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Reducing Tobacco Use

A Report of the Surgeon General

Executive Summary

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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NOTICE

This issue of *MMWR Recommendations and Reports* (Vol. 49, No. RR-16) is a reprint of the Executive Summary of the Surgeon General's report entitled *Reducing Tobacco Use*, released earlier this year. The report is included in the *MMWR* series of publications so that the material can be readily accessible to the public health community.

Copies of the full report (stock no. 017-023-00204-0) are available for $47 from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800.

Message from Donna E. Shalala
Secretary of Health and Human Services

This nation is faced with many challenges in its efforts to improve the health status of all people living in the United States. One of the biggest challenges is to remedy the fact that approximately one-fourth of our adults continue to smoke and that tobacco use rates among our youth have increased since the early 1990s. Tobacco use, particularly cigarette smoking, remains the leading cause of preventable illness and death in this country. Our overall success in improving the health status of the U.S. population thus depends greatly on achieving dramatic reductions in the rate of tobacco use among both adults and young people.

Reducing tobacco use is a key component of *Healthy People 2010*, the national action plan for improving the health of all Americans for the first decade of the 21st century. No fewer than 21 specific national health objectives related to tobacco are listed, including a goal to more than halve the current rates of tobacco use among young people and adults. Attaining all of the *Healthy People 2010* tobacco use objectives will require significant commitment and progress in numerous areas.

This Surgeon General's report provides a major resource in our national efforts to achieve the *Healthy People 2010* tobacco use objectives. The research findings reviewed indicate that many strategies and approaches have been shown to be effective in preventing tobacco use among young people and in helping tobacco users end their addiction. The challenge to public health professionals, health care systems, and other partners in our national prevention effort is to implement these proven approaches.

Through the Secretary's Initiative to Prevent Tobacco Use Among Teens and Preteens, the Department works with federal and nonfederal efforts to reduce young people's demand for tobacco products. This Surgeon General's report highlights additional strategies and approaches that this initiative can expand upon. Only by a coordinated national effort will the tobacco use rates among our young people be reduced. Each day that we delay in developing a comprehensive national response to this problem, 3,000 additional teens and preteens become regular smokers. That statistic poses an urgent public health challenge and—given that we have at hand numerous strategies proven to be effective—a moral imperative.

Contents

Foreword

For more than three decades, the Surgeon General of the U.S. Public Health Service has released reports focused on tobacco use and the health of the American people. The tone and content of these reports have changed over the years. Early on, there was a need for critical review of the epidemiologic and biologic aspects of tobacco use. Today, the deleterious effects are well documented, and the reports have begun to investigate the social, economic, and cultural consequences of these effects and what can be done to address them. The present report assesses past and current efforts to reduce the use of tobacco in this country and thereby ameliorate its disastrous health effects.

Tobacco use is an extraordinary phenomenon. Although substantial progress has been made since the initial report of the Surgeon General's Ad Hoc Committee in 1964, approximately a quarter of the U.S. adult population smokes, and the percentage of high school youth who smoke has steadily increased throughout the 1990s.

Results from community-based interventions and statewide programs show that a comprehensive approach to tobacco control is needed to curtail the epidemic. This report summarizes several effective approaches to reducing tobacco use and presents the considerable evidence—as well as the attendant controversies—supporting their application. Multifaceted school-based education programs that are performed in conjunction with community-based campaigns have met with substantial success. The management of nicotine addiction in persons who already smoke has the benefit of clinical tools, that is, systems for weaning persons from nicotine, the efficacy of which is clearly demonstrated. Product regulation, enforcement of clean indoor air standards, and protecting young people from the supposed attractiveness of cigarettes all promise substantial impact. By analyzing the economics of tobacco and by examining models that assess the effect of economic policies, we find that various approaches can mitigate the adverse outcomes associated with tobacco use—and can do so without the dire economic consequences claimed by those who profit from tobacco use.

