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Health, Nutrition and Population (NHP) Discussion Paper. Progression of Tobacco Control Policies: Lessons from the United States and Implications for Global Action



## Authors

Novotny, Thomas E
Mamudu, Hadii M

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# Health, Nutrition and Population (HNP) Discussion Paper

## Progression of Tobacco Control Policies: *Lessons from the United States and Implications for Global Action*

Thomas E. Novotny [a] Hadii M. Mamudu [b]

[a] Director of International Programs, UCSF School of Medicine, Center for Tobacco Control Research and Education, University of California, San Francisco, CA, United States
[b] Post Doctoral Fellow, UCSF School of Medicine, Center for Tobacco Control Research and Education, University of California, San Francisco, United States

Paper prepared for The World Bank Consultation *"Taxes for Tobacco Control: improving effectiveness at the country level"*, October 2-3, 2007, Washington DC.

**Abstract**:
This paper examines the historical experience of tobacco control in the last five decades and shares important lessons of public health interventions to inform current and future tobacco control programs in other countries. The paper is divided into four parts. The first part gives an overview of the political economy, principal influences and interventions in tobacco control in the United States. It stresses the importance of information shocks and the role played by grassroots organizations. The current situation of tobacco control in the United States is further discussed in the second part, with emphasis on the economic case that led to litigation, as well as the response of the industry and the States. The third part focuses on the present efforts of multilaterals like the World Bank, technical UN agencies such as the World Health Organization, in the context of the new global governance structure: the Framework Convention on Tobacco Control (FCTC). The last section discusses lessons learned and provides recommendations for comprehensive tobacco control programs.
The paper suggests five major policy drivers that constitute components of a comprehensive tobacco control program: – science to inform policy, information strategies to educate consumers, advocacy to stimulate interventions, legal actions to develop regulations, and international collaboration through the FCTC. The paper concludes that while government has the responsibility for funding and implementing these activities; these can be most effective when supported by civil society.

**Keywords**: "tobacco", "public policy", "international agencies/history", "international agencies/legislation"



**Correspondence Details**:
Thomas E. Novotny, 530 Parnassus Avenue, Library Suite 366, University of California, San Francisco, CA. 94143 – 1390, United States. Phone: 415-476-3115. Fax: 415-514-9345, Email: novotnyt@globalhealth.ucsf.edu

## Executive Summary

The historical experience of tobacco control in the United States in the last five decades provides evidence of effective public health interventions. The tobacco industry has been working to embed tobacco use in the personal behavior of individuals as well as in national structures which extend across disparate government sectors. To face these challenges multi dimensional efforts by national governments as well as civil society are crucial. Public - Private partnerships and new funding sources would also help to achieve success in global tobacco control.

Tracing the history of tobacco control in the United States takes us back to the 1950s and 1960s when knowledge of the harmful effects of tobacco use was minimal. In 1964 the US Department of Health, Education, and Welfare through the Office of the Surgeon General, officially established that Smoking was a medical problem and a public health challenge. This shaped tobacco control science, policy, and advocacy for four decades in which a major influence has been the role of *science leading to policy change.* This has resulted in the reduction of smoking prevalence by at least half since 1964. In 2000, the US Surgeon General's Report proposed five approaches to reduce tobacco use and its disease impact - educational, clinical, regulatory, economic, and comprehensive. Though the qualitative assessment of their impact has been mixed, laws and policies to support these measures have been effective. The science of tobacco control strongly supports a multi-component comprehensive programme that integrates various programmatic and policy interventions to influence social and health systems. Regulatory approaches that entail increasing the price of tobacco products through taxation, implementing smoke free policies and regulations, and restricting the sale and distribution of tobacco products have supporting evidence of effectiveness. Globally, these interventions can be implemented with strong government support. However, in many countries regulatory approaches appear to have been underutilized compared to behavioral-educational approaches.

Media campaigns in the US to educate the public on the health consequences of smoking have proved effective. Another influencing factor has been litigation against the tobacco industry, the legal settlements of which were used to fund comprehensive programs. Media advocacy also influenced the establishment of other policies such as clean indoor air policies, smoking cessation programs, and taxation to recover smoking related health costs. Social norms supporting tobacco use can be changed slowly with multi-dimensional interventions that depend not only on strong government support, but on strong grassroot efforts and partnerships. These efforts have been a key component of tobacco control successes in the United States and in other developed countries.

In low and middle-income countries, tobacco control is increasingly important for economic development and poverty reduction. The World Bank's research in the late 1990's including *The Economics of Tobacco Control: Towards an Optimal Policy Mix and Tobacco Control in Developing Countries* provided the analytical basis for such evidence. However, as smoking rates increase in some developing economies, additional evidence is needed to understand the direct impact of these increases and the benefits of reducing the burden of tobacco related diseases.

A new global health governance initiative, the WHO Framework Convention on Tobacco Control (FCTC) has now emerged as an important mechanism to address tobacco control through multi-lateral cooperation. The FCTC is an evidence-based treaty that establishes the "baseline" for developing and sustaining tobacco control programs at the national level. The FCTC has been ratified by 151 parties and has the secretariat at WHO headquarters in Geneva. The critical issue now is implementation of the treaty at national levels.

Lack of financial resources to develop and sustain tobacco control programs has been a key barrier to the implementation of the FCTC in developing countries. Even though Article 26 of the FCTC points out the need to provide funding for tobacco control programs, there has not been any institutionalized way of funding the initiation, development, and sustainability of tobacco control programs in developing countries until the recent infusion of the Bloomberg Initiative funding. In 2007, Michael R. Bloomberg, philanthropist and Mayor of New York City, launched a US$125 million global tobacco control initiative to reduce tobacco use in low and middle-income countries. This funding will be critical in helping to overcome many national barriers to tobacco control, helping to build capacity and leveraging other international.

The FCTC as global governance may strengthen multinational cooperation on tobacco control in the future. In order to do so, collaboration among the members of the UN Ad Hoc Task Force on Tobacco Control would be needed. The World Bank should continue to contribute analytic capacity, country assistance and financing, and leadership through partnerships in support of global tobacco control; the World Bank has produced some of the most important documents on the economic basis for tobacco control, and its analytic role in this field should be sustained. However, the World Bank deals primarily with governments, and thus the interactions between government and civil society may need to be explored further in the World Bank's development investment strategies.

Governments have the lion's share of responsibility to control tobacco as a global public 'bad', but grassroots and community efforts have been shown to stimulate governments and to help carry out government programs with less than adequate funding. New funding sources should address civil society development in order to achieve success in global tobacco control.

There are several major policy drivers that can not only lead to a collective approach to tobacco control at the global level but also affect local levels, sub-national-levels and national governments. These have also influenced the efforts of multinational organizations and new multinational structures:

- Science to inform the public and policy makers about health risks, economic costs, program effectiveness, and clinical interventions regarding tobacco use;
- Information strategies to educate consumers and potential consumers, motivate advocates, and support behavior change among smokers;
- Advocacy to stimulate interventions and hold accountable decision-makers who do not support or enforce evidence-based policy;

- Legal actions to develop regulations, product contents, advertising, packaging, and labeling; hold the tobacco industry accountable through litigation; and stimulate global tobacco control through multinational agreements;
- Collaboration now codified by the FCTC, to work across borders, including national governments, multi-national organizations, and the private sector. Most importantly the FCTC requests that countries provide information to monitor implementation.

These are critical components of a comprehensive approach to global tobacco control. Without science and continued exploration of evidence on what works, the tobacco control community would not be able to formulate policy. Without dissemination of information, tobacco as a major cause of the current and future global burden of disease will not be recognized. Without advocacy to disseminate information and cause policies to be implemented, not enough will happen in tobacco control through government. Without regulations and legislative approaches governments will not be able to intervene against tobacco use as a public health problem. Without collaboration, the multi-national community of nations will be divided by the multi-national tobacco industry. This industry has the resources, economic motivations, and fiduciary responsibility to its stakeholders to do all that is possible to subvert international agreements such as the FCTC as well as national programs to protect the public's health. The evidence for these efforts has been relatively well documented in developed countries such as the United States, but there is still need for additional evidence to support developing countries' tobacco control programs.

In conclusion, while government has the responsibility for implementation of most comprehensive activities, these can be most effective when supported by grassroots efforts. Stakeholders are important at multiple levels. These may include representatives from the ministries of agriculture, trade, security education, consumer protection, youth, sport, the media, the business community, and health NGOs. The contributions from these must be from top down as well as from the bottom up. WHO could support policy development at the national level in cooperation with other UN agencies. The World Bank could provide country-level support. Academia could be an essential partner in research and the evaluation of current interventions.

The production of new knowledge, the consistent dissemination of information to the public and policy makers about the health consequences of tobacco use, commitment of multinational organizations and investments by philanthropy and bilateral donors will continue to be the cornerstone of effective tobacco control programs.

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# INTRODUCTION

This paper reviews the political economy of tobacco control in the United States and globally to demonstrate what lessons can be learned from history and transferred to future global tobacco control efforts. The reasons for this analysis are that a number of common elements in tobacco control have emerged as a result of trial and error in the United States and other developed countries; there have been substantial analytic efforts by the World Bank and others that support global tobacco control; the tobacco industry continues to adapt to these tobacco control efforts, thus requiring advocates and professionals to look back in order to step forward; and political challenges continually arise that require continued civil society (primarily grassroots) efforts to assure accountability of government in tobacco control policy.

