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New Directions in Tobacco Control

Rahul Rajkumar

ON THE COVER Heather Tauschek, Cornell University School of Medicine, Crimson, watercolor,

26.6×33 cm.

THE WORLD HEALTH ORGANIZATION (WHO) ESTIMATES THAT 4 MILLION people will die of tobacco-related illness in 2001 and that this number will climb to 10 million per year by the 2020s.¹ Despite this overwhelming mortality, a significant gap exists between the scientific consensus on the dangers of tobacco use and the political reality of what governments have been able to achieve in terms of tobacco control. Last year, a US Supreme Court judgment stripped the Food and Drug Administration of its authority to regulate tobacco. The past few months have revealed a more insidious setback: a recent study found that the \$206 billion master settlement agreement between 46 states and the tobacco industry, which was designed to fund a nationwide campaign to curb tobacco use, has had little effect on cigarette advertising in magazines and on the exposure of young people to these advertisements.²

Tobacco control involves both politics and science-and since the scientific evidence supporting tobacco regulation is sound and well documented, this suggests that there has been a breakdown in the political process. The health sector and its allied antitobacco forces have been stymied in their efforts to bring about enactment of effective tobacco control measures. While the consensus opinion of the medical community about tobacco-related mortality reflects the strength of epidemiologic and scientific evidence, this opinion does not prescribe any assured method for effecting political change. Having conclusively established the harm that results from tobacco use, the medical community must now find political direction in its antitobacco initiative if it is to be effective.

This issue of MSJAMA explores the future of tobacco control. Asaf Bitton, Caroline Fichtenberg, and Stanton Glantz contend that an aggressive national tobacco control program can reduce US smoking prevalence from 22.7% to 10% in 5 years. Anticipating the criticism that such a program might provoke in a nation with a rich and longstanding libertarian tradition, Brion Fox reviews the barriers to tobacco control legislation and argues that such legislation is both appropriate and legally sustainable. Recognizing the emergence of a global tobacco market that demands global regulation, 2 articles present the nascent WHO-sponsored Framework Convention on Tobacco Control (FCTC), the first-ever international health treaty, currently being negotiated. Matthew Myers and Judith Wilkenfeld discuss how the international nature of tobacco trade necessitates an international treaty. Finally, Douglas Bettcher and Chitra Subramaniam describe the ethical and practical imperatives that have led the World Health Organization to pursue the FCTC.

As the societal costs of tobacco use continue to grow, the time has come to evaluate the role of legislation in the reduction of tobaccorelated deaths. Having conclusively established the harm that results from tobacco use, the medical community must now find an equally effective political strategy.

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Reducing Smoking Prevalence to 10% in Five Years

Asaf Bitton, Caroline Fichtenberg, MS, and Stanton Glantz, PhD, University of California, San Francisco School of Medicine

WHILE PEOPLE HAVE SMOKED TOBACCO FOR MANY CENTUries, the epidemic of tobacco-related morbidity and mortality did not begin until the early 20th century. Three technological breakthroughs around 1900 created this phenomenon: cigarette rolling machines that reduced costs; safety matches; and mass-marketing programs. Later, the tobacco industry systematically increased the addictive potential of cigarettes.¹ Thanks to these innovations, yearly cigarette use by adults in the United States grew from 54 in 1900 to 4148 in 1973, when use peaked.² In 1999, 22.7% of US adults smoked, with a range between 29.7% in Kentucky and 13.9% in Utah.³ Because tobacco is the leading cause of preventable death in the United States, killing 430000 US smokers and 53000 nonsmokers annually,⁴ reducing smoking is the single most important action that can be taken to improve overall US health status.

The goal of the US Public Health Service's "Healthy People 2010" is to reduce adult smoking prevalence to 15% by 2010. This goal seems daunting given that adult US smoking prevalence reached a plateau between 1990 and 1999 and has since fluctuated between 23% and 26%.⁵ Some have argued that this goal is a policy mistake because it is unattainable through decreases in smoking initiation alone, and would require an unrealistic increase in the rate of smoking cessation.⁶ However, the success of aggressive state tobacco control programs indicates that this goal could be achieved if there were sufficient political will to overcome the tobacco industry's opposition to these programs.

