

Chapter 1

Issues in Reducing Tobacco Use, Summary, and Conclusions

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Introduction

What works?

It would be a boon if the answer were as easy to state as the question. Programs to reduce the use of tobacco have a long history in the United States and in other countries, and the accumulated experience has provided considerable empirical understanding of the prospects and pitfalls of such efforts. Rigorous answers to formal evaluation questions are difficult to obtain, however, in part because of the wide variety of influences that are brought to bear on the use of tobacco. Researchers have little control over many of these influences and are only beginning to learn how to measure some of them.

Nonetheless, a substantial body of literature exists on attempts to reduce the use of tobacco. This report provides an overview of the major modalities that have been studied and used intensively, and it attempts, where possible, to differentiate their techniques and outcomes. The report also attempts a more difficult task: to provide some qualitative observations about how these efforts interact. The report is thus a prologue to the development of a coherent, long-term policy that would permit these modalities to be used as effectively as possible.

Development of the Report

This report of the Surgeon General was prepared by the Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, to report current information on the health effects of cigarette smoking and smokeless tobacco use. Previous reports have dealt with some of the issues included in this report, but a composite assessment of efforts to reduce tobacco use is a new topic for this series. However, the current report must acknowledge the considerable contributions of three prior monographs: *Growing Up Tobacco Free*, a report of the Institute of Medicine (Lynch and Bonnie 1994), *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, and *Healthy People 2010*, an ongoing work of the Office of Health Promotion and Disease Prevention (U.S. Department of Health and Human Services [USDHHS] 1991, 2000).

The current report is the result of the work of 16 experts in the field of reducing tobacco use who contributed initial drafts in major chapter areas. The chapters were reviewed separately by some 60 researchers and public health workers whose expertise was specific to particular subject areas. After revision, a preliminary draft volume was reviewed by an additional 40 experts, including representatives of the institutes and agencies within the Department of Health and Human Services that have special interests in reducing tobacco use.

Several concerns guided preparation of the report. First, it was clear that the primary countervailing influence against reducing tobacco use is the effort of the tobacco industry to promote the use of tobacco products. Although this report was not conceived as a documentation of such industry efforts, repeated reference to them is necessary to underscore the difficulties both in achieving desired outcomes and in evaluating the effectiveness of efforts to reduce the use of the industry's products. Second, the report has attempted to present the wide variety of techniques and methods used for tobacco control, but the disparate methods make comparisons difficult. The result is more a menu than a cookbook—a set of activities, as outlined in Chapter 7, whose combination depends on specific circumstances and the context in which they are undertaken. Third, a result of this methodological diversity is that rigorous evaluation of the ways in which tobacco reduction efforts interact remains part of the unfinished research agenda. Although interaction of interventive efforts is noted several places in the report (see, for example, the discussion of the interaction of school education with community-based programs in Chapter 3), such demonstration of synergy has been elusive.

Finally, during the report's preparation, a cascade of legal and legislative events substantially changed the landscape where the diverse efforts to reduce tobacco use take place. Several legal rulings, still under adjudication, and the Master Settlement Agreement between states and the tobacco industry to recover costs of government programs have altered prospects for reducing tobacco use through large-scale social maneuvers. Many of these issues are still unresolved, and they are likely to influence activities in the coming years.

Major Conclusions

1. Efforts to prevent the onset or continuance of tobacco use face the pervasive, countervailing influence of tobacco promotion by the tobacco industry, a promotion that takes place despite overwhelming evidence of adverse health effects from tobacco use.
2. The available approaches to reducing tobacco use—educational, clinical, regulatory, economic, and comprehensive—differ substantially in their techniques and in the metric by which success can be measured. A hierarchy of effectiveness is difficult to construct.
3. Approaches with the largest span of impact (economic, regulatory, and comprehensive) are likely to have the greatest long-term, population impact. Those with a smaller span of impact (educational and clinical) are of greater importance in helping individuals resist or abandon the use of tobacco.
4. Each of the modalities reviewed provides evidence of effectiveness:
 - Educational strategies, conducted in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
 - Pharmacologic treatment of nicotine addiction, combined with behavioral support, will enable 20 to 25 percent of users to remain abstinent at one year posttreatment. Even less intense measures, such as physicians advising their patients to quit smoking, can produce cessation proportions of 5 to 10 percent.
 - Regulation of advertising and promotion, particularly that directed at young people, is very likely to reduce both prevalence and uptake of smoking.
 - Clean air regulations and restriction of minors' access to tobacco products contribute to a changing social norm with regard to smoking and may influence prevalence directly.
 - An optimal level of excise taxation on tobacco products will reduce the prevalence of smoking, the consumption of tobacco, and the long-term health consequences of tobacco use.

5. The impact of these various efforts, as measured with a variety of techniques, is likely to be underestimated because of the synergistic effect of these modalities. The potential for combined effects underscores the need for comprehensive approaches.
6. State tobacco control programs, funded by excise taxes on tobacco products and settlements with the tobacco industry, have produced early, encouraging evidence of the efficacy of the comprehensive approach to reducing tobacco use.

Issues in Reducing Tobacco Use

Two themes have permeated the history of tobacco use in the United States. First, and most obviously, tobacco is an extraordinary economic fuel, and its powerful economic impact comes into direct conflict with its vast social costs. Second, antitobacco activity has a continuous history characterized by waxing and waning and by a changing mix of motivations and strategies. These two themes are inextricably linked, and their interaction provides a backdrop for current efforts to reduce tobacco use.

Such efforts take place in a complicated context. Chronic diseases have largely replaced infectious processes as the leading causes of death during the 20th century (Rothenberg and Koplan 1990). But this replacement has occurred during a period of remarkable gains in life expectancy. Mortality is now less than half of what it was in 1900. The single most important risk associated with the leading chronic diseases is cigarette smoking; the evidence for that statement fills volumes of Surgeon General's reports on smoking and health, and these volumes are merely summaries of a massive literature. Since the first of these reports in 1964, the prevalence of smoking has declined by nearly half, and it is clear that the declining use of tobacco has contributed to the observed decline in mortality. But paradoxically, as life expectancy increases, an increasing proportion of deaths are caused by the chronic diseases associated with smoking—primarily cancer, cardiovascular disease, and emphysema. This interplay raises key questions.

First, does the current smoking prevalence of about 25 percent represent a remarkable public health success, or is it evidence of continuing failure? The answer is yes to both questions. Health advocates can be both pleased with overall trends and loathe to declare success for a job unfinished, because goals and standards change with evolving efforts to reduce tobacco use. If the worldwide public health response to

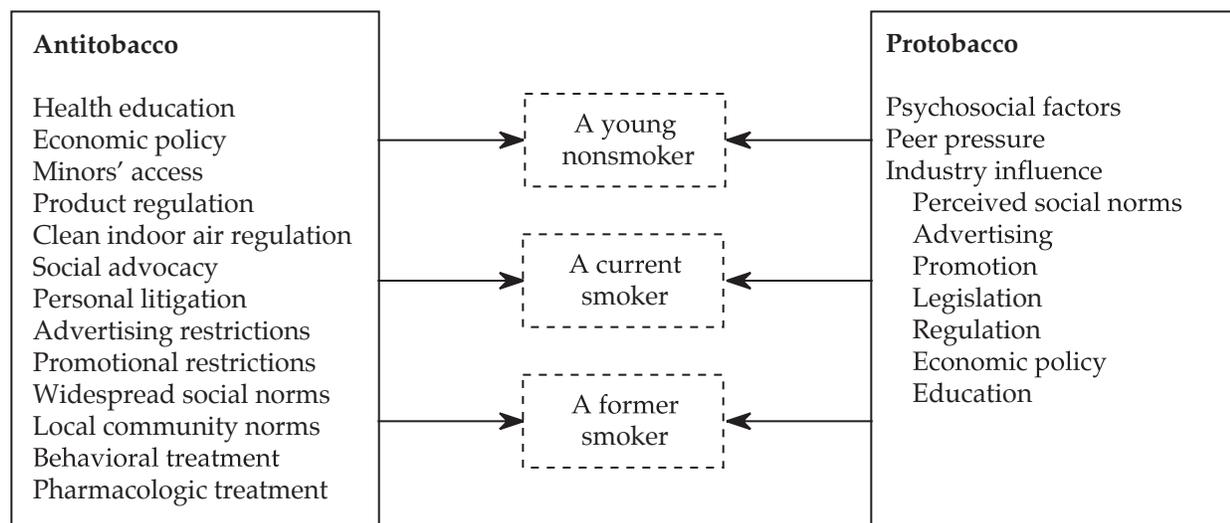
smallpox can be used as an analogy, the control program reached a point at which a single case was deemed unacceptable.