We will examine four main questions concerning tobacco control in the 21st Century:

I. What have we learned over the last fifty years regarding what works in reducing tobacco use?

II. What are the lessons from past tobacco control efforts?

III. What is the current status of global tobacco control efforts?

IV. How can these lessons from the past inform current and future investments in global tobacco control?

Part I consists of an overview of the major influences and types of interventions on tobacco control primarily in the United States; we will review the science on these interventions and provide examples of successful programs.

Part II distills the lessons from the history presented in Part I. These discussions include the economic analyses necessary to encourage government action in tobacco control, the influence of the advocacy movement and counterinfluences of the tobacco industry, and the current status of national tobacco control activities.

Part III discusses historic and current efforts by the World Bank, philanthropic community, World Health Organization (WHO), and the tobacco industry on global tobacco control efforts. A detailed discussion of the Framework Convention for Tobacco Control (FCTC) is included.

Part IV discusses the lessons learned that may lead to successful comprehensive tobacco control programs globally.

# PART I – FIFTY YEARS OF LEARNING

This section reviews the relevant historical experiences in tobacco control over the last five decades in the United States, focusing on the evidence for the effectiveness of several specific interventions that may have future global health applications. These historical perspectives may then provide suggestions about what we might expect to happen regarding tobacco control and tobacco's health consequences in a changing global health environment.

## INFLUENCES AND INTERVENTIONS ON TOBACCO CONTROL IN THE UNITED STATES

The question of what works to reduce the burden of disease due to tobacco use is as multi-faceted a consideration as are the forms of tobacco used around the world. In the United States, this question has been explored thoroughly in a number of important publications.[1-4] According to a recent report of the Institute of Medicine[5] the public health response over the four decades since the 1964 *Report of the Surgeon General on the Health Consequences of Smoking* is characterized as biphasic: phase one lasted through the late 1980s and was mostly a set of unsuccessful efforts to gain political footing against the tobacco industry. In phase two (mid-1980s), smoking was recognized as a form of drug addiction, especially affecting children, fostered by deceptive marketing and promotion; in addition, the harm of second-hand smoke to non-smokers changed political opinion towards smoking from consideration as an independent personal behavior to one of concern for the direct health effects of second-hand smoke on the general public. This was accomplished largely through grassroots efforts in the United States rather than through top-down government initiatives alone. In addition, the externalities of smoking (economic costs of illness) became another concern for government and the private sector. Finally, the role of litigation (especially the Master Settlement Agreement between State Attorneys General and the tobacco companies) that exposed secret tobacco documents, provided funding to State and non-governmental tobacco control activities, and later labeled the tobacco industry as 'organized crime,' cannot be overstated.

Perhaps the first major intervention against tobacco use in the United States and in other developed countries might be considered as i*nformation shock.* In the 1950s and 1960s, knowledge of the health consequences of smoking by the general public was minimal, and the current smoking prevalence among adult men was more than 50%. Consider then, the impact that the following official government statement had on tobacco use in the United States:

**"Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action" (U.S. Department of Health, Education, and Welfare 1964)**

This declaration by the US Surgeon General was published in an official, US Government Report that would drive four decades of tobacco control science, policy, and

advocacy.[6] Of note is that the Royal College of Physicians' Report from the United Kingdom actually predated (1962) the US report. Smoking had officially become a medical problem and a public health challenge, fueling not only a significant change in public attitudes about smoking and reduced per capita consumption, but also a concerted effort by a multi-national industry to mislead the public.[1] The evidence for this intentional deception is wide spread and well-documented in the secret tobacco industry papers now available for research (http://legacy.library.ucsf.edu/). Such deception supported (and continues to support) asymmetry of information, especially between lower- and higher-socioeconomic (SES) groups, as to the true nature of the tobacco product, its addictiveness, and the enormous health consequences of tobacco use on individual and population health. In addition, information asymmetry is also evident concerning the enormous economic interests at play to support global tobacco marketing and sales.

Since the Surgeon General's statement, the prevalence of smoking in the United States has declined by at least one-half, signaling a major public health victory in chronic disease control. However, even with this public health success, there are still more than 45 million adult smokers who could die prematurely from smoking-related diseases.[7] The challenge now is how to sustain or develop information shock as a viable public health intervention for those with the least access to information about tobacco's health and economic consequences.

A second major influence in tobacco control in developed countries has been the role of s*cience leading to policy change.* Following the 1964 Report, Federal legislation called for annual reviews of the science on the health consequences of smoking (the US Surgeon General's Reports). In 2000, the US Surgeon General's Report expanded this review to consider five approaches to reducing tobacco use and its disease impact (Table 1). Qualitatively, all of these approaches may have some measurable impact, and all have associated policy actions that support or inhibit their effectiveness. It should be noted, however, that it is very difficult to compare these interventions quantitatively, though several attempts have been made.[8]

**Table 1**. **Qualitative assessment of intervention impact for tobacco control in the United States, 2000.**

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

*Note:* Examples use a five-point ordinal scale (very small, small, moderate, large, very large), with additional "unpredictable"
*Source:* US DHHS 2000

The evidence on many of these interventions is certainly mixed or at least worthy of further analysis. For example, the above table suggests that there are very large effects of product regulation, but there is not sufficient evidence to support such a claim. Product sales effects (if considering youth access restrictions) could not possibly be 'large' given the lack of evidence for these as well. Public venue regulations are likely to be large rather than moderate as shown here. For example, Ong and Glantz showed that smoke free environments could achieve more impact than high cigarette taxes (including changing the social norm around smoking).[9, 10]

The prevailing evidence[11] is that *comprehensive* approaches are needed for effective tobacco control and that funding from government is essential to implement such approaches, particularly at the State level. A comprehensive tobacco control program focuses simultaneously on changing social norms, implementing smoke-free policies, expanding efforts to assist quitting, and strengthening efforts to prevent smoking initiation. It involves educational, clinical, regulatory, economic, and social strategies. The science of tobacco control strongly supports the effectiveness of laws and policies to support these measures. For example, increasing the price of tobacco products through taxation, implementing smokefree policies and regulations; providing insurance coverage for tobacco use treatment; and limiting minors' access to tobacco products all have supporting evidence for effectiveness. Research has shown greater effectiveness with multi-component intervention efforts that integrate the various programmatic and policy

interventions to influence social and health systems more broadly. Many of these interventions can be implemented globally, and many have been reviewed in World Bank documents (such as *Tobacco Control in Developing Countries*) with applicability likely in many settings.

We will now consider each of the interventions in more detail.

## School-based Education

Behavioral interventions in public health have long depended on educational approaches, especially those directed at children through school-based campaigns. Unfortunately, these 'immunization' campaigns against smoking initiation have mixed to negligible results. Numerous meta-analyses of a variety of programs report a range of short term effects from 22 to 28 percent reduction in smoking initiation for students in grades 8 to 9. These evaluated programs include the Tobacco and Alcohol Prevention Project,[12] the Life Skills Training program,[13] and Project SHOUT.[14] However, when adjusted for levels of adoption and implementation, effective school-based programs could reduce smoking onset by age 24 years by only 10 percent.[15] This effect size may increase if combined with coordinated mass media or community programming in support of the non-smoking norm, including smoke-free school environments. These types of interventions have been codified in national guidelines for school health programs, but the largest trial with the longest follow up on these national guidelines found no long-term effects of an intensive eight-year program to prevent smoking.[16] Such educational programs are expensive and labor intensive; unfortunately, they are often relied upon instead of more evidence-based interventions because they are politically acceptable. Many developing countries begin their tobacco control efforts with such programs, yet the evidence showing their efficacy in both developed and developing countries is lacking.

Because the tobacco industry has based its own corporate responsibility strategy on preventing youth from smoking (calling it 'an adult custom'), one may further doubt the value of such educational approaches. For example, see the Altria website for tips on how parents can prevent smoking uptake among their children (www.pmusa.com/en/prc/index.asp?source=home_fca2); according to Philip Morris:

> *"Research shows that strong parental support is significantly associated with reduced risk of smoking among youth. Parental support involves such things as emotional support, closeness and good communication-key elements in developing the relationship you want to have with your kids. ...Kids today may be influenced to smoke by many factors, including peer pressure, whether their family members smoke, and the media. Having one or two parents who smoke has a strong effect on a kid's likelihood of smoking. Children of smokers are twice as likely to smoke as children the same age whose parents don't smoke.*

Despite this declaration, the tobacco industry continues to recruit new smokers from among children through its aggressive advertising and promotion efforts worldwide. This is evidenced by the fact that smoking initiation is still a 'pediatric disease'; in 2003, the average age of initiation in the United States among people 12 years and older was 15.4 years (CDC 2005). The approach to tobacco control by Altria and the other companies, focusing on preventing uptake among children, can only be described as counterproductive. Public health programs tend to expect educational approaches to prevent risky behaviors, but history and careful analyses have not shown these to be effective in most settings or in isolation. In fact, the Altria program has been found by some researchers to have actually been associated with an increase in smoking.[17] Fortunately, there are other policies that may have more robust outcomes.

