Morin 1988). Some analysts predicted that future fraud and conspiracy claims would be strengthened when the court documents from *Haines* were released to plaintiffs' attorneys or when other documentary evidence of tobacco industry misdeeds was uncovered (Daynard 1993a,b). In the additional trove of documents reviewed by Judge H. Lee Sarokin in *Haines*—many of them relating to the Council for Tobacco Research's "special projects" division—was information that might support a finding that "the industry research which might indict smoking as a cause of illness was diverted to secret research projects and that the publicized efforts were primarily directed at finding causes other than smoking for the illnesses being attributed to it" (*Haines v. Liggett Group, Inc.*, Civil No. 84-678 [HLS] [D.N.J. 1992], *cited in* 7.1 TPLR 2.1 [1992]). Calling the tobacco industry "the king of concealment and disinformation" (*Haines v. Liggett Group Inc.*, 975 F.2d 81, 88 [3d Cir. 1992])—a remark that led an appellate court to disqualify Judge Sarokin from further consideration of the case on the grounds that he failed to appear impartial (p. 98)—Judge Sarokin concluded that the documents he had reviewed were not protected by the attorney-client privilege, as the industry had claimed, because the industry's attorneys had been participating in an ongoing fraud, and the documents were therefore discoverable under the well-recognized crime/fraud exception (*Haines*, *cited in* 7.1 TPLR 2.1). The same court that disqualified Judge Sarokin from

further consideration of the case also agreed that the evidence cited by him would support his conclusion that the crime/fraud exception would apply (*Haines*, 975 F.2d 81).

The Third Wave of Tobacco Litigation

The third wave of tobacco litigation was sparked by two key events. On February 25, 1994, FDA Commissioner David Kessler, relying primarily on a document discovered in the *Cipollone* case, sent a letter to the CSH reporting that the FDA had received "mounting evidence" that "the nicotine ingredient in cigarettes is a powerfully addictive agent" and that "cigarette vendors control the levels of nicotine that satisfy this addiction" (Kessler 1994a). The letter made front-page news. The second event occurred three days later, when an ABC television *Day One* report alleged that tobacco companies manipulated the nicotine levels in cigarettes (Daynard 1994b).

A series of journalistic and congressional investigations ensued in the spring of 1994, and internal Brown & Williamson Tobacco Corporation documents were leaked to the press. These documents indicated that the company had studied nicotine for years, that its internal stance on several issues related to smoking and health differed from what it was telling the public, that it possessed findings regarding the addictiveness of nicotine and the health dangers of smoking and ETS that had been withheld, and that Brown & Williamson attorneys were involved in the management of the research projects (Hanauer et al. 1995). When on April 14, 1994, the chief executive officers of the seven leading U.S. tobacco companies testified under oath before a congressional subcommittee—and a large television news audience—that they did not believe that nicotine was addictive, the industry's public credibility plummeted. Suddenly the industry appeared to millions of people, including plaintiffs' attorneys, as dishonest, disreputable, and legally vulnerable (Daynard 1994a; *Seattle Post-Intelligencer* 1994; see "Nature, Extent, and Focus of the Criminal Investigation," later in this chapter).

Further revelations about the tobacco industry's knowledge of the harmfulness of smoking and the addictiveness of nicotine, as well as about the industry's misbehavior, subsequently surfaced in several forms:

- Philip Morris documents indicated that the company's researchers studied and wrote about the pharmacologic effects of nicotine on smokers (Hilts and Collins 1995).
- Documents obtained from Brown & Williamson and its parent, British-American Tobacco Company, were analyzed (Hanauer et al. 1995).
- Investigative journalists obtained documents from R.J. Reynolds Tobacco Company (Levy 1995).
- In November 1995, Dr. Jeffrey Wigand, Brown & Williamson's former vice president for research, testified under deposition (*Tobacco Products Litigation Reporter* 1995c).
- Sworn statements were given to the FDA (first made public on March 18, 1996) in which three former Philip Morris employees (Ian L. Uydess, Ph.D., a former associate senior scientist; Jerome Rivers, a shift manager at a cigarette manufacturing plant in Richmond, Virginia; and William A. Farone, Ph.D., the director of applied research at Philip Morris' tobacco unit) stated that Philip Morris not only believes it is in the nicotine delivery business but also controls nicotine levels in its brands (*Tobacco Products Litigation Reporter* 1996a,b,c).
- The FDA analyzed both the public evidence and the additional evidence that its investigators gathered about the tobacco industry's past and present knowledge of, and behavior toward, the addictive quality of the nicotine in its products (*Federal Register* 1995b).
- On March 20, 1997, Liggett Group Inc., the smallest domestic cigarette manufacturer, admitted that nicotine was addictive and that the industry had targeted minors. Liggett turned over incriminating industry documents to the attorneys general and class action attorneys whose cases the company had agreed to settle (*Attorneys General Settlement Agreement*, *cited in* 12.1 TPLR 3.1 [1997]).
- Beginning in 1997, first hundreds, then thousands, and finally millions of industry documents began to surface after being uncovered through the discovery process in litigation by the Minnesota attorney general and Blue Cross and Blue Shield. These documents began appearing on Internet Web sites of the Commerce Committee of the U.S. House of Representatives (http://www.house.gov/commerce), Minnesota Blue Cross and Blue Shield (http://www.mnbluecrosstobacco.com), and the Minnesota District Court (http://www.courts.state.mn.us/district). The analysis of these documents has only begun, but they appear to support a wide range of legal claims against the industry.

This third wave of tobacco litigation is more diverse than its predecessors, in part because of the new wealth of factual information available to plaintiffs' attorneys. The series of revelations described above has generated a new set of allegations. For example, the industry has consistently claimed that nicotine is not pharmacologically active, that it is not addictive, and that anyone who smokes makes a free choice to do so. But as was made clear by the FDA's 1995 Statement of Jurisdiction over cigarettes as drug-delivery devices; the documents of Philip Morris Companies Inc., Brown & Williamson–British-American Tobacco Company, and R.J. Reynolds Tobacco Company relating to nicotine; and the information being provided by whistle-blowers such as Jeffrey Wigand and Ian Uydess, the industry was well aware of the pharmacologically active, addictive, and harmful nature of its products and was not forthright with its customers, the public, and public authorities about these facts. There is also evidence that the industry understood its consumers' need for adequate nicotine to sustain their addictions and that the industry designed its products accordingly.

The tobacco industry also has claimed that there is no definitive proof that smoking causes diseases such as cancer and heart disease. Yet the discovered company documents show that by the 1960s various tobacco companies had proved in their own laboratories that cigarette tar causes cancer in laboratory animals (Daynard and Morin 1988; Hanauer et al. 1995). Finally, the industry has claimed that it is committed to determining the scientific truth about the health effects of tobacco by conducting internal investigations and by funding external research. However, the Brown & Williamson–British-American Tobacco Company documents indicate that rather than conducting objective scientific research, Brown & Williamson attorneys have been involved in selecting and disseminating information from internal as well as external scientific projects for decades. An example of the latter is the industry's misrepresenting the work of the Council for Tobacco Research as objective scientific research on smoking and health. All research findings from this council are sent through the industry's attorneys, thereby gaining the protection of attorney-client privilege and potentially enabling the industry to choose which findings it will release and how it will present those findings to the public. The potential for this practice was suggested when certain Brown & Williamson–British-American Tobacco Company documents were found to include directions for disposing of damaging documents held by the company's research department (Hanauer et al. 1995). This conduct by the industry arguably misled the public and caused them to buy tobacco products; it also deflates the free choice argument the tobacco industry has used to deter further government regulation of its products and to defend itself in products liability lawsuits (Hanauer et al. 1995).

The information outlined above has generated a host of claims put forward by plaintiffs in the third wave of tobacco litigation. Some of these are similar to claims raised in the first two waves but have a much fuller factual support. These common-law (judge-created) legal theories include fraud, fraudulent concealment, and negligent misrepresentation; negligence; negligent performance of a voluntary undertaking; breach of express and implied warranties; strict liability; and conspiracy. Other, statutory (statute-created) claims new to tobacco litigation include violation of consumer protection statutes, antitrust claims, unjust enrichment/indemnity, and civil violations that invoke prosecution under the federal Racketeer Influenced and Corrupt Organizations Act (Kelder and Daynard 1997).

Common-Law Claims

An illustrative use of currently available evidence to support a common-law legal theory of fraudulent misrepresentation is Count Five of the complaint filed in April 1998 by 21 Blue Cross and Blue Shield plans against the tobacco industry (*Blue Cross and Blue Shield of New Jersey v. Philip Morris* [E.D.N.Y. Apr. 29, 1998], *cited in* 13.2 TPLR 3.51 [1998]). Among the allegations listed in Count Five are the following (*Blue Cross and Blue Shield*, p. 3.95):

> 301. Defendants represented and promised to those who advance and protect the public health and provide or pay for health care and health care services that they would discover and disclose all material facts about the effects of cigarette smoking and other tobacco product use on human health, including addiction.
>
> 302. Defendants have made and continue to make representations, statements and promises about the safety of cigarettes, other tobacco products and nicotine in general and their effect on human health and addiction. Such representations, statements and promises were and remain materially false, incomplete and fraudulent at the time Defendants made them, and Defendants knew or had and continue to have reason to know of their falsity. Only Defendant Liggett has recently conceded that the nicotine in cigarettes is addictive;

Liggett made this admission for the first time only in March 1997.

303. In testimony before Congress in January 1998, executives of other Tobacco Companies tried to have it both ways concerning the question of addiction. They stated that they personally did not think nicotine was addictive, but conceded that under some definitions, it would be considered addictive.

304. In view of the documentary record establishing that the Tobacco Companies have known for years with certainty that nicotine is addictive, such testimony is dishonest and part of an on-going attempt to disseminate false and misleading information.

305. At all relevant times Defendants intentionally, willfully or recklessly misrepresented material facts about the human health hazards of tobacco use, including addiction, and the association of cigarette smoking and other tobacco product use with various diseases of the heart, lung and other vital organs.

306. Because of Defendants' secret internal research, Defendants' knowledge of the material facts about tobacco use, health and addiction was and is superior to the knowledge of the BC/BS [Blue Cross and Blue Shield] Plans' members who purchased, used and consumed the Tobacco Companies' cigarettes and other nicotine tobacco products. Defendants' knowledge of the material facts about tobacco use, health and addiction was and is also superior to that of the BC/BS Plans, which undertook to provide health care financing for their members. Public access to these facts is limited because such facts are exclusively within Defendants' control.

313. The BC/BS Plans reasonably and justifiably relied on Defendants' materially false, incomplete and misleading representations about tobacco use, health and addiction. As a result of such reliance, the BC/BS Plans did not take, or would have taken sooner, actions to minimize the losses resulting from tobacco-related injuries and diseases and to discourage and reduce cigarette and other nicotine product use and the costs associated therewith by the BC/BS Plans' members.

314. As a direct, foreseeable and proximate result of the foregoing conduct of Defendants, the BC/BS Plans have suffered damages through payments for the costs of medical care due to smoking.

315. As direct and proximate result of Defendants' fraudulent misrepresentations and nondisclosures, the BC/BS Plans have suffered and will continue to suffer substantial injuries and damages for which the BC/BS Plans are entitled to recovery, and for which Defendants are jointly and severally liable.

Statutory Claims

The newer claims include a variety of theories based on federal and state statutes. As with the common-law claims, these statute-based actions are illustrated in the April 1998 complaint that 21 Blue Cross and Blue Shield plans filed against the tobacco industry.

Consumer Protection

Consumer protection claims are based on state statutes, which vary somewhat from state to state but generally forbid unfair methods of competition and unfair or deceptive acts or practices in commerce. A typical set of consumer protection allegations is that of Blue Cross and Blue Shield of Florida (*Blue Cross and Blue Shield*, p. 3.102). It makes the following allegations:

378. In the conduct of trade or commerce, Defendants have engaged and do engage in unfair methods of competition, unconscionable acts or practices and unfair or deceptive acts or practices including but not limited to the following:

a. Intentionally, willfully and knowingly seeking to addict persons, including BC/BS Florida members and their children, to the use of hazardous cigarettes and other nicotine tobacco products, knowing that such addiction physically changes and damages smokers' brain structures and creates and constitutes a substantial unfair impediment or interference in the smokers' ability to choose whether to continue smoking, making the transaction no longer an arm's length one between an equally willing buyer and seller, which is similar to many other deceptive and/or unfair devices

and practices that affect bargaining power or relative information;

b. Targeting people with deceptive advertising by misrepresenting the characteristics, ingredients, uses or benefits of Defendants' tobacco products; and

c. Engaging for decades in a wide variety of misrepresentations and fraudulent concealment of material facts, directly or by implication, including but not limited to: (1) misrepresentations and fraudulent concealment of the addictive nature of nicotine and of the adverse health consequences of nicotine tobacco products; (2) misrepresentations and fraudulent concealment about Defendants' ability to manipulate and their practice of manipulating nicotine levels and the addictive qualities of nicotine tobacco products; (3) misrepresentations that the Defendants would provide the public and governmental authorities with objective, scientific information regarding cigarettes and other tobacco products; (4) fraudulent concealment of certain aspects of cigarettes and other tobacco products, including the availability of safer, less-addictive products as a substitute to cigarettes and other tobacco products; (5) causing a likelihood of confusion about the source, sponsorship, approval or certification of cigarettes and other tobacco products; (6) misrepresenting that nicotine tobacco products have sponsorship, approval, characteristics, ingredients or benefits that they do not have and that Defendants knew that they did not have; (7) misrepresenting that cigarettes and other tobacco products were of a particular quality or grade, when Defendants knew that they were not; (8) engaging in unconscionable trade practices; (9) fraudulently promoting filter and low-tar cigarettes as safer; (10) fraudulently manipulating scientific research into the health hazards of smoking; and (11) fraudulently creating their "research councils" and using them to spread false information about their products and to promote false information that cigarettes or other tobacco products were safe or that adverse health effects had not been established.

379. The conduct described above and throughout this Complaint constitutes deceptive and unfair methods of competition, unconscionable acts or practices and unfair or deceptive acts or practices all impacting the public interest, in violation of Fla. Stat. § [section] 501.204.

380. As a direct and proximate result of such wrongful activity, BC/BS Florida has suffered losses and will continue to suffer substantial losses and injuries to its business or property, including but not limited to its being required to pay and paying the costs of medical care for disease, illness, addiction and adverse health consequences caused by cigarettes and other tobacco products.

Antitrust

The federal government and most states have antitrust laws. These are designed to prevent businesses in the same industry from cooperating in ways that deprive consumers or other entities of benefits they would otherwise receive from a competitive marketplace.

Count Three of the complaint by the 21 Blue Cross and Blue Shield plans explains how antitrust theory applies in a tobacco case (*Blue Cross and Blue Shield*, p. 3.93):

281. Since the early 1950s, and continuing until the present date, the Defendant Tobacco Companies, aided and abetted by the other Defendants herein, have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by entering into, adhering to and continuing to observe the terms of a combination or conspiracy in unreasonable restraint of trade and commerce in the market for cigarettes in the United States. Such illegal concerted action has eliminated commercial competition that would have existed but for the conspiracy. Specifically, Defendants have conspired: (1) to suppress innovation and competition in product quality by agreeing not to engage in research, development, manufacture and marketing of less harmful cigarettes and other nicotine products; (2) to suppress output in a market, and to engage in concerted refusal to deal, by agreeing to keep at zero the output of less harmful cigarettes and other nicotine products; and (3) to suppress competition in marketing by agreeing not to take business from one another by making claims as to the relative safety of particular brands, whether or not such claims would have been truthful. But for the conspiracy, competition in the market for cigarettes in the United States would have been far more

vigorous, and consumers and others would have reaped enormous benefits.

282. But for the conspiracy, one or more of the Tobacco Companies would have developed a commercially successful, less harmful cigarette; such a cigarette would have garnered a substantial share of the cigarette market; and those who used that product rather than conventional cigarettes would have had significantly fewer health problems. As a consequence of the above, the BC/BS Plans would have incurred substantially lower costs.

283. A relevant market in which Defendants' violations occurred is the manufacture and sale of cigarettes and other nicotine products in the United States. Because, inter alia, such products are physically addictive, they are not reasonably interchangeable with other consumer products, nor are they characterized by cross-elasticity of price with other consumer products. Within this broad relevant market there would have existed, but for Defendants' conspiracy, a relevant submarket for the manufacture and sale in the United States of less harmful cigarettes and other nicotine products which would still have delivered nicotine but which would have had materially less deleterious health effects than the products actually manufactured and sold by Defendants. Such products would have proven attractive to many smokers, who would have chosen to buy them if they had been available.

284. Because Defendants have conspired to suppress output of less harmful cigarettes and other nicotine products, and to refuse to deal in such products, their conduct is unreasonable per se under the Section 1 of the Sherman Act. There is, moreover, no colorable justification for the concerted action alleged herein, which is unrelated to any lawful business transaction, does not promote efficiency, does not advance the interests of consumers and does not promote interbrand or intrabrand competition.

285. Antitrust law protects competition over innovation and product quality just as it protects price competition. Defendants willfully violated antitrust law by agreeing to suppress competition related to the safety of their products. It was clearly foreseeable that this antitrust violation would injure smokers' health, and it was just as foreseeable that the violation would, at the same time, cause those financially responsible for smokers' health care to suffer an injury in their business or property, by paying increased costs and expenses for health care services and products. These two kinds of injury are inextricably intertwined. Each flows directly from the anticompetitive effects of the illegal conduct. The harm suffered by the BC/BS Plans is the precise type of harm that a conspiracy to suppress competition related to product safety would be likely to cause. Accordingly, this harm reflects the anticompetitive effects of the violation.