Second, why has the decline in smoking prevalence been slow? In the face of voluminous evidence about adverse health effects, prevalence has declined sluggishly (an average of about 0.5 percent per year since the mid-1960s). Currently, the decline exhibits epidemiologic signs of pausing in its downward trajectory, and it has even reversed in some population subgroups. There is no single, facile explanation for the persisting practice of tobacco use. If rationality were the only force at work, tobacco use would have been abandoned long ago. But as is shown in Figure 1.1, the forces that can be brought to bear on current or potential smokers are more complex and subtle than the mere awareness that smoking is harmful to one's health. A young person on the threshold of deciding to smoke may be subject to various influences, including the existence or nonexistence of targeted health education programs that discourage smoking, as well as of restrictions on access to cigarettes and a variety of regulations that determine the content and packaging of the product. Widespread and local norms, affecting this young person in the form of peer pressure, perceived smoking prevalence, and the commercial presentation of tobacco products, can affect the decision either way. The cost of cigarettes is likely to have significant influence on a young person, and other economic policies—largely unseen by the potential smoker—can affect the outcome. Personal psychosocial factors undoubtedly play a role and are likely to interact with these other

influences. Arrayed among and against such factors are the variety of conduits—also largely unseen by the current or potential smoker—through which the influences of the tobacco industry are manifested: use of advertising and promotion to alter perceived social norms, alteration or prevention of legislation that would inhibit smoking, legal mechanisms to influence regulation, political mechanisms to influence economic policy, and countereducation that can serve to encourage the uptake of smoking.

Whatever the precise interplay of these influences, the net result has been a slower decline than would be warranted by awareness of the well-publicized public health threat that smoking poses. The forces that have tried to accelerate the decline may be thought of collectively as “interventions,” although the term, in a more narrow sense, is often reserved for circumscribed, planned, and measurable activities. Many of the maneuvers described in this report do not meet the narrower definition, but all share the common characteristic of being directed toward a reduction in tobacco use. With a broader definition in mind, Ramström (1995) has classified tobacco interventions by the point they affect on the spectrum of tobacco use. These classifications, depicted in Figure 1.2, are creating a nonsmoking norm, reducing stimuli to smoke, strengthening motivation to quit, and reducing impediments to quitting. Although the conceptualization is useful, a line could legitimately be drawn from each box to any other box in Figure 1.2, as these activities are all intimately tied to each other in both process and outcome. To borrow from the language

Figure 1.1. Influences on the decision to use tobacco



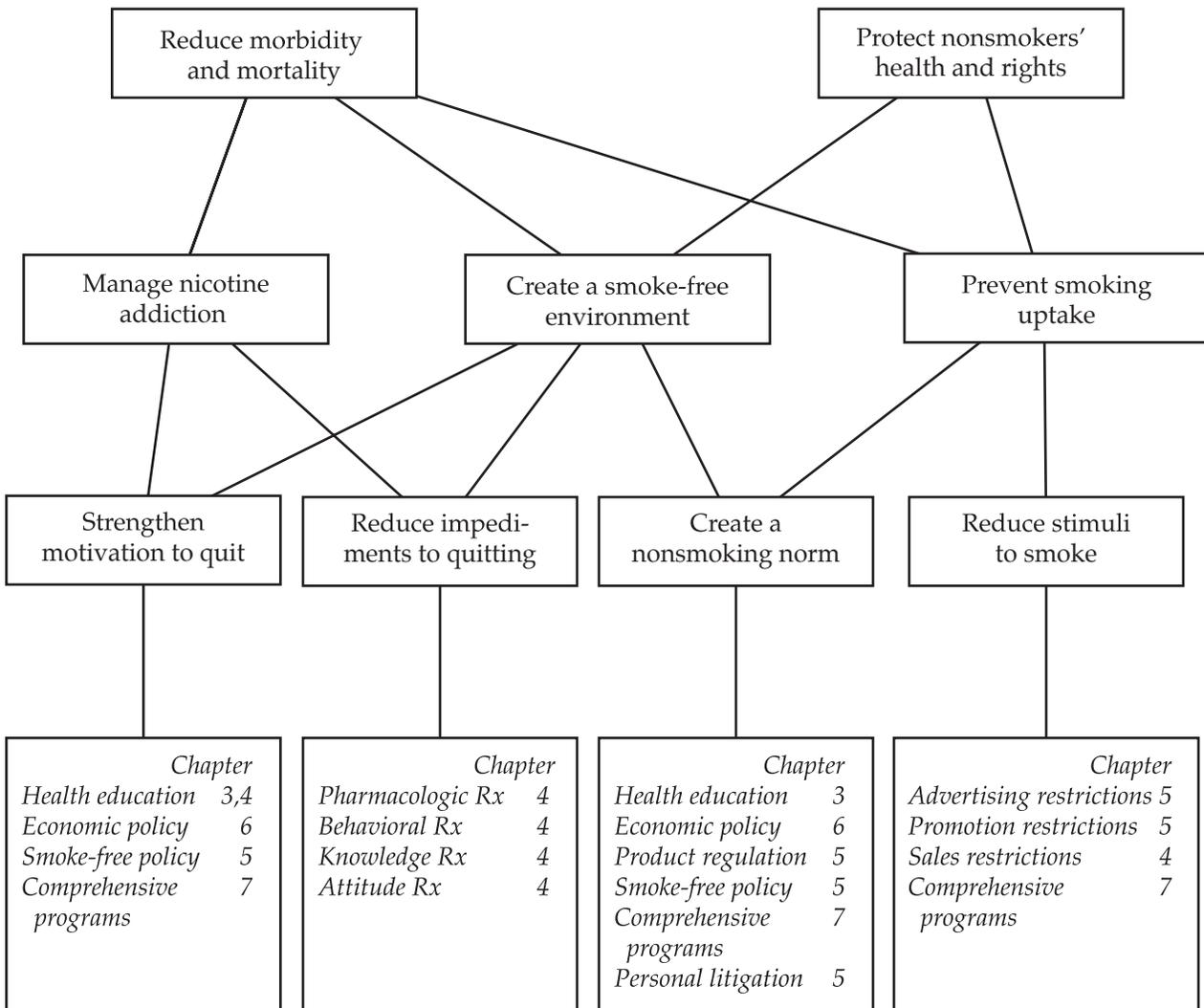
of statistics, the main effects of these efforts may be much less important than their interactions, both with each other and with the counterinfluences of the tobacco industry.

The result is a considerable challenge for evaluation. Suppose the young person in Figure 1.1 “decides” not to smoke, or the current smoker quits. Attribution of cause to this outcome in individual cases is highly unlikely. The totality of such decisions—which leads to a decline in prevalence—poses similar problems of attribution. Although the epidemiologic methods exist, data are rarely available to make attributive judgments. The challenge of evaluating these separate

efforts and strategies results from their disparate nature and the type of metric that may be appropriate to their evaluation (Table 1.1).

Management of nicotine addiction (Chapter 4), for example, is usually studied by using standard epidemiologic study design—often a prospective comparison of a study group and a control group—and the effect is measured by some form of the relative or attributable risk statistic. Educational strategies (Chapter 3), like other behavioral studies, may use similar statistics but usually invoke a different set of confounding factors to be considered; sorting out the relative influence of such factors often requires

Figure 1.2. Overview of relationships among interventions



Source: Adapted from Ramström 1995.