## Media approaches

Media campaigns as a form of public education on the health consequences of smoking really began in 1967 with the Fairness Doctrine mandate to require television stations airing cigarette commercials to also provide antismoking public service announcements (PSAs).[18] Warner[19] found that these PSAs (1967-1970) were associated with the first real decline in per capita smoking consumption in the United States in the 20th century, reducing consumption by almost 20 percent. By a consent decree (i.e., consent of the tobacco industry), Federal law was implemented to ban advertising of tobacco products on television and radio, and by 1971 the mandate for PSAs disappeared, along with most of the anti-smoking media messages, until the State campaigns of the 1990s.

State tobacco control programs, especially those in California, Massachusetts, Minnesota, Oregon, and Florida, included initially strong media campaigns on television, radio, billboards, and newspapers.[20, 21] In California, these paid advertisements were designed to increase general awareness of the health effects of tobacco (to reduce information asymmetry) but were also directed at the tobacco industry as cause of tobacco-related disease, using hard-hitting and even sarcastic imagery to vilify the industry. Massachusetts closely followed California's campaign, focusing on second-hand smoking, cessation, and health risks.[22] Both these programs were funded by cigarette tax increases and were also accompanied by comprehensive programs at the state and local levels (including education, research, advocacy, cessation, etc). These early media campaigns paved the way for subsequent activities, many of which were incorporated into the Centers for Disease Control and Prevention's Best Practices for Comprehensive Tobacco Control Programs[23]

Florida used part of its legal settlement with the tobacco industry (the MSA) to fund a large-scale anti-tobacco media campaign, appealing primarily to youth in the 'Truth Campaign'.[24] This campaign provided information to adolescents on the tactics the tobacco company was using to attract young people to smoking. Because of its success, it was largely adopted by the American Legacy Foundation[1] in 2000 for the first comprehensive national antismoking media campaign since the Fairness Doctrine in

[1] The American Legacy Foundation was established by the MSA at the national level fund research, conduct media campaigns, and support tobacco control programs.

1971. Legacy promoted a counter-industry approach to appeal to youth, spending more than $100 million per year from 2000-2002 on this campaign.[20] Overall, effect sizes for youth-oriented media campaigns are about six percentage points (in reduced uptake), and the absolute change in youth smoking prevalence is nationally about two percentage points less as a result of the media campaigns. Evaluations emphasize that these campaigns are most effective when imbedded in comprehensive programs at the State and community level.[25]

One particularly important media issue is that of smoking in motion pictures. Images in such media may encourage unhealthy risk behaviors, not just nationally, but globally. Smoking in the movies doubled in the 1990s to levels reminiscent of the 1950s.[26] With high youth exposure (87 percent) in movies rated less than R.[2] Social cognitive theory suggests that adolescents especially may be vulnerable to the social role-modeling seen in these movies. In several studies, a dose-response between such exposure and smoking uptake has been found.[27] Efforts are now being made to encourage the motion picture industry to show anti-smoking messages before films with smoking in them, and to consider rating movies with tobacco use in them as R.[28] The movie industry clearly has a global reach, and thus its impact on supporting smoking behavior must be taken seriously by the global tobacco control community.

One can often judge the impact of a particular intervention on tobacco as to how well it is recognized by the general public, the tobacco industry, and policy makers. This is a sign of social change toward a nonsmoking norm that may be supported by media interventions. The initial success of the national PSAs and the subsequent high rates of recognition of the California and Legacy campaigns (including paid air time on National media) suggest that these types of media campaigns can raise the level of attention to tobacco use as a public health problem needing strong policy support. Media approaches can provoke public interest in advocacy and support a non-smoking norm through clever imagery, culturally appropriate messages, and reframing counter arguments. They can help market the behavioral changes necessary to affect disease outcomes far more effectively than school-based educational campaigns can ever hope to do.[29] By creating demand for a non-smoking norm, media interventions may influence the establishment of many other policies, including clean-indoor air, access to smoking cessation treatment, and taxation to recover smoking-related health costs.

According to recent analyses on media campaigns against smoking, there have been two issues of interest over the period 1967-2006.[23] First, the industry itself has learned from these campaigns as to what works and what does not; it has forced tobacco control programs through political influence to either stop or weaken them so that they lose effectiveness. Most importantly, however, it has been found that aggressive, hard-hitting campaigns (such as the Legacy Truth campaign) that directly confront the industry are the most effective media approaches. The lessons learned from this long history of media advocacy suggests that media is important, that it works best when confronting the industry head on, and when it is not weakened by political influence at any level. However, how this evidence translates to the developing environment is not yet clear;

[2] In R rated movies in the United States no one under age 17 admitted without parent or guardian.

nonetheless, the history of media advocacy against tobacco use is a rich field from which to consider global translation of the proved approaches.

## Clinical Interventions

The management of nicotine addiction is the primary goal of cessation programs. This is a complex field that includes self-help manuals, community-based programs, and minimal or intensive clinical interventions such as nicotine replacement therapy (NRT) and bupropion (an anti-depressant medication). US clinical practice guidelines call for universal insurance coverage for evidence-based treatment for nicotine dependency and reduction of financial barriers to receive such treatment. These guidelines state that less intensive interventions such as brief provider advice to quit smoking may produce cessation rates of five to 10 percent per year. Combining behavioral counseling and pharmacologic treatment may produce 20 to 30 percent quite rates at one year.[30] Co-morbidities (psychiatric especially) require more intensive care. Even minimal interventions (such as telephone Quitlines and internet-based programs) may have extensive population-based effects and have proved to be effective in clinical trials. Greater duration and intensity of contacts improves cessation outcomes, measured as six-month abstinence. Most of these programs, however, work best with individuals who already have a well developed intention to quit.[31]

Particular challenges in smoking cessation programs are the less than 50 percent rate of quit attempts among current smokers each year and the 90 percent relapse rate for those who do quit. Thus, comprehensive programs including media campaigns, non-smoking policies, and higher prices are necessary to assure the success of smoking cessation programs at the population level. These may increase demand for such programs through marketing as well as support a non-smoking norm for quitters and non-smokers.

Health services can provide sustained messages to all smokers, through strict non-smoking policies in health facilities and consistent attention by all health providers to support smoking cessation among all patients who report for care. Providers must also attend to their own smoking cessation, and health facilities as employers may effectively assist them with this. The decline in smoking among health personnel has been shown to precede the decline in smoking among the general population in several countries.[32] Fully integrating tobacco control into health systems (including worksite policies, cessation programs for staff and patients, reimbursement schemes for smoking cessation, etc.) means that behavioral modeling by the health professions and institutions can lead the way for the average smoker to quit. Effective public health programs will support the success of such health system based approaches; they should not be thought of separately.

Much debate surrounds the potential application of harm-reduction approaches in cessation using new tobacco products such as Snus (a form of snuff popularized in Scandinavia) as opposed to supporting a clear message to cease any form of tobacco use. Harm reduction through the use of NRT is more clinically relevant and consistent with public health approaches than supporting any reduced harm tobacco product use. The tobacco industry has certainly taken note of the potential for new, reduced harm products, but this approach is not new. For years, ‘safer cigarettes’ have been promoted, and the

addition of the cellulose acetate or other filters proved to be one of the most important marketing efforts ever to improve sales by alleviating the concerns of smokers through technological improvements of tobacco products. However, these products have not been found to reduce the population burden of disease but rather they encourage the smoker not to quit and make it easier for the new smoker to begin smoking.[33]

## Regulatory Approaches

Regulatory approaches include those involving advertising and promotion restrictions, package labeling, and product regulation (product sales and manufacturing); clean indoor air legislation (product use); and youth access restrictions (product sales).

*Advertising and promotion restrictions* began with the Cigarette Smoking Act of 1969 and the Cigarette Labeling Act of 1969, which banned television and radio advertising of cigarettes and mandated health warnings on packages. These Acts, ironically, also made it difficult for States to regulate advertising and promotion due to protections under the Interstate Commerce Act (fair access to legal products and the right to advertise these products nationally). In 1996, the Food and Drug Administration (FDA) sought to regulate advertising of nicotine-containing products as part of their existing regulatory authority over addictive drugs. The proposed 1996 FDA Tobacco Rule would have provided for further restrictions on magazine advertising, prohibited distribution of promotional material, prohibited the use of brand sponsorship of sporting and other events, and restricted trade in certain products. This rule was disavowed by the Supreme Court, referring it back to the US Congress to develop appropriate authority. However, under the 1998 MSA, tobacco manufacturers did agree to eliminate billboard advertising, brand item promotion, and public advertising in entertainment venues. New proposed legislation would permit FDA to further restrict advertising and promotion in accordance with the 1996 Rule. Comprehensive bans on advertising and promotion may achieve up to six percent reduction in cigarette consumption if coupled with strong comprehensive tobacco control programs. Partial bans would have little effect owing to the proved capacity of the tobacco industry to subvert the intent of such restrictions.[34] The tobacco industry shifted its focus in advertising and promotion after the MSA to magazine advertising with colorful imagery appealing to youth, point-of-sale advertising, and continued sports and entertainment sponsorship.[35]

*Clean-indoor air legislation* (including worksites, public places, health facilities, and government buildings) are arguably one of the most effective strategies to reduce tobacco use. Led by grassroots actions since 1971, these restrictions followed the development of considerable epidemiologic evidence on the adverse health effects of second-hand smoking. As of 2005, most states restrict smoking on public transportation and almost all (44) restrict smoking in government work sites. Only 30 states ban smoking in private-sector work sites, but even in states where this is not mandatory, many private-sector work sites support non-smoking work environments. As of 2006, 342 municipalities ban smoking in restaurants and 252 require smoke-free bars, often enacted in defense of workers' health.[36] Such regulation may protect nonsmokers from the health effects of and irritation from second-hand smoking, may help or support smokers who wish to quit, may reduce the number of cigarettes smoked per day by smokers, and may change the

social norm to support non-smoking. Comprehensive restrictions on smoking in public places may reduce smoking prevalence rates by five to 15 percent.[37] One study estimated that effective clean-air legislation for the worksite alone may reduce smoking as much as 3.8 percentage points; in comparison to higher cigarette taxes, this would require a tax hike of USD$1.11 to have the same effect.[38] Household smoking bans in selected circumstances, bans on smoking in outdoor spaces, and bans on smoking in privately owned vehicles have all been considered or implemented in several venues, especially California. These are mainly community efforts that support a non-smoking norm and reduced nuisance from cigarette smoke.