Antitrust violations permit the injured party to receive treble damages as well as attorneys' fees.

Federal Racketeer Influenced and Corrupt Organizations (RICO) Act

The federal government and some states have statutes designed to control or eradicate "racketeer influenced and corrupt organizations." "Racketeering" is defined as a pattern of violations of specified criminal statutes ("predicate acts") (18 U.S.C. section 1961[1]). Among these statutes are those criminalizing mail and wire fraud (18 U.S.C. sections 1341, 1343). The evidence put forth that the industry committed these predicate acts is similar to the evidence that it committed common-law fraud (*Blue Cross and Blue Shield*, p. 3.88, para. 260[a]):

> The Defendants engaged in schemes to defraud members of the public, including the BC/BS Plans and their members, regarding the health consequences associated with using nicotine tobacco products. Those schemes have involved suppression of information regarding the health consequences associated with smoking, as well as fraudulent misrepresentations and omissions reasonably calculated to deceive persons of ordinary prudence and comprehension. Defendants' misrepresentations and fraudulent concealment of material facts, directly or by implication, include but are not limited to the following: misrepresentations and fraudulent concealment of the addictive nature of nicotine and the adverse health consequences of tobacco products; misrepresentations that such health effects of addictiveness were unknown or unproven; misrepresentations about Defendants' ability to manipulate and about the manipulation of nicotine levels and the addictive qualities of cigarettes; misrepresentations that

> they would provide the public and governmental authorities with objective, scientific information regarding all phases of smoking and health; and fraudulent concealment of certain aspects of smoking and health, including the availability of safer cigarettes and less addictive cigarettes. Defendants executed or attempted to execute such schemes through the use of the United States mails and through transmissions by wire, radio and television communications in interstate commerce.

The federal RICO Act makes it unlawful to receive income derived, directly or indirectly, from a pattern of racketeering activity or to participate, directly or indirectly, in the conduct of an enterprise's affairs through a pattern of racketeering activity. The relevance of the RICO Act to tobacco litigation was also delineated in the Blue Cross and Blue Shield plans' complaint (*Blue Cross and Blue Shield*, p. 3.92):

> 271. At all relevant times, the Tobacco Institute, CTR (formerly TIRC) and STRC [the Smokeless Tobacco Research Council] have constituted an enterprise within the meaning of 18 U.S.C. § 1961(4) or, in the alternative, each Defendant has constituted an enterprise within the meaning of 18 U.S.C. § 1961(4). Each enterprise is an ongoing organization. Each enterprise and its activities affect interstate commerce in that the enterprise is engaged in the business of maximizing the sales of cigarettes and other nicotine products.
>
> 272. As alleged above, Defendants have engaged in a pattern of racketeering activity that dates from 1953 through the present and threatens to continue into the future. These racketeering acts generated income for Defendants because they contributed to: the suppression and concealment of scientific and medical information regarding the health effects of nicotine products; the suppression of a market for alternative safer or less addictive tobacco products; the manipulation of nicotine to create and sustain addiction to Defendants' products; the targeting of teenagers and children and minorities with marketing and advertising designed to addict them, all to protect and ensure continued sales of Defendants' unsafe and addictive tobacco products; and the avoidance and shifting of smoking related health care costs to others including the BC/BS Plans by the methods stated above, including illicit litigation tactics such as unfounded claims of attorney-client privilege and other means.
>
> 273. Defendants have used or invested their illicit proceeds, generated through the pattern of racketeering activity, directly or indirectly in the acquisition of an interest in, or in the establishment or operation of each enterprise, in violation of 18 U.S.C. § 1962(a). Defendants' use and investment of these illicit proceeds in each enterprise is for the specific purpose and has the effect of controlling the material information distributed to the public concerning the health effects of smoking; suppressing and concealing scientific and medical information regarding the adverse health effects of smoking and the alternatives of safer or less-addictive cigarettes; devising means for manipulating nicotine to create and sustain addiction to Defendants' products; directing marketing and advertising toward minorities, teenagers and children to addict them; and enticing more individuals to smoke or to use Defendants' unsafe nicotine tobacco products.
>
> 274. Each Defendant also conspired to violate 18 U.S.C. § 1962(a), in violation of 18 U.S.C. § 1962(d). As detailed above, the conspiracy began in 1953, continues to the present and threatens to continue into the future. The object of the conspiracy was and is to protect the Tobacco Companies' business operations by investing their illicit proceeds, generated through a pattern of racketeering activity, in each enterprise. Each Defendant agreed to join the conspiracy, agreed to invest racketeering-generated proceeds in each enterprise in order to continue enterprise operations and agreed to the commission of and knowingly participated in at least two predicate acts within ten years of each other. Each Defendant knew that those predicate acts were part of racketeering activity that would further the conspiracy.
>
> 275. Defendants' violations of 18 U.S.C. §§ 1962 (a) and (d) have proximately caused direct injury to the business and property of the BC/BS Plans because the BC/BS Plans have been required to incur significant, concrete financial costs and expenses attributable to tobacco-related diseases; have been unable to participate in a market for alternative less harmful or less addictive nicotine products, or to advise, suggest, promote, subsidize or require their members to use alternative products such as safer or less addictive tobacco products or other nicotine delivery devices; and have not been as effective as they would otherwise have been in helping their members not to use hazardous tobacco

> products. In absence of the Defendants' violation of 18 U.S.C. §§ 1962 (a) and (d), these costs and expenses would have been substantially reduced.

Finally, the RICO Act provides a civil remedy for entities that have been financially injured as a result of RICO violations (18 U.S.C. section 1964[c]). As with the antitrust laws, the remedy includes treble damages and the recovery of attorneys' fees.

Taken together, the allegations in the case brought by the 21 Blue Cross and Blue Shield plans provide an important summary of the legal approaches that are now available to plaintiffs but were not available to earlier third-wave cases.

Individual Third-Wave Cases

Some third-wave cases involve only minor modifications of standard second-wave product liability claims by individual smokers against cigarette makers. In September 1995, one such case achieved the distinction of being the first clear plaintiff's victory after *Cipollone*. A state court jury awarded $2 million, including $700,000 in punitive damages, to a smoker who had developed mesothelioma (a cancer associated with asbestos exposure) after smoking asbestos-filtered Kent cigarettes in the 1950s. The defendant had won four of these filter cases since 1991. While awaiting appeals, observers speculated whether the result signified a change in public perceptions (Hwang 1995a; MacLachlan 1995c). Ultimately, the jury's awards of both compensatory and punitive damages were upheld on appeal (*Horowitz v. Lorillard Tobacco Co.*, No. 965-245 [Super. Ct. San Francisco Cty. 1995], *cert. denied*, 118 S. Ct. 1797 [1998]).

In what is perhaps the most important damage recovery case to date (*Tobacco Products Litigation Reporter* 1996d), on August 9, 1996, a jury in Jacksonville, Florida, awarded $750,000 to Grady Carter, a former air traffic controller who smoked from age 17 in 1947 until cancer was diagnosed in 1991. Grady and his wife, Mildred, sued Brown & Williamson Tobacco Corporation on the grounds of negligence and strict liability. The jury found that the Lucky Strike cigarettes that were manufactured by the defendant were "unreasonably dangerous and defective" (*Tobacco Products Litigation Reporter* 1996d, p. 1.114). Of special significance was that the plaintiff's attorney did not have to undergo the burdensome discovery process that industry attorneys had used successfully in the past. The means of avoiding this process was a special court order issued to ease the management of the large number of tobacco liability cases filed in that jurisdiction (*In re Cigarette Cases* [Fla., Duval Cty. Jan. 23, 1996], *cited in* 11.1 TPLR 2.3 [1996]; Ward 1996). Doubt was cast on the impact of the case, however, when a Florida appellate court overturned the jury's findings on the basis that the plaintiff had failed to file his claim within Florida's four-year statute of limitations (*Brown & Williamson Corp. v. Carter*, No. 96-4831, 1998 Fla. App. LEXIS 7477 [Fla. Dist. Ct. App. June 22, 1998]).

In an individual damage recovery action similar to *Carter* and brought by Norwood Wilner (the same plaintiff attorney who had successfully argued the *Carter* case), a jury found Brown & Williamson Tobacco Corporation liable for the wrongful death of smoker Roland Maddox and awarded his family just over $1 million in compensatory and punitive damages (*Widdick/Maddox v. Brown & Williamson Tobacco Corp.*, No. 97-03522-CA, Div. CV-H [Fla. 4th Cir. Jacksonville 1998]). Attorney Wilner has taken two other tobacco cases to trial that have resulted in jury verdicts for the defense, and it is estimated that he had 150 additional cases pending as of July 1998 (*Connor v. R.J. Reynolds Tobacco Co.*, No. 95-01820-CA, Div. CV-H [Fla. Cir. Duval Cty. May 5, 1997]; *Karbiwnyk v. R.J. Reynolds Tobacco Co.*, No. 95-04697-CA, Div. CV-H [Fla. Cir. Duval Cty. Oct. 31, 1997]; *Economist* 1998).

The growth of individual tobacco litigation during the third wave has been exponential. For example, R.J. Reynolds Tobacco Company reported in July 1995 that 68 cases of all sorts were pending against it; the number had risen to 203 cases in July 1996 and to 448 cases as of August 7, 1997 (Daynard 1997).

Aggregation Devices

The third wave got much of its impetus from the use of procedural devices and legal theories that aggregated claims. Aggregation raised the potential value of each case for plaintiffs' attorneys, increasing their willingness to invest large amounts of money and time in pursuing them. This process denied the industry the ability to discourage such cases by escalating litigation costs, a strategy that had served it well during the previous two waves of tobacco litigation (see "The Aftermath of the First Two Waves," earlier in this chapter). The most important of these aggregation devices have been class actions and third-party payer reimbursement actions.

Class Actions

The class action device figures prominently in the third wave of tobacco litigation. This set of procedures

enables a group of persons suffering from a common injury to bring a suit to secure a definitive judicial remedy for that injury on behalf of all members of the group. Class action procedures have two principal forms—one for cases that seek a single remedy for the common benefit of a category of plaintiffs (Federal Rules of Civil Procedure, Rule 23[b][1]), and a somewhat more complicated one known as (Rule 23[b][3] procedures) for cases that seek the resolution of a large number of individual claims that share common factual or legal issues (Federal Rules of Civil Procedure, Rule 23[b][3]).

Tobacco class actions have, in the main, raised two types of issues. One type, exemplified by the claims in the *Castano* case (*Castano v. American Tobacco Co.*, No. 94-1044 [E.D. La. Feb. 17, 1995], *cited in* 10.1 TPLR 2.1 [1995], *rev'd* 84 F.3d 734 [5th Cir. 1996]) and its progeny, seeks recovery for the cost of treating addicted smokers for their addictions and for monitoring their medical condition for signs of impending disease. It does not, however, seek recovery for the cost of treating tobacco-caused diseases, nor for the other costs (tangible or intangible) to smokers and their families that flow from tobacco-caused disease. The other type of issue, exemplified by the claims in the *Engle* case (*Engle v. R.J. Reynolds Tobacco Co.*, No. 94-08273 CA [20] [Fla., Dade Cty. Oct. 31, 1994], *cited in* 9.5 TPLR 2.147 [1994], *aff'd* 672 So. 2d 39 [1996]), seeks damages for the full range of costs that flow from tobacco-caused diseases. The *Castano* case involves a much larger number of plaintiffs than *Engle*, but each plaintiff seeks a much smaller recovery.

To date, both *Castano*- and *Engle*-type claims have been brought under the more complex Rule 23(b)(3) class action procedures designed for the resolution of individual claims that share common legal or factual issues. Courts have generally been reluctant to allow these procedures for *Castano*-type claims, with the courts particularly concerned about the individualized proceedings on behalf of millions of addicted smokers, each making relatively small claims, that would follow from a favorable resolution of the common issues (*Castano v. American Tobacco Co.*, 84 F.3d 734 [5th Cir. 1996]; *Small v. Lorillard Tobacco Co.*, 1998 WL 398176 [N.Y.A.D. 1 Dept. July 16, 1998]; *Barnes v. American Tobacco Co.*, No. 96-5903 [E.D. Pa. Aug. 22, 1997], vacated 176 F.R.D. 479 [1997], *cited in* 12.4 TPLR 2.227 [1997]). The possibility of using the simpler class action procedure for *Castano*-type claims, which would seek a single judicial order setting up an insurance-type fund that claimants could draw on as they used addiction-related medical or pharmaceutical services, has not been fully explored. By contrast, courts have been more willing to permit Rule 23(b)(3)-type procedures for *Engle*-type claims, where class action procedures promise to simplify the trials of a smaller (but still very large) number of serious individual claims (*Engle*, 672 So. 2d 39; *Broin v. Philip Morris Cos.*, No. 92-1405 [Fla., Dade Cty. Mar. 15, 1994], *cited in* 9.1 TPLR 2.1 [1994]; *Richardson v. Philip Morris, Inc.*, No. 96145050/CE212596 [Md. Cir. Ct. Baltimore City Jan. 28, 1998]).

For a class action of either type to be certified, four technical requirements must be met. First, the members of the proposed plaintiff class must be so numerous that joining each plaintiff to the suit would be impractical. Second, the claims of each member of the class must turn on some questions of law or fact that are common to all the members of the class. Third, claims of the class representatives must not be antagonistic to those of the other members of the class. Fourth, the representative plaintiffs and their attorneys must be able to fairly and adequately represent the interests of the entire class (Federal Rules of Civil Procedure, Rule 23[a]). Where members of the class have conflicting interests, the class may be divided into subclasses represented by different attorneys (Federal Rules of Civil Procedure, Rule 23[c][4][A]).

Besides meeting these four requirements, a Rule 23(b)(3) class action needs to surmount two other significant hurdles. First, the court must determine that the action is "manageable," meaning that a reasonable plan for trying the entire case, including the individual claims, can be devised. Second, the common issues must "predominate" over the individual issues, leaving the court to make the judgment whether the benefits likely to be obtained from trying the case as a class action outweigh the difficulties likely to be encountered in doing so (Federal Rules of Civil Procedures, Rule 23[b][3]).

Once a Rule 23(b)(3) class is certified, the class representatives must undertake the onerous and expensive process of notifying each member of the class. This is necessary because Rule 23(b)(3) class members have the significant right to opt out of the class and pursue their claims individually.

The class action device solves the problem of aggregation, reduces the imbalance of resources often found between the parties, achieves economies of scale, and avoids duplicative litigation. The great advantage of the class actions being pursued in the third wave of tobacco litigation is that resources are expended on behalf of thousands or millions of class members rather than on behalf of a single individual (Kelder and Daynard 1997). This advantage provides more of a level playing field and means that the

tobacco companies will not be able to successfully pursue their usual first- and second-wave strategy of forcing opponents to spend exorbitant sums of money until, nearly bankrupted, they are forced to withdraw (Kelder and Daynard 1997). In its unanimous decision, the appellate court in *Broin*, after considering and rejecting defense objections to the plaintiffs' request for class certification, alluded to the great promise that the class action strategy holds for plaintiffs challenging the tobacco industry: ". . . if we were to construe the rule to require each person to file a separate lawsuit, the result would be overwhelming and financially prohibitive. Although defendants would not lack the financial resources to defend each separate lawsuit, the vast majority of class members, in less advantageous financial positions, would be deprived of a remedy. We decline to promote such a result" (*Broin*, *cited in* 9.1 TPLR 2.4).

But with these benefits come new problems. Only common issues can be dealt with in a class proceeding, thus leaving individualized features to be dealt with in separate trials. As noted, some or many potential class members may choose to opt out of the class to pursue individual cases, thereby reducing the advantage of eliminating duplicative litigation. If some class members are more severely injured than others, intractable conflict may arise over distributing the proceeds (Coffee 1986, 1987). If the injury is continuing outside the class, as it is in the case of tobacco use, there is the problem of providing for future plaintiffs (Hensler and Peterson 1993). These problems are overlaid and compounded by issues involving the legal agents representing the plaintiffs. Class actions are organized and managed by entrepreneurial lawyers, and their interests and those of the client class may diverge (Coffee 1986). Finally, there is the danger that the class action device elevates the stakes so high that defendants and plaintiffs settle without resolution of other (nonmonetary) merits of the claim. Just which of these problems are sufficiently salient to discourage use of the class action device in the several varieties of tobacco cases is still an issue.

Castano v. American Tobacco Co., filed March 29, 1994, in federal court in New Orleans (MacLachlan 1994–95), was an unparalleled attempt by a coalition of traditional plaintiffs' lawyers, mass disaster lawyers, and class action specialists from around the country to diminish the organizational advantages enjoyed by the tobacco industry during the first two waves of tobacco litigation. Each of a coalition of 62 law firms pledged $100,000 annually to fund a massive class action suit, on behalf of millions of nicotine-dependent smokers, charging the tobacco industry with promoting addiction and thus disabling smokers from quitting (Janofsky 1994a; Shapiro 1994a; Curriden 1995). The plaintiffs requested damages for economic losses and emotional distress, as well as medical monitoring and injunctive relief. In February 1995, the district court granted the plaintiffs' request for class certification conditionally and in part (*Castano*, *cited in* 10.1 TPLR 2.1). Judge Okla Jones II granted certification for issues of fraud, breach of warranty (express or implied), intentional tort, negligence, strict liability, and consumer protection issues. Certification was denied for other issues, including the questions of causation, injury, and defenses regarding the claims of each smoker.