Table 1.1. Characteristics of interventions

Type of intervention	Targets	Tools	Study approaches	Outcome measurements
Educational	Children and adolescents, usually in school Administrative groups (e.g., members of health maintenance organizations) General population Health care providers	School curricula Interactive training Targeted services Mass media	Epidemiologic and behavioral: • Usually a comparison of “treatment” and “no treatment” groups • Control of confounding by behavioral and social variables	Relative risk Attributable risk Effect size (absolute or relative)
Clinical	Persons who smoke, usually in a health care setting General population of smokers in a commercial or quasi-commercial setting	Pharmacologic methods Behavioral modification Reinforcing environment	Epidemiologic and behavioral: • Usually a comparison of “treatment” and “no treatment” groups • Control of confounding by behavioral and demographic variables	Relative risk Attributable risk Effect size (absolute or relative)
Regulatory	Product manufacture Product sale Vendors and buyers Public venues Public transportation Worksites Health care sites	Local ordinance State regulation Federal regulation Federal law Nongovernment action (e.g., joint commission accreditation of hospital organization)	Observational Knowledge/attitude/practice studies Surveillance Case study	Linear trend Cross-sectional comparison of proportions Case analysis results
Economic	Taxes Tariffs and trade Price supports	Local ordinance State regulation Federal regulation Federal law International agreements	Econometric analysis Trend analysis Multivariate models	Linear trend Parameter estimates (e.g., elasticities)
Social/Comprehensive	Legislators Media Communication networks Case-by-case strategy State/local programs	Media advocacy Direct advocacy Community interventions Countermarketing Regulation Policy formation	Observational Case study General epidemiologic methods Trend analysis Knowledge/attitude/practice studies	Linear trends Case study analysis Cross-sectional comparisons

complex multivariate procedures. Regulatory efforts (Chapter 5) are frequently evaluated after the effect (with a pre- and post-type of study design) or are evaluated according to ecological correlations with changes in epidemiologic trends. Economic measures (Chapter 6) depend for their evaluation on econometric information—that is, on administrative data sets and survey results that are subjected to correlation and trend analysis. Finally, comprehensive program strategies are often evaluated using surveillance data systems, trend analyses, and case studies.

In each instance, some form of evaluation is possible, but the ability to connect the intervention to the outcome differs greatly among these efforts, as does the ability to estimate impact. Theoretically, it might be possible to associate each effort with some presumed number of persons who start smoking or some number who quit, but to do so would usually require numerous assertions and assumptions. For example, to estimate the number of persons who would benefit, through prevention or cessation of smoking, from an educational strategy, assumptions would be needed about its generalizability to the U.S. population, the variability of its impact, the use-effectiveness to which it is put, the proportion of the population reached, and the permanence of its effect. It is even more difficult to create a set of assumptions for the impact of a regulation that is promulgated in an environment of declining prevalence and whose existence may depend on the prior emergence of the very changes it wishes to create. For example, a ban on smoking during airline flights, a measure intended not only to protect nonsmokers from environmental tobacco smoke (ETS) but also to promote a norm of nonsmoking, was possible only in an era when the dangers of ETS were widely known and when the danger and discomfort experienced by nonsmokers had begun to outweigh the inconvenience, discomfort, and even social ostracism experienced by smokers being subjected to such restrictions. It is virtually impossible to link a social strategy to a direct effect on prevalence, however successful by other criteria. (Many would argue, quite justly, that the impact measure of reducing prevalence by reducing uptake and increasing cessation is not the only outcome of interest. Unfortunately, proximal process measures are even more variable among the different strategies, and the ultimate outcome measures—morbidity and mortality—are too distal to easily consider.)

Without a common metric, the various types of efforts to reduce tobacco use are difficult to compare quantitatively, although several attempts have been made (USDHHS 1998a; U.S. Department of the Treasury,

Office of Economic Policy, unpublished report, 1998). Perhaps a more qualitative approach could be used. One approach, illustrated in Table 1.2, would be to consider the potential span of impact (the proportion of the population, or population sectors) that the particular effort can exercise in the context of a qualitative estimate of its potential impact. Several examples of each type of effort are presented, and a qualitative assessment is made based on the data provided in the report. The assessments in Table 1.2 are by no means meant to be definitive but are meant to provide a framework for approaching the difficult issue of relative effectiveness. Although some observers would urge a more quantitative approach (e.g., using only randomized controlled trials as a measure of effectiveness), a number of effective modalities would likely be falsely discredited. For example, advocacy activity played a critical role in the formulation of the Food and Drug Administration's (FDA's) policy regarding regulation of tobacco products (see "Product Regulation" in Chapter 5), yet linking that policy, or antecedent advocacy work, directly to changing prevalence would be difficult.

In a qualitative assessment of relative impact, the examples provide a basis for a hierarchy of activities, but that hierarchy requires still another framework: consideration of the entity conducting the activity (individual, nongovernment citizens group, nongovernment agency, or government agency) and the organizational level at which the activity is conducted (local, state, national, or international). Thus, no single set of rules is available for invoking these efforts to reduce tobacco use, and relative efficacy depends on the context in which an effort takes place. For example, local efforts to reduce tobacco use might include regulatory ordinances (with potentially large impact on many people), education programs in schools (smaller impact on fewer people), and promotion of treatment for nicotine addiction (targeting a still smaller group). Specific local circumstances would dictate the specific activities. The federal government would more likely act to put in place economic measures and a variety of regulatory efforts (both types of interventions having very large span and size of impact), depending on the specific political context.

In summary, then, these efforts to reduce tobacco use line up side by side and not in relative order. Their use is predicated on the particular context in which they are to operate. Because they all face the same counterinfluence of the industry's tobacco promotion (the right-hand side of Figure 1.1), a reasonable case can be made that the large-scale strategies (economic and regulatory) have the greatest direct impact on that

Table 1.2. Examples of a qualitative assessment of intervention impact

Type of intervention	Specific modality	Span of impact	Size of impact
Educational	School curriculum	Large	Moderate
	Mass media	Large	Small
Clinical	Pharmacologic	Small	Moderate
	Behavioral (alone)	Small	Very small
Regulatory	Product manufacture	Very large	Very large
	Product sale	Large	Large
	Public venues	Large	Moderate
	Worksites	Large	Small
Economic	Taxation	Very large	Very large
	Tariffs and trade	Very large	Very large
Comprehensive programs	Statewide programs	Large	Large
	Case-by-case strategy	Unpredictable	Unpredictable

Note: Examples use a five-point ordinal scale (very small, small, moderate, large, very large), with the additional use of “unpredictable.” (See text for the context for such assessment.)

barrier. But the context necessary for those large-scale efforts to work depends on public attitudes and social norms that must be influenced by other means.

In the 1990s, it became increasingly apparent that a public health success in reducing tobacco use requires activity on all fronts. A comprehensive approach—one that optimizes synergy from a mix of strategies—has emerged as the guiding principle for future efforts to reduce tobacco use. Such an approach makes moot the issue of a hierarchy of interventions, since a comprehensive approach presupposes an interdependence of the available strategies. A coordinated, cohesive infrastructure makes intuitive sense, since it permits a modular approach to the interventions themselves, but has been challenged on analytic grounds. In such a framework, attribution of success to particular program elements is difficult, and there is no experimental evidence (nor is there likely to be) that an approach that is comprehensive is superior to one that is not. Nonetheless, the 20th century’s difficult experience with tobacco control (as described in Chapter 2) and the previous decade’s success in changing social norms and generating assets (as discussed in Chapter 7) lend empirical credibility to the comprehensive approach.

Eliminating Disparities Related to Tobacco Use and Its Effects

The elimination of health disparities related to tobacco use poses a great challenge to this nation. This was not a main focus of the current report, because two other recent, important publications have emphasized the issue. The 1998 Surgeon General’s report *Tobacco Use Among U.S. Racial/Ethnic Minority Groups* (USDHHS 1998b) was the first to address the diverse tobacco control needs of the four major U.S. racial/ethnic minority groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics. *Healthy People 2010* (USDHHS 2000) presents two overarching goals: increase quality and years of healthy life and eliminate health disparities among different segments of the U.S. population. Evidence reviewed in these two publications highlights the significant disparities that exist in the United States. These publications also discuss the critical need for a greater focus on this issue, both in research and in public health action.