*Youth access restrictions* have no practical effect on smoking. Despite the popularity of this approach (in fact, encouraged by the tobacco industry), there is little firm evidence to support restrictions on sales to minors as an effective approach to reducing smoking among young people. In 1992, the US Congress attempted to emulate a successful intervention against youthful drinking and driving (raising the State alcohol purchase age to 21 years or lose Federal highway funds) by requiring all states to enact and enforce access laws or lose Federal substance abuse block grant funding (the Synar Amendment). All states have some sort of youth access restriction, but enforcement is extraordinarily problematic and has not shown significant public health effects.

*Restrictions on Internet sales* may be indicated given the opportunity for minors to purchase cigarettes illegally or to avoid paying excise taxes on such sales.[39] This issue may have global significance with the growth of internet commerce across borders.

*Tobacco Product Regulation* is now being considered by the US Congress to authorize a Federal agency (such as FDA) to regulate tobacco products, or to delegate this to State control, obviating the concerns of the previously mentioned Interstate Commerce Act. The 1969 Cigarette Labeling Act currently pre-empts State control over product labeling. Current Federal regulations also require tar and nicotine yield disclosures, but these have little health value and may in fact obscure the health risks of smoking by suggesting that low-tar and low-nicotine yield cigarettes are somehow safer. Also, laws enacted in the mid-1980s called for disclosure of tobacco product additives to the Secretary of Health and Human Services, but thus far, tobacco products are explicitly protected from regulation in various consumer safety laws. The goals of tobacco product regulation may be to:

- Reduce harm by changing the tobacco product so that it is in fact safer or providing substitution products to reduce nicotine addiction;
- Make tobacco products less addictive by lowering nicotine content and changing palatability to reduce the addiction potential;
- Increase the availability of nicotine alternatives over the counter.[40]

New legislation has been proposed to provide FDA with authority to restrict the sale and distribution of tobacco products to protect public health. This bill requires disclosure by tobacco companies of all chemicals in tobacco products and smoke, grants FDA authority

to regulate testing methods, promulgates tobacco product standards to protect public health, and develops standards for evaluating potential reduced-exposure products marketed by tobacco manufacturers.

By no means is this proposed legislation comprehensive in scope or assured of reducing tobacco use. Nonetheless, it extends government authority over an industry long-neglected in terms of consumer safety. On the first two objectives, there has been no historic evidence to show that reduced harm cigarettes can change the disease burden of tobacco use. On point two, there are already effective therapeutic approaches to nicotine addition, and adding low nicotine products may just keep smokers smoking and not quitting. Thus, some tobacco control advocates feel that harm-reduction is actually capitulation to the industry (Altria has expressed support for the regulations in fact). The evidence published on this is mixed, but some simulations suggest caution: if new products reduce harm to smokers by 20 percent, long-term prevalence reductions may not follow; in other words, harm reduction again may lull smokers into thinking they can stay addicted without significant risk (the historic consequence of marketing filtered and 'light' cigarettes).[33] On the other hand, the disease impact of reduced harm products may be significant (e.g., Snus does not cause lung cancer, the chief form of tobacco-caused mortality). This debate does not seem to have a conclusion in sight.

*Package warnings* in the United States are not thought to be effective in reducing tobacco use. Federal law on warnings has been unchanged for more than 20 years, but changes in regulations on package warnings in other countries suggest that large graphic messages (50% of package surface) with pictorial content have been clearly effective in providing health information, thereby leading to greater public understanding of risks and actually affecting smoking behavior.[41] One important aspect of packaging changes would be to ban the reference to 'lights', 'ultra-lights', and other misleading labeling that encourage misinformation about the safety of tobacco products. In fact, a US District Court judgment against the tobacco industry (2006) required 'corrective communications' on websites, point of sale, and package inserts regarding these designations.[42]

Overall, except for regulations requiring smokefree environments, the regulatory approach to tobacco use seems to be underutilized compared with the behavioral-educational approach. Regulatory approaches can de-normalize tobacco use, increase costs to the consumer (and thereby reduce consumption), protect nonsmokers from involuntary exposure to toxic second-hand smoking, and reduce the marketability of cigarettes. Government has a responsibility to regulate hazardous consumer products (witness the current concern about Chinese exports into the United States with potential health risks), and thus cigarettes may be more carefully regulated to prevent initiation and to support cessation. Cross-border agreements on product regulations are clearly called for as a global approach to tobacco use. Without such international cooperation, loopholes will be exploited, and best practices will not be assimilated in resource-poor environments.

## EXAMPLES OF SUCCESSES AND CHALLENGES AT THE STATE LEVEL

In the United States, the State is primarily responsible for the health of its citizens; this responsibility may be stimulated or led by the Federal Government, but federalism is a major contentious issue in addressing a national public health challenge---States do not always wish to have a Federal mandate. The efforts to encourage State regulations (such as the Synar Amendment of 1992) have not worked well in general. Thus, States are the primary policy battleground for tobacco control.[43] The US Centers for Disease Control ([CDC] the lead being the Office on Smoking and Health within this Agency), has reported substantial progress in developing and funding comprehensive State programs. However, the programs substantially funded at the State level for tobacco control under the MSA have been fragile in their implementation and irregular in their sustainability. In addition, the lack of regulatory authority at the Federal level has served to constrain progress at the State level.

The Office on Smoking and Health provided modest support to States in the late 1980s, relying on minimal funding and some technical assistance to call attention to economic costs, clean-indoor air legislation, and public information campaigns. In 1990, however, California assumed leadership in state tobacco control efforts through the passage of Proposition 99, a 25-cent additional tax on cigarette packages that created more than US$600 million in annual tax revenue, 20 percent of which was for tobacco control and another five percent for tobacco research.[44] This landmark action was closely followed by Federal programs to the States, including the American Stop Smoking Intervention Study (ASSIST) and the CDC's IMPACT program. Foundation funding from the Robert Wood Johnson Foundation also supported the SmokeLess States programs. Several other states, most notably Massachusetts and Florida, used taxes and MSA funding to support comprehensive State programs. In 1999 and again in 2007, CDC published a set of recommendations for Best Practices in State Comprehensive Tobacco Control Programs; these benchmarks all call for funding support, monitoring, and evaluation of such programs.

Funding among State programs varies according to source of revenue and political leadership and the willingness of civil society to demand high-quality well-funded programs from elected officials. In 2005, the mean per capita expenditure for tobacco control was US$2.76. On average, this amounts to approximately one-half the recommended minimum level for comprehensive State tobacco control programs.[45] The range of recommended funding is from USD$5.85 to 15.85 per capita per year, depending on prevalence, population, and other factors. It has been politically difficult for the public health community to assert ownership of the MSA funds for State tobacco control; these have been diverted by Legislatures to non-health projects, including deficit reduction and road building. These diversions are widely condemned as failing the Attorneys Generals' litigation intents of the late 1990s.

In 2005, the CDC reported the impact of State programs[46] on mortality, prevalence, consumption, cessation, and policy. This evaluation and others found that a program's intensity and funding levels were associated with lower prevalence, consumption, and quit rates. In particular, in California and Massachusetts, with aggressive media

campaigns, local investment in policy actions, adequate funding, and public support, substantial effects compared to background changes in general have been appreciated.[47] However, funding for these programs and other state programs has been substantially cut over the last few years, in direct confrontation with the terms of the MSA or the tax bills that originated the programs. As a possible consequence, nationwide the decline in smoking rates in persons age 18 and older has stagnated at 20.8% since 2004.[48] These funding cuts imply the need for public vigilance, advocacy, and political action to sustain tobacco control programs in the face of changing political leadership and budgetary demands on States. Through a combination of local and State-specific actions and leadership from the national level, momentum can be sustained; without continued funding and recognition of the persistent population effects of tobacco use, progress against smoking-attributable disease is unlikely.

It is clear that a comprehensive approach, involving multiple channels tailored to specific audiences is most likely to achieve success. Government has the primary responsibility for assuring this comprehensive approach, including monitoring and evaluating its outcomes through behavioral surveys and revenue records. Moreover, changing social norms through more robust regulatory approaches, media programs, cessation supports, and policy integration at multiple levels will be necessary for additional significant changes in consumption to be achieved.

# PART II – TAKE HOME MESSAGE

This section discusses the key lessons learned from tobacco control science and interventions at a variety of levels.