Several states have found that such programs can dramatically decrease the rates of decline in both smoking prevalence and per capita consumption.⁷ Prior work has established that the changes in smoking rates are directly due to these programs and not to other coincidental factors.⁷⁻⁹

Using data from state and federal sources, we estimated the average rate of decline in consumption and prevalence for the first 4 states to create large tobacco control programs— California (started in 1989), Massachusetts (1992), Arizona (1994), and Oregon (1996). Florida started a program in 1998 to reduce youth tobacco use. To determine these rates of decline we used prevalence or consumption as the dependent variable and time (over the life of the program) as the independent variable and used the slope of the resulting regression as an estimate of the average rate of change over this period. All these programs substantially accelerated the decline in smoking prevalence and per capita consumption above the rates observed in the rest of the country (TABLE). On average, the 4 adult programs yielded an average rate of decline in adult prevalence of 1% a year over the duration of the programs, compared to a 0.3% decline in the rest of the nation.

California's tobacco control program is an illustration of the possibilities and problems associated with running a successful program.^{7,8,10} After rapid declines in smoking between 1989 and 1993, when the program was large and aggressive, the progress in reducing smoking prevalence in California stopped in the mid-1990s due to the tobacco industry's success working with allies such as the California Medical Association to reduce funding for the program.¹¹ Even so, adult smoking prevalence in California in 1999 was about 18%, well below the national average.³

The reductions in prevalence, however, do not tell the whole story. Despite the fact that prevalence in California has not changed significantly between 1994 and 1998, per capita consumption continued to decline during this period.⁸ The overall decline in cigarette consumption in the 7 years between 1989 and 1997 has translated into 59000 fewer coronary heart disease deaths in California than would have been expected in the absence of the program.^{9,11}

The situation in California demonstrates that the Healthy People 2010 goal of 15% prevalence by 2010 is not only

	California	Massachusetts	Arizona	Oregon	Florida (Focus Only on Teens)	US Baseline (Excluding CA, MA, AZ, OR, and FL)
Tax increase per pack	25 cents	50 cents	40 cents	30 cents	No	45 cents (National tax)
Per capita spending ¹⁶ (1999 US dollars)	1989-93: \$3.27 1994-96: \$1.78	1994-97: \$7.09	1996-1998: \$3.89	1997-99: \$2.59	1998: \$4.73	Not available
Annual per capita consumption decline	1989-93: –7.7 packs/person/yr 1994-96: –2.0 packs/person/yr ⁸	1992-96: –7.7 packs/ person/yr ¹⁷	1996-2000: -2.7 packs/person/yr ¹⁸	1996-89: -5.0 packs/person/yr ¹⁹	Not available	1989-93: -5.0 packs/person/yr 1992-96: -2.4 packs/person/yr 1996-98: -2.1 packs/person/yr
Annual absolute adult prevalence decline	1989-93: -1.1%/yr 1993-96: 0.0%/yr ³	1992-99: -0.43%/yr ²⁰	1996-99: -1.7%/yr ²¹	1996-1998: -0.75%/yr ²²	1998 (High school): -2.4%/yr ²³	1989-93: -0.57%/yr 1992-96: +0.03%/yr 1996-98: -0.30%/yr

Table. Overview of Effective State Tobacco Control Program Components and Results

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achievable in California, but surpassable. Indeed, it is possible to reduce smoking prevalence in California to 10% in five years. While prevalence has not been dropping, the percentage of light smokers (those who smoke less than 15 cigarettes/day) increased by 9% between 1996 and 1999, to 60% of all smokers.12 The fact that most smokers are light smokers will make it easier to reduce overall smoking rates as light smokers are more likely to quit than heavy smokers. The National Cancer Institute COMMIT trial, an experiment involving a cohort of 13415 smokers from 20 US and 2 Canadian communities, showed that 40% of those who smoked fewer than 15 cigarettes per day had stopped smoking after 5 years compared to 21% who smoked 15 cigarettes or more.¹³ Applying these quit rates to California (where 60% are light smokers) corresponds to 24% of the light smokers quitting within 5 years. Therefore, approximately 30% of all smokers would be expected to quit within 5 years. If smoking initiation does not increase substantially, this effect would correspond to a decline in prevalence of 1.2% per year. Reaching a goal of 10% prevalence in California in 5 years only requires accelerating this rate to 1.4% per year.