But if the evidence is clear that tobacco use is harmful and if the tools are available to reduce its use, why has the reduction in prevalence been less than would be expected? The answer is very complex. As described in Chapter 1 of this report, numerous forces influence a person's decision to smoke, or if that person is a smoker, the forces that drive continued use. The most important force for smoking is the totality of industry activity, including advertising, promotion, organizational activity, support for ancillary issues, and political action, which maintains marketability and profitability of the product. Efforts to reduce tobacco use face a more than $5 billion annual budget that the tobacco industry dedicates to advertising and promotion aimed at sustaining or increasing tobacco use. Nonetheless, there is cause for optimism based on considerable public support for efforts to prevent children from becoming addicted to tobacco. If the recent pattern of increases in youth tobacco use can be reversed, we can make progress toward tobacco-free generations in the future.

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Preface
from the Surgeon General
U.S. Department of Health and Human Services

Almost 50 years ago, evidence began to accumulate that cigarette smoking poses an enormous threat to human health. More than 30 years ago, an initial report from the Surgeon General's office made an unqualified announcement of tobacco's harm. Beginning in 1969, the series of Surgeon General's reports began meticulous documentation of the biologic, epidemiologic, behavioral, pharmacologic, and cultural aspects of tobacco use. The present report, an examination of the methods and tools available to reduce tobacco use, is being issued at a time of considerable foment. The past several years have witnessed major initiatives in the legislative, regulatory, and legal arenas, with a complex set of results still not entirely resolved.

This report shows that a variety of efforts aimed at reducing tobacco use, particularly by children, would have a heightened impact in the absence of countervailing pressures to smoke. Besides providing extensive background and detail on historical, social, economic, clinical, educational, and regulatory efforts to reduce tobacco use, the report indicates some clear avenues for future research and implementation. It is of special concern to derive a greater understanding of cultural differences in response to tobacco control measures. Since racial and ethnic groups are differentially affected by tobacco, elimination of disparities among these groups is a major priority.

Perhaps the most pressing need for future research is to evaluate multifocal, multichannel programs that bring a variety of modalities together. For example, as Chapter 3 demonstrates, school-based education programs are more effective when coupled with community-based initiatives that involve mass media and other techniques. As pointed out in Chapter 4, a combination of behavioral and pharmacologic methods improves the success rate when managing nicotine addiction. Synergy among economic, regulatory, and social approaches has not been fully explored, but may offer some of the most fruitful efforts for the future. Chapter 7 provides the preliminary data on new statewide, comprehensive tobacco control programs, which offer great promise as new models for tobacco control and combine multiple intervention modalities. Although all aspects—social, economic, educational, and regulatory—have not been combined into a fully comprehensive effort, it is exciting to contemplate the potential impact of such an undertaking to eventually ensure that children are protected from the social and cultural influences that lead to tobacco addiction, that all smokers are encouraged to quit as soon as possible, and that nonsmokers are protected from environmental tobacco smoke.

David Satcher, M.D., Ph.D.
Surgeon General and
Assistant Secretary for Health

Executive Summary

This report of the Surgeon General on smoking and health, *Reducing Tobacco Use*, appears at a time of considerable upheaval in the arena of tobacco use control and prevention. Legal and legislative efforts to protect children from tobacco initiation and to diminish the prevalence of smoking among adults are in a state of flux, with some important gains and some sobering setbacks. Major changes in the public stance of the tobacco industry have evoked a reevaluation of strategies for controlling and preventing tobacco uptake. Enormous monetary settlements have provided the resources to fuel major new comprehensive antitobacco efforts, but the ultimate cost and benefit of these resources are still to be determined. Into this changing landscape, the report introduces an assessment of information about the value and efficacy of the major approaches that have been used—educational, clinical, regulatory, economic, and comprehensive—to reduce tobacco use. The report evaluates the scientific evidence for each approach, attempts to place the approaches in the larger context of tobacco control, and provides a vision of the trajectory for tobacco use prevention and control based on these available tools. Thus, *although our knowledge about tobacco control remains imperfect, we know more than enough to act now*. Widespread dissemination of the approaches and methods shown to be effective in each modality and especially in combination would substantially reduce the number of young people who will become addicted to tobacco, increase the success rate of young people and adults trying to quit using tobacco, decrease the level of exposure of nonsmokers to environmental tobacco smoke, reduce the disparities related to tobacco use and its health effects among different population groups, and decrease the future health burden of tobacco-related disease and death in this country.