Normally, a trial judge's decision to certify a class is not subject to review by a higher court until the trial court has reached a final disposition of the whole case, which may be years later. But Judge Jones in *Castano* granted special permission to allow the defendants to appeal his class certification decision to the United States Court of Appeals for the Fifth Circuit (Collins 1995c). On May 23, 1996, a three-judge panel of the appellate court vacated Judge Jones' decision and remanded the case back to the district court with instructions to dismiss the class action. The court of appeals reasoned that the variations in the state laws of the 50 states in which the injuries occurred classwide, combined with trial management problems not addressed by the district court, justified decertification of the nationwide class (*Castano*, 84 F.3d 734).

The coalition of lawyers that formed around *Castano* opted to pursue another approach and began to file statewide class actions shortly after the decertification by the court of appeals. By mid-1998, the coalition had filed 26 such cases (Torry 1998).

Another class action, *Engle v. R.J. Reynolds Tobacco Co.*, No. 94-08273 CA (20) (Fla., Dade Cty.), *cited in* 9.3 TPLR 3.293 (1994), filed in a Florida state court May 5, 1994, on behalf of smokers suffering from "diseases like lung cancer and emphysema," sought billions of dollars in damages from the seven leading tobacco companies, the Council for Tobacco Research U.S.A. Inc., and the Tobacco Institute, a tobacco-financed public relations association (Janofsky 1994a, p. 11). The suit alleged that by denying that smoking is addictive and by suppressing research on the hazards of smoking, the tobacco industry has deceived the public about the dangers of using tobacco products (Janofsky 1994c). On October 31, 1994, *Engle*, filed by a personal injury lawyer who chose to remain apart from the *Castano* coalition, had the distinction of becoming the first tobacco-related class action lawsuit to be granted class certification (*Engle v. R.J. Reynolds Tobacco Co.*, No. 94-08273 CA [20] [Fla., Dade Cty. Oct. 31, 1994], *cited in*

9.5 TPLR 2.147 [1994]). When the defendants sought to overturn the class certification, the Florida Supreme Court upheld it, paving the way for the case to go to trial (*R.J. Reynolds Co. v. Engle*, 672 So. 2d 39 [Fla. Ct. App. 1996]). A jury selection for the trial began on July 6, 1998 (*Economist* 1998).

Recovery Claims by Third-Party Health Care Payers

In the late 1970s, a number of scholars and advocates began urging legal theories and statutory reforms that would permit third-party health care payers to collect the expenses of caring for tobacco-caused disease from the manufacturers themselves (Garner 1977; Daynard 1993a,b, 1994a; Gangarosa et al. 1994). Such claims involve complex questions about ascertaining the amount of tobacco-caused injury and the apportionment of damages attributable to each defendant. The stakes in these potential cases are undoubtedly large: one study estimates that 7.1 percent of total medical care expenditures in the United States is attributable to smoking-related illnesses (CDC 1994c). Another study estimates that tobacco use is responsible for about 18 percent of all Medicaid expenses (Clymer 1994). However, calculation of such effects invites the counterargument (albeit amoral) that tobacco's costs to the state are offset in part by the savings afforded by the premature deaths of smokers (Geyelin 1995).

Beginning in 1994, the governments of three states—Minnesota, Mississippi, and West Virginia—as well as Blue Cross and Blue Shield of Minnesota, filed lawsuits to secure reimbursement from the tobacco industry for health care expenditures for ailments arising from tobacco use. Three years later, 41 states had filed such legal actions. Since this settlement has not yet been embodied in the congressional legislation necessary to give it the force of law (see "Legislative Developments" and "Master Settlement Agreement," earlier in this chapter), four states—Florida, Minnesota, Mississippi, and Texas—have settled their claims with the tobacco industry. Additional third-party payers—such as labor union pension funds and Blue Cross and Blue Shield plans (whose joint case is described in detail in "Common-Law Claims," earlier in this chapter) in states other than Minnesota—also began to file suit against the industry in 1997 and 1998.

Medicaid Reimbursement Cases

Mississippi filed suit on May 23, 1994, against tobacco manufacturers, wholesalers, and trade groups on the basis of common-law theories of restitution, unjust enrichment, and nuisance to recover the state's outlays for treating the tobacco-related illnesses of welfare recipients (Janofsky 1994a; Woo 1994c; *Moore v. American Tobacco Co.*, Cause No. 94:1429 [Miss., Jackson Cty. Feb. 21, 1995], *cited in* 10.1 TPLR 2.13 [1995]). The first state to do so, Mississippi, embraced a strategy that merited the attention of other third-party claimants. Rather than proceeding in a trial court on a theory of subrogation (whereby the state would have acted in the place of injured smokers to recover claims the state had paid to those smokers), *Moore* chose to proceed in equity (i.e., before a single judge in a nonjury proceeding) on theories of unjust enrichment and restitution (Kelder and Daynard 1997). *Moore*'s equity claims were grounded in the notion developed in the literature that the State of Mississippi had been injured directly by the behavior of the tobacco industry because Mississippi's taxpayers had been forced to pay the state's Medicaid costs due to tobacco-related illnesses.

The state planned to use statistical analysis to illustrate the percentage of Medicaid costs that can be attributed to tobacco use. If the lawsuit succeeded, the defendants would pay for Medicaid costs under a formula that calculates liability according to market share (Lew 1994). The lawsuit sought tens of millions of dollars in damages, including punitive damages as well as recovery for future tobacco-related expenditures (Woo 1994c). Lawyers from 11 private plaintiffs' law firms participated in the suit. Instead of promising the private lawyers a percentage of the potential damages, the state sought to compel the tobacco companies to pay the lawyers' fees (Woo 1994c).

Superficially, this state case (and that of other states) resembled subrogation claims, in which a party who pays a claim (typically an insurer) may pursue that claim, acting in the place of the original claimant and subject to the defenses that might be raised against him or her. But the Mississippi complaint avoided asserting the claims of the health care recipients; instead, it asserted the proprietary claims of the state as a health care funder (distinct from any claims of those whose health was injured by tobacco).

This proprietary stance is significant because, as detailed earlier in this section, the tobacco companies won many of the first- and second-wave cases by asserting the defenses of assumption of risk and contributory negligence or by asserting that the smoker's willfulness, not the industry's misbehavior, was the proximate cause of the smoker's smoking and consequent illness. These defenses should not be available to the tobacco industry in medical cost reimbursement

suits because these suits are not brought on behalf of injured smokers. They are brought, instead, on behalf of the states themselves to recover the medical costs they have been forced to pay to care for indigent smokers. The tobacco industry cannot plausibly argue that the states chose to smoke or that they contributed to the financial harm caused to them (Daynard 1994b; Kelder and Daynard 1997).

The decision in the Mississippi medical cost reimbursement suit demonstrates that this commonsense argument can prevail, even in states that lack special legislation that creates an independent cause of action for the state. The tobacco industry defendants in *Moore v. American Tobacco Co.* filed a motion for judgment on the pleadings on October 14, 1994. The defendants argued that, under Mississippi law, assignment/subrogation was the state's exclusive remedy for pursuing the recovery of medical benefits from potentially liable third parties. Further, the defendants argued that because Mississippi's counts for restitution, indemnity, and nuisance in the complaint did not assert a subrogation claim, they had to be dismissed. Alternatively, the defendants argued that the case should be transferred to a Mississippi circuit court, where thousands of jury trials would have to be conducted (Kelder and Daynard 1997).

In response, Mississippi Attorney General Mike Moore pointed out that "this 'remedy,' as the industry knows, would be cost prohibitive and exhaustive of our State's limited judicial resources" (*Moore v. American Tobacco Co.*, No. 94:1429 [Miss., Jackson Cty. Oct. 14, 1994], *cited in* 9.5 TPLR 3.597, 3.598 [1994]). He argued that "although the Medicaid Law did further codify the State's right to be subrogated, this right is in *addition* to, and not in derogation of, the State's statutory and common law remedies. There is no language in the Medicaid Law that implies an exclusive remedy, and well-settled rules of statutory interpretation require a construction that the Medicaid Law *expanded*, not contracted, the State's remedies [emphasis in original]" (p. 3.598).

On February 21, 1995, Chancellor William H. Myers, presiding over the Chancery Court of Jackson County, denied the tobacco industry defendants' motions to obtain a judgment on the pleadings and to remove the claim from the chancery court to a Mississippi circuit court. The court simultaneously granted the state's motion to strike the affirmative defenses of the defendants; the tobacco industry thus could not rely on the defenses of assumption of risk and contributory negligence, which have proved a mainstay in earlier battles—and which might have been allowed had the state proceeded on a theory of subrogation (*Tobacco Products Litigation Reporter* 1995a).

On July 2, 1997, Mississippi settled its claims so that it would receive at least $3.3 billion over 25 years, with annual payments of at least $135 million continuing in perpetuity. A provision of the settlement agreement guaranteeing Mississippi most favored nation (MFN) treatment, which meant that Mississippi would get the benefit of any better agreement that another state might achieve, was little noticed at the time but has since proved immensely important; additional settlement terms from later industry arrangements with the other three states have been granted to Mississippi.

The second state to bring suit against the tobacco industry was Minnesota *(Minnesota v. Philip Morris Inc.*, No. C1-94-8565 [Minn., Ramsey Cty. Nov. 29, 1994], *cited in* 9.3 TPLR 3.273 [1994]). Minnesota's suit alleged an antitrust conspiracy and an elaborate course of fraudulent behavior on the part of the defendants. Specifically, the tobacco companies were alleged to have violated the state's laws against consumer fraud, unlawful trade practices, deceptive trade practices, and false advertising, as well as violated the duty they voluntarily undertook to take responsibility for the public's health, to cooperate closely with public health officials, and to conduct independent research and disclose to the public objective information about smoking and health. The suit sought various damages, including restitution, forfeiture of tobacco profits, attorneys' fees, and treble damages for several statutory violations. Blue Cross and Blue Shield of Minnesota, the state's largest private medical insurer, joined as a co-plaintiff with the state (Woo 1994b). Like most other states that brought Medicaid reimbursement cases, Minnesota and the insurer retained private counsel to provide representation under a contingency fee arrangement.

Following a three-month trial and in the midst of closing arguments, Minnesota settled its case—the last of the four states to do so—on May 8, 1998. The industry agreed to pay about $6.1 billion to Minnesota and $469 million to Blue Cross and Blue Shield of Minnesota (which was also a plaintiff) over 25 years, an amount substantially larger proportionately than the three earlier state settlements, resulting in substantial increases in their settlement packages under the MFN clauses. The industry also agreed to the following public health concessions (*Minnesota v. Philip Morris Inc.*, *cited in* 13.2 TPLR 2.112):

- Disband the Council for Tobacco Research.

- Not pay for tobacco placement for movies (a provision that inherently extends beyond Minnesota's borders).
- Stop offering or selling in Minnesota nontobacco merchandise, such as jackets, caps, and T-shirts, bearing the name or logo of tobacco brands.
- Remove all tobacco billboards in Minnesota within six months and eliminate such ads on buses, taxis, and bus shelters.
- Refrain from targeting minors in future advertising and promotions.
- Refrain from misrepresenting the evidence on smoking and health.
- Refrain from opposing in Minnesota certain new laws designed to reduce youth tobacco use, as well as clean indoor air laws that could adversely affect the industry.
- Institute new lobbying disclosure rules for Minnesota.
- Release internal indexes to millions of previously secret industry documents, thereby providing a means for attorneys and researchers to find relevant information more easily.
- Maintain at industry expense for 10 years a depository of millions of tobacco documents in Minneapolis and another such depository in Great Britain.
- Instruct retailers in Minnesota to move cigarettes behind the counter to restrict minors' access to those cigarettes.
- Pay out $440 million in fees to the private attorneys who represented the plaintiffs.
- Give Minnesota its own MFN clause, limited to improved public health provisions in future state settlements.

Through the MFN process, many of the public health concessions that Minnesota obtained from the industry are also being incorporated in the prior state agreements (Branson 1998).

The Florida case (*Florida v. American Tobacco Co.*, No. 95-1466AO [Fla., Palm Beach Cty. Feb. 21, 1995], *cited in* 10.1 TPLR 3.1 [1995] [Complaint]; Geyelin 1995) was the first conforming with a statute tailored for the purpose of establishing such a claim. In May 1994, Florida amended this little-used statute, which provided for recovery by the state from third parties responsible for Medicaid costs, to permit the state to sue on behalf of the entire class of smokers on Medicaid, to use statistical proof of causation, to bar assumption of risk as a defense, and to permit recovery according to the defendants' share of the cigarette market (Rohter 1994; Woo 1994a). Apparently having second thoughts about the statute (which had passed by a wide margin), the state legislature considered repealing it, eliciting a vow from Florida's Governor Lawton Chiles to veto a repeal (Hwang 1995a). After an unsuccessful last-minute attempt by the tobacco companies to have the Florida Supreme Court bar state agencies from initiating a lawsuit under the statute, Florida filed its medical cost reimbursement suit on February 21, 1995, seeking $4.4 billion (*Florida*, *cited in* 10.1 TPLR 3.1; Geyelin 1995).

The complaint in the Florida lawsuit contains extended factual allegations regarding the defendants' knowledge (or lack of knowledge) about the harmfulness of tobacco. Raising the familiar causes of action, the complaint also emphasizes the tobacco industry's alleged violations of consumer protection laws. Specifically, it criticizes the industry's use of advertising to target minors.

The Florida Supreme Court narrowly upheld the liability law, on which the state's case is based, in a 4 to 3 ruling that produced equivocal results for both sides. The court agreed with the defendants that the state could only use the law to recover damages incurred since July 1, 1994, and that the names of individual Medicaid recipients would have to be supplied so that the tobacco companies could challenge their claims (*Agency for Health Care Administration v. Associated Industries of Florida*, 678 So. 2d 1239 [Fla. 1996]). But the majority decision left most of the law's key provisions intact. The presiding state circuit court judge, Harold J. Cohen, next ordered both parties to try to resolve the dispute by engaging in mediation, which broke off after four days and produced no results (Kennedy 1996). Judge Cohen then dismissed 15 counts of the state's 18-count claim against the tobacco industry in a ruling issued September 1996 (*Florida v. American Tobacco Co*., No. CL 95-1466 AH [Fla., Palm Beach Cty. Sept. 16, 1996]). The following month, however, he rejected the defendants' request to depose the hundreds of thousands of Medicaid recipients supplied to the court by the state in compliance with the supreme court decision. The judge held that the hundreds of thousands of recipients need only be identified by case number, not by name (*Florida v. American Tobacco Co.*, No. CL 95-1466 AH [Fla., Palm Beach Cty. Oct. 18, 1996], *cited in* 11.7 TPLR 2.236 [1996]). In yet another setback for the defendants, Judge Cohen

permitted the state to add a count of racketeering to its claim (MacLachlan 1996–1997).

Florida settled its case on August 25, 1997, for at least $11 billion over 25 years, with annual payments of at least $440 million continuing thereafter. It obtained its own MFN clause, as well as an additional $200 million for a two-year initiative to reduce youth smoking, an agreement to ban cigarette billboards and transit advertisements, and an agreement by the industry to lobby for a ban on cigarette vending machines. As a consequence of Mississippi's MFN clause, Florida received similar benefits.

The Texas suit was innovative in that it was brought in federal rather than state court. The case was also the first to include claims under the federal RICO Act. On January 16, 1998, Texas settled its claims for at least $14.5 billion over 25 years, with annual payments of at least $580 million continuing thereafter, as well as public health provisions similar to those negotiated by Florida and its own MFN clause.

Although West Virginia was one of the first three states to file a suit against the tobacco companies, its case did not fare as neatly as those of Mississippi, Minnesota, and the later-arrived Florida and Texas. Filed on September 20, 1994 (*McGraw v. American Tobacco Co.*, No. 94-1707 [W.Va. Cir. Ct. Kanawha Cty. Sept. 20, 1994], *cited in* 9.4 TPLR 3.516 [1994]), West Virginia's suit named 23 defendants, including Kimberly-Clark Corporation, developer of a process once used in Europe—but never, according to a company spokesperson, in the United States—to control nicotine levels in tobacco products (Hwang and Ono 1995), and United States Tobacco Company, the largest manufacturer of chewing tobacco and snuff. The West Virginia action "asks the Court for damages to cover what West Virginia has paid providing medical care to people afflicted with tobacco-related illness, and what the state will pay in the future for tobacco victims. The lawsuit also seeks punitive damages to prevent a repetition of such conduct in the future" (West Virginia Attorney General 1994, p. 2). Citing an "intentional and unconscionable campaign to promote the distribution and sale of cigarettes to children," the complaint also requires that the defendants be enjoined from "aiding, abetting or encouraging the sale . . . of cigarettes to minors" (p. 4) and be fined $10,000 for each violation of the injunction. West Virginia's complaint is signed by lawyers from five private firms, including a prominent asbestos litigation firm that is also involved in the Mississippi case.

Unlike the Mississippi and Minnesota claims, the West Virginia case met with early difficulties. On May 3, 1995, Kanawha County Circuit Court Judge Irene C. Berger dismissed 8 of the suit's 10 counts, including fraud, misrepresentation, and conspiracy, as being outside of the state attorney general's powers. Ironically, Berger's decision is based in part on a decision that Attorney General Darrell V. McGraw Jr. himself, the named plaintiff in the suit, authored when he served on West Virginia's Supreme Court, holding that the state attorney general lacked common-law authority (i.e., he could bring only statutory claims). The two remaining counts of the West Virginia action dealt with consumer and antitrust charges (MacLachlan 1995a).