A reinvigorated, well-funded tobacco control program in California could achieve a reduction to 10% smoking prevalence if it includes a few proven elements.⁷ These include a large, aggressive antitobacco media campaign similar to the early successful campaign that focused on exposing the tobacco industry's lies, the dangers of secondhand smoke, and nicotine addiction; strong community-based programs concentrating on clean indoor air laws and countering protobacco influences in the community; a smokers' quitline. Achieving this degree of reduction in smoking prevalence would require restoring not only the level of aggressiveness, but also the level of funding that was present in the early years of the effective California program (Table).

The public health and medical communities have historically set their sights too low and instituted tobacco control programs that have focused either on individual smoking cessation or on smoking prevention in children. Medically mediated smoking cessation programs, while an important element of treatment, are too expensive to achieve major results on a mass basis. In addition, most smokers quit without using such programs.¹⁴ Primary prevention programs for youth do not result in significant population health benefits for at least 30 years.¹⁵

Smoking is inherently a social and cultural phenomenon with an addictive individual aspect. The experience in California and other states suggests that an effective, aggressive tobacco control program employing political, legal, and social action can reduce smoking prevalence by 1% per year. Putting money from the 1998 master settlement agreement into these types of programs across the country would achieve the 10% goal by 2010.

Overall smoking prevalence need not hover at 23%-26% nationwide if public health advocates are willing to force poli-

ticians to create and fund effective tobacco control programs. Doing so will require overcoming formidable opposition from the tobacco industry, which is highly motivated and experienced at protecting its profits. Rather than reaching a floor in prevalence below which it cannot be lowered, if prevalence is reduced below 10%, the public acceptability and social support networks for smoking might collapse. Should this situation develop, smoking in the early 21st century could return to the low levels of a hundred years earlier.

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Removing Barriers to Local Tobacco Regulation

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LAWS AND REGULATIONS GOVERNING TOBACCO NEED TO BE AN essential part of an overall strategy to reduce tobaccorelated morbidity and mortality. Indeed, the US Surgeon General supports regulation as an important component of a comprehensive tobacco control program. His recent report identified 3 particularly effective regulatory approaches: reducing tobacco advertisements, promoting clean air, and restricting youth access to tobacco products.¹ The misperception remains, however, that state and local efforts to regulate in these areas have outpaced what the public supports or what the law allows. The public health community can overcome these misperceptions by providing appropriate support, education and technical assistance to policy makers.

Tobacco control seems particularly well suited to regulatory action because it meets basic criteria necessary for appropriate public health legislation.² First, the public health need is great, with more than 430000 US citizens dying annually from smoking-related behavior.³ Second, regulatory restrictions can reduce morbidity and mortality related to tobacco. Clean-air ordinances, advertising restrictions, and youth access laws have all been established as effective preventive measures.1 Third, the normal police power of the state allows it to regulate known public health hazards, to protect nonconsenting individuals from exposure to hazards, and to educate children and adults about harmful behaviors. Given that many local tobacco control laws clearly meet these 3 basic criteria, barriers that prevent the passage of these laws should be removed. Two such barriers are the misperceptions that most people do not favor tobacco control laws and that these laws are legally indefensible.

Reports of individuals flouting tobacco control laws or of opposition to tobacco laws can give the impression that the laws are outpacing the popular will for change. These reports, however, are often contradicted by the data. For example, there were several reports of public opposition to the California state law eliminating smoking in bars, and opponents of the law used these reports to lobby for its repeal. In reality, a majority of Californians support the restrictions. Indeed, the visibility of the reports of opposition arose from a tobacco industry strategy to overturn the law by using anecdotal accounts to obscure the law's general popularity.⁴ Support has also been demonstrated for regulating tobacco advertising, promoting clean air ordinances, and restricting youth access to tobacco.⁴ Understanding both the widespread support for these laws and the measures that the tobacco industry will take to manufacture opposition to them will provide decision-makers important information. Decision-makers must look at scientific evidence and not headlines.