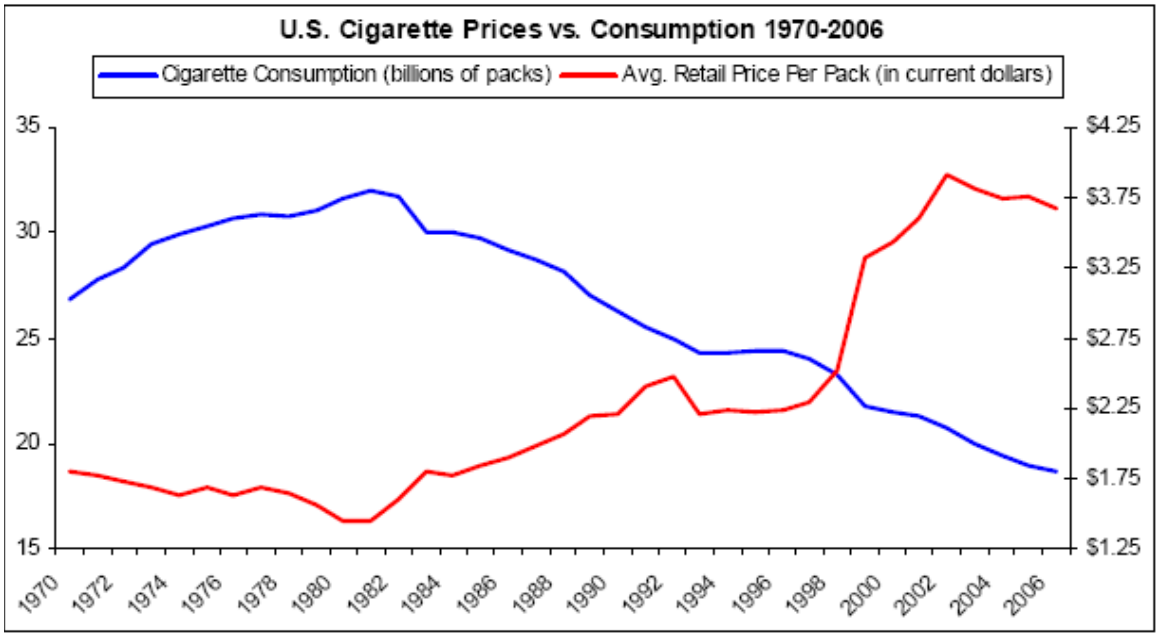
## THE ECONOMIC CASE FOR TOBACCO CONTROL

The economics of tobacco control are extraordinarily important in influencing policy, justifying government commitments, and evaluating the success of programs. These issues are quite complex, encompassing tax and pricing policy, agricultural policy, trade law and smuggling controls, cost-of-illness research, health care financing, public health financing, and non-price-related measures with economic implications. In this paper, we consider two important economic issues related to tobacco control economic policies: Price of tobacco products and costs of tobacco-attributable illness.

### Tobacco prices

In 1999 and 2000, the World Bank published its landmarks, *The Economics of Tobacco Control: Towards and Optimal Policy Mix* and *Tobacco Control in Developing Countries*. These and numerous other economic studies have documented that cigarette tax or price increases reduce both adult and underage smoking. For every 10 percent increase in the real price of cigarettes, overall cigarette consumption declines by approximately three to five percent, reducing the number of young-adult smokers by 3.5 percent.[49] Adding in tax funded programs to control tobacco embellishes the effects of tobacco taxation, though these types of hypothecated programs are an anathema to most legislative authorities and criticized by the macroeconomists. Nonetheless, the inverse relationship between price and tax is very robust (Figure 1), both in the United States and in several other developed and developing countries.

**Figure 1.**




*Source*: Tobacco Free Kids 2007

Jha et al. established the economic rationale for intervention in the tobacco market, asserting three major market failures that justify public intervention: 1) Information asymmetry, where consumers do not know the true risks of smoking; 2) Information failure, where the addictive nature of tobacco is underestimated, hence, creating an unfair situation in consumer choices to smoke; and 3) Cost externalities, in which costs of smoking are imposed by smokers on others.[50] In 2002, Gruber et al. proposed an additional argument based on the addictive nature of tobacco and our knowledge of behavioral change.[51] Persons make inconsistent preferences and continue to smoke in spite of knowing about the harms, believing that they can quit in the future. Hence imposing high prices of cigarettes act as a deterrent and helps people make a decision today that would benefit them in the future.

The World Bank publications and other studies fueled additional international research, policy and consideration of taxes as both revenue raising tools and behavioral interventions. Some have argued against these taxes as being regressive (i.e., adversely affecting the least economically capable consumers), but the counterargument that the societal benefits of reduced smoking in economically disadvantaged populations now outweighs this concern. Taxes prompt smokers to quit or cut back, thereby reducing the disease burden due to smoking. High prices prevent some children and adolescents from starting to smoke and encourage those who do smoke to reduce consumption. Tobacco tax-funded programs in fact benefit the low-resource consumer through public information and public health actions. Of course, this approach continues to be of concern to the tobacco industry; according to Philip Morris documents:

> *'Of all the concerns, there is one - taxation - that alarms us the most. While marketing restrictions and public and passive smoking*

*[restrictions] do depress volume, in our experience taxation depresses it much more severely. Our concern for taxation is, therefore, central to our thinking . . .*'[52]

Tax and price increases are proved interventions in the United States and elsewhere, and they are key to the success of any tobacco control program in both developing countries and developed countries. Not discussed here is the impact of taxation and price policies on tobacco smuggling. In general terms, the answer to increased smuggling is improved enforcement and tracking of tobacco products, not reduced taxes or prices.

## Tobacco costs

Smoking-attributable economic cost studies date to the mid-1980s, with such studies utilizing epidemiologic estimations (attributable risk calculations) incorporating the prevalence of smoking and the relative risk of utilization of medical care (these relative risks were variably derived from mortality risks or excess morbidity risks). More sophisticated econometric analyses followed with the development of panel survey data (the 1989 National Medical Expenditure Survey and its heirs), real utilization and behavioral data among US citizens, real expenditure data provided by payers, and sophisticated modeling to account for demographics, other risk behavior, and early mortality among smokers.[53] These studies lent themselves to assessing the costs of smoking….to individuals for their own costs of illness, to governments for State and Federal program costs, to taxpayers for the expenses of others, to families for the costs of caring for their tobacco-sickened family members (all these are direct costs), and to economies for the loss of income, taxation, and labor (these are indirect costs). In addition, costs to health systems may also include anti-tobacco program costs and the costs of responding to tobacco industry challenges (such as those under the Freedom of Information Act). Overall, the lifetime social cost of smoking, including private costs to the smoker and costs imposed on others (second-hand smoking, Medicare, Medicaid, and Social Security) is $106,000 for a woman and $220,000 for a man.[54] In 2002, the CDC estimated total direct and indirect costs to the nation of smoking at $157 billion per year, or $3,391 per smoker per year.[55] Historically, these cost estimations provided enormous fuel to State, Federal, and private tort actions by various plaintiffs' attorneys and the States' Attorneys General against the tobacco industry.

Several developing countries have enacted tobacco control policies prompted, in part, by the high cost of illness. In Brazil, for example, a study using data from the Brazil Unified Health System (SUS) for the period 1996-2005, found serious impacts on health care utilization and costs caused by smoking.[56] More than one million hospitalizations were attributable to smoking during this period, with 1.07 billion Reais[3] in total estimated costs associated with these hospitalizations. This study used an attributable risk calculation involving the prevalence of smoking, the relative risk of mortality for several smoking-related diseases, and the total expenditures for hospitalization for these diseases.

[3] Reais is the Brazilian currency.

Excluded from this discussion are a number of other costs. These include the costs of cigarette-caused fires (most common cause of fire death and an important cause of forest fires in the United States and elsewhere); costs of cleaning up cigarette butts, indoor air pollution due to smoking, and cigarette production waste;[57] and lost economic opportunity costs in purchasing cigarettes instead of other consumer products.

Economic arguments and the issue of externalities are powerful messages in showing how demand for tobacco can be reduced through increased prices (also, through restricting smuggling, which essentially raises the price of cigarettes). Taxes alone have proved to be an essential component of a comprehensive approach to tobacco control; with dedicated taxes supporting tobacco control programs, the evidence seems to support adding cigarette taxes as a public health and revenue resource. At the same time, careful understanding of the true costs of smoking, including health care costs, lost wages, opportunity costs, environmental costs, and personal suffering costs, can create a powerful rationale with which to support comprehensive programs, including those that can raise revenues to recover the costs of smoking. The market failure demonstrated by these externalities may encourage Ministers of Finance and others responsible for the economic security of health systems and the economic development of populations to address tobacco use as an economic issue.

## THE ADVOCACY MOVEMENT VERSUS THE TOBACCO INDUSTRY

### Changing public attitudes toward tobacco

Tobacco use has long been criticized through moral, religious, populist, and public health perspectives.[1] In spite of these perspectives, smoking became institutionalized in US culture, and even supported through advertising in medical journals such as the Journal of the American Medical Association. Public concern about the health consequences of smoking arose around 1950, with scientific publications as well as popular journals calling attention to these consequences. With the publication of the 1964 *Report of the Surgeon General*, the tide turned and advocates acquired solid scientific information with which to support the growing anti-tobacco movement, halting the steady growth in consumption that began in about 1900. The 'information shocks' following this Report and that of the 1962 Royal College of Physicians in the United Kingdom led to initial declines of four to nine percent and longer term cumulative declines in consumption of 15 to 30 percent.[58] The value of scientific evidence coupled with clear national statements on this emerging public health problem cannot be over-emphasized. No longer was smoking to be considered only a matter of individual choice; it was a public health problem demanding government attention.