On May 13, 1996, Judge Berger permitted the West Virginia Public Employees Insurance Agency Finance Board to join as co-plaintiffs. This ruling "essentially revived" (*Mealey's Litigation Reports: Tobacco* 1996a) the case by providing the state with a means of hiring legal counsel after the tobacco companies won an October 1995 order barring the attorney general from retaining private law firms on a contingency fee basis (MacLachlan 1995a,b,c).

Among the numerous other states currently trying to recoup Medicare expenditures, Oklahoma stands out for an innovation in its suit. The Oklahoma suit names, among other defendants, three industry law firms: Shook, Hardy and Bacon of Kansas City, Missouri; Jacob, Medinger and Finnegan of New York; and Chadbourne and Parke of New York. Shook, Hardy and Bacon has represented tobacco companies since 1954 (Kelder and Daynard 1997). The suit accuses the law firms of helping the tobacco companies conceal the health risks of smoking and alleges they kept documents confidential by falsely claiming they were protected by attorney-client privilege (*Oklahoma v. R.J. Reynolds Tobacco Co.*, No. CJ961499L [Okla., Cleveland Cty. Aug. 22, 1996], *cited in* 11.7 TPLR 3.901 [1996]).

Other notable settlements mentioned earlier in this chapter include the Liggett Group Inc.'s 1997 settlement with most of the states, in return for a fraction of future profits, public admissions of the dangers and addictiveness of nicotine and the past misbehavior of the industry, and disclosure of secret industry documents (*Tobacco Products Litigation Reporter* 1997a). The same year brought in another key settlement—that of R.J. Reynolds Tobacco Company and a dozen California cities and counties, which had alleged that R.J. Reynolds' Joe Camel campaign was aimed at minors (see "A Critical Example: Joe Camel," earlier in this chapter). R.J. Reynolds agreed to discontinue the campaign in California and to give the plaintiffs $9 million for a counteradvertising campaign (*Mangini*, *cited in* 12.5 TPLR 3.349). In October 1997,

the industry settled the first phase of a class action brought on behalf of nonsmoking flight attendants for substantial money and other concessions (*Broin*, *cited in* 12.6 TPLR 3.397). This case is discussed in detail in "Claims of Nonsmokers," later in this chapter.

Finally, at the time of writing, a group of state attorneys were holding discussions about settling some or all of the remaining state cases. According to published reports, as a starting point "the states have decided to use the [public health] concessions gained by Minnesota as part of its $6.5 billion settlement" (Meier 1998a).

Other Third-Party Reimbursement Cases

Although the parties seeking recovery in Medicaid reimbursement cases are public officials, the cases are based on private law theories of recovery—that is, the officials proceed not as authoritative public regulators but as holders of rights conferred by the general law. Such use of private law recovery as an instrument of state policy suggests further possibilities of analogous suits by private funders of health care and may provide incentives for attorneys to organize such suits. Health insurers, widely seen as reluctant to enforce their rights to recoup from third parties, may be mindful of such opportunities in an increasingly competitive health care setting.

Indeed, Blue Cross and Blue Shield of Minnesota was a co-plaintiff with the State of Minnesota in its action against the tobacco industry. In 1996, the Minnesota Supreme Court unanimously rejected an industry challenge that co-plaintiff Blue Cross and Blue Shield could not remain in the case. This ruling permitted the insurance company and the state to pursue their claims directly against the defendants, rather than on behalf of individual smokers (*Minnesota v. Philip Morris Inc.*, 551 N.W.2d 490 [Minn. 1996]). When the industry settled with the State of Minnesota in May 1998, it also settled with Blue Cross and Blue Shield of Minnesota—for $469 million to be paid over a five-year period (Weinstein 1998a).

In March 1998, two Minnesota health maintenance organizations filed a separate suit against the industry, with claims paralleling those in the Minnesota case that was still in trial (Howatt 1998). The following month, Blue Cross and/or Blue Shield Plans in 37 states combined in three legal actions to sue the major tobacco companies and their public relations firms to recover damages allegedly caused by a conspiracy to addict their insurance plan members to cigarettes (e.g., *Blue Cross and Blue Shield*, *cited in* 13.2 TPLR 3.51; *National Law Journal* 1998).

These plans are alleging that tobacco companies conducted an "ongoing conspiracy and deceptive, illegal and tortious acts" that have resulted in the plaintiffs suffering "extraordinary injury in their business and property," having been required to expend many millions of dollars on costs attributable to tobacco-related diseases caused by defendants who "knowingly embarked on a scheme to addict millions of people, including members of the [Blue Cross and Blue Shield] Plans, to smoking cigarettes and other tobacco products—all with the intent of increasing their annual profits . . . [and forcing] others to bear the cost of the diseases and deaths caused by the conspiracy" (*Blue Cross and Blue Shield*, p. 3.52).

The plans allege a conspiracy to hide the health effects of tobacco products, violations of federal racketeering laws and of antitrust laws, and unjust enrichment, among other theories (*Tobacco Products Litigation Reporter* 1998). They request damages in the forms of payments for treatments of tobacco-related diseases, court orders to require corrections of unlawful behavior, damages in excess of $1 billion for past and future harm, and other forms of relief.

Bankruptcy trusts representing the interests of injured plaintiffs who have made claims against the asbestos industry filed suit against the tobacco industry in late 1997 (Bourque 1997). The trusts allege that they paid claims to victims of asbestos exposure whose injuries were substantially caused by either active or passive exposure to cigarette smoke. Alleging the unjust enrichment of the tobacco companies at the expense of the trusts, the latter seek to recover expenditures and payments made to the asbestos settlement class and seek punitive damages against the defendants (*Tobacco Products Litigation Reporter* 1997b).

The trusts allege that among persons exposed to asbestos, direct or indirect exposure to tobacco smoke is a substantial contributing factor in both the development of cancer and the frequency and severity of symptoms of asbestosis, a disease from which many asbestos workers suffer. The trusts also allege that tobacco companies knew or should have known that their products would cause these injuries (*Falise v. American Tobacco Co.*, No. 97-CV-7640 [E.D.N.Y. Dec. 31, 1997], *cited in* 12.8 TPLR 3.504 [1997]).

The asbestos trusts accuse the tobacco companies of suppressing the truth concerning the nature of their products and their carcinogenic effects. They allege that tobacco industry products were at least partly responsible for the illnesses suffered by asbestos plaintiffs. The trusts thus want the tobacco companies to pay a share of the billions of dollars in damages awarded to those plaintiffs (Bourque 1997).

Small Claims Tribunals to Recover the Cost of Quitting

Related to these expansive addiction suits are a series of more limited claims based on the addictive properties of cigarettes. As with large suits, small claims for the recovery of costs related to quitting tobacco use depend on whether judges and juries accept the addiction argument that underlies the product liability portion of the third wave of tobacco litigation. In this scaled-down version, claims for modest amounts might be brought in small claims courts, obviating some of the litigation advantages enjoyed by the manufacturers. In one case, an individual smoker sued Philip Morris Companies Inc. for $1,154 in a Washington State small claims court to recover the costs of consulting a doctor, buying nicotine patches, and joining a health club—all activities undertaken to help the plaintiff quit smoking cigarettes (Hayes 1993; Janofsky 1993). Because the court rejected the suit on the preliminary ground that the statute of limitations had expired, the substantive merits of the claim were not considered (Montgomery 1993).

In July 1998, an Australian appellate court allowed a formerly addicted smoker to proceed before the New South Wales consumer claims tribunal with a $1,000 claim for the cost of a stop-smoking program, as well as for mental suffering caused by the addiction and the effort to quit (Australian News Network 1998). Were a timely small claims case to succeed, the recovery would be small. Incentives for lawyers to supply and plaintiffs to consume the legal services needed to pursue such a claim might be provided by statutory provision allowing winning plaintiffs to recover attorneys' fees. Or if such claims could be sufficiently standardized and simplified, they might proceed without lawyers (e.g., by preparing "kits" to enable plaintiffs to represent themselves).

Other Cost Reduction Procedures

Several other procedures have been used or may be available to reduce the costs—for plaintiffs, their attorneys, and the courts—of resolving individual claims. One such procedure is to combine pretrial and perhaps trial proceedings for several, or even many, cases. In July 1998, a California court ordered that proceedings in a variety of actions pending in various California courts be combined (Associated Press 1998). Earlier, a Tennessee court ordered several pending individual cases to be combined for trial (*Mass Tort Litigation Reporter* 1998). Asbestos trials have occasionally combined hundreds and even thousands of individual claims (*Acands, Inc. v. Abate*, 710 A.2d 944 [Md. Ct. Spec. App. 1998]). These procedures permit courts to achieve substantial efficiencies with the formalities of class action certification. Efficiencies can also be obtained by case management orders that set firm schedules for trials and pretrial proceedings (*In re Cigarette Cases*, *cited in* 11.1 TPLR 2.3).

Another procedure available in some jurisdictions is "offensive collateral estoppel," which exempts future plaintiffs from retrying issues on which specific defendants have lost in prior trials (*Blonder-Tongue Laboratories v. University of Illinois Foundation*, 402 U.S. 313, 91 S. Ct. 1434 [1971]). This device has not yet been used in tobacco litigation.

Claims of Nonsmokers

ETS Claims Against Manufacturers

Although most litigation involving adverse health effects from exposure to ETS has not directly involved tobacco companies, a line of cases has developed during the 1990s naming tobacco companies as defendants and targeting the companies' behavior in attempting to, as a British-American Tobacco Company Ltd. document from 1988 put it, "keep the controversy alive"—referring to the industry's common strategy of shifting the focus from personal health to personal freedom (Boyse 1988; Chapman 1997).

Claims of nonsmokers asserting damages from ETS have been filed on behalf of both individual and class plaintiffs. As nonsmokers, alleged victims of ETS are not vulnerable to the defense that they knowingly subjected themselves to the dangers of tobacco use. *Butler v. American Tobacco Co.* ([Miss., Jones Cty. May 12, 1994], *cited in* 9.3 TPLR 3.335 [1994] [Amended Complaint]), filed May 13, 1994, seeks damages from six tobacco companies and others for the lung cancer death of Burl Butler, a nonsmoker and "paragon of clean living" (Greising and Zinn 1994, p. 43), who allegedly contracted the disease after inhaling customers' tobacco smoke for 35 years while working at his barber shop (Kraft 1994). Butler became the first case in which documents allegedly stolen from Brown & Williamson Tobacco Corporation by one of its former employees were admitted into evidence, despite objections by the defendants that attorney-client privilege prohibited disclosure. Lawyers for Butler's estate contend that "the documents will show, among other things, that tobacco companies manipulated and suppressed scientific research for years to mislead their customers about smoking's dangers" (Ward 1996). State Circuit Court Judge Billy Joe Landrum postponed

commencement of the trial on motion by the plaintiffs to allow new defendants to be added to the action. The amended complaint now contends that manufacturers of talcum powder used by Butler in his barber shop "knew or should have known that Environmental Tobacco Smoke can act synergistically with . . . Talc, to cause respiratory diseases, including lung cancer, and other health problems" (*Butler v. Philip Morris Inc.*, Civil Action No.:94-5-53 [Miss., Jones Cty. Mar. 4, 1996], *cited in* 11.3 TPLR 3.307, 3.315 [1996] [Second Amended Complaint and Request for Trial by Jury]). A new trial date has not yet been set.

Another case involved a woman who had never smoked but who was subjected to prolonged and repeated exposure to ETS since childhood and died of lung cancer in 1996 at the age of 44 (*Buckingham v. R.J. Reynolds Tobacco Co.*, 713 A.2d 381 [N.H. 1998]). Two years before her death, Roxanne Ramsey-Buckingham sued the major tobacco companies and a local store in strict liability and under Restatement (Second) of Torts, section 389. She alleged "that the defendants knew or should have known that it was unlikely that their products would be made reasonably safe prior to their customary and intended use, and that it was foreseeable that Ms. Ramsey-Buckingham would be endangered by ETS from the defendants' cigarettes" (p. 383). A superior court judge dismissed her lawsuit in 1995 on the basis that New Hampshire does not recognize a strict liability cause of action under section 389. However, the New Hampshire Supreme Court reinstated the lawsuit in May 1998, ruling that "section 389 is not a form of strict liability because it requires the defendant's knowledge of the product's dangerous condition and does not require that the product be defective. . . . The comments to section 389 make it clear that a bystander, assuming he is within the scope of foreseeability of risk, is owed a duty under law and may recover on a showing of breach, damage, and causation" (p. 385). The case was sent back to the trial court for further proceedings.

One case that was tried before a jury in March 1998 resulted in a verdict for the defendants. In that case, *RJR Nabisco Holdings, Corps. v. Dunn* (657 N.E.2d 1220 [Ind. 1995]) a nonsmoking nurse who worked for 17 years at a Veterans Administration Hospital died of lung cancer at the age of 56. Her widower sued a group of tobacco companies, claiming that her exposure to ETS from her patients at the hospital had killed her. A six-person jury returned a verdict for the defendants. Interviewed after the trial, some of the jurors explained that they had had doubts as to whether the cancer that killed Mrs. Wiley had originated in the lungs or, as the tobacco companies' lawyers had argued, in the pancreas and had then spread to the lungs (Dieter 1998).

The most prominent ETS case with tobacco company defendants has been *Broin v. Philip Morris Cos.*, which was brought against the six major cigarette manufacturers in 1991. Seven current and former nonsmoking flight attendants, who contracted lung cancer or other ailments and who face an increased risk of disease as a result of exposure to ETS on airplanes, filed a class action suit on behalf of thousands of flight attendants harmed by exposure to ETS on flights that predated the federal ban on smoking on domestic airline flights. In 1992, a Dade County circuit judge dismissed the class action aspect of the complaint, but two years later, a three-judge panel of the District Court of Appeal of Florida, Third District, unanimously reversed the order of dismissal and ordered that the class action allegations be reinstated (*Broin*, *cited in* 9.1 TPLR 2.1).

In late December 1996, the Circuit Court for Dade County authorized the mass notification of some 150,000 to 200,000 flight attendants so they could either sign up as plaintiffs or exclude themselves from the case to pursue their own suits if they wished. In June 1997, jury selection in the trial began. More than three months later, midway through the companies' presentation of their defense, the parties announced a proposed settlement whereby the defendants would pay $300 million to establish the Broin Research Foundation. The settlement would permit flight attendants harmed by ETS exposure aboard airlines to sue the tobacco companies, regardless of statute of limitations issues. In the event of such individual actions, the defendants would assume the burden of proof on the issue of whether ETS exposure is capable of causing disease in nonsmokers. Dade County Circuit Judge Robert P. Kaye approved the proposed settlement on February 3, 1998, calling it "fair, reasonable, adequate and in the best interests of the class," but challengers to the settlement have appealed (*Broin v. Philip Morris Cos.*, No. 91-49738 CA [22] [Fla., Dade Cty. Feb. 3, 1998], *cited in* 13.1 TPLR 2.79 [1998]). As of August 1998, the appeal was pending.

One workplace setting that has generated substantial exposure to ETS has been casinos. In 1997, nine casino dealers filed a class action lawsuit against 17 tobacco companies and organizations. The lawsuit seeks tens of millions of dollars in damages and class certification of up to 45,000 casino dealers working in Nevada, along with their estates and family members. The plaintiffs in this case, *Badillo v. American Tobacco Co.* (No. CV-N-97-00573-DWH [D. Nev. 1997]), are also seeking to get medical monitoring for the dealers who have had years of exposure to ETS on the job. In April

1998, a federal judge denied all of the motions to dismiss by the defendants, except for The American Tobacco Company, which has merged with Brown & Williamson Tobacco Corporation.

In April 1998, a group of nonsmoking casino workers filed a lawsuit in New Jersey Superior Court against several tobacco companies and the industry's trade association, the Tobacco Institute, because the workers were being made sick by their exposure to ETS at work (Smothers 1998).

Suing Tobacco Companies Over Failure to Disclose Harm From ETS

In a unique case from California, the City Attorney of Los Angeles filed suit in July 1998, against 16 tobacco companies (those that sell cigarettes, cigars, or pipe tobacco) and 15 retailers on the grounds that they are violating Proposition 65, an initiative statute passed by the voters of California in 1986. That law, known as the Safe Drinking Water and Toxic Enforcement Act of 1986 and contained in California Health and Safety Code section 25249.6, provides that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."

The lawsuit specifically lists 46 chemicals referred to as carcinogenic constituents of tobacco smoke and 8 (arsenic, cadmium, carbon disulfide, carbon monoxide, lead, nicotine, toluene, and urethane) as reproductive toxicants. The city attorney's complaint cites a number of prominent government studies: *The Health Consequences of Involuntary Smoking*, the 1986 report of the U.S. Surgeon General on smoking and health; *Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects*, published in 1986 by the National Research Council; *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*, a report issued by the U.S. Environmental Protection Agency in January 1993; and *Health Effects of Exposure to Environmental Tobacco Smoke*, published by the California Environmental Protection Agency in September 1997. The complaint alleges that "Notwithstanding this overwhelming body of governmental information, and notwithstanding their own knowledge of these facts since at least 1981, the Tobacco Defendants have each knowingly and intentionally concealed from, and thereby deceived, every nonsmoking individual exposed to environmental tobacco smoke by the sale and use of tobacco products in California. By these acts of knowing and intentional concealment and deception, the Tobacco Defendants, and their agents, the Retailer Defendants, have each individually violated Proposition 65" (*California v. Philip Morris Inc.*, No. BC194217 [Calif., Los Angeles Cty. July 14, 1998], *cited in* 13.4 TPLR 3.195 [1998]).