Other headline-grabbing events that have acted as barriers to local initiatives include 2 recent US Supreme Court decisions. The first, in March 2000, overturned the US Food and Drug Administration (FDA) jurisdiction to regulate tobacco products.⁵ The other, in June 2001, overturned a Massachusetts ordinance restricting tobacco advertising.⁶ A common interpretation of these decisions is that they leave no room to regulate tobacco. In fact, rather than hindering all regulatory approaches, these opinions provide a roadmap for future initiatives. For example, the FDA case specifies that the US Congress can give jurisdiction to the FDA. Similarly, many avenues for state regulation fit within the standards set up by the Supreme Court in the Massachusetts case, including the restriction of self-service displays. Moreover, the court's rulings do not restrict smoke-free workplaces, licensing, and restriction of youth access.

Developing appropriate local tobacco regulation will necessitate understanding both tobacco science and tobacco law. This will require scientists to conduct targeted studies to demonstrate the need for such laws, and public health practitioners to educate decision-makers on the science and strategies for tobacco control. Equally important, however, public health professionals and policy makers should work collaboratively with experts who can provide technical legal assistance. These experts can help navigate the roadmaps set up by the Supreme Court, avoid potential pitfalls in regulation, and provide protection from those who would use common misperceptions or inflammatory arguments to challenge the regulations. In particular, the public health community and states should promote the development of tobacco control centers to provide legal assistance and ensure that the centers are supported by the best available science. By working together, scientists, public health practitioners, and lawyers can overcome perceived barriers to passing tobacco control regulation, and insulate decisionmakers from erroneous claims that the laws go too far.

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The Worldwide Tobacco Treaty

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THE NEGOTIATIONS ON THE FRAMEWORK CONVENTION ON TObacco Control (FCTC), sponsored by the World Health Organization, are an opportunity to fashion the international controls necessary to stem the worldwide increase in tobaccorelated mortality. It is an opportunity that should not be squandered. We believe that a treaty that merely suggests guidelines for countries to follow will not advance global public health. It must contain concrete provisions to tackle the problems of international tobacco trade. It is also important that the FCTC not act as a restraint on countries' ability to go beyond what is negotiated by stating explicitly that it and subsequent protocols should serve as a minimum standard. While we will discuss advertising, the treatment of tobacco products in international trade,¹ and the positions taken by the US delegation, action is needed in many additional areas.

Advertising

Despite industry denials, tobacco advertising and promotion lead to dramatic increases in consumption and have an especially powerful effect on young people.² Moreover, bans on tobacco advertising, sponsorship, and other promotional activities are effective in reducing tobacco use and preventing new smokers from starting.3 The World Bank examined data from 102 countries and found that per-capita cigarette consumption in countries with comprehensive advertising bans declined by about 8%, while consumption rates in other countries declined by only about 1%.4 However, limited or partial bans, such as those proposed by the tobacco industry, have little or no effect. Both the World Health Organization and the World Bank recommend that countries prohibit all forms of tobacco advertisement and promotion.⁴ During the negotiations, a global ban was supported by most countries with a few exceptions, including the United States.

Given the evidence, we believe that the parties to the FCTC should prohibit all tobacco advertising, sponsorship, and promotion, including all cross-border advertising, promotion and sponsorship. There should be exceptions only for countries with pre-existing constitutional constraints, and those countries should be required to enact the most stringent restrictions possible.

Trade

Historically, global trade agreements have focused on promoting and expanding trade with scant regard to the public health implications. In the case of tobacco, this oversight has resulted in a public health disaster. According to the World Bank, liberalization of trade in tobacco products has contributed significantly to increases in cigarette consumption in low- and middle-income countries.⁵ Since tobacco products are unique in that their promotion and expansion to additional markets merely raises the death rate and incurs a net economic loss, we believe that they can and should be treated differently in international trade. The Convention should encourage countries to modify existing trade agreements to make exceptions for tobacco. Such action is not unprecedented. Other legal but harmful products, such as guns and toxic waste, are subject to limitations on unrestrained free trade. Establishing separate treatment for tobacco products is a logical extension of these precedents.