Summary and Implications

In fact, each of the approaches described in this report shows evidence of effectiveness. In some instances, the synergism that might be expected through interaction among these various efforts has been documented. The remainder of this chapter describes the major findings and implications for each type of activity and presents the conclusions of the other chapters.

Historical Review (Chapter 2)

The forces that have shaped the movement to reduce tobacco use over the past 100 years are complex and intertwined. In the early years (1880–1920), antitobacco activity—some of it quite successful—was motivated by moral and hygienic principles. After important medical and epidemiologic observations of the midcentury linked smoking to lung cancer and other diseases, and after the subsequent appearance of the 1964 report of the advisory committee to the Surgeon General on smoking and health (USDHEW 1964), the movement to reduce tobacco use was fueled by knowledge of the health risks that tobacco use poses and by reaction against the continued promotion of tobacco in the face of such known risks. Despite overwhelming evidence of adverse health consequences of smoking, the stubborn norm of smoking in the United States has receded slowly, in part because of such continued promotion that works synergistically with tobacco addiction. Although strategies have varied, health advocates have focused in recent years on the prevention of harm to nonsmokers and on the concept of smoking as a pediatric disease, with the consequent need for protecting young persons from forces influencing them to smoke.

Educational Strategies (Chapter 3)

The design of educational programs for tobacco use prevention and the methods used to evaluate them have become increasingly refined over the past two decades. Early studies tended to be confined to the school context, to have short duration, and to be of low intensity. Studies tended to focus on a single modality and to ignore the larger context in which prevention takes place. The reported size, scope, and duration of program effects have become larger in recent reports. In particular, several large programs have attempted a multifaceted approach that incorporates

other than school-based modalities. Improvements in evaluation designs have increased confidence in the validity of these reports. The pattern of consistency across this group of large studies also provides assurance that these effects can be achieved in a variety of circumstances when programs include the critical multiple elements that have been defined by this research literature.

To summarize the major findings, school-based social influences programs have significant and substantial short-term impacts on smoking behavior. Those programs with more frequent educational contacts during the critical years for smoking adoption are more likely to be effective, as are programs that address a broad range of educational needs. These effects have been demonstrated in a range of implementation models and student populations. The smoking prevention effects of strong school programs can be extended through the end of high school or longer when combined with relatively intensive efforts directed through other powerful channels, such as strategies that vigorously engage the influences of parents, the mass media, and other community resources. These conclusions have been codified in national guidelines for school programs to prevent tobacco use.

Thus, an extensive body of research findings document the most effective educational programs for preventing tobacco use. This research has produced a wide array of curricula, protocols, and recommendations that have been codified into national guidelines for schools. Implementing guidelines could postpone or prevent smoking onset in 20 to 40 percent of U.S. adolescents. Unfortunately, existing data suggest that evidence-based curricula and national guidelines have not been widely adopted. By one set of criteria, less than 5 percent of schools nationwide are implementing the major components of CDC's *Guidelines for School Health Programs to Prevent Tobacco Use and Addiction* (CDC 1994). Almost two-thirds of schools (62.8 percent) had smoke-free building policies in 1994, but significantly fewer (36.5 percent) reported such policies that included the entire school environment.

Schools, however, should not bear the sole responsibility for implementing educational strategies to prevent tobacco use. Research findings, as noted, indicate that school-based programs are more effective when combined with mass media programs and with community-based efforts involving parents and other community resources. In addition, CDC's school health

guidelines and numerous *Healthy People 2010* objectives recognize the critical role of implementing tobacco-free policies involving faculty, staff, and students and relating to all school facilities, property, vehicles, and events. Although significant progress is still required, the current evaluation base provides clear direction for the amalgamation of school-based programs with other modalities for reducing tobacco use.

Management of Nicotine Addiction (Chapter 4)

The management of nicotine addiction is a complex field that continues to broaden its understanding of the determinants of smoking cessation. Current literature suggests that several modalities are effective in helping smokers quit. Although the overall effect of such intervention is modest if measured by each attempt to quit, the process of overcoming addiction is a cyclic one, and many who wish to quit are eventually able to do so. The available approaches to management of addiction differ in their results.

Self-help manuals and minimal clinical interventions. Although self-help manuals have had only modest and inconsistent success at helping smokers quit, manuals can be easily distributed to the vast population of smokers who try to quit on their own each year. Adjuvant behavioral interventions, particularly proactive telephone counseling, may significantly increase the effect of self-help materials. Process measures are not routinely incorporated into self-help investigations, but the available process data suggest that persons who not only have a self-help manual but also perform the exercises recommended in the manual are more likely to quit smoking than are persons who try to quit smoking without them.

Substantial evidence suggests that minimal clinical interventions (e.g., a health care provider's repeated advice to quit) foster smoking cessation and that the more multifactorial or intensive interventions produce the best outcomes. These findings highlight the importance of cessation assistance from clinicians, who have access to more than 70 percent of smokers each year. Moreover, minimal clinical interventions have been found to be effective in increasing smokers' motivation to quit and are cost-effective (see "Cost-Effectiveness" in Chapter 4). However, research has not fully clarified the specific elements of minimal interventions that are most important to clinical success nor the specific changes they produce in smokers that lead to abstinence.

Intensive clinical interventions. Intensive programs—more formally systematic services to help people quit smoking—serve an important function in

the nation's efforts to reduce smoking, despite the resources the programs demand and the relatively small population of smokers who use them. Such programs may be particularly useful in treating those smokers who find it most difficult to quit. Because intensive smoking cessation programs differ in structure and content, evaluation is often hampered by variation in methodology and by a lack of research addressing specific treatment techniques. Because few studies have chosen to isolate single treatments, assessment of the effectiveness of specific approaches is difficult. Nonetheless, skills training, rapid smoking, and both intra-treatment and extra-treatment social support have all been associated with successful smoking cessation. When such treatments are shown to be effective, they are usually part of a multifactorial intervention. Little clear evidence has implicated particular psychological, behavioral, or cognitive mechanisms as the agents of change. The specific impact of intensive interventions may be masked by the efficacy of several multi-component programs, some of which have achieved cessation proportions of 30 to 50 percent. Thus, in their positive effect on smoking cessation and long-term abstinence rates, intensive interventions seem little different from other forms of counseling or psychotherapy. With intensive interventions, as with counseling, it is difficult to attribute the efficacy to specific characteristics of the interventions or to specific change mechanisms.

Pharmacologic interventions. Abundant evidence confirms that nicotine gum and the nicotine patch are effective aids to smoking cessation. The efficacy of nicotine gum may depend on the amount of behavioral counseling with which it is paired. The 4-mg dose (rather than the 2-mg dose) may be the better pharmacologic treatment for heavy smokers or for those highly dependent on nicotine. The nicotine patch appears to exert an effect independent of behavioral support, but absolute abstinence rates increase as more counseling is added to patch therapy. Nicotine inhalers and nicotine nasal spray are effective aids for smoking cessation, although their mechanisms of action are not entirely clear. All nicotine replacement therapies produce side effects, but these are rarely so severe that patients must discontinue use. Nicotine nasal spray appears to have greater potential for inappropriate use than other nicotine replacement therapies. Nicotine replacement therapies, especially the gum and the patch, have been shown to delay but not prevent weight gain following smoking cessation. All nicotine replacement therapies are thought to work in part by reducing withdrawal severity. The available evidence suggests that they do ameliorate some elements

of withdrawal, but the relationship between withdrawal suppression and clinical outcome is inconsistent.

Bupropion is the first nonnicotine pharmacotherapy for smoking cessation to be studied in large-scale clinical trials. Results suggest that it is an effective aid to smoking cessation. In addition, bupropion has been demonstrated to be safe when used in conjunction with nicotine replacement therapy. In the only direct comparison with a nicotine replacement product, bupropion achieved quit rates about double those achieved with the nicotine patch. Bupropion appears to delay but not prevent postcessation weight gain, and available literature contains inconsistent evidence about bupropion-mediated withdrawal relief. Bupropion does not appear to work by reducing postcessation symptoms of depression, but its mechanism of action in smoking cessation remains unknown.