The City of Los Angeles' lawsuit will likely benefit from a court decision rendered in 1997 in a federal court located some 3,000 miles away. A nonsmoker in Florida filed a lawsuit against various tobacco companies, alleging that she suffers from severe emphysema and an array of other injuries as a result of prolonged exposure to ETS from the normal and foreseeable use of the companies' products. The companies filed a motion to dismiss her case, contending that the Federal Cigarette Labeling and Advertising Act preempts claims based on state law duties to disseminate information relating to smoking and health. A judge in the U.S. District Court for the Southern District of Florida denied the motion to dismiss, concluding that the federal act's preemption of state regulations "based on smoking and health" does not preempt regulations involving ETS. "The Court finds it unlikely that Congress intended the word 'smoking' to mean inhaling second-hand smoke," since the "Congressional reports make clear the purpose of the [federal act] is not to inform non-smokers of the hazards of breathing second-hand smoke but rather to inform smokers and potential smokers of the dangers of actively smoking" (*Wolpin v. Philip Morris, Inc.*, No. 96-1781-CIV-KING, 1997 WL 535218 [S.D. Fla. Aug. 18, 1997]). The court also ruled that the federal act did not by implication preempt a claim based on harm from ETS (Sweda 1998).

ETS Cases Against Nontobacco Parties

Injunctive relief from ETS. In 1976, Donna Shimp (see "Legal Foundation for Regulation of Public Smoking," earlier in this chapter), an office worker in New Jersey, sought intervention from the courts to provide her relief from exposure to ETS at her worksite (*Shimp*, 368 A.2d 408). The court ruled that the evidence was "clear and overwhelming. Cigarette smoke contaminates and pollutes the air, creating a health hazard not merely to the smoker but to all those around her who must rely upon the same air supply. The right of an individual to risk his or her own health does not include the right to jeopardize the health of those who must remain around him or her in order to properly perform the duties of their jobs" (p. 415). In granting an injunction to ensure that Shimp be provided a smoke-free workplace, the New Jersey Superior Court provided a clear example of taking seriously the health concerns of nonsmokers who are forced to breathe ETS.

The *Shimp* decision preceded most of the medical studies that have demonstrated the adverse health effects of ETS. In the 22 years since *Shimp*, lawsuits designed to protect nonsmokers from the health hazards caused by involuntary exposure to ETS have escalated.

A 1982 decision from the Missouri Court of Appeals gave additional momentum to nonsmoking workers seeking legal relief from on-the-job exposure to ETS. In *Smith* (643 S.W.2d 10), the Missouri Court of Appeals reversed a trial court's dismissal of a lawsuit brought by a nonsmoking worker who was seeking an injunction—a form of direct intervention by a court—to prevent his employer from exposing him to tobacco smoke in the workplace. The court of appeals ruled that if Paul Smith were to prove his allegations at trial, then "by failing to exercise its control and assume its responsibility to eliminate the hazardous condition caused by tobacco smoke, defendant [Western Electric Co.] has breached and is breaching its duty to provide a reasonably safe workplace" (p. 13). Although the nonsmoking worker eventually lost his case after it was sent back to the trial court, the court of appeals decision remains as a precedent that will help similar cases survive motions to dismiss (Sweda 1998).

The following year, a nonsmoking social worker in Attleboro, Massachusetts, was granted a temporary restraining order (which by law could last no more than 10 days) against smoking in the open office area where she worked with about 39 coworkers, 15 of whom smoked. In *Lee* (*cited in* 1.2 TPLR 2.82), a superior court judge denied a motion by the employer to dismiss the case, ruling that "an employer has no duty to make the work place safe if, and only if, the risks at issue are inherent in the work to be done. Otherwise, the employer is required to 'take steps to prevent injury that are reasonable and appropriate under the circumstances'. . . . Accordingly, this court cannot say that plaintiff's claim fails to make out a legally cognizable basis for relief" (p. 2.83). The case was settled in January 1985 when the employer, the Commonwealth of Massachusetts, agreed to provide the plaintiff, Marie Lee, and the other nonsmoking workers there, with a separate nonsmoking area with ventilation separate from the ventilation in the smoking area. As it turned out, only 4 of the office's 40 workers chose to work in the smoking area (Sweda 1998).

Handicap Discrimination/Americans With Disabilities Act

A new theory for ensuring ETS protection for nonsmokers involved using the ADA. As the rationale for applying the ADA to the workplace, Parmet and colleagues (1996) explained: "The ADA was enacted in 1990 to provide a 'clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities' [42 U.S.C. section 12101(b)(1)]. The act prohibits discrimination against individuals with disabilities on the job [42 U.S.C. section 12112(a)] and in places of 'public accommodation' [42 U.S.C. section 12182(a)], as well as by state and local governments [42 U.S.C. section 12132]" (p. 909).

Initially, some plaintiffs did not succeed in acquiring relief from ETS under the ADA. For example, in *Harmer v. Virginia Electric and Power Co.* (831 F. Supp. 1300 [E.D. Va. 1993]), an employee suffering from bronchial asthma sued his employer, contending that in failing to ban smoking at the workplace, the company had violated the ADA by discriminating against him because of his disability. Harmer contended that after he requested a smoke-free work environment, the company retaliated against him by reducing his job authority and failing to promote him. Though recognizing Harmer's disability, the district court dismissed the claim, saying that he "still must show that he is entitled to a complete smoking ban as a reasonable accommodation to his disability, and he is unable to do so" (p. 1306). This was so "because the many smoking limitations that the employer had put in place, coupled with improvements such as the installation of air filtration devices, were sufficient to enable the plaintiff to work. Of course, a patient more severely disabled might have required further accommodations" (Parmet et al. 1996, p. 912).

In *Emery v. Caravan of Dreams, Inc.* (879 F. Supp. 640 [N.D. Tex. 1995]), two women hypersensitive to ETS filed suit under the ADA, contending that they were effectively precluded from attending musical performances at the defendant's establishment because smoking was permitted there. After a one-day, jury-waived trial, a federal judge ruled against the plaintiffs, but noted that they should have brought their claim under the ADA's reasonable accommodation provision, instead of the section of the act that bars the establishment of rules that "screen out" disabled people (p. 643).

A different result had occurred in a case from Connecticut. In *Staron v. McDonald's Corp*. (51 F.3d 353 [2d Cir. 1995]), plaintiffs brought an action under the ADA, 42 U.S.C. section 12101, saying that the presence of tobacco smoke in the defendants' restaurants was preventing the plaintiffs from having the opportunity to benefit from the defendants' goods and services. The plaintiffs, all of whom have adverse reactions to ETS, also alleged that the defendants' restaurants are places of public accommodation under 42 U.S.C. section 12181.

After a district judge granted the defendants' motion to dismiss the case, the United States Court of Appeals for the Second Circuit reversed, ruling that "we find that plaintiffs' complaints do on their face state a cognizable claim against the defendants under the Americans with Disabilities Act" (p. 355). The court noted that "the determination of whether a particular modification is 'reasonable' involves a fact-specific, case-by-case inquiry that considers, among other factors, the effectiveness of the modification in light of the nature of the disability in question and the cost to the organization that would implement it [p. 356]. . . . We see no reason why, under the appropriate circumstances, a ban on smoking could not be a reasonable modification" (p. 357).

An Illinois woman suffering from chronic severe allergic rhinitis and sinusitis sought a smoke-free work environment and sued her former employer after it "repeatedly refused to provide" the plaintiff with a reasonable accommodation to her disability. After filing an ADA claim with the Equal Employment Opportunity Commission and a worker's compensation claim, she was terminated. A federal judge in *Homeyer v. Stanley Tulchin Associates, Inc.* (No. 95 C 4439, 1995 WL 683614 [N.D. Ill. Nov. 17, 1995]) granted the defendants' motion to dismiss, saying that the plaintiff "does not, and cannot, allege that her sensitivity to [ETS] substantially limits her ability to find employment as a typist generally. Thus, Homeyer is not a qualified individual with a disability, and, accordingly, is not entitled to the protection of the ADA" (p. 3).

However, the United States Circuit Court of Appeals for the Seventh Circuit unanimously reversed the district court's ruling and sent the case back for trial. Noting that the district court had ignored Homeyer's claim that she was disabled in that her breathing, an essential life activity, was affected by ETS, the court of appeals ruled that "we cannot say at this stage that it would be impossible for her to show that her chronic severe allergic rhinitis and sinusitis either alone or in combination with ETS substantially limits her ability to breathe" (*Homeyer v. Stanley Tulchin Associates, Inc*., 91 F.3d 959, 962 [7th Cir. 1996]).

In October 1997, a New York jury awarded $420,300 to an asthmatic prison guard, Keith Muller (*Muller v. Costello*, No. 94-CV-842 (FJS) (GJD), 1996 WL 191977 [N.D.N.Y. May 20, 1996]), who had been fired after he had made numerous complaints about the effect of ETS exposure on his health. While serving as a correctional officer, Muller had become seriously ill—including numerous occasions when he had to be taken to a hospital directly from the prison where he worked—after being exposed to ETS. After Muller's treating physician had recommended that he work in a smoke-free environment, the New York State Department of Correctional Services instead provided him with a mask that, according to Muller, made him even more ill. Furthermore, wearing the mask had subjected Muller to widespread ridicule, putting him in even greater personal danger from the breakdown in the respect that the inmates had for him. Whereas a judge in 1996 had barred the plaintiff's negligence and civil rights claims in *Muller v. Costello*, the court allowed Muller's ADA claim to proceed.

Ruling on posttrial motions, the judge reduced the award to $300,000 because of the cap on compensatory damages contained in 42 U.S.C. section 1981a(b)(3). The court also rejected the defendant's motion to vacate or reduce the verdict as excessive, ruling that the "plaintiff submitted evidence of discrimination that had taken place over a period of years during which time he was forced to endure mental suffering, embarrassment, economic hardship, actual termination and physical injury. In view of this evidence, the Court finds that the jury award of $300,000 is not excessive and does not shock the conscience as a matter of law" (*Muller v. Costello*, 997 F. Supp. 299, 303 [N.D.N.Y. 1998]).

In a more recent case, three asthmatic women sued Red Lobster and Ruby Tuesday restaurants under the ADA. The plaintiffs in *Edwards v. GMRI, Inc.* (No. 119S93 [Md., Montgomery Cty. Nov. 26, 1997], *cited in* 13.1 TPLR 3.1 [1998]) said that they attempted to patronize the defendants' restaurants but were forced to leave because of the ETS there. In their complaint, the plaintiffs stated that the defendants' "failure to establish a policy prohibiting smoking in their restaurants throughout the state discriminates against the Plaintiffs on the basis of their disability in their use and enjoyment of" the restaurants (p. 3.3).

Seepage of Smoke From One Dwelling Unit to Another

The 1990s have seen the development of cases in which a nonsmoker living in an apartment or condominium unit is being adversely affected by smoke entering his or her dwelling space from elsewhere. In June 1998, a Boston Housing Court judge ruled in favor of nonsmoking tenants who were being evicted for nonpayment of rent (*50-58 Gainsborough Street Realty Trust v. Reece and Kristy Haile*, No. 98-02279, Boston Housing Court [1998]). After pleading with the landlord for several months to do something about the problem of smoke from a first-floor nightclub constantly entering their second-floor apartment and disrupting their ability to use and enjoy their

apartment, the tenants got no relief. After they withheld their monthly rent payments of $1,450, the landlord brought an action in housing court seeking their eviction. The court ruled that "the evidence does demonstrate to the Court that the tenants' right to quiet enjoyment [of their apartment] was interfered with because of the second hand smoke that was emanating from the nightclub below" (p. 34). The court ruled that "as the tenants describe the second hand smoke within their apartment at nighttime, the apartment would be unfit for smokers and non-smokers alike" (p. 7). That interference with the quiet enjoyment of the tenants' apartment was a defense to the effort to evict them. Also, the court found for the tenants in the amount of $4,350—the same amount that the tenants had withheld over the course of three months.

In *Dworkin v. Paley* (93 Ohio App. 3d 383, 638 N.E.2d 636 [Ohio Ct. App. 1994]), Dworkin, a nonsmoker, entered into a one-year lease with Paley to reside in a two-family dwelling; the lease was later renewed for an additional one-year term. During the second year, Paley, a smoker, moved into the dwelling unit below Dworkin's. Two weeks later, Dworkin wrote to Paley to tell her that her smoking was annoying him and causing him physical discomfort, noting that the smoke came through the common heating and cooling systems shared by the two units. Within a month, Dworkin vacated the premises. Eight months later, he brought a legal action to terminate the lease and recover his security deposit from Paley. The lawsuit, which alleged that Paley had breached the covenant of quiet enjoyment and statutory duties imposed on landlords (including doing "whatever is reasonably necessary to put and keep the premises in a fit and habitable condition," p. 387) was dismissed on a motion for summary judgment. However, the Cuyahoga County Court of Appeals reversed the dismissal, concluding that a review of the affidavits in the case "reveals the existence of general issues of material fact concerning the amount of smoke or noxious odors being transmitted into appellant's rental unit" (p. 387). The case was thus sent back to the trial court.

In June 1998, a prominent New York law firm, Weil, Gotshal & Manges LLP, sued the owner and landlord of the office building where it is located, as well as the tenant located one floor below, because of ETS seepage into its office space. The firm alleges in its lawsuit, that as a result of the smoke infiltrating into its 29th floor offices, "some of WG&M's partners, associates and employees have suffered illness, discomfort, irritation and endangerment to their health and safety, and/or have been unable to use or occupy their offices or workstations on the WG&M 29th Floor Premises" (*Weil, Gotshal & Manges LLP v. Longstreet Associates, L.P.* [N.Y., N.Y. Cty. June 12, 1998], *cited in* 13.4 TPLR 3.188 [1998]).

Many landlords are not waiting to be sued. The Building Owners and Managers Association International, a trade association for 16,000 office landlords and owners, has been advising its members to lessen their risk of ETS liability by banning smoking whenever possible. During the past two years, the proportion of member office buildings that banned smoking increased from 68 to 80 percent (White 1998).

United States Supreme Court Ruling on ETS in Prisons—Eighth Amendment Issues

Perhaps the most frequent area of litigation involving exposure to ETS has come in a setting where the exposure is both involuntary and inescapable—prisons. A landmark case that eventually reached the United States Supreme Court started in Nevada when a nonsmoking prisoner was housed in the same cell as a heavy smoker (*McKinney v. Anderson*, 924 F.2d 1500 [9th Cir. 1991]). The nonsmoker brought a civil rights lawsuit against the prison officials, claiming that his Eighth Amendment right to be protected from cruel and unusual punishment was being violated due to his constant exposure to ETS. Although his case was thrown out initially by a district court in Nevada, the lawsuit was reinstated by the United States Court of Appeals for the Ninth Circuit. The court ruled that even if the inmate could not show that he suffered from serious, immediate medical symptoms caused by exposure to ETS, compelled exposure to that smoke is nonetheless cruel and unusual punishment if at such levels and in such circumstances as to pose an unreasonable risk of harm to the inmate's health.

On June 18, 1993, the Supreme Court ruled in a 7 to 2 decision that McKinney's case could go forward. The Court affirmed "the holding of the Court of Appeals that McKinney states a cause of action under the Eighth Amendment by alleging that petitioners [the prison officials] have, with deliberate indifference, exposed him to levels of ETS that pose an unreasonable risk of serious damage to his future health" (*Helling v. McKinney*, 113 S. Ct. 2475 [1993]).

ETS and Child Custody Cases

Disagreements between parents who are divorcing can, of course, cover a wide variety of subjects. One of the issues that has increasingly become a significant subject of disputes that have ended up before a judge in probate court has been the exposure to ETS on the part of a child or children caught up in a

custody battle. Over the past 11 years, there have been recorded cases in at least 20 states (Sweda 1998). One of the earliest was *Wilk v. Wilk* (*In re Wilk v. Wilk*, 781 S.W.2d 217 [Mo. App. 1989]). The trial court in this case granted primary custody of the children to the mother, who had been advised by a doctor that the children, one of whom was asthmatic, should not be taken to the father's home because he smoked. The Missouri Court of Appeals ruled that the trial court did not err in awarding custody of the minor children to the mother.

In a case from Kansas, an ex-wife with custody sought permission to move with her children to another state; the ex-husband responded with a motion to obtain custody. The district court did make the change by awarding custody to the ex-husband after finding that the ex-wife's smoking had harmed the children. The ex-wife appealed, arguing that there had been no evidence to prove that her smoking had caused her children's health problems. The court of appeals affirmed the district court's change of custody, noting that there was evidence that her smoking had harmed the children: "That finding is supported by the testimony of three doctors that second-hand smoke aggravated the children's health problems and placed them at risk for further health problems" (*In re Aubuchon*, 913 P.2d 221 [Kan. Ct. App. Mar. 22, 1996]).