These achievable improvements parallel the health objectives set forth in *Healthy People 2010*, the national action plan for improving the health of all people living in the United States for the first decade of the 21st century (U.S. Department of Health and Human Services [USDHHS] 2000a). Twenty-one specific national health objectives related to tobacco use are listed in *Healthy People 2010*, including reducing the rates among young people and adults to less than half of the current rate of use. Attaining all of these tobacco-related objectives will almost certainly require significant national commitment to the various successful approaches described in this report.

The major conclusions of this report are not formal policy recommendations. Rather, they offer a summary of the scientific literature about what works. In short, this report is intended to offer policymakers, public health professionals, professional and advocacy organizations, researchers, and, most importantly, the American people guidance on how to ensure that efforts to prevent and control tobacco use are commensurate with the harm it causes.

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.

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 Food and Drug Administration (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.

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 environmental tobacco smoke (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, 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 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.

BACKGROUND

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.

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 two prior monographs: *Growing Up Tobacco Free*, a report of the Institute of Medicine (Lynch and Bonnie 1994), and *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, an ongoing work of the Office of Health Promotion and Disease Prevention (USDHHS 1991).

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.

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 the decline 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.

The result is a considerable challenge for evaluation. In an environment in which multiple interventions are in play, the ability to attribute an individual positive outcome (e.g., smoking cessation, prevention of smoking uptake) to one of them is virtually impossible. Although the epidemiologic methods exist to evaluate attribution in the aggregate, data are rarely available to make such 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.

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 complex multi-variate 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. Without a common metric, the various types of efforts to reduce tobacco use are difficult to compare quantitatively, and perhaps a more qualitative approach should be used. One approach 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. For example, clinical methods to manage nicotine addiction may now be thought to have relatively high impact, but a relative small span. Economic measures can be judged to have both high impact and large span. Each of the interventions has its appropriate place and context: they 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, a reasonable case can be made that the large-scale strategies (economic and regulatory) have the greatest direct impact on that 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.

Finally, a separate theme—not a major focus of the current report because two other recent, important publications have emphasized this issue—is the elimination of health disparities related to tobacco use, which poses a great challenge to this nation. The 1998 Surgeon General's report, *Tobacco Use Among U.S. Racial/Ethnic Minority Groups* (USDHHS 1998), 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* has 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 in health that exist in the United States. These publications also highlight the critical need for a greater focus on this issue, both in research and in public health action.

FINDINGS

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, and the implications for future tobacco control and prevention activities are noted.

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 (U.S. Department of Health, Education, and Welfare 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 or 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 intratreatment and extratreatment 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 multicomponent 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 bupropion is an effective aid to smoking cessation. In addition, bupropion has been demonstrated to be safe when used jointly 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. The available literature contains inconsistent evidence regarding 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 has suggested that clonidine is capable of improving smoking cessation rates. Clonidine is hypothesized to work by alleviating withdrawal symptoms. Although

clonidine may reduce craving for cigarettes after cessation, it does not consistently ameliorate other withdrawal symptoms, and its effects with weight gain are 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 under-served 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 (USDHEW 1964). 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 smoke-free environments have not reduced smoking prevalence in most studies, such environments have been shown to decrease daily tobacco consumption among smokers and to increase smoking cessation.

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. Though 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 United States 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.

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.

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. Nevertheless, the Institute of Medicine (2000) has concluded that these "multifaceted state tobacco control programs are effective in reducing tobacco use" (p. 4). 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* 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)

In its assessment of the trajectory of tobacco control activities in the coming years, the report focuses on six future challenges: the scientific base, the changing tobacco industry, the need for comprehensive approaches, identifying and eliminating disparities, improving dissemination of interventions, and influencing tobacco use in developing nations.