Led by a remarkable change in behavior among physicians (the first PSA from the Office on Smoking and Health stated, '*A hundred thousand doctors have quit smoking; do they know something you don't?'*), the public health campaign against tobacco use grew primarily with public information campaigns and later local efforts driven by advocacy groups and State-funded public health programs. In fact, the tax legislation funding the California Program was implemented not by the State legislature but by public

referendum (Proposition 99). This public initiative process, however, is a challenge for State legislatures; legislatures abhor dedicated taxes for specific programs due to the fact that their control over State funds is not subjected to the legislative process. The political interference in State politics is well known; for example, in California during the early part of the Proposition 99 process, tobacco industry lobbying groups spent hundreds of thousands of dollars in efforts to derail the intent of the Proposition. Legislative restraints on the California tobacco program, supported by the tobacco industry, nearly doomed the program on several occasions. The scope of the media campaign was limited such that the strength and reach of these campaigns dissipated in the mid-1990s.[23] It is clear that the strong resistance shown by the tobacco industry to this State tax-funded program indicated the concern it had for its potential global impact. Nonetheless, the advocacy movement continued to flourish, particularly with respect to campaigns against second-hand smoking.

Supported by new research on the health consequences of second-hand smoking, public opinion on smoking continued to shift. When sufficient restrictions in specific communities were in place, additional data became available from income tax records (for businesses) to demonstrate the beneficial economic impact of these restrictions compared with communities where these restrictions were absent.[59] Workers' health concerns (especially in bars and restaurants) also became a crucial tipping point to restrict smoking in such venues or face the consequences of workmen's compensation claims and even lawsuits by employees for unwilling exposure to a known carcinogen (second-hand smoking was classified by the California Environmental Protection Agency as a Class A Carcinogen, exposure to which has no safe minimum[60]). Reports from the US Surgeon General (1986 and again in 2006) fueled the call for immediate measures to protect nonsmokers. Advocacy groups such as the Group to Alleviate Smoking Pollution (GASP), the Coalition on Smoking OR Health, the Americans for Nonsmokers' Rights, the Campaign for Tobacco-Free Kids, and later the American Legacy Foundation, provided organizational identification and expertise to the anti-tobacco movement on multiple fronts. These advocacy groups have repeatedly held government accountable to implement effective policies, but sustained efforts were necessary to counteract the adaptations of the industry and their allies within State or local government bodies.

In addition to the anti-SHS campaigns, nicotine's identification as an addictive drug by the US Surgeon General in 1988, as well as through declarations by professional societies and the World Health Organization, undermined the tobacco industry arguments in support of smoking as individual choice. This recognition of the addictive potential of nicotine supported petitions to the FDA for regulation of tobacco products. Key to the FDA approach was the question of intent.[61] If the tobacco industry intended to exploit the addictive nature of nicotine and cigarettes, then the FDA might rightfully regulate nicotine under the existing Federal Food, Drug, and Cosmetic Act. As we have mentioned, the Supreme Court rejected the existing authority and sent the question back to Congress to delegate such authority. This regulatory approach is now being revisited by the US Congress, but the proposed legislation, as discussed, is unlikely to significantly impact the health burden of tobacco use.

A key piece in the advocacy process was the mandate in the MSA to release millions of pages of tobacco industry documents (some of which had been previously exposed by former tobacco industry insiders) for use in research and advocacy work. These documents clearly demonstrated that the tobacco industry had lied about the fact that cigarettes were addictive. Their own documents have codified the industry's admission regarding nicotine as the reason why people smoke and the cigarette as the drug delivery device for nicotine. These documents are now the source of a rich body of research on the inside workings of the tobacco industry,[62] and this new form of scientific discovery in turn fuels the advocacy movement.

In summary, the effectiveness of tobacco control advocacy clearly grew from both the science on the harms of tobacco use and the revelations about the tobacco industry's misinformation and political tactics. Information shocks, lawsuits, secret documents, hard-hitting media campaigns, and restrictions on smoking in public places all fueled the advocacy efforts, especially at the grassroots level. The success of these efforts depended on both diligence within the scientific community to conduct investigations on tobacco's harms and also the tenacity of advocacy community in reframing the smoking as socially unacceptable, environmentally harmful to non-smokers, and the source of unnecessary costs to health systems and the general public. Regulations and policies that seemed impossible five decades ago (such as banning smoking in bars and in multi-unit housing) now support a non-smoking social norm.

## Tobacco industry responses

The tobacco industry response to the growing anti-tobacco movement has been extraordinary in its reach, funding, complexity, and political acumen. It is difficult to describe the extensive adaptability of the industry as it confronted scientific evidence and government policy on the harms of tobacco use. These policies asserted that there is no safe level of cigarette consumption, and that when used as directed, cigarettes kill the consumer. Briefly, the industry response has included the following key approaches:

- *Fierce opposition to advocacy.* From the ASSIST project funded by the National Cancer Institute, to state tobacco programs, to Federal law that could prohibit advocacy by the foundations set up by the MSA, the tobacco industry has recognized the power of science and advocacy and sought to label these as political meddling, illegal lobbying, and improper government influence with legal business. Advocacy has diminished somewhat in importance in the implementation of comprehensive tobacco control programs, but at the global level, advocacy was critically revived with the establishment of the Framework Convention Alliance (see below).[25]

- *Sowing doubt.* Perhaps more than any other response, the industry has sought to cast doubt on the science behind the health risks, first of direct smoking, and then continually about the risks of SHS. These risks have been described by the industry as controversial, overstated, self-imposed, and not really the most important thing facing our country. Nonetheless, smoking is the single most important cause of premature death in the United States, and there is no lingering doubt either inside or outside the industry about the risks of smoking. The industry has been now forced to

admit publicly that smoking causes many diseases; doubt is a less powerful resource for them.

- *Political influence.* The documents released through state litigation against the tobacco industry have revealed the enormity of political influences by the industry at the national, State, and local level. In addition to direct political contributions, the industry often allies itself with front groups, legitimate organizations (such as the International Tobacco Growers Association and the Keep America Beautiful Campaign), and academia to sustain influence through corporate social responsibility, the funding of scientific research, and other actions. Tobacco control researchers have been able to draw correlations between the volume of political contributions to legislators and their anti-tobacco scoring in voting and attitudes.[63] The now defunct Tobacco Institute was responsible for doling out millions of dollars of political largesse to the US Congress and lesser bodies in order to directly influence policy and legislation. These contributions now are harder to track given the complexity of the political process, the presence of front groups, and the corporate social responsibility activities of the industry. Nonetheless, political influence in both developed and developing countries is still arguably the most important tool the industry can wield to sustain global sales of tobacco products.

- *Corporate Social Responsibility (CSR).* CSR is the attempt by corporations to redress the adverse effects their products have on society through some sort of positive behavior.[64] As noted above, recent efforts by the multi-national tobacco corporations include television ads, website resources, alliances with front groups, and diversification of corporate identity (shifting from Philip Morris to Altria, for example). As a corporate entity, Altria uses the concept of CSR to maintain its responsibility to its principal stakeholder, the investor. In its efforts to show corporate social responsibility, Altria also claims that its key stakeholder is the "adult smoker" who makes an informed 'choice' to smoke; thus, the company must defend this right of choice. However, tobacco industry advertising and promotion of smoking undermines the ability of parenting to prevent adolescents from starting to smoke—which contradicts the tobacco industry's contention that parenting practices, and not their marketing activities, are the critical determinants for smoking initiation among youth.[65]

- *Subversion of science.* In 2001, Ong and Glantz wrote that 'tobacco companies carefully planned to undermine accepted epidemiologic practices and hoped that by partnering with a broad range of academic and private commercial interests, they could create confusion about the role of epidemiology and risk assessment in public policy development.'[66] The goal of the industry was to trivialize the risk of tobacco use as a "risky pleasure."[67] It continues to deny most scientific evidence about SHS and to suggest ventilation as an alternative to smoking restrictions. The industry also has invested heavily in "reduced harm" products as an important strategic and financial priority for the future, trying to convince the public again that there may be safe cigarette products. As noted previously, this concept has been embedded in proposed new FDA regulations on tobacco. Clearly, the tobacco industry's political tools have adapted to a changing advocacy and regulatory environment.

The tobacco industry has retained enormous political power in opposing public health efforts to control tobacco-related diseases. No other set of diseases has such a group supporting the main vector of these diseases, the tobacco product. The fiduciary responsibility of these corporations to their stakeholders (investors) drives them to continue to keep smoking a profitable risk behavior, even in the face of exposure through the tobacco industry documents and wide spread public criticism for their deceptions and practices. Thus, history shows that advocacy groups, tobacco control professionals, and policy makers need to be continually informed as to the practices of the tobacco industry in managing the political process at multiple levels: globally, nationally, and at the local level.