In some cases, the smoking issue is not sufficient to produce a change of custody. For example, in *Helm v. Helm* (01-A-01-9209-CH00365, 1993 WL 21983 [Tenn. App. Feb. 3, 1993]), the trial court awarded custody of a five-year-old child to the father. The mother appealed the divorce decree, arguing before the Court of Appeals of Tennessee that the father smoked around the child. The court said that "Other than exposure to violent movies and cigarette smoke, no evidence is cited that the father has neglected or mistreated the child" (p. 2). The trial court's judgment was affirmed, with the mother being accorded visitation rights. In *Baggett v. Sutherland* (No. CA 88-224, 1989 WL 5399 [Ark. App. Jan. 25, 1989]), a nonsmoking father attempted to obtain a change in custody on the basis of, among other things, the fact that the mother smoked in the presence of children who were allergic to smoke. Although the lower court had found that circumstances were not so changed as to warrant a change in custody, it did acknowledge that smoking was detrimental to the children. The mother was forbidden to smoke in the home or allow anyone else to smoke in the home; the judge "made it clear that he would exercise continuing jurisdiction over the parties to insure compliance with that order" (p. 3).

Rulings in other cases have been the product of compromise. In *Northcutt v. Northcutt*, a 1997 case, a nonsmoking father objected to ETS around his 2-year-old son, who has asthma and has had repeated respiratory infections, bronchitis, allergies, and earaches (Sweda 1998). As part of a joint custody agreement, a Warren County, Tennessee, judge ordered the mother to keep her son away from ETS. Each parent was to have custody for six months per year.

Victims of Smoking-Related Fires

Smoking is the leading cause of deaths and injuries by residential fire. According to the Building and Fire Research Laboratory of the National Institute of Standards and Technology, cigarettes start more fatal fires than any other ignition source, causing about 30 percent of all fire deaths in this country. For example, in 1989, 44,000 cigarette-ignited fires caused 1,220 deaths, 3,358 injuries, and $481 million in property damage (Karter 1993).

In 1984, Congress passed the Cigarette Safety Act (Public Law 98-567), creating a Technical Study Group to assess the feasibility of developing a less incendiary cigarette. The group concluded that changing a standard cigarette's diameter, paper porosity, and tobacco density would produce a cigarette that would not transfer enough heat to cause a fire when dropped on most upholstery (Technical Study Group on Cigarette and Little Cigar Fire Safety 1987). The tobacco industry maintains that even if such cigarettes could be manufactured, when smoked they would not burn as thoroughly as current brands, meaning that fire-safe cigarettes would deliver more tar, nicotine, and carbon monoxide to the smoker (Levin 1987).

The prospect of technologies for making less incendiary cigarettes raises the question of whether the manufacturers might be held liable for failure to incorporate such a feature. Until now, product liability litigation for fires caused by cigarettes has met with no more success than smokers' claims for injuries to health. The first such case to produce a judicial decision, *Lamke v. Futorian Corp.* (709 P.2d 684 [Okla. 1985]), involved a fire started when a cigarette ignited a sofa, resulting in severe burns to much of the plaintiff's body. The Oklahoma Supreme Court applied the so-called consumer expectation test to find that the cigarettes in question were not dangerous to an extent beyond what would be expected by the ordinary consumer. The consumer expectation test, which evolved from comments to section 402A of the Restatement (Second) of Torts, today survives as the law in a minority of jurisdictions (American Law Institute 1995).

The prevailing view, endorsed by the current draft of the Restatement (Third) of Torts, would determine liability for defective product design by a risk-benefit standard that evaluates the quality of the manufacturer's design decision by reviewing whether the manufacturer properly weighed the comparative costs, safety, and mechanical feasibility of one or more alternative designs (Green 1995). In *Lamke*, the court found that evidence regarding the feasibility of manufacturing a less incendiary cigarette was irrelevant to considerations of consumer expectation, but such evidence might be found persuasive in a jurisdiction following a risk-benefit standard for determining design defects. Whether the tobacco companies suppressed research and product development regarding fire-safe cigarettes is under investigation by the antitrust division of the U.S. Department of Justice (Shapiro 1994c).

Fire claims by smokers would face many of the familiar obstacles to recovery but, as two pending claims illustrate, many of the potential plaintiffs in fire litigation are not smokers but third parties untainted by the decision to smoke. In *Kearney v. Philip Morris Cos.* ([D. Mass. May 11, 1992], *cited in* 7.2 TPLR 3.65 [1992]), suit was brought on behalf of a woman who died in a fire started by her husband's cigarette. The plaintiff's attorneys focused "on the issue of additives and other manufacturing techniques that cigarette makers use to ensure that cigarettes will stay lit even if they aren't being smoked" (Wilke and Lambert 1992). On February 16, 1996, Judge Robert E. Keeton granted summary judgment[6] in favor of Philip Morris, holding that even under the more forgiving standard of liability for design defect, "fatal gaps" existed in evidence submitted by the plaintiff in supporting her claim that adoption of an alternative design by the company would have prevented the fire started by Mr. Kearney's cigarette (*Kearney v. Philip Morris Inc.*, 916 F. Supp. 61, 66 [D. Mass. 1996]).

Another cigarette-caused fire claim seeks recovery based on the fire-related injuries received by a 21-month-old infant trapped in her child car seat (*Shipman v. Philip Morris Cos.*, Cause No. 26294 [Tex., Johnson Cty. Oct. 7, 1994], *cited in* 10.1 TPLR 3.91 [1995]).

Enhancing Prohibitory Regulation by Private Litigation

Enforcing Minors' Access Laws

Although selling cigarettes to minors is prohibited in all states and the District of Columbia, retail store employees frequently ignore the law (Lew 1992). Enforcing these widespread and important statutes is typically left to government officials who have competing commitments and limited sanctioning powers. A pioneering suit, brought by tobacco activists against a Massachusetts convenience store chain, sought to supplement this ineffectual arrangement by private enforcement. The initiative first took the form of a test case, sponsored by the Tobacco Products Liability Project, charging that Philip Morris was engaged in a "civil conspiracy" with the convenience store chain to sell cigarettes to minors. A divided Massachusetts Supreme Court found the conspiracy unproven (*Kyte v. Philip Morris Inc.*, 408 Mass. 162, 556 N.E.2d 1025 [Mass. 1990]). The plaintiffs then refocused the suit directly against the convenience store chain, alleging that it had violated the Massachusetts Consumer Protection Act, which allows consumers to bring civil suits directly against vendors for money damages and injunctions. The suit terminated in a settlement in which the chain agreed to demand proof of age from would-be cigarette purchasers. In 1992, the Tobacco Products Liability Project launched a project to research the legal basis for such suits in all 50 states and to provide informational and strategic support for such litigation (Lew 1992).

After the settlement in *Kyte*, the attorney general in Massachusetts, acting under the state's consumer protection laws (Mass. Ann. Laws ch. 93a, sec. 1) began to conduct tests using minors posing as customers to gauge retailer compliance with state bans on tobacco sales to persons under 18 years of age (Mass. Ann. Laws ch. 270, sec. 6). Settlements were reached with several supermarket chains in 1994 for monetary damages as well as implementation of measures designed to reduce the risk of further illegal tobacco sales to minors (Tobacco Products Liability Project 1996). By 1998, state attorneys general offices in 26 states began working with the National Association of Attorneys General and the Tobacco Control Resource Center (1998) to develop approaches to prevent illegal tobacco sales to minors.

Kyte presents an instance of a lawyer functioning as a private attorney general to secure the enforcement of underenforced public standards. This case suggests that restrictions on sales to minors might be enforced more effectively by establishing informational networks and incentives (such as the recovery of attorneys' fees) to facilitate widespread and routine

[6] A summary judgment is a judgment granted without a formal trial when it appears to the court that there is no genuine issue of fact and that the moving party is entitled to judgment as a matter of law.

exertions by lawyers. Such private enforcement is a well-established feature of a number of regulatory regimes, including consumer credit regulations, securities laws governing insider trading, and bounties paid for apprehending persons who defraud the government. In devising such strategies, the risks of underuse, overuse, and abuse must be identified to frame a scheme of incentives that yields optimum results.

One state's highest court has upheld the legal validity of using the civil provisions of consumer protection statutes to enforce penal laws prohibiting tobacco sales to minors. The California Supreme Court held that a private and for-profit enterprise had standing under that state's consumer protection laws to maintain a private action in the public interest, even though the underlying penal statute contained no provisions for a private right of action (*Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 17 Cal. 4th 553, 557, 71 Cal. Rptr. 2d 731 [1998]).

Restrictions on Advertising

State and local laws restricting the advertising and promotion of tobacco products (see "Advertising and Promotion," earlier in this chapter) provide another occasion for private initiatives. The California Supreme Court held that federal preemption did not extend to bar a suit claiming that the "Joe Camel" advertising campaign targeted minors and thus violated California's ban on unfair business practices (see "A Critical Example: Joe Camel," earlier in this chapter) (*Mangini*, 875 P.2d 75). This suit, like *Kyte*, invites consideration of the benefits and costs of the private attorney general device. Such an evaluation must compare the performance of private efforts with actual rather than idealized governmental regulatory activity. For example, the FTC did secure a consent decree against the Pinkerton Tobacco Company (*In re Pinkerton Tobacco Co.*, 115 F.T.C. 60, 1992 F.T.C. LEXIS 35 [Jan. 9, 1992]) to cease promotion of its smokeless products at a televised tractor pull. On the other hand, after FTC staff lawyers recommended in 1994 that the FTC charge R.J. Reynolds Tobacco Company with using the Joe Camel campaign to promote cigarettes to children, the commissioners voted 3 to 2 to take no action (*FTC:Watch* 1994).

The presence of private attorneys general may add to the limited resources of public regulators. The U.S. Department of Justice recently settled a lawsuit against Madison Square Garden for circumventing the 1971 federal ban on broadcast advertising of cigarettes by placing cigarette advertising where it would be displayed in television broadcasts. The case ended with a consent decree in which the arena admitted no wrongdoing but agreed to remove cigarette advertising from sites where it would be seen on television (Thomas and Schwartz 1995). The government's enforcement capacity in this area could be amplified if there were sufficient incentives for private litigants.

The International Dimension of Tobacco Litigation

Tobacco Litigation Abroad

The first and second waves of tobacco litigation were uniquely U.S. phenomena, but the third wave has an international dimension that its predecessors lacked. Only a few years after a 1990 survey reported that "there has been no history of tobacco litigation in the [European Community]" (Cooper 1990, p. 291), counterparts of many of the third-wave litigation initiatives have appeared in other countries. In Australia, employees injured by ETS have recovered substantial damages from their employers (Daynard 1994a). A public interest group, the Consumer's Federation of Australia, secured a judicial declaration that the Tobacco Institute of Australia Ltd. had falsely claimed that "there is little evidence and nothing which proves scientifically that cigarette smoke causes disease in non-smokers" (Daynard 1994a, p. 60). A French public interest group, acting as private attorneys general, successfully enforced bans against tobacco advertisements on radio and television (*Gourlain v. Societe Nationale D'Exploitation Industrielle des Tabacs et Allumettes [SEITA]* [Tribunal de Grande Instance de Montargis Dec. 19, 1996], *cited in* 11.8 TPLR 3.1073 [1996]). In Canada, a class action suit based on addiction was filed against Canada's three largest tobacco manufacturers. To show that the tobacco companies knew of nicotine's addictiveness, the suit relied on documents uncovered in the United States (Van Rijn 1995). In England, the Legal Aid Board granted certificates of eligibility for legal aid to fund 200 cases brought by smokers alleging that tobacco manufacturers had failed to meet their legal duty to minimize the risks of smoking (PR Newswire 1995). Legal Aid's willingness to finance the litigation comes after a three-year battle for funding, led by the British group Action on Smoking and Health (Milbank 1995).

Foreign Plaintiffs in the American Courts

Overseas sales are an increasingly important sector of the American tobacco industry: exports grew from 8 percent of total production in 1984 to 35 percent in 1996 (MacKenzie et al. 1994; U.S. Department of Agriculture 1996). The absence of warnings on the

packaging of exports and the aggressive promotional activity might help foreign plaintiffs who brought claims in U.S. courts overcome some of the barriers that have protected tobacco companies from domestic plaintiffs. However, such litigation would face other formidable obstacles, including the problem of establishing a substantive right to recover according to foreign law and an expanded notion of the responsibilities of multinational corporations for merchandise sold overseas. Such an expansion seems unlikely in the light of the reluctance of U.S. courts to provide a forum for foreign victims of corporate misconduct. This reluctance was dramatized in the litigation arising from the 1984 chemical plant explosion in Bhopal, India (Jasanoff 1985; Cassels 1993; Galanter 1994). Although the U.S. courts decided that the case should be tried in India rather than in the United States (*In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India in December, 1984*, 634 F. Supp. 842 [S.D.N.Y. 1986], *aff'd in part* 809 F.2d 195 [2d Cir. 1987], *cert. denied*, 484 U.S. 871, 108 S. Ct. 199 [1987]), the U.S. parent company was required, as a condition of moving the case to India, to submit to the jurisdiction of the Indian courts. A number of rulings in the Bhopal litigation also created the basis for enhanced liability of U.S. multinational corporations for their overseas operations. In a later proceeding, a U.S. court acknowledged that a foreign government might establish itself as the exclusive representative of victims of a mass tort (*Bano Bi v. Union Carbide Chems. & Plastics Co*., 984 F.2d 582 [2d Cir. 1993]). If any of the current third-wave claims flourish, foreign claims will likely be presented to U.S. lawyers and filed in U.S. courts.

On May 12, 1998, the Republic of Guatemala became the first nation to file a lawsuit against the U.S. tobacco industry for the recovery of public health care expenses (Davis 1998) (*Guatemala v. Tobacco Institute* [D.C. May 12, 1998], *cited in* 13.3 TPLR 3.121 [1998]).

Counterthrust: Tobacco Industry Initiation of Litigation and Other Tactics

The Tobacco Industry Response to the Science of ETS

In its 1993 lawsuit filed in U.S. District Court in Greensboro, North Carolina, the tobacco industry accused the EPA of using improper procedures, including statistical manipulation, to arrive at a predetermined conclusion and sought "a declaration that EPA's classification of ETS as a Group A [known human] carcinogen and the underlying risk assessment are arbitrary, capricious, violative of the procedures required by law, and unconstitutional" (*Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency* [M.D.N.C. June 22, 1993], *cited in* 8.2 TPLR 3.97 [1993]). As discussed earlier in this chapter (see "Health Consequences of Exposure to ETS"), on July 17, 1998, U.S. District Judge William L. Osteen Sr. issued a ruling whereby the court annulled Chapters 1–6 and the Appendices to EPA's *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* (EPA 1992; Meier 1998b). The judge reached his conclusion only after having denied the EPA's motion to dismiss the case even though the EPA had never taken, and indeed had no authority to take, final agency action (e.g., the adoption of a regulation restricting smoking) based on its report (*Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency,* 857 F. Supp. 1137 [M.D.N.C. 1994]).

This lawsuit, filed in 1993, was not the first instance of the tobacco industry attacking scientists and their work on ETS. Internal industry memos were cited in an article in April 1998 in the *Wall Street Journal*: "Determined to keep reports about second-hand smoke from mushrooming, the tobacco industry mobilized a counter attack in the mid-1980s to systematically discredit any researcher claiming perils from passive smoke" (Hwang 1998). In a February 25, 1985, letter, Anthony Colucci, who was a top scientist at R.J. Reynolds Tobacco Company, wrote to H.E. Osmon, a director of public affairs at R.J. Reynolds: ". . . we anticipate that if [then-EPA scientist James] Repace runs true to form there will be a good deal of media copy written about their [Repace's and naval researcher Alfred Lowrey's] analyses and thus we should begin eroding confidence in this work as soon as possible" (Hwang 1998).

A British-American Tobacco Company memo from 1988 details a meeting at which Philip Morris unveiled its plans to organize the "selection, in all possible countries, of a group of scientists either to critically review the scientific literature on ETS to maintain controversy, or to carry out research on ETS. In each country a group of scientists would be carefully selected, and organized by a national coordinating scientist" (Boyse 1988, p. 2). The Philip Morris plan begins by drawing up a list of "European scientists who have had no previous association with tobacco companies" (p. 2). The scientists are then contacted and

> asked if they are interested in problems of Indoor Air Quality: tobacco is not mentioned at this stage. CVs are obtained and obvious "anti-smokers" or those with "unsuitable backgrounds" are filtered out. The remaining scientists are sent a literature pack containing approximately 10 hours of

> reading matter, including "anti-ETS" articles. They are asked for a genuine opinion as independent consultants, and if they indicate an interest in proceeding further a Philip Morris scientist makes contact. Philip Morris then expects the group of scientists to operate within the confines of decisions taken by PM scientists to determine the general direction of research, which apparently would then be "filtered" by lawyers to eliminate areas of sensitivity (p. 2).

As this observer notes, "Although the industry is in great need of concerted effort and action in the ETS area, the detailed strategy of Philip Morris leaves something to be desired. The excessive involvement of external lawyers at this very basic scientific level is questionable" (Boyse 1988, p. 275). Chapman (1997) has described this 1988 memo as one that "promises to blow apart the façade that the tobacco industry carries out neutral research into passive smoking" (p. 1569).