Continuing to Build the Scientific Base

Beginning with the 1964 Surgeon General's report, *Smoking and Health*, tobacco control policy in this nation has been built on a foundation of scientific knowledge. Each of the subsequent 24 reports of the Surgeon General on tobacco use has documented a vast and growing body of scientific literature. The substantial research reviewed in this report focuses on a key segment of the literature—what has been tried in the decades-old effort to reduce tobacco use. In turn, this focus clarifies which efforts work best. Certainly more research is needed so that these efforts can be more efficient and effective; the key conclusion from this report, however, is that we know more than enough to take actions now to decrease the future health burden of tobacco-related disease and death in this country.

In the process of applying our current state of knowledge about preventing and controlling tobacco use, accountability and evaluation of the public health effort will be critical. However, because of the wide array of educational, clinical, regulatory, economic, and social influences that have and will need to be brought to bear on the tobacco use problem, the direct impact of a specific maneuver on a specific outcome becomes less meaningful as the combined effects become more substantial. Investigators tend to work on small, manageable aspects of the tobacco use problem, but the synergistic influence of multiple factors over time will likely extend far beyond the outcomes predicted from these smaller research undertakings. For example, as this report demonstrates, the most efficacious educational programs are those that take place in a larger community context, one that engenders and supports an environment of nonsmoking. Similarly, although clinical interventions to manage tobacco addiction clearly have some specific power to help smokers quit, primarily through pharmacologic means, the social environment remains a major determinant of whether these new former smokers maintain their abstinence from nicotine addiction. Regulatory efforts, on the other hand, raise a host of social and economic issues and can produce broad societal changes—issues and changes, however, that are difficult to isolate, document, and evaluate. Economic

strategies also have a great potential, but being fundamentally political in nature, they require public consensus and changes in social norms before they can be attempted. Finally, the public health advocacy involved in social program modalities is virtually impossible to assess in a prospective or controlled research design.

The research and evaluation tools of public health must expand to meet these complex issues. Comprehensive, multifactorial approaches to tobacco control appear to offer the most promise. However, the penalty for comprehensive approaches is a loss of statistical power to attribute outcomes to specific activities. Within each of the modalities, appropriate evaluation methodologies are being used. However, many of these methodologies involve retrospective case study, time trend, econometric, and surveillance approaches to evaluate the "natural experiment" as it evolves in the changing social environment. Thus, the traditional biomedical and epidemiologic research methods that have worked so well in defining the health consequences of tobacco use are not well suited to evaluate the potentially most efficacious methods to reduce tobacco use.

The Changing Tobacco Industry

This report documents that this country's efforts to prevent the onset or continuance of tobacco use have faced the pervasive, countervailing influences of tobacco promotion by the tobacco industry. Despite the overwhelming and continually growing body of evidence of adverse health consequences of tobacco use, the norm of social acceptance of tobacco use in this nation has receded more slowly than might be expected, in part because of such continued promotion.

Litigation and legal settlements have produced notable changes in the tobacco industry's public positions on health risks, nicotine addiction, and advertising and promotion limits. Additionally, individual manufacturing companies have become more directly involved in efforts to limit the access of underage persons to tobacco products and to prevent young people from initiating tobacco use. In this rapidly changing social and legal environment, it is difficult to project the nature and scope of future changes by the industry or their impact on the national effort to reduce tobacco use. Nevertheless, any analysis of changes in patterns of tobacco use must consider the influence of these industry changes.

One of the major arenas of potential change will be in the tobacco product itself. The manufactured cigarette that is widely marketed in the developed world was noted to be changing dramatically when this issue was first considered by the Surgeon General in 1981, *The Changing Cigarette* (USDHHS 1981). Recent public statements by the tobacco industry suggest that the pace of changes in the manufactured cigarette could be accelerating in the future. The public health implications of changes in manufactured cigarettes and other tobacco-containing products will require careful and significant attention from both public health researchers and policymakers.

The litigation environment has demonstrated the importance of tobacco industry documents in analyzing the industry's influence. Legal and public health analyses are just beginning to sift through the millions of pages of documents made public as part of the various legal actions undertaken over the last decade. As this process continues, public health researchers may develop better methods to define and evaluate the industry's past activities that may have contributed to the character, pace, or direction of changes in tobacco use patterns in this country or around the world.