Evidence suggests that clonidine is also capable of improving smoking cessation rates. Clonidine is hypothesized to work by alleviating withdrawal symptoms. Although clonidine may reduce the craving for cigarettes after cessation, it does not consistently ameliorate other withdrawal symptoms, and its effect on weight gain is unknown. Unpleasant side effects are common with clonidine use.

Antidepressants and anxiolytics are potentially useful agents for smoking cessation. At present, only nortriptylene appears to have consistent empirical evidence of smoking cessation efficacy. However, tricyclic antidepressants produce a number of side effects, including sedation and various anticholinergic effects, such as dry mouth.

In summary, research on methods to treat nicotine addiction has documented the efficacy of a wide array of strategies. The broad implementation of these effective treatment methods could produce a more rapid and probably larger short-term impact on tobacco-related health statistics than any other component of a comprehensive tobacco control effort. It has been estimated that smoking cessation is more cost-effective than other commonly provided clinical preventive services, including Pap tests, mammography, colon cancer screening, treatment of mild to moderate hypertension, and treatment of high levels of serum cholesterol.

Contemporaneously with the appearance of this report, research advances in managing nicotine addiction have been summarized in evidence-based clinical practice guidelines by the Centers for Disease Control and Prevention (CDC). That document confirms that less intensive interventions, such as brief physician advice to quit smoking, could produce cessation rates of 5 to 10 percent per year. More intensive

interventions, combining behavioral counseling and pharmacologic treatment of nicotine addiction, can produce 20 to 25 percent quit rates at one year. Thus, the universal provision of even less intensive interventions to smokers at all clinical encounters could each year help millions of U.S. smokers quit (Fiore et al. 2000).

Progress has been made in recent years in disseminating clinical practice guidelines on smoking cessation. *Healthy People 2010* Objective 27-8 calls for universal insurance coverage of evidence-based treatment for nicotine dependency by both public and private payers. Similarly, CDC's *Best Practices for Comprehensive Tobacco Control Programs* advises states that tobacco-use treatment initiatives should include

- Establishing population-based counseling and treatment programs, such as cessation help lines.
- Making the system changes recommended by the CDC-sponsored cessation guidelines.
- Covering treatment for tobacco use under both public and private insurance.
- Eliminating cost barriers to treatment for underserved populations, particularly the uninsured (CDC 1999, p. 24).

Regulatory Efforts (Chapter 5)

Advertising and Promotion

Attempts to regulate advertising and promotion of tobacco products were initiated in the United States almost immediately after the appearance of the 1964 report to the Surgeon General on the health consequences of smoking. Underlying these attempts is the hypothesis that advertising and promotion recruit new smokers and retain current ones, thereby perpetuating a great risk to public health. The tobacco industry asserts that the purpose of marketing is to maintain brand loyalty. Considerable evidence has accumulated showing that advertising and promotion are perhaps the main motivators for adopting and maintaining tobacco use. Attempts to regulate tobacco marketing continue to take place in a markedly adversarial and litigious atmosphere.

The initial regulatory action, promulgated in 1965, provided for a general health warning on cigarette packages but effectively preempted any further federal, state, or local requirements for health messages. In 1969, a successful court action invoked the Fairness Doctrine

(not previously applied to advertising) to require broadcast media to air antitobacco advertising to counter the paid tobacco advertising then running on television and radio. Indirect evidence suggests that such counteradvertising had considerable impact on the public's perception of smoking. Not surprisingly, the tobacco industry supported new legislation (adopted in 1971) prohibiting the advertising of tobacco products on broadcast media, because such legislation also removed the no-cost broadcasting of antitobacco advertising. A decade later, a Federal Trade Commission (FTC) staff report asserted that the dominant themes of remaining (nonbroadcast) cigarette advertising associated smoking with "youthful vigor, good health, good looks and personal, social and professional acceptance and success" (Myers et al. 1981, p. 2-13). A nonpublic version of the report detailed some of the alleged marketing strategy employed by the industry; the industry denied the allegation that the source material for the report represented industry policy. Nonetheless, some of these concerns led to the enactment of the Comprehensive Smoking Education Act of 1984 (Public Law 98-474), which required a set of four rotating warnings on cigarette packages. The law did not, however, adopt other FTC recommendations that product packages should bear information about associated risks of addiction and miscarriage, as well as information on toxic components of cigarettes. In fact, many FTC-recommended requirements for packaging information that have been enacted in other industrialized nations have not been enacted in the United States.

The role of advertising is perhaps best epitomized by R.J. Reynolds Tobacco Company's Camel brand campaign (initiated in 1988) using the cartoon character "Joe Camel." Considerable research has demonstrated the appeal of this character to young people and the influence that the advertising campaign has had on minors' understanding of tobacco use and on their decision to smoke. In 1997, the FTC brought a complaint asserting that by inducing minors to smoke, R.J. Reynolds' advertising practices violated the Federal Trade Commission Act (Public Law 96-252). The tobacco company subsequently agreed to cease using the Joe Camel campaign. Although the FTC's act grants no private right of enforcement, a private lawsuit in California resulted in a settlement whereby the tobacco company agreed to cease its Joe Camel campaign; notably, the Supreme Court of California rejected R.J. Reynolds' argument that the Comprehensive Smoking Education Act of 1984 preempted the suit's attempt to further regulate tobacco advertising.

Product Regulation

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) 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. The current federal laws preempt, in part, states and localities from imposing other labeling regulations on cigarettes and smokeless tobacco. Federal law (the Comprehensive Smokeless Tobacco Health Education Act of 1986 and the Comprehensive Smoking Education Act of 1984) requires cigarette and smokeless tobacco product manufacturers to submit a list of additives to the Secretary of Health and Human Services; attorneys for the manufacturers released such lists in 1994 to the general public. Smokeless tobacco manufacturers are required to report the total nicotine content of their products, but these data may not be released to the public. Tobacco products are explicitly protected from regulation in various federal consumer safety laws. No federal public health laws or regulations apply to cigars, pipe tobaccos, or fine-cut cigarette tobaccos (for "roll-your-own" cigarettes).

Although much effort has been devoted to considering the need for regulating nicotine delivery, tar content, and the use of additives, until recently no regulation had directly broached the issue of whether tobacco should be subject to federal regulation as an addictive product. Responding in part to several petitions filed by the Coalition on Smoking OR Health in 1988 and 1992, the FDA began serious consideration of the need for product regulation. Motivated by the notion that the cigarette is a nicotine delivery system, by allegations of product manipulation of nicotine levels, and by the concept that smoking is a pediatric disease and that young people are especially susceptible to cigarette advertising and promotion, 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 final regulations published by the FDA on August 28, 1996, differed only slightly from the proposed regulation. The announcement prompted immediate legal action on the part of the tobacco industry, advertising interests, and the convenience store industry, which challenged the FDA's jurisdiction over

tobacco products. In April 1997, a federal district court upheld the FDA's jurisdiction over tobacco products, but held that it lacked authority under the statutory provision relied on to regulate tobacco product advertising.

Although many of the FDA's regulations on tobacco sales and distribution were incorporated, to some extent, in the June 20, 1997, proposed settlement of lawsuits between 41 state attorneys general and the tobacco industry, the settlement presupposed congressional legislation that would uphold the FDA's asserted jurisdiction. After considerable congressional negotiation, no such legislation emerged. In August 1998, a three-judge panel of the United States Court of Appeals for the Fourth Circuit held that the FDA lacked jurisdiction to regulate tobacco products. In November 1998, the full Court of Appeals rejected the government's request for rehearing by the entire court. On March 21, 2000, in a 5 to 4 decision, the United States Supreme Court affirmed the decision of the United States Court of Appeals for the Fourth Circuit and held that the FDA lacks jurisdiction under the Federal Food, Drug, and Cosmetic Act to regulate tobacco products as customarily marketed. As a result of this decision, the FDA's August 1996 assertion of jurisdiction over cigarettes and smokeless tobacco and regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents (principally codified at 21 Code of Federal Regulations Part 897) are invalid.