## The Trials of Tobacco

Its seems logical that litigation against the tobacco industry might have a fair chance for success in containing their transgressions given the convincing scientific evidence about the health consequences and costs of smoking to individuals, to non-smokers, and to the society at large. The experience with litigation against the industry is quite informative, however, as to the industry's persistent political effectiveness; normally, the courts can be an effective venue in which to secure justice against a major social crime. However, as we shall see, justice does not always prevail with the tobacco industry. Since 1954, hundreds of cases had been brought against the industry, including those based outside the United States, without success until Rose Cipollone filed a case against four tobacco companies in 1983. The industry usually just outspent the plaintiffs in these cases, including in their defense arguments assertions of doubt about the risks of smoking, assertions that everyone knew these risks, and suggestions that smoking was not the only cause of illness in the particular plaintiff. However, in *Cipollone*, the plaintiff's lawyer gained access to internal tobacco industry documents in the discovery process, with subsequent release of these documents to the public. The case was based largely on the addictiveness of nicotine and the industry's denial of this and the known health effects of smoking; it became the first successful judgment against the industry for conspiracy and fraud. However, on appeal, the judgment was set aside, but the litigation process had opened new doors. A succession of additional individual cases led to a class action suit on behalf of flight attendants (*Broin vs Philip Morris)*, relying on a large number of plaintiffs (in this case, flight attendants) who had not chosen to smoke yet suffered adverse health consequences. This case was settled for $300 million to establish a research institute on tobacco illness, with individual cases permitted to proceed regarding lung cancer and chronic emphysema among non-smokers.[1] Several individual settlements were reached, and the race for punitive damages and new litigation approaches was on.

The most important of these, arguably, was the case for recovery of state Medicaid costs for smoking-related diseases. With first actions in Mississippi, the Attorneys General of more than thirty states banded together with private (but deputized) attorneys to establish a substantial financial resource base, hire expert witness, and file suit on behalf of the states. With one of the largest five tobacco companies sued reaching a separate agreement, new documents were produced in the discovery process. Soon a Multi-state Settlement Agreement (MSA) was reached in order to avoid a court trial. Initially, the

settlement was for $365.5 billion over 25 years to compensate the states for medical costs, smoking cessation programs, and other health initiatives. Other concessions on advertising, youth smoking, and punitive damage immunity were discussed, but ultimately, the various stakeholders had acrimonious disagreements on compromises vs. definitive litigation against the industry. Through Congressional wrangling, lack of compromise from many sides, and tenacious political interventions by the industry, the MSA became a weakened version of the original victory. Regulation, package warning requirements, enforcement on sales to youth, public smoking bans, and other measures were excluded. It did require the five major companies to pay $206 billion to 46 states over 25 years. The other four states settled separately for another $40 billion. The American Legacy Foundation was established and was devoted to public health work; some modest restrictions on advertising and promotion by the industry were accepted.

Unfortunately, the MSA excluded any consideration of the international aspects of tobacco marketing, with an anticipation that any reduction in the US market caused by the settlement might be made up abroad. Even with these huge settlement awards, the costs of smoking to the states would not be covered; future litigation by the states was also preempted. The resultant effect was really an excise tax on cigarettes, with costs passed on to the consumer (about 45 cents per pack). Only a handful of states accommodated the recommendation that 20 percent of settlement funds be designated for tobacco control work (only four percent has gone to this purpose).[68] In addition, if tobacco consumption declines, the settlement funds are reduced to reflect market reductions. In fact, the states now have a vested interested in maintaining their revenue flows from the MSA, as the settling companies may withhold payments if their profits decline. The public health effects of this settlement are debatable, but the cash flow to the states is significant.

Finally, the tobacco industry was taken to task by the US Government in 2006 using the organized crime statute (RICO). Briefly, this litigation began in 1999 in the US District Court in Washington, DC, to recover damages on behalf of the US Government. In August 2006, the Federal judge on the case ruled that the tobacco industry had violated the RICO statute. She found that the tobacco companies purposely deceived the public in marketing of cigarettes to children, but she was unable to impose most of the penalties proposed by the Government. The judge did prohibit the tobacco industry from marketing their cigarettes using descriptors that convey any diminished effect on health, and she ordered the companies to begin a newspaper and television advertising campaign to correct their past misrepresentations about the health effects of smoking.[69]

Litigation has not reaped the huge economic benefits for the tobacco control movement that were hoped for in the 1990s. It is not entirely clear where litigation will next turn, but for now, individual cases are still being brought against the industry. These raise the cost of doing business for the industry at least, and if successful, provide some restitution for a few smokers and an incentive for plaintiffs' lawyers to keep bringing such suits. The institutes funded by the lawsuits and the documents disclosed in discovery are probably the biggest benefits to arise from litigation, and these have been put to good use in the advocacy and scientific efforts against tobacco use.

## CURRENT STATE OF AFFAIRS IN THE UNITED STATES

Tobacco control in the United States does not benefit from a unified national tobacco control program as called for in many international recommendations; however, there are other US national health programs (on hypertension, immunization, HIV/AIDS, and Diabetes). The declines in smoking prevalence noted in the last fifty years have now leveled off, with still 45.5 million current smokers in the United States and a major disease burden attributable to smoking. The problems of federalism notwithstanding, the national government has not asserted support for tobacco control programs nor control of tobacco use through policy development, regulation, priority setting, or funding. The MSA provided some hope for State-funded tobacco control programs, but that hope has faded along with much of the promised funding from the MSA. States have not been encouraged sufficiently to implement the proved comprehensive State programs identified through evaluations in the 1990s. The US District Court has found the tobacco industry guilty of violating organized crime statutes, yet the industry continues to mount successful counter-measures to public health. Altria stocks continue to be profitable, owing in part to the substantial efforts of US-based Trans-National Tobacco Corporations to capture globalized markets and the failure of litigation to really hurt their status.

Academia in the United States has had a prominent role in tobacco research, with funding from the National Institutes of Health supporting substantial international and domestic research programs in tobacco (The Fogarty International Center, the National Cancer Institute, and others). Two academic Centers (the Johns Hopkins Institute for Global Tobacco Control and the UC San Francisco Center for Tobacco Control Research and Education) are WHO Collaborating Centers with the WHO's Tobacco Free Initiative (along with the Office on Smoking and Health of the CDC). These and many other academic centers are producing research, training programs, and new health professionals with a focus on tobacco control and global health as never before. These are tremendous intellectual resources, funded in part by governments but also by nongovernmental organizations, such as the American Cancer Society, American Heart Association, Legacy Foundation, and the Robert Wood Johnson Foundation, to conduct research and training.

Given the substantial financial resources available through tax and litigation funding, it is both gratifying to see the progress that has been made and disturbing to note the persistence of smoking, especially among the most vulnerable populations. Smoking is still normative, as evidence by its resurgence in movies and by its continued lack of regulatory controls. The CDC has developed extensive reports (Best Practices 2007) on what works in tobacco control at the state level, emphasizing comprehensive programs. Not all the states have implemented such programs, and there is wide variability in the strength and coverage of them.

These comprehensive approaches also depend on partnerships and policy coherence across different sectors. For example, tobacco agriculture may be an important source of income, especially to poor communities. Tobacco control professionals need to

understand the issues and to address the economics of tobacco agriculture. In some cases in the United States and Canada, State programs to buy out tobacco farmers were implemented, thus obviating the political influence provided by these farmers under the guidance of the tobacco industry. Similarly, partnerships with the movie industry, health insurance companies, labor unions, educational authorities, and social service organizations are critical to implementing tobacco control interventions against persistent challenges. Finally, for cigarette exporting countries such as the United States, foreign policy and trade policy needs to be consistent with the science and health policy developed over the last five decades.

# PART III - WHAT IS THE CURRENT STATUS OF GLOBAL TOBACCO CONTROL EFFORTS?

This section describes current efforts by multi-national organizations, including the World Bank, UN Agencies, and especially the WHO in current global tobacco control activities. A detailed discussion of the Framework Convention on Tobacco Control is included.

## THE WORLD BANK AND UN AGENCIES ACTIVITIES ON TOBACCO CONTROL

The World Bank's mission is to reduce poverty in low- and middle-income countries by promoting sustainable development through loans, guarantees, risk management products, and analytical and advisory services.[70] At the inception of the organization in 1944, it had no mission in health, but rather solely in reconstruction after World War II and economic development

### Shifting World Bank positions on health

The World Bank has evolved since the 1970s to become a major multilateral financier of health.[71, 72] Recently, the Bank's annual development assistance for health increased from about US$6.3 billion in 1997 to more than US$10 billion in 2003.[73] Between 1997 and 2006, the World Bank committed US$13.9 billion to projects in the Health, Nutrition and Population (HNP) program, which was created in October 1979 to translate development theory and research into action.[74] In addition, research and preparation of reports for HNP are part of the design and execution of the World Bank's health programs.[72] The Bank has several comparative advantages such as global experience, strong country presence, capacity to engage with all government sectors, and capacity for large-scale program investments that make its work in tobacco all the more relevant.[71]

### Shifting position on tobacco control

Until the early 1990s, the World Bank supported tobacco growing and manufacturing as part of many developing economies' productive base.[75] Between the 1950s and 1992, it provided loans for tobacco farmers but made no attempt to implement tobacco control measures in any developing country.[75] This trend changed in 1991 when the World Bank adopted a policy of not supporting tobacco projects, excluding tobacco and related products from trade liberalization recommendations and refusing any support for agricultural or industrial development supporting tobacco production.[76-78]

Since 1992, the Bank has emerged as a major multilateral actor in global tobacco control, providing knowledge on economic benefits of tobacco control policies to complement WHO's normative and technical work as well as that of other agencies (such as the UN Food and Agricultural Organization [FAO]). As we have seen, the economic analyses and arguments are critical components in justifying the need for tobacco control at many

different levels. With its analyses, it made important contributions to the development of the FCTC, which culminated in ratification of this first-ever health treaty by 151 Member States of the WHO. The history of the Bank's involvement in tobacco and health is shown in Table 2.