A study published in May 1998 in the *Journal of the American Medical Association* (Barnes and Bero 1998) concluded that of the 37 percent (39 out of 106) of articles reviewed that concluded that ETS is not harmful to health, 74 percent (29 out of 39) of these were written by authors with tobacco industry affiliations. In this survey, the authors included articles whose stated or implied purpose was to review the scientific evidence that ETS is associated with one or more health outcomes. Articles were excluded if they did not focus specifically on the health effects of ETS or if they were not written in English. The authors noted, "In multiple logistic regression analyses controlling for article quality, peer review status, article topic, and year of publication, the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry" (p. 1566). The authors also found that the "conclusions of review articles are strongly associated with the affiliations of their authors. Authors of review articles should disclose potential financial conflicts of interest, and readers should consider authors' affiliations when deciding how to judge an article's conclusions" (p. 1566).

Other Industry-Sponsored Opposition to State Tobacco Control Initiatives and Advocates

Tobacco interests have used the courts proactively against other measures to prevent smoking. The proliferation of third-wave litigation against the tobacco industry has been matched by a more aggressive use of litigation by tobacco interests. For example, the industry and its allies filed a preemptive challenge, on state constitutional grounds, to the Florida legislation authorizing the state to recover tobacco-related health spending; the suit was ultimately unsuccessful (*Agency for Health Care Administration v. Associated Industries of Florida*, No. 86,213 [Fla. June 27, 1996], *cited in* 11.4 TPLR 2.113 [1996]). Similarly, the Governor of Mississippi, along with the tobacco industry, brought unsuccessful proceedings in the Mississippi Supreme Court to stop the Mississippi Medicaid reimbursement suit from going forward (*In re Kirk Fordice as Governor of Mississippi* [Miss. S. Ct.], *cited in* 12.1 TPLR 2.5 [1997]; *In re Corr-Williams Tobacco Co.* [Miss. S. Ct.], *cited in* 12.1 TPLR 2.1 [1997]). The tobacco industry also filed preemptive challenges on federal constitutional grounds to other state lawsuits even before these suits were filed (e.g., *Philip Morris Inc. v. Harshbarger*, Civil Action No. 95-12574-GAO [Mass. Nov. 22, 1996], *cited in* 11.8 TPLR 2.259 [1996]; *Philip Morris Inc. v. Graham*, Case No. 960904948 CV [Utah Dist. Ct. Salt Lake Cty.], *cited in* 12.1 TPLR 2.46 [1997]; *Philip Morris Inc. v. Blumenthal*, No. 97- 7122 [2d Cir. 1997], *cited in* 12.5 TPLR 2.305 [1997]), and the industry has tried to remove these suits from state to federal court once they were filed (e.g., *Massachusetts v. Philip Morris Inc.*, No. 96-10014-GAO [D. Mass. May 20, 1996], *cited in* 11.3 TPLR 2.33 [1996]; *Louisiana v. American Tobacco Co.*, No. 96-0908 [La. July 16, 1996], *cited in* 11.5 TPLR 2.164 [1996]; *Maryland v. Philip Morris Inc.*, No. CCB-96-1691 [Md. July 31, 1996], *cited in* 11.5 TPLR 2.167 [1996]; *Connecticut v. Philip Morris Inc.*, No. CV960153440S [Conn. Oct. 9, 1996], *cited in* 11.7 TPLR 2.238 [1996]).

Arguably, the most sweeping litigation measure taken by the tobacco industry was initiated on August 10, 1995, when Philip Morris and others filed suit to block the FDA from regulating the sale, promotion, and distribution of cigarettes to minors. Discussed earlier in this chapter (see "Further Regulatory Steps"), the suit challenged the agency's authority to regulate cigarettes under the Federal Food, Drug, and Cosmetic Act. The lawsuit further charged that the proposed regulations would violate the tobacco companies' freedom of speech and would impair their ability to compete (Collins 1995b).

Tobacco companies have also used litigation tactically to impede the flow of damaging information. Brown & Williamson Tobacco Corporation brought suit against a paralegal aide accused of stealing confidential and potentially incriminating documents *(Wyatt, Tarrant & Combs v. Williams*, 892 S.W.2d 584 [Ky. 1995]). The documents, some of which were ultimately obtained by members of Congress, have shown that the tobacco manufacturers not only knew of both the addictive and the carcinogenic properties of tobacco

use but also concealed the evidence for decades (Shapiro 1994b). R.J. Reynolds brought suit (*R.J. Reynolds Tobacco Co. v. John Does*, 94-CVS-5867 [N.C., Forsyth Cty. 1994], *cited in* 9.4 TPLR 2.95 [1994]) to stop the solicitation of damaging information from tobacco insiders (*National Law Journal* 1994). In March 1994, Philip Morris filed a $10 billion libel suit in Virginia circuit court against the American Broadcasting Company (ABC) television network, a reporter, and a producer of the network's magazine program *Day One*. The suit concerned a broadcast segment that focused on Philip Morris' chief competitor, R.J. Reynolds Tobacco Company, and that accused R.J. Reynolds (and, in effect, the entire tobacco industry) of increasing the levels of nicotine in cigarettes to cause addiction among smokers (Chamberlain 1994; Janofsky 1994b). R.J. Reynolds subsequently filed a similar suit. In August 1995, after a siege of unusually aggressive discovery (Frankel 1995), ABC agreed to apologize for its "mistake" in accusing the manufacturers of "spiking" nicotine and to pay for Philip Morris' legal expenses, reportedly some $15 million (Freedman et al. 1995). ABC preferred to avoid the rigors of further litigation even though "the network's own lawyers felt they had a 65 percent chance of winning the case" (Landler 1995). Philip Morris subsequently took out full-page advertisements in the *New York Times*, *Washington Post*, *Wall Street Journal*, and other newspapers, proclaiming ABC's capitulation. That Philip Morris chose to respond to the news report with legal action, rather than mounting an aggressive advertising campaign as it has done in the past, is seen as reflecting the company's decision to turn over responsibility for public relations to its lawyers (Landler 1995).

Tobacco companies have heavily funded organizations that oppose smoke-free laws and policies. The National Smokers Alliance (NSA), for example, purports to be a membership organization on behalf of smokers. When NSA's Senior Vice President Gary Auxier was asked why his organization, which boasts that it is "a nonprofit, grass-roots membership organization with more than 3 million members," in fiscal year 1996 collected only $74,000 from dues (enough for 7,400 members) while its total receipts were more than $9 million, Auxier chose not to answer (Levin 1998). The NSA has vigorously attacked the smoke-free bar law in California, including publicizing bar owners who have engaged in civil disobedience (PR Newswire 1998b). Regarding this and other media-attracting actions, Morain (1998) points out, "Assisting that group is one of the world's largest public relations firms, Burson-Marsteller. The company has a long-standing account with the tobacco industry and is renowned for its ability to generate news coverage. As the organizers tell it, they're merely tapping the grass roots of the body politic, giving a voice to everyday people. Opponents deride the [supposed grass-roots] campaign as 'Astroturf' " (p. A23).

In opposing a lawsuit based on harm from ETS, Philip Morris tried to subpoena scientific researchers' raw data that support epidemiologic research on the link between ETS and lung cancer. A state judge rejected the company's attempt to get the raw data, citing a 1990 Louisiana privacy law. The court found that "enforcement of the subpoenas would leave the researchers with the knowledge throughout continuation of their studies [that] the fruits of their labors had been appropriated by and were being scrutinized by a not unbiased third party whose interests were arguably antithetical to theirs" (*In re Philip Morris Inc.*, 706 So. 2d 665, 1998 La. App. LEXIS 138 [4th Cir. Jan. 28, 1998]).

One important industry tactic is to attack the integrity of leading tobacco control researchers and advocates (Sweda and Daynard 1996). For example, a group called Californians for Scientific Integrity (CSI) sued the University of California in 1997, in part, over Dr. Stanton Glantz's 1994 study on the economic impact of smoke-free restaurant laws. Public officials around the country have used that study to support passage of clean indoor air laws in their cities and towns. Funded by the NSA (Sullivan 1997), the CSI lawsuit alleged that public funds were used improperly in supporting the study. Earlier in 1997, the NSA had paid $10,000 to Michael Evans, clinical professor of managerial economics at the J.L. Kellogg Graduate School of Management at Northwestern University, to write a report that attacked the Glantz study on smoke-free restaurants (Price 1997). In November 1997, Sacramento County Superior Court Judge Joe S. Gray dismissed the CSI lawsuit, saying that "there were no grounds for the case" (Weinstein 1997b). A lawyer for the university wrote in a brief that led to the dismissal that the "true agenda of this action was patently obvious—to muzzle scientists whose research publications and speech on subjects relating to tobacco, tobacco control and the politics of tobacco have been a thorn in the side of the tobacco industry for decades" (Weinstein 1997b).

Industry-Sponsored Litigation Against Local Tobacco Control Efforts

The tobacco industry has used litigation, as well as the threat of litigation, to try to thwart local measures to reduce tobacco use. For example, R.J. Reynolds Tobacco Company financed a 1994 lawsuit filed by local restaurant owners in Puyallup, Washington (Suttle

1994). The suit alleged that the recently enacted ordinance requiring that restaurants be smoke free was preempted because state law permitted smoking sections in restaurants and that the city had unlawfully and substantially deprived the plaintiffs of their rights guaranteed by the U.S. Constitution. Even though the legal arguments seemed dubious, the City Council decided to repeal the ordinance rather than expend the funds necessary to fight the lawsuit (Sweda and Daynard 1996).

In contrast, a board of health regulation banning all public smoking in Northampton, Massachusetts, was unsuccessfully challenged in 1994 (*Alexander's Restaurant, Inc. v. City of Northampton*, Civil Action No. 94-307 [Mass. Super. Ct. Oct. 25, 1994]).

Philip Morris joined with some local businesses to file a lawsuit on February 1, 1994, against the city of San Francisco to try to block an ordinance banning smoking in public buildings (Holding 1994; Schmeltzer and Arndt 1994). The plaintiffs argued that the ordinance was preempted by state rules governing workplace health and safety. However, five months later, California Governor Pete Wilson signed into law a measure banning smoking in most indoor workplaces and allowing local governments to enforce even stricter antismoking ordinances. The tobacco industry shifted away from its lawsuit against San Francisco and sponsored Proposition 188, an initiative that would eliminate local smoking laws and replace them with a weaker statewide standard (Epstein and Russell 1994). Although the tobacco industry spent $18.9 million on behalf of Proposition 188, about 18 times the amount spent by opponents, California voters resoundingly rejected the measure. Proposition 188 garnered less than 30 percent of the vote (Morain and Ellis 1994).

Local restrictions against cigarette vending machines have increasingly come under attack by cigarette distribution companies suing in several states (Schmit 1994; Sullivan 1994). In one such instance, the Massachusetts Supreme Judicial Court unanimously upheld a Provincetown bylaw that banned cigarette vending machines from that town (*Take Five Vending, Ltd. v. Town of Provincetown*, 415 Mass. 741, 615 N.E.2d 576, 1993 Mass. LEXIS 440 [Mass. Mar. 4, 1993]).

In addition to the above-mentioned cases, other local ordinances forbidding tobacco use in public places and regulating various forms of outdoor advertising have been challenged. As discussed earlier in this chapter (see the case description of *Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore* in a subsection of "Constitutionality of Regulating Tobacco Advertising"), the outcomes of these challenges have been mixed.

Anticipatory Effects

Law works not only by coercive imposition but also by signals about authoritative (and potentially changeable) norms and about the potential disposition of legal coercion. Litigation may have an effect not only on those who are parties to it but also on other potential legal actors (plaintiffs, defendants, and attorneys who learn about the litigation) (Galanter 1983). Depending on the outcome of a litigation, similarly situated injured parties, for example, may abandon or modify—or conversely, may decide to continue—their risk-creating behavior or may be either encouraged to make a legal claim or discouraged from claiming. Lawyers may be encouraged to mount or discouraged from mounting claims or defenses. Uninvolved actors (such as potential business partners) who anticipate dealing with parties or potential parties may respond to litigation signals by modifying (or even terminating) their dealings with those parties. Such signals may be derived not only from authoritative decisions but also from the process of the litigation itself, which may exhibit advantages to be gained or costs to be avoided. For example, news organizations viewing the fierce and expensive industry response to critical depiction may hesitate to portray industry practices negatively (Freedman and Stevens 1995).

More often, third-wave tobacco litigation provides dramatic evidence of the indirect, anticipatory effects of litigation on reducing tobacco use. In early 1995, three prominent manufacturers recoiled from business dealings with cigarette makers to avoid the risk of getting embroiled in liability litigation. The Manville Corporation sued R.J. Reynolds Tobacco Company for a declaratory judgment that the corporation does not have a contract to supply fiberglass for cigarette filters (Appleson 1995). A few days later, Harley-Davidson, Inc., responding to a 1993 suit by the Lorillard Tobacco Company to enforce an agreement licensing the motorcycle maker's name for a brand of cigarettes, countersued, alleging that tobacco liability risks reduced Lorillard's ability to fulfill its contract (Rose and Hwang 1995). Papermaker Kimberly-Clark Corporation (which had been named a defendant in the West Virginia health care provider suit), the world leader in tobacco papers, decided to sell its cigarette paper business. The company denied that liability fears or shareholder activism played any part in its decision, but analysts said that such concerns were dominant factors (Collins 1995a). Other companies, such as Pfizer, have adopted policies "prohibiting units from doing business with Big Tobacco and its suppliers" (Mallory 1995, p. 39).

Another set of actors responsive to signals about liability are insurers. Presumably, virtually all of the suppliers and professionals who serve cigarette makers carry liability insurance. The tobacco manufacturers themselves have been insured for at least some liability risks, although the amount of insurance coverage of the tobacco companies is unknown (Reidy and Carter 1995). If any of these insured parties are found liable for promoting or selling tobacco products, the insurers can be expected to contest coverage, using as defenses against liability to the insured many of the same arguments that plaintiffs use to establish the liability of the insured. If, for example, liability involves attribution to the industry of knowledge of a causal link to disease or concealment of that information, then to defeat coverage, the insurer may likewise claim that the insured had wrongfully and knowingly obtained coverage for a business practice whose dangers were concealed from the insurer. "In effect," note two analysts, "the insurance industry will have to prove the very thing the policyholder is trying to deny in the tobacco-related suits" (Reidy and Carter 1995, p. S38). Thus a "breakthrough" by tobacco plaintiffs may lead to a "second front" of liability battles between tobacco defendants and their insurers.

Indeed, in 1996, Imperial Tobacco Limited (No. 500-05-014084-964 [Canada S. Ct., Prov. of Quebec, Dist. of Montreal Jan. 12, 1996], *cited in* 11.1 TPLR 3.39 [1996]) filed suit in the Superior Court of Quebec against two Toronto-based liability insurance companies—American Home Insurance Company and Commercial Union Assurance Company of Canada—demanding that they pay legal costs and any damages arising from a class action suit filed against Imperial in Ontario by Mr. David Caputo and three other persons in 1995. The Canadian class action suit, which has not yet been resolved, seeks damages on behalf of nicotine-addicted persons who have suffered because of their addiction to nicotine. Imperial claims to have had policies issued by the insurers obligating them to reimburse Imperial for legal costs incurred in the class action and to pay any further costs they may incur in this matter. The tobacco company is, in essence, asking the Superior Court of Quebec for a declaration that the two named insurance companies must pay all of Imperial's legal fees and all sums awarded by an eventual finding of liability by the Ontario court *(Tobacco Products Litigation Reporter* 1995b).

Finally, the investment community is greatly interested in the potential effects of legal liability on the future profitability and solvency of the tobacco companies. Tobacco cases are closely tracked by investment analysts, and "even interim events in peripheral cases can propel share prices in one direction or another" (Orey 1995, p. 70). The overhang of potential liability casts a shadow on tobacco stocks. Opinions differ about just how much these stocks are discounted for liability, but there is general agreement that the removal of the liability shadow would be worth many billions in increased stock value. This volatile combination of possible liability and latent value means that any breach in the previously impregnable liability ramparts would inaugurate a period of pronounced instability among tobacco investors. Some analysts imagine a zone of agreement that would locate a comprehensive settlement, which would in turn unlock the unrealized value of tobacco stocks while providing generously for the victims of tobacco. However, because present litigants cannot preclude future plaintiffs, it remains unclear whether litigation can provide the finality and closure that a comprehensive settlement would require. Litigation can set off ramifying effects and in general advance a formerly sluggish or obstructed state of affairs, but it is not clear whether it can contain these effects or design an all-encompassing resolution or policy.

Criminal Proceedings

Another arena in which attention is being given to the activities of the tobacco industry is the criminal justice system. Since 1995, the U.S. Department of Justice has conducted an ongoing investigation of the alleged violation of federal criminal laws by tobacco companies, tobacco company executives, tobacco industry-supported trade and scientific associations, and other entities that have conducted business with the tobacco industry.

The Justice Department initiated a formal investigation of the tobacco industry in response to the filing in 1994 of a comprehensive legal analysis, referred to as a prosecution memorandum, by Representative Martin T. Meehan (D-MA) with the U.S. Attorney General (Hohler 1994; Mallory 1994, 1995; Meehan 1994; Schwartz 1994; Miga 1995; Reuters 1996; Rodriguez and Taylor 1998). The prosecution memorandum petitioned the Justice Department to consider allegations that tobacco companies, tobacco company executives, and others had violated multiple criminal laws by providing false information to the FDA and the U.S. Surgeon General (18 U.S.C. section 1001), committing perjury in testimony before Congress (18 U.S.C. section 1621), perpetrating mail and wire fraud (18 U.S.C. sections 1341 and 1343, respectively), engaging in deceptive advertising practices (15 U.S.C. section 52), and

violating federal conspiracy and racketeering laws (18 U.S.C. sections 371 and 1962, respectively) (Meehan 1994; Shane 1997; *Corporate Crime Reporter* 1998; Clifford E. Douglas. The criminal investigation of the tobacco industry. Speech to the 13th Annual Conference of the Tobacco Products Liability Project; May 31, 1998; Boston; unpublished data).