Clean Indoor Air Regulation

Unlike the regulation of tobacco products per se and of their advertising and promotion, regulation of exposure to ETS has encountered less resistance. This course is probably the result of (1) long-standing grassroots efforts to diminish exposure to ambient tobacco smoke and (2) consistent epidemiologic evidence of adverse health effects of ETS. Since 1971, a series of rules, regulations, and laws have created smoke-free environments in an increasing number of settings: government offices, public places, eating establishments, worksites, military establishments, and domestic airline flights. As of December 31, 1999, smoking was restricted in public places in 45 states and the District of Columbia. Currently, some 820 local ordinances, encompassing a variety of enforcement mechanisms, are in place.

The effectiveness of clean indoor air restrictions is under intensive study. Most studies have concluded that even among smokers, support for smoking restrictions and smoke-free environments is high. Research

has also verified that the institution of smoke-free workplaces effectively reduces nonsmokers' exposure to ETS. Although most studies indicate that smoke-free environments have not reduced smoking prevalence, such environments have been shown to decrease daily tobacco consumption and to increase smoking cessation among smokers.

Minors' Access to Tobacco

There is widespread approval for restricting the access of minors to tobacco products. Recent research, however, has demonstrated that a substantial proportion of teenagers who smoke purchase their own tobacco, and the proportion varies with age, social class, amount smoked, and factors related to local availability. In addition, research has shown that most minors can easily purchase tobacco from a variety of retail outlets. It has been suggested that a reduction in commercial availability may result in a reduced prevalence of tobacco use among minors.

Several approaches have been taken to limiting minors' access to tobacco. All states prohibit sale or distribution of tobacco to minors. More than two-thirds of states regulate the means of sale through restrictions on minors' use of vending machines, but many of these restrictions are weak, and only two states have total bans on vending machines. Restrictions on vending machines are a subclass of the larger category of regulation of self-service cigarette sales; in general, such regulation requires that cigarettes be obtained from a salesperson and not be directly accessible to customers. Such policies can reduce shoplifting as well, an important source of cigarettes for some minors.

Regulations directed at the seller include the specification of a minimum age for sale (18, in all but two states and Puerto Rico), a minimum age for the seller, and the prominent in-store announcement of such policy. Providing merchant education and training is an important component of comprehensive minors' access programs. Penalties for sales to minors vary considerably; in general, civil penalties have been found to be more effective than criminal ones. Requiring licensure of tobacco retailers has been found to provide a funding source for compliance checks and to serve as an incentive to obey the law when revocation of the license is a provision of the law. Applying penalties to business owners, instead of to clerks only, is considered essential to preventing sales to minors. Tobacco retail outlets and the tobacco industry have vigorously opposed this policy. An increasing number of states and local jurisdictions are imposing sanctions against minors who purchase, possess, or use

tobacco products. Sanctions against both buyers and sellers are enforced by a variety of agencies and mechanisms. Because regulations in general may be more effective if generated and enforced at the local level, considerable energy is devoted to the issue of opposing or repealing preemption of local authority by states. Public health analyses have resulted in strong recommendations that state laws not preempt local action to curb minors' access to tobacco.

Litigation Approaches

Private litigation shifts enforcement of public health remedies from the enterprise or the government to the private individual—typically, victims or their surrogates. In the tort system, the coalescence of instances in which injurers are forced to compensate the injured can create a force that generates preventive effects. Although relatively inefficient as a system for compensating specific classes of injuries, the tort system is justified by its generation of preventive actions and by its flexibility. Tobacco represents an atypical pattern of litigation and product modification, because private law remedies have not yet succeeded in institutionalizing recovery for tobacco injuries or have not yet generated significant preventive effects. In the case of tobacco, regulation has been the predominant control, and such regulation has been distinctive in relying primarily on notification requirements rather than safety requirements.

Private litigation against tobacco has occurred in several distinct waves. The first wave was launched in 1954 and typically used one or both of two legal theories: negligence and implied warranty. Courts proved unreceptive to both these arguments, and this approach had receded by the mid-1970s. In many of these and subsequent cases, legal devices and exhaustion of plaintiff resources figured prominently in the defendants' strategy. A second wave began in 1983 and ended in 1992. In these cases, the legal theory shifted from warranty to strict liability. The tobacco industry based its defense on smokers' awareness of risks and so-called freedom of choice. For example, plaintiffs argued that the addictive nature of nicotine limited free choice; defense counsel rebutted by pointing to the large number of former smokers who successfully quit. Taking freedom-of-choice defense even further, counsel argued that the claimant's lifestyle was overly risky by choice or was in some way immoral. The case that symbolized the second-wave litigation was that filed by Rose Cipollone, a dying smoker, in 1983. The Supreme Court accepted the tobacco industry's defense that federal law requiring warning

labels on product packages had preempted claims under state law that imposed liability for failure to warn. The Supreme Court left open several other approaches, but the likelihood of recovery seemed small, and counsel for the Cipollone estate withdrew.

In the third wave, begun soon after the Cipollone decision and still ongoing, diverse legal arguments have been invoked. This third wave of litigation differs from its predecessors by enlarging the field of plaintiffs, focusing on a range of legal issues, using the class action device, and making greater attempts to use private law for public policy purposes. These new claims have been based on theories of intentional misrepresentation, concealment, and failure to disclose, and such arguments have been joined to a new emphasis on addiction. For example, in one case that ended as a mistrial, plaintiffs were barred from presenting evidence that the tobacco companies may have manipulated nicotine levels. The class action device has figured prominently in these new cases, which have included claims of smokers as well as claims of those who asserted that they have been injured by ETS. Arguably the most notable series of third-wave claims brought against tobacco companies is the proposed 1997 settlement of suits brought by 41 state attorneys general attempting to recover the states' Medicaid expenditures for treating tobacco-related illnesses. In the absence of congressional legislation needed to give that settlement the force of law, four states made independent settlements with the tobacco industry. Notably, each state obtained a concession guaranteeing that it would benefit from any more favorable agreement that another state might later obtain from the tobacco industry. Subsequently, a multistate Master Settlement Agreement was negotiated in November 1998 covering the remaining 46 states, the District of Columbia, and five commonwealths and territories. Another notable recent development is the filing of large claims by other third-party payers, such as large health care plans.

Perhaps in partial response, the level of litigation initiated by the tobacco industry itself has increased in recent years and has included a number of well-publicized cases, including a threatened suit against the media to prevent airing of a program that accused a tobacco company of manipulating nicotine levels. The company was successful in making the network withdraw the program, even though similar information was later made public in other contexts. Although the industry continues aggressive legal pursuit of its interests on a number of fronts, litigation against the industry has had undoubted impact on

tobacco regulation and is likely to continue to play a key role in efforts to reduce tobacco use.

Overview and Implications

Tobacco products are far less regulated in the United States than they are in many other developed countries. This level of regulation applies to the manufactured tobacco product; to the advertising, promotion, and sales of these products; and to the protection of nonsmokers from the involuntary exposure to ETS from the use of these products. As with all other consumer products, adult users of tobacco should be fully informed of the products' ingredients and additives and of any known toxicity when used as intended. Additionally, as with other consumer products, the manufactured tobacco product should be no more harmful than necessary given available technology. The sale, distribution, and promotion of tobacco products need to be sufficiently regulated to protect underage youth from influences to take up smoking. Finally, involuntary exposure to ETS remains a common public health hazard that is entirely preventable by appropriate regulatory policies.

Such are the basic, reasonable regulatory issues related to tobacco products. Yet these issues remain unresolved as the new millennium begins. When consumers purchase a tobacco product, they receive little information regarding the ingredients, additives, or chemical composition in the product. Although public knowledge about the potential toxicity of most of these constituents is negligible, findings in this report conclude that the warning labels on cigarette packages in this country are weaker and less conspicuous than in other countries. Further, the popularity of "low tar and nicotine" brands of cigarettes has shown that consumers may be misled by another, carefully crafted kind of information—that is, by the implied promise of reduced toxicity underlying the marketing of these products.

Current regulation of the advertising and promotion of tobacco products in this country is considerably less restrictive than in several other countries, notably Canada and New Zealand. The review of current case law in this report supports the contention that greater restrictions of tobacco product advertising and promotion could be legally justified. In fact, the report concludes that regulation of the sale and promotion of tobacco products is needed to protect young people from smoking initiation.