**Table 2. Involvement of the UN and World Bank in global tobacco control**

| Dates | Key Events |
|---|---|
| 1991 | World Bank adopted a policy not to support tobacco projects [78] |
| 1994 | Howard Barnum delivered a speech on the economic of tobacco control at 9th World Conference on Tobacco OR Health, Paris, France that was subsequently published in *Tobacco Control* |
| 1994 | Research for International Tobacco Control (RITC) was introduced at the 9th World Conference on Tobacco or Health. It has become a partner of World Bank on the economics of tobacco control |
| May 1995 | The 48th World Health Assembly adopted resolution WHA.48.11, International Strategy for Tobacco Control |
| June 1995 | The World Bank and 21 other organization and individuals met at the Rockefeller Foundation's Bellagio Study and Conference Centre in Italy, to examine the implications of current global trends in tobacco production and consumption, especially in developing countries, for sustainable development. |
| June 1996 | World Bank/WHO sponsored workshop on economics of tobacco and tobacco control in Washington, D.C. |
| August 1997 | World Bank/WHO sponsored panel on economics of tobacco control at the 10th World Conference on Tobacco OR Health Beijing, China |
| January 1998 | Presentation on economics of tobacco control made before James Wolfensohn, President of World Bank[79] |
| February 1998 | World Bank/WHO sponsored workshop on economics of tobacco control in Cape Town, South Africa |
| July 1998 | WHO Tobacco Free Initiative (TFI) created to focus international attention, resources and action on the global tobacco epidemic and promote the Framework Convention on Tobacco Control (WHO) |
| May 1999 | World Bank releases *Curbing the Epidemic: Governments and Economics of Tobacco Control* |
| May 1999 | The 52nd World Health Assembly approved initiation of FCTC negotiation |
| July 1999 | The United Nations Ad Hoc Inter-Agency Taskforce for Tobacco Control was established |
| September 1999 | First session of the United Nations Ad Hoc Inter-Agency Taskforce for Tobacco Control in New York, USA |
| October 1999 | First FCTC Working Group Meetings |
| August 2000 | World Bank published *Tobacco Control in Developing Countries,* the background papers for *Curbing the Epidemic.* |
| March 2000 | UN Food and Agricultural Organization (FAO) announces that it is launching a study on impact of tobacco on tobacco economies with the cooperation of UN agencies, including WHO and with funding from the Swedish International Development Assistance (SIDA) |
| March 2000 | Second FCTC Working Group meeting in Geneva, Switzerland |
| May 2000 | First report of the UN Secretary-General on the work of the United Nations Ad Hoc Inter-Agency Taskforce for Tobacco Control to the UN Economic and Social Council |
| October 2000 | First session of the FCTC Intergovernmental Negotiating Body |
| December 3-4, 2001 | FAO circulated original form of cases study of global tobacco economy of Brazil, China, India, Malawi, Turkey and Zimbabwe at International Meeting on Economic, Social and Health Issues in Tobacco Control, Kobe, Japan[80] |
| July-August 2002 | International Conference on Illicit Trade in Tobacco (ICITT) |
| May 2003 | 56th World Health Assembly adopted FCTC |
| 2003 | FAO published its study of economics of tobacco for Brazil, China, India, Malawi, Turkey and Zimbabwe |
| February 2005 | FCTC became international law on tobacco control |
| February 2006 | First meeting of the FCTC Conference of Parties |
| July 2007 | Second meeting of the FCTC Conference of Parties |

## The economics of tobacco control

The World Bank's shift on the economic aspects of tobacco control began in the early 1990s when Howard Barnum, then a senior economist at the World Bank, provided a new perspective on the welfare economics of tobacco.[81] An underlying argument of this perspective is that unlike other consumption choices, market efficiency does not apply to smoking because many smokers are not fully aware of the high probability of disease and premature death (information asymmetry) and because tobacco is addictive. The inevitable conclusion was that reducing tobacco consumption would increase net social benefits.[82] In 1994, Barnum concluded that "The World tobacco market produces an annual global loss of US$200 billion." [83] This new perspective provided the framework for subsequent World Bank work on the economics of tobacco control at the country level. The WHO Tobacco Free Initiative (TFI), which was established in July 1998 to promote global tobacco control, also cited this figure as a rationale for WHO's support for an international health treaty (the FCTC).[84]

In April 1998 , a World Bank issues paper, *Tobacco Control Policies in Developing Countries* [85] presented three directions for the Bank: 1) increase efforts in tobacco control, 2) provide global knowledge on economic issues of tobacco control, and 3) work closely with WHO and partners.[85] On April 14, 1998, a discussion paper for the HNP sector Board suggested that the Board "should know that the Bank's overall tobacco control efforts have three long-term objectives: 1) to raise taxes on tobacco products ; 2) to adopt a global and complete ban on advertising and promotion; and 3) to build multi-disciplinary capacity in developing countries.[86] The Bank later produced an Internet-based economic tool kit for analyses at the country level, and several countries have made use of this kit for their background research.

The World Bank efforts included an analytic report on the economics of tobacco and tobacco control; partnerships with WHO, the United Nations Children's Fund (UNICEF), the US Centers for Disease Control and Prevention (CDC), and nongovernmental organizations (NGO)s.[86] The World Bank became a significant force during the negotiation of the FCTC (1999-2003) by collaborating with WHO and other UN agencies on global tobacco control issues. The most important World Bank contribution to the FCTC development was publication of *Curbing the Epidemic: Governments and Economics of Tobacco Control,* [87] which WHO used as technical document to provide economic justifications for the treaty. *Curbing the Epidemic* concludes that reducing tobacco consumption through price policies such as excise tax and duty on tobacco, and non-price policies such as smoke-free workplaces have significant positive impacts on health outcomes, without harming most economies.[88]

The World Bank strengthened partnership relationships with the IMF, ILO, WHO, and FAO, as well as organizations such as the CDC's Office of Smoking and Health and the Canadian Secretariat for Research for International Tobacco Control (RITC) to engage on economic research in tobacco control. The Bank's analytic work focused on the link between poverty and tobacco use and the economic impact of tobacco control on tobacco-related employment and revenues in specific settings.[88]

## The United Nations Ad Hoc Interagency Taskforce on Tobacco Control

This Task Force was established in 1999 to replace the UN Focal Point, which was created in 1993 by UN Economic and Social Council (ECOSOC) resolution 1993/79 and located in United Nations Conference on Trade and Development (UNCTAD).[89] Later, the UN Task Force on Tobacco Control was created by the Secretary-General in accordance with ECOSOC resolution 1999/56. The Task Force is chaired by WHO and comprises 17 Agencies of the UN system and two organizations outside the system namely, UN Department of Economic and Social Affairs, UN Office of Human Resources and Management and the Medical Service, UN Food and Agriculture Organization (FAO), International Civil Aviation Organization (ICAO), International Labor Organization (ILO), International Monetary Fund (IMF), Joint United Nations Program on HIV/AIDS (UNAIDS), UN Educational, Scientific and Cultural Organization (UNESCO), the World Bank , UN Children's Fund (UNICEF) , UN Development Program (UNDP), UN Environment Program (UNEP), the UN Industrial Development Organization (UNIDO), UN Economic and Social Council (ECOSOC), UN Office for Drug Control and Crime Prevention (UNDCP), UN Population Fund (UNFPA), World Intellectual Property Organization (WIPO), and World Trade Organization (WTO) .[90] The Secretary-General is required to report to the ECOSOC at its Substantive Session every two years on progress made by the Task Force in the implementation of multi-sectoral collaboration on tobacco or health.

The purpose of this Task Force is to coordinate the tobacco control work being carried out by different UN agencies and different relevant sectors.[90] Since 1999, the Task Force has had seven sessions; the first session in 1999 in New York and five sessions in 2005 in Geneva.[91] The sixth session discussed tobacco control issues such as smoke-free workplaces, the illicit trade of tobacco products, the link between tobacco control and economic development, and implementation of the FCTC.[89, 91] The seventh session took place on February 2008 and discussed the work of the Study Group on Economically sustainable alternatives to tobacco growing among other topics concerning the implementation of the FCTC.

The Bank and the UN recognize the centrality of health in economic development. [93, 94] Ironically, the Millennium Development Goals, the health development objectives for the entire UN system that aim to cut by half the proportion of people living in poverty by 2015 does not cover non-communicable diseases such as those related to tobacco.[71] In spite of the this omission, the UN recognizes that "incorporating tobacco control into development assistance goals aimed at the attainment of the Millennium development Goals could provide important improvement in poverty, malnutrition and the environment."[95] The long-term economic, social, environmental and other consequences of tobacco use have been assessed in *Curbing the Epidemic*, and thus, tobacco control is central to the achievement of the Millennium Development Goals.[94, 96]

## Tobacco industry tactics regarding the World Bank and United Nations

The World Bank policy shift on tobacco in the early 1990s created problems for the tobacco companies, and they closely monitored the Bank's activities on tobacco, working