Nature, Extent, and Focus of the Criminal Investigation

The Justice Department's investigation began as a preliminary inquiry focused on alleged perjury arising out of testimony delivered under oath by seven tobacco company executives who stated before a congressional subcommittee on April 14, 1994, that they did not believe that nicotine is addictive. The initial inquiry was later expanded to a formal grand jury investigation to address broader allegations that tobacco companies had, among other things, violated 18 U.S.C. section 1001.

Section 1001 prohibits the making of false statements to agencies and officials of the federal government (Hilts 1995; Novak and Freedman 1995; Appleson 1996; Blum 1996; Freedman 1996; Thomas and Schwartz 1996; Stohr 1997). In contrast to the level of proof required for a showing of perjury, section 1001 does not require a showing that a person knowingly lied under oath. It also allows prosecution for the withholding of information. Besides addressing potential section 1001 violations, the investigation continues to focus on other allegations of criminal conduct, including fraud, conspiracy, and racketeering (Cole and Taylor 1998; *Corporate Crime Reporter* 1998; Davis and Duffy 1998; Douglas, unpublished data; Duffy and Taylor 1998; Meier 1998c).

As of mid-1998, two federal grand juries were considering evidence of alleged tobacco industry wrongdoing. One grand jury was assigned to hear evidence presented by prosecutors from the Fraud Section of the Justice Department's Criminal Division regarding the broad allegations of criminal misconduct described above. The second grand jury was assigned to review information presented by the U.S. attorney for the Eastern District of New York. The work of the second grand jury concerned a related criminal investigation whose focus is an alleged conspiracy by major tobacco manufacturing companies to suppress legitimate medical research and promote biased research through the industry-sponsored Council for Tobacco Research. The Justice Department coordinated these complementary investigations (Cohen and Geyelin 1996; Thomas and Schwartz 1997; Davis and Duffy 1998).

A third criminal investigation was begun in 1995 to determine whether a major cigarette manufacturing company may have committed securities fraud by failing to disclose all it knew about nicotine. Under securities laws, companies are required to disclose significant information that may affect their stock price. The third investigation was initiated by the U.S. attorney for the Southern District of New York, following the publication of an investigative news article that reported that, based on a review of 2,000 pages of previously undisclosed documents, Philip Morris Companies Inc. had conducted many years of secret research into the pharmacologic effects of nicotine on the human brain and central nervous system (Freedman and Lambert 1995; Hilts and Collins 1995). The securities fraud investigation subsequently was consolidated with the main Justice Department investigation (Philip Morris Companies Inc. 1998).

Federal prosecutors have interviewed witnesses, compiled comprehensive company dossiers, and issued subpoenas, all under the supervision of the U.S. Attorney General. Several of the major cigarette manufacturing companies, such as R.J. Reynolds Tobacco Company and Philip Morris Companies Inc., as well as others, confirmed publicly that they are the subject of federal criminal investigations relating to the matters described above and that employees of the companies have received requests for information, including orders to produce internal documents and subpoenas to testify before the grand juries (Goshko 1995; Hilts 1995; Miga 1995; Associated Press 1996a,b; Bloomberg Business News 1996a,b; Federal Filings-Dow Jones News 1996; Johnston 1996; Jones 1996; Reuters 1996; Thomas and Schwartz 1996; Tribune News Services 1996; Weiser and Schwartz 1996; Shaffer 1997; Philip Morris Companies Inc. 1998).

In an April 1998 announcement that it had reached a cooperation agreement with a cigarette manufacturing company in support of the criminal investigation, the Justice Department identified five main subject matter areas on which it was focused (U.S. Department of Justice 1998). These were industry knowledge of the health consequences of smoking cigarettes and the addictive nature of nicotine; the targeting of children and adolescents by the industry; the manipulation of nicotine by the industry; control of research by the Council for Tobacco Research, including special projects conducted under the auspices of the council; and lawyer involvement in directing research or crafting false or misleading statements by any of the tobacco companies to the Congress, the FDA, and the American consumers concerning the above.

The announcement of the cooperation agreement was interpreted by legal experts as a sign that the criminal investigation was accelerating and the Justice Department was likely to file broad conspiracy charges against major cigarette companies in the future (Cole and Taylor 1998; *Corporate Crime Reporter* 1998; Douglas, unpublished; Duffy and Taylor 1998; Keil 1998; Levin and Ostrow 1998; Schwartz 1998a).

Key Sources of Evidence

The gathering of evidence by the Justice Department was advanced by the increased availability of an array of outside resources. These included the results of the extensive investigation of the tobacco industry conducted by the FDA from 1994 to 1996. The FDA's administrative record and investigative files were made available to the Justice Department, providing prosecutors and investigators with a significant body of information concerning tobacco manufacturers' knowledge of the addictive nature of nicotine and of the manipulation and control of the substance (*Federal Register* 1995b, 1996).

Another important source of information for Justice Department officials was the voluminous hearing record produced over a 10-month period in 1994 by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce in the U.S. House of Representatives (1995a,b,c,d). The subcommittee, chaired by U.S. Representative Henry A. Waxman (D-CA), held numerous hearings in which testimony was obtained from a variety of witnesses, including the commissioner of the FDA, other federal government health officials, experts in nicotine addiction, tobacco company representatives, and former tobacco company scientists, among many others. In addition, Representative Waxman made available hundreds of previously secret nicotine research documents from the largest cigarette manufacturer by reading them into the public record on the floor of the House of Representatives in July 1995 (Associated Press 1995; *Congressional Record* 1995a,b; Schwartz 1995).

A third significant source of evidence in support of the Justice Department's criminal investigation was the emergence of internal tobacco company documents and testimony obtained in private lawsuits brought against tobacco industry defendants. Starting in 1994, these civil cases were initiated by state attorneys general, private classes of allegedly addicted and injured smokers, and individual plaintiffs, as described earlier in this chapter (see "The Third Wave of Tobacco Litigation"). The simultaneous litigation of numerous civil suits and the Justice Department's pursuit of its criminal investigation have produced a notable synergy. Millions of previously undisclosed tobacco industry documents that were obtained through the discovery process in civil lawsuits became, in many instances, readily accessible to federal prosecutors (Curriden and Rodrigue 1997; Geyelin 1998; Meier 1998c; Rodriguez and Taylor 1998; Scherer and Rybak 1998; Schwartz 1998c).

Initial Results of the Criminal Investigation

The Justice Department's ongoing investigation resulted in a first conviction in 1998. Under the terms of an agreement with the government, a biotechnology company, DNA Plant Technology Corporation, pleaded guilty to a misdemeanor charge of conspiring to break a law that had made it illegal to export tobacco seeds. The company was found to have engaged in such unlawful conduct in cooperation with a leading cigarette manufacturing company, identified as an unindicted coconspirator, with whom it had contracted to patent and develop a genetically altered tobacco code-named Y-1, which contained approximately twice the nicotine of ordinary tobacco. According to the Justice Department, the prosecution memorandum submitted by Representative Meehan, and the FDA, one of the goals of the cigarette company in conspiring with the biotechnology company was to develop a reliable source of supply of high-nicotine tobaccos that could then be used to control and manipulate the nicotine levels in several popular cigarette brands (Meehan 1994; *Federal Register* 1995b, 1996; Meier 1998d; Neergaard 1998; Schwartz 1998b; Schwartz and Connolly 1998; Taylor 1998; Taylor and Rodriguez 1998; Weinstein 1998b).

Beginning in 1997, the threat of criminal liability led certain individuals associated with the tobacco industry, such as Thomas S. Osdene, Ph.D., former Director of Research for Philip Morris Companies Inc., and Roger R. Black, current Director of Leaf Blending for Brown & Williamson Tobacco Corporation, to decline to answer questions under oath, choosing instead to invoke the Fifth Amendment right against self-incrimination (Geyelin 1997; Meier 1997; Weinstein 1997a; Anderson 1998). Some officials sought immunity from prosecution in exchange for their cooperation. Such offers were met with mixed responses from the Justice Department. Typically they were rejected, but in one publicized instance a request for immunity was granted (Geyelin 1997; Stohr 1997; Weinstein 1997a). The Justice Department granted immunity to Janis A. Bravo, a scientist formerly with DNA Plant Technology Corporation and coholder of the patent for

a high-nicotine tobacco plant called Y-1, developed for Brown & Williamson Tobacco Corporation.

Prognosis for Future Actions Through the Criminal Justice Process

Federal prosecutors possess considerable discretion both in terms of bringing charges against alleged wrongdoers and, in the event a strong case is developed, in seeking concessions from criminal targets in the plea-bargaining process. In light of these options, the Justice Department may seek to require tobacco manufacturing companies to modify their advertising and marketing practices so as to render them unappealing to young people, stop manipulating nicotine or using nicotine-enhancing chemicals, pay the federal government significant monetary penalties, and submit to regulation by the FDA (*Corporate Crime Reporter* 1998; Douglas, unpublished data).

Given the breadth and complexity of the criminal investigation of the tobacco industry, as well as the substantial burdens of proof that prosecutors must satisfy pursuant to the federal criminal statutes noted above, it is not possible to predict the outcome of the current criminal investigative process. From its inception, the investigation was anticipated to be a lengthy, complicated operation, in part because of the government's responsibility to process and review millions of pages of documents obtained from the tobacco industry and other sources (Thomas and Schwartz 1996).

With the Justice Department's accumulation of a growing body of evidence, including company documents and grand jury testimony, as well as the cooperation of the Liggett Group Inc. in support of the government's investigation, some legal experts have described the investigation as likely to result in further action (Cole and Taylor 1998; *Corporate Crime Reporter* 1998; Douglas, unpublished data; Duffy and Taylor 1998; Keil 1998; Levin and Ostrow 1998; Schwartz 1998a). One recent indicator that the issuance of indictments might be near was the delivery by Justice Department officials of letters to Brown & Williamson Tobacco Corporation and its officials, formally notifying them that they are the targets of a criminal investigation and that they face possible prosecution (Davis and Duffy 1998; Meier 1998c; *Wall Street Journal* 1998).

Further criminal action against the tobacco industry also raises the likelihood of diluting the influence of the industry's political lobby, thereby strengthening the ability of public health proponents to advocate for more stringent regulation of the manufacture, sale, distribution, advertising, and promotion of tobacco products (Douglas 1998).

Comment

After 40 years in which two waves of product liability litigation proved unavailing, there has been a recent upsurge of investment and innovation in tobacco litigation. This third wave of litigation departs from its predecessors in various ways:

- It moves away from exclusive reliance on smokers as plaintiffs, because so many cases have been decided against them as the victims of their own, informed behavior choices. Plaintiffs now include states, cities, pension funds, private health care providers, and persons exposed to ETS, none of whom can be blamed for smoking in the face of warnings.
- It multiplies the range of legal issues. Instead of focusing exclusively on common-law tort doctrine, third-wave litigation also invokes various statutory claims under consumer, antitrust, and other protective legislation.
- It expands from the classic private lawsuit by a discrete plaintiff to the class action device.
- It expands from solely seeking monetary damages to including claims for injunctive relief, medical monitoring, and the recovery of attorneys' fees.
- It shifts from a pure model of private law to mixed strategies in which private law is used to effectuate public policy by defending public fiscal interests and by enhancing the performance of statutory and regulatory controls of tobacco.
- It enlarges the roster of claimants' lawyers from those who specialize in representing individual plaintiffs in personal injury cases to include mass tort specialists and entrepreneurial securities class action lawyers. These attorneys, who typically practice in larger firms than individual plaintiff attorneys and have greater financial resources, are joined in more complex coalitions, including alliances with government lawyers.

Considerable uncertainty surrounds each of the several third-wave litigation initiatives and their potential contribution to reducing tobacco use. The prospect of using private law in these ways has captured attention only recently. In a wide-ranging 1993 review of tobacco policy (Rabin and Sugarman 1993), virtually all of the attention to private law was devoted

to smokers' product liability litigation. The newer legal theories that are now available to plaintiffs have considerable potential. Just how these initiatives will fare depends both on developments within the legal system and on forces outside it.

Normally, law incorporates and reflects public opinion. In a setting where smoking declines and becomes disreputable, particularly among the educated and influential (Zimring 1993), where smokers are increasingly viewed either as victims of coercion and addiction or as a minority group becoming more distanced from others (Gusfield 1993), and where evidence accumulates that the tobacco companies aggressively recruit new smokers and suppress knowledge of harmful effects of smoking, the law can be expected to respond to pressures to extend accountability and to provide remedies, if not to smokers then to those who are otherwise adversely affected by smoking.

However, other forces are working against an enlarged role for the civil justice system in the effort to reduce tobacco use. Important groups, displeased with the expansion of legal accountability, have mounted a protracted and influential campaign to curtail the civil justice system and weaken the position of claimants within it (Galanter 1993, 1994). Apart from these external constraints, the very magnitude of tobacco injury—the vast number of potential claimants involved—raises apprehension about the courts' institutional capacities to respond. Driven by the desire to conserve their scarce resources, courts will find ways to ration the judicial attention bestowed on any sizable set of related cases (Sanders 1992). As the size of the potential victim class increases, the chances for individualized judicial resolution decrease. It has been argued that the litigation about Agent Orange, the Bhopal disaster, and asbestos-related injury should be viewed as instances in which the sheer number of claims "simply overwhelm[ed] the capacity of legal institutions to meet victim compensation needs" and led to improvisation of formulaic administrative solutions (Durkin and Felstiner 1994, p. 159; cf. Henderson and Twerski 1991, on judicial aversion to such massive projects).

A balanced assessment of the possible contribution of private law initiatives to the effort to reduce tobacco use must consider not only the costs and benefits of the various initiatives but also the likelihood of accomplishing similar results by other institutional means (Komesar 1994). Typically, private law involves high transaction costs (Galanter 1994). Private law is by definition the creature of independent actors whose operations are not centrally managed and are at most partially and intermittently coordinated; each actor is trying to maximize its own gains as it defines them. No single initiative or the sum of such efforts will necessarily produce an optimal policy to reduce tobacco use. Yet private law may be a valuable component in reducing tobacco use precisely because it is an arena in which multiple courses of action are advanced by energetic champions who are open to new ideas and who, independent of government, can undertake innovative and even risky initiatives without securing official approval or competing for priority with other political commitments. Such initiatives may thus be able to stimulate and shape policy solutions. Other than as an agent or catalyst, however, it seems unlikely that the judicial forum, in a setting involving politically powerful actors and an unpredictable number of inchoate future claimants, will itself provide the ultimate policy resolution.

Conclusions

Advertising and Promotion

1. Since 1964, numerous attempts to regulate advertising and promotion of tobacco products have had only modest success in restricting such activity.

2. Current regulation in the United States is considerably less restrictive than that in several other countries, notably Canada and New Zealand.

3. Current case law supports the contention that advertising does not receive the protections of free speech under the First Amendment to the Constitution that noncommercial speech does.

Product Regulation

1. Warning labels on cigarette packages in the United States are weaker and less conspicuous than those of other countries.

2. Smokers receive very little information regarding chemical constituents when they purchase a tobacco product. Without information about toxic constituents in tobacco smoke, the use of terms such as "light" and "ultra light" on packaging and in advertising may be misleading to smokers.

3. Because cigarettes with low tar and nicotine contents are not substantially less hazardous than higher-yield brands, consumers may be misled by the implied promise of reduced toxicity underlying the marketing of such brands.

4. Additives to tobacco products are of uncertain safety when used in tobacco. Knowledge about the impact of additives is negligible and will remain so as long as brand-specific information on the identity and quantity of additives is unavailable.

5. Regulation of tobacco product sale and promotion is required to protect young people from influences to take up smoking.

Clean Indoor Air Regulation

1. Although population-based data show declining ETS exposure in the workplace over time, ETS exposure remains a common public health hazard that is entirely preventable.

2. Most state and local laws for clean indoor air reduce but do not eliminate nonsmokers' exposure to ETS; smoking bans are the most effective method for reducing ETS exposure.

3. Beyond eliminating ETS exposure among nonsmokers, smoking bans have additional benefits, including reduced smoking intensity and potential cost savings to employers. Optimal protection of nonsmokers and smokers requires a smoke-free environment.

Minors' Access to Tobacco

1. Measures that have had some success in reducing minors' access include restricting distribution, regulating the mechanisms of sale, enforcing minimum age laws, having civil rather than criminal penalties, and providing merchant education and training. Requiring licensure of tobacco retailers provides both a funding source for enforcement and an incentive to obey the law when revocation of the license is a provision of the law.

2. The effect of reducing minors' access to tobacco products on smoking prevalence requires further evaluation.

Litigation Approaches

1. Two historic waves of tobacco litigation were initiated by private citizens, were based largely on theories of negligence and implied warranty, and were unsuccessful.

2. A third wave has brought in new types of claimants, making statutory as well as common-law claims and using more efficient judicial procedures. Although several cases have been settled for substantial money and have yielded public health provisions, many other cases remain unresolved.

3. Private law initiative is a diffuse, uncentralized activity, and the sum of such efforts is unlikely to produce optimal results for a larger policy to reduce tobacco use. On the other hand, the litigation actions of individuals are likely to be a valuable component in some larger context of strategies to make tobacco use less prevalent.

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