ETS contains more than 4,000 chemicals; of these, at least 43 are known carcinogens (Environmental Protection Agency 1992). Exposure to ETS has serious health effects (USDHHS 2000b). Despite this

documented risk, research has demonstrated that more than 88 percent of nonsmokers in this country aged 4 years and older had detectable levels of serum cotinine, a marker for exposure to ETS (Pirkle et al. 1996). The research reviewed in this report indicates that smoking bans are the most effective method for reducing ETS exposure. Four *Healthy People 2010* objectives address this issue and seek optimal protection of nonsmokers through policies, regulations, and laws requiring smoke-free environments in all schools, worksites, and public places.

Despite the widespread support among the general public, policymakers, and the tobacco industry for restricting the access of minors to tobacco products, a high proportion of underage youth smokers across this country continue to be able to purchase their own tobacco. National efforts by the Substance Abuse and Mental Health Services Administration to increase the enforcement of state laws to comply with the Synar Amendment and by the FDA to implement the access restrictions defined in their 1996 rule have reduced the percentage of retailers in many states who sell to minors. Unfortunately, nine states failed to attain their Synar Amendment targets in 1999. Additionally, the March 2000 Supreme Court ruling that the FDA lacks jurisdiction to regulate tobacco products has suspended all enforcement of the agency's 1996 regulations. Although several states have increased emphasis on this issue as part of their state-funded program efforts, the loss of the FDA's program removes a major infrastructure in support of these state efforts. The current regulatory environment poses considerable challenges for the interweaving of regulation into a comprehensive, multicomponent approach to tobacco use control and prevention.

Economic Approaches (Chapter 6)

The argument for using economic policy for reducing tobacco use requires considerable technical and analytic understanding of economic theory and data. Because experiments and controlled trials—in the usual sense—are not available to the economist, judgment and forecasting depend on the results of complex analysis of administrative and survey data. Such analyses have led to a number of conclusions regarding the importance of the tobacco industry in the U.S. economy and regarding the role of policies that might affect the supply of tobacco, affect the demand for tobacco, and use different forms of taxation as a possible mechanism for reducing tobacco use.

Supply. The tobacco support program has successfully limited the supply of tobacco and raised the price of tobacco and tobacco products. However, the principal beneficiaries of this program are not only the farmers whose income is supported but also the owners of the tobacco allotments. If policies were initiated to ameliorate some short-run effects, the tobacco support program could be removed without imposing substantial losses for many tobacco farmers. Eliminating the tobacco support program would lead to a small reduction in the prices of cigarettes and other tobacco products, which would lead to slight increases in the use of these products. However, because the support program has created a strong political constituency that has successfully impeded stronger legislation to reduce tobacco use, removing the support program could make it easier to enact stronger policies that would more than offset the impact that the resulting small reductions in price would have on demand.

Throughout the 1980s and 1990s, competition within the tobacco industry appeared to have decreased as a result of the favorable deregulatory business climate and an apparent increase in collusive behavior. This reduction in competition, coupled with the addictive nature of cigarette smoking, has magnified the impact that higher cigarette taxes and stronger smoking reduction policies would have on demand.

The recent expansion of U.S. trade in tobacco and tobacco products through multinational agreements, together with the U.S. threat of retaliatory trade sanctions were other countries to impede this expansion, is nearly certain to have increased the use of tobacco products worldwide. Such an increase would result in a consequent global rise in morbidity and mortality related to cigarette smoking and other tobacco use. These international trade policy efforts conflict with current domestic policies (and the support of comparable international efforts) that aim to reduce the use of tobacco products because of their harmful effects on health.

Industry importance. Although employment in the tobacco industry is substantial, the industry greatly overstates the importance of tobacco to the U.S. economy. Indeed, most regions would likely benefit—for example, through redistribution of spending and changes in types of job—from the elimination of revenues derived from tobacco products. Moreover, as the economies of tobacco-growing regions have become more diversified, the economic importance of tobacco in these areas has fallen. Higher tobacco taxes and stronger prevention policies could be joined to other efforts to further ease the transition from tobacco in major tobacco-producing regions. Finally, trading

lives for jobs is an ill-considered strategy, particularly with the availability of stronger policies for reducing tobacco use.

Demand. Increases in the price of cigarettes will lead to reductions in both smoking prevalence and cigarette consumption among smokers; relatively large reductions are likely to occur among adolescents and young adults. Limited research indicates that increases in smokeless tobacco prices will similarly reduce the use of these products. More research is needed to clarify the impact of cigarette and other tobacco prices on the use of these products in specific sociodemographic groups, particularly adolescents and young adults. Additional research also is needed to address the potential substitution among cigarettes and other tobacco products as their relative prices change.

Taxation. After the effects of inflation are accounted for, federal and average state excise taxes on cigarettes are well below their past levels. Similarly, average cigarette excise taxes in the United States are well below those imposed in most other industrialized countries. Moreover, U.S. taxes on smokeless tobacco products are well below cigarette taxes. Studies of the economic costs of smoking report a wide range of estimates for the optimal tax on cigarettes. However, when recent estimates of the costs of ETS (including the long-term costs of fetal and perinatal exposure to ETS) are considered, and when the premature death of smokers is not considered an economic benefit, a tax that would generate sufficient revenues to cover the external costs of smoking is almost certainly well above current cigarette taxes. The health benefits of higher cigarette taxes are substantial. By reducing smoking, particularly among youth and young adults, past tax increases have significantly reduced smoking-related morbidity and mortality. Further increases in taxes, indexed to account for the effects of inflation, would lead to substantial long-run improvements in health.

The revenue potential of higher cigarette and other tobacco taxes—obviously not in itself a goal—is considerable; significant increases in these taxes would lead to sizable increases in revenues for many years. However, because of the greater price responsiveness of adolescents and young adults and the addictive nature of tobacco use, the long-run increase in revenues is likely to be less than the short-run gain. Nevertheless, current federal and most state tobacco taxes are well below their long-run revenue-maximizing levels.

In short, the research reviewed in this report supports the position that raising tobacco prices is good public health policy. Further, raising tobacco excise taxes is widely regarded as one of the most effective

tobacco prevention and control strategies. Research indicates that increasing the price of tobacco products would decrease the prevalence of tobacco use, particularly among minors and young adults. As noted, however, this report finds that both the average price of cigarettes and the average cigarette excise tax in this country are well below those in most other industrialized countries and that the taxes on smokeless tobacco products are well below those on cigarettes. Making optimal use of economic strategies in a comprehensive program poses special problems because of the complexity of government and private controls over tobacco economics and the need for a concerted, multilevel, political approach.

Comprehensive Programs (Chapter 7)

Community-based interventions were originally developed as research projects that tested the efficacy of a communitywide approach to risk reduction. A number of national and international efforts to control cardiovascular disease (in the United States, notably the Minnesota, Stanford, and Pawtucket studies) used controlled designs. The results from these and other studies were largely disappointing, particularly regarding prevention and control of tobacco use. Other large-scale research efforts, such as the Community Intervention Trial (COMMIT) for Smoking Cessation, also failed to meet their primary goals for smoking reduction and cessation. Similarly, the results to date from numerous worksite-based cessation projects suggest either no impact or a small net effect (summarized in Chapter 4).

As these studies were under way in the 1970s and 1980s, health promotion—an organized approach to changing social, economic, and regulatory environments—emerged as a more effective mechanism for population behavior change than traditional health education. Although the aforementioned community-based research projects used a health promotion perspective, they lacked the reach and penetration required for effective social change. In any event, the results made clear the distinction between a specific program (even one using multiple modalities) and a comprehensive multimessage, multichannel approach that used some or all of the modalities described in Chapters 3 through 6. The legal and economic events of the 1990s—most notably large excise tax increases and the settlements with the tobacco industry for reimbursement of Medicaid costs incurred by caring for smokers—have provided those states with the resources necessary to mount such a comprehensive approach. The early

results are encouraging, as exemplified by results from California, Massachusetts, Oregon, and Florida. The well-funded, coherent, and organized approach to tobacco prevention and control provides a credible counterweight to the advertising and promotional efforts of the tobacco industry and fosters a powerful nonsmoking norm.