The Need for Comprehensive Approaches

The evidence of effectiveness summarized in this report emphasizes that public health success in reducing tobacco use requires activity using multiple modalities. A comprehensive approach—one that optimizes synergy from applying a mix of educational, clinical, regulatory, economic, and social strategies—has emerged as the guiding principle for future efforts to reduce tobacco use. The public health goals of such comprehensive programs are to reduce disease, disability, and death related to tobacco use through prevention and cessation, as well as through protection of the nonsmoker from ETS.

The emerging body of data on statewide tobacco control efforts is coming from programs broadly focused on prevention, cessation, and protection of the nonsmoker from ETS (Chapter 7). Preventing initiation among young people is a primary goal of any tobacco control effort. However, young people will perceive contradictory or inconsistent messages in our prevention efforts if programs do not also address the smoking behavior of millions of parents and other adult role models and the public health risks of ETS.

CDC recently released *Best Practices for Comprehensive Tobacco Control Programs* (CDC 1999), which recommends that states establish tobacco control programs that are comprehensive, sustainable, and accountable. This document draws on "best practices" determined by evidence-based conclusions from research and evaluation of such comprehensive programs at the state level. In the review of evidence from these states, it was evident that reducing the broad cultural acceptability of tobacco use necessitates changing many facets of the social environment. Nine specific elements of a comprehensive program are defined in the guidance document. Although the importance of each of the elements is highlighted, the document stresses that these individual components must work together to produce the synergistic effects of a comprehensive program.

Best Practices thus provides effective guidance for state-level efforts; a comprehensive national tobacco control effort, however, requires strategies that go beyond this guidance to states. Moreover, a comprehensive national effort should involve the application of a mix of educational, clinical, regulatory, economic, and social strategies. In each of these modalities, some of the program and policy changes that are needed can be addressed most effectively at the national level.

Identifying and Eliminating Disparities

The elimination of health disparities related to tobacco use poses a great national challenge. Although this issue was not a major aspect of the current report, two other recent USDHHS publications have taken this focus. The 1998 Surgeon General's report *Tobacco Use Among U.S. Racial/Ethnic Minority Groups* 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 (USDHHS 1998). Similarly, *Healthy People 2010*, released in January 2000, has two overarching goals: increase quality and years of healthy life and eliminate health disparities among different segments of the U.S. population (USDHHS 2000a). Both publications not only highlight the significant disparities in health that exist in the United States but also stress the critical need for a greater focus on this issue, both in research and in public health action.

Cultural, ethnic, religious, and social differences are clearly important in understanding patterns of tobacco use, but little research has been completed on the relative

effectiveness of interventions for prevention and treatment in some of the population groups or communities. Reaching the national goal of eliminating health disparities related to tobacco use will necessitate improved collection and use of standardized data to correctly identify disparities in both health outcomes and efficacy of prevention programs among various population groups. Broader historical, societal, and community characteristics can have a significant influence on the manner in which prevention and control strategies that work overall for the population as a whole may impact diverse groups. Many of these broader variables do not lend themselves to traditional measurement methods nor are they easily assessed at the individual level through using traditional epidemiologic methods.

Improving the Dissemination of State-of-the-Art Interventions

One of the greatest challenges in tobacco control and public health in general continues to be overcoming the difficulty in getting advances in prevention and treatment strategies effectively disseminated, adopted, and implemented in their appropriate delivery systems. Simply stated, our recent lack of progress in tobacco control is attributable more to the failure to implement proven strategies than it is to a lack of knowledge about what to do. The result is that each year in this nation, more than 1 million young people continue to become regular smokers, and more than 400,000 adults continue to die prematurely from tobacco-related diseases.

Within each of the modalities reviewed in this report, some specific research advances in tobacco prevention and control strategies have not been fully implemented. Studies are urgently needed to identify the social, institutional, and political barriers to the more rapid dissemination of these research advances. Understanding these barriers and determining how they could be overcome would benefit not only tobacco control but public health efforts more broadly.