US Involvement

In April 2001, the US delegation sought several changes to the FCTC. These included eliminating a provision prohibiting the use of dangerously deceptive terms like "low tar," "light," and "mild" to market tobacco products; deleting provisions prohibiting tax-free and duty-free sales of cigarettes and calling for "imposition of taxes on tobacco products so as to achieve a stable and continuous reduction in tobacco consumption"; reconsidering a provision encouraging governments to protect non-smokers by banning smoking in workplaces and public buildings; deleting a provision supporting the licensing of tobacco retailers as an effective means to enforce youth access laws; and weakening the overall obligations of nations to implement the provisions of the proposed treaty.

While the Convention represents hope for real progress in halting the leading preventable cause of death, the United States' recent behavior in the negotiations has been negative. We believe that the positions the United States proposed at the last negotiating session would weaken or eliminate precisely those provisions that could have a significant impact, while offering text proposals that seem favorable to the interests of tobacco companies. Because the United States is the leading exporter of tobacco products, we believe that it has an obligation to put aside the parochial interests of domestic tobacco manufacturers and be a leader in writing a strong and effective FCTC.

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The Necessity of Global Tobacco Regulations

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WHILE MULTINATIONAL TOBACCO COMPANIES MARKET HIGH tar and nicotine cigarettes worldwide, in developing countries they advertise these products with techniques that are banned in their home countries.¹ Of the 8.4 million deaths that tobacco is expected to cause by 2020, 70% will occur in transitional countries.² Global legislation must hold tobacco companies to the same standards of safety in developing markets that they are held to in their industrialized home markets. To create such global legislation, the World Health Organisation's (WHO's) 191 member states are currently negotiating a legally binding international agreement, the Framework Convention on Tobacco Control (FCTC), which may include legally binding rules on tobacco smuggling, international standardization, disclosure of product contents, and package design and labeling.³

The ethical basis of the FCTC is the principle that a multinational corporation has a nondelegable duty to protect citizens from harm caused by its products. This includes the duty to ensure that all activities are conducted with the highest standards of safety and to provide all necessary information and warnings regarding the activity involved.⁴ In addition, the "negative harm" principle of business ethics requires that, in their operations abroad, corporations have an obligation not to add to the suffering and deprivation of people.

Tobacco companies have argued that people should be allowed to consume products of their choice freely.⁵ However, a recent World Bank report cites 3 ways in which the choice to buy tobacco products differs from the purchase of other consumer goods. First, many smokers are not aware of the high probability of disease and premature death their choice to smoke entails, and thus, their consent to be exposed to harm is uninformed. Children and teenagers in particular may not have the capacity to assess properly information on the health effects of smoking. Second, the highly addictive nature of nicotine, particularly as it is delivered in a manufactured cigarette, limits the tobacco user's freedom to choose not to smoke.⁶ Third, smokers impose both direct and indirect costs on other non-consenting individuals. These failures to meet "free" market standards provide a rationale for demand-reduction interventions.⁷

Beyond this theoretical justification for action, there is also a practical one. Tobacco companies have shown themselves to be incapable of self-regulation.⁸ Despite the fact that cigarette smoke contains some 4000 different constituents, 60 of which are known carcinogens,⁹ there is evidence that tobacco companies have failed to perform inhouse smoking and health research, and that this failure was, in part, the result of tobacco company efforts to mislead the public about the health effects of smoking.¹⁰ The tobacco companies have deliberately increased the addictive potential of cigarettes through their well-documented strategy of manipulating nicotine levels.⁶ Furthermore, a WHO committee concluded that tobacco companies had conspired to undermine the agency's tobacco control programs around the world. The committee made 58 recommendations to protect against the subterfuge of the tobacco industry.¹¹

During a global public hearing in October 2000, the WHO supported measures and policies to restrict youth access to tobacco. Recently, 3 major tobacco companies proposed weak voluntary global marketing standards, but such measures are known to have only limited impact on youth and adult consumption of tobacco.¹² At the same time, tobacco companies opposed comprehensive advertising bans and price increases, interventions that have had a measurable and sustained impact to decrease tobacco use.

Tobacco companies have an ethical responsibility to minimize the harm caused by their products in developing countries and to adhere to the same safety standards in developing countries that they use in their home countries. They have proven themselves unwilling or unable to meet this responsibility voluntarily, and the cost of this failure is enormous. The kind of legally binding global regulation of dangerous practices that the FCTC could provide has become necessary.

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