On a broader scale, other social initiatives can also serve some of these same purposes through means that are not directly related to changing population behavior. For example, direct advocacy—the presentation of information to decision makers to encourage their support for nonsmoking policies—has been pursued vigorously by health advocates since the organization of grassroots movements for nonsmokers' rights in the early 1970s. Much of the clean air legislation now in place may be attributed in part to such direct advocacy. An interesting observation that supports the logic behind comprehensive programs is that initial shortcomings in direct advocacy activity may have been related to a failure of coordination among grassroots groups and professional organizations. In recent years, in part as the result of electronic networking and mediating by the Advocacy Institute, a more unified approach to reducing tobacco use has been achieved among the participating organizations.

Media advocacy—the use of mass media to advance public policy initiatives—has also been effective in placing smoking issues in the public eye and maintaining a continued impetus for reducing tobacco use. Case analysis of several instances of such activity—advocacy opposing the promotion of the “X” cigarette, the marketing of “Dakota” cigarettes, the Philip Morris-sponsored Bill of Rights tour, and the attempted marketing of “Uptown” cigarettes—highlights several successes but also indicates that such activities do not always achieve their immediate aims. Nonetheless, considerable experience has been gained in seizing such opportunities.

Countermarketing activities can promote smoking cessation and decrease the likelihood of initiation. Countermarketing campaigns also can have a powerful influence on public support for tobacco control activities and provide an educational climate that can enhance the efficacy of school- and community-based efforts. For youth, the CDC has estimated that the average 14-year-old has been exposed to more than \$20 billion in imagery advertising and promotions since age 6, creating a “friendly familiarity” for tobacco products. The recent increase in movie depictions of tobacco use further enhances the image of tobacco use as glamorous, socially acceptable, and normal. In light

of the ubiquitous and sustained protobacco messages, countermarketing campaigns need to be of comparable intensity and duration to alter the general social and environmental atmosphere supporting tobacco use.

In sum, the comprehensive approach that has been developed within the statewide tobacco control programs has produced results that led the Institute of Medicine (2000) to conclude that “multifaceted state tobacco control programs are effective in reducing tobacco use” (p. 4). Although these initial results are encouraging, they need to be considered from the perspective of the less favorable results from the community trials. Nevertheless, although our knowledge about the mechanisms by which these new comprehensive tobacco control efforts function is imperfect, the results are sufficiently favorable to support the continued application of this model. But, accountability and program evaluation must be emphasized in these new statewide tobacco control programs to improve our understanding of how the various components of the comprehensive programs work.

Perhaps the most important aspect of comprehensive programs has been the emergence of statewide tobacco control efforts as a laboratory for their development and evaluation. The number of states with such programs grew slowly in the early and mid-1990s, but in recent years there has been a surge in funding for such efforts fueled by the state settlements with the tobacco industry. Although the data on the impact of these programs on per capita consumption, adult prevalence, and youth prevalence are generally favorable, the uniform data systems needed to conduct more controlled evaluations of these efforts are still emerging. The challenge for the new millennium will be to ensure that these ever increasing comprehensive statewide tobacco control programs are as efficient and effective as possible.

The review of statewide tobacco control programs indicates that reducing the broad cultural acceptability of tobacco use necessitates changing many facets of the social environment. In addition, this report stresses—as does the *Best Practices* (CDC 1999) document—that these individual components must work together to produce the synergistic effects of a comprehensive

program. However, both of these findings highlight the complexity involved in evaluating these types of programs.

Within the current statewide tobacco control programs, each of these various modalities discussed in this report is represented with varying degrees of intensity. As noted above, some of the recommendations for actions within these modalities could most effectively be done at the national rather than the state level. Thus, the overall efficacy of these emerging statewide programs will depend in some ways on public health advances at the national level. Again, this synergy between the statewide and national efforts adds greater complexity to the evaluation issue.

Finally, this report concludes that the span of impact of these educational, clinical, regulatory, economic, and social approaches indicates the importance of their sustained and long-term implementation. Program evaluation and research efforts are needed to improve our understanding of how these various elements work. Although knowledge about the efficacy of comprehensive programs is imperfect, evidence points to early optimism for their continuance. With the expansion of tobacco control surveillance and evaluation systems and increases in the number and diversity of statewide tobacco control programs, critical questions can be answered about how to make these efforts more efficient and effective.

A Vision for the Future—Reducing Tobacco Use in the New Millennium (Chapter 8)

Chapter 8 outlines broad strategies and courses of action for tobacco control in the future. Six future challenges are outlined: continuing to build the scientific base, responding to the changing tobacco industry, using a comprehensive approach in reducing tobacco use, eliminating health disparities, improving dissemination of state-of-the-art interventions, and influencing tobacco use in developing nations.

Chapter Conclusions

Following are the specific conclusions for each chapter of the report. Note that Chapters 1 and 8 have no conclusions.

Chapter 2. Historical Review

1. In the years preceding the development of the modern cigarette, and for some time thereafter, antismoking activity was largely motivated by moralistic and hygienic concerns. Health concerns played a lesser role.
2. In contrast, in the second half of the 20th century, the impetus for reducing tobacco use was largely medical and social. The resulting platform has been a more secure one for efforts to reduce smoking.
3. Despite the growing scientific evidence for adverse health effects, smoking norms and habits have yielded slowly and incompletely. The reasons are complex but attributable in part to the industry's continuing stimulus to consumption.

Chapter 3. Educational Strategies

1. Educational strategies, conducted in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
2. Although most U.S. schools have tobacco use prevention policies and programs in place, current practice is not optimal.
3. More consistent implementation of effective educational strategies to prevent tobacco use will require continuing efforts to build strong, multiyear prevention units into school health education curricula and expanded efforts to make use of the influence of parents, the mass media, and other community resources.

Chapter 4. Management of Nicotine Addiction

1. Tobacco dependence is best viewed as a chronic disease with remission and relapse. Even though both minimal and intensive interventions increase smoking cessation, most people who quit smoking with the aid of such interventions will eventually relapse and may require repeated attempts before achieving long-term abstinence. Moreover, there is little understanding of how such treatments produce their therapeutic effects.
2. There is mixed evidence that self-help manuals are an efficacious aid to smoking cessation. Because these materials can be widely distributed, such strategies may have a significant public health impact and warrant further investigation.
3. Programs using advice and counseling—whether minimal or more intensive—have helped a substantial proportion of people quit smoking.
4. The success of counseling and advice increases with the intensity of the program and may be improved by increasing the frequency and duration of contact.
5. The evidence is strong and consistent that pharmacologic treatments for smoking cessation (nicotine replacement therapies and bupropion, in particular) can help people quit smoking. Clonidine and nortriptylene may have some utility as second-line treatments for smoking cessation, although they have not been approved by the FDA for this indication.

Chapter 5. Regulatory Efforts

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.
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.

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.

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.

Chapter 6. Economic Approaches

1. The price of tobacco has an important influence on the demand for tobacco products, particularly among young people.
2. Substantial increases in the excise taxes on cigarettes would have considerable impact on the prevalence of smoking and, in the long term, reduce the adverse health effects caused by tobacco.
3. Policies that influence the supply of tobacco, particularly those that regulate international commerce, can have important effects on tobacco use.
4. Although employment in the tobacco sector is substantial, the importance of tobacco to the U.S. economy has been overstated. Judicious policies can be joined to higher tobacco taxes and stronger prevention policies to ease economic diversification in tobacco-producing areas.

Chapter 7. Comprehensive Programs

1. The large-scale interventions conducted in community trials have not demonstrated a conclusive impact on preventing and reducing tobacco use.
2. Statewide programs have emerged as the new laboratory for developing and evaluating comprehensive plans to reduce tobacco use.
3. Initial results from the statewide tobacco control programs are favorable, especially regarding declines in per capita consumption of tobacco products.
4. Results of statewide tobacco control programs suggest that youth behaviors regarding tobacco use are more difficult to change than adult ones, but initial results of these programs are generally favorable.

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