Tobacco Use in Developing Nations

Analyses by the World Health Organization (WHO) have concluded that by 2030, current smoking patterns will produce about 500 million premature deaths from tobacco-related disease among people alive today (WHO 1999). WHO further estimates that by 2030, tobacco is expected to be the single greatest cause of death worldwide, accounting for an estimated 10 million deaths per year. Although the impact of tobacco-related disease and death has been until recently a problem primarily for the developed countries of this world, WHO now estimates that by 2020, 7 of every 10 tobacco-related deaths will be in the developing world.

This report addresses research on strategies to reduce tobacco use within our nation's social, legal, and cultural environments. Nevertheless, findings from this report may have broad utility in the planning of tobacco control efforts around the world. As Chapter 2 documents, the public health response in this country to the scientific findings about the health consequences of tobacco products has taken more than four decades to emerge. In many parts of the developing world, the problems of tobacco use are similar to those in this country in the 1950s and 1960s. Hence, a key public health question for this millennium may be the following: can the time interval be significantly shortened between when the health risks of tobacco for a developing country are recognized and when a comprehensive national response is begun?

WHO, the World Bank, and the United Nations Foundation, with technical assistance from the CDC, have undertaken major new initiatives to address this problem. The WHO Tobacco Free Initiative is developing an international tobacco control infrastructure, which includes a global tobacco surveillance system, intervention tool kits, and regional technical assistance workshops. The World Bank has published *Curbing the Epidemic: Governments and the Economics of Tobacco Control* (Jha and Chaloupka 1999). This document provides an economic analysis that supports a multipronged approach to tobacco control, involving raising excise taxes, promoting policy changes related to the sales and promotion of tobacco products as well as to restrictions on smoking in public places, and widening access to smoking cessation therapies. The scientific findings in this report are consistent with the programmatic recommendations of both the WHO Tobacco Free Initiative and the World Bank document.

A momentous undertaking of WHO and member states, including the United States, is the development and negotiation of the Framework Convention on Tobacco Control. If brought to its intended ratification in the next few years, this agreement would provide a framework within which countries could develop more specific bilateral and multilateral protocols for cooperation on containing the spread of the tobacco epidemic. The framework would enable countries to start from a common understanding of the issues, priorities, and strategies necessary to harmonize tobacco control efforts among themselves so that some countries do not benefit at the expense of others. This is the spirit of the other activities of U.S. governmental and nongovernmental agencies in their effort to collaborate with WHO and with other countries in their development of surveillance, cessation, prevention, mass media, regulatory, economic, and social approaches to global tobacco control.

In the near future, emphasis must be placed on the development of surveillance systems so that countries can know the extent, distribution, and trends of the tobacco consumption problems in their populations. These systems will also track—for international comparison and monitoring of progress—the emergence of new forms of tobacco promotion, as well as new legislation, regulations, and programs for countering tobacco use. In the longer term, the gaps must be filled in each country's defenses against the incursions of tobacco use on their young people and other vulnerable populations. In particular, there will be a continuing need to ensure that the rapidly expanding knowledge about the efficacy of various tobacco control modalities be made available to the developing world.

The challenge to the world is to prevent tobacco use, particularly smoking, from ever becoming the leading cause of preventable illness and death in the world. Dr. Gro Harlem Brundtland, the current director-general of WHO, clearly defined this challenge when she stated, "If we do not act decisively, a hundred years from now our grandchildren and their children will look back and seriously question how people claiming to be committed to public health and social justice allowed the tobacco epidemic to unfold unchecked" (Asma et al., in press).

TOBACCO CONTROL IN THE NEW MILLENNIUM

Tobacco use will remain the leading cause of preventable illness and death in this nation and a growing number of other countries until tobacco prevention and control efforts are commensurate with the harm caused by tobacco use. This report provides the composite review of the major methods—educational, clinical, regulatory, economic, and social—that can guide the development of this expanded national effort. This report

is, therefore, a prologue to the development of a coherent, long-term tobacco policy for this nation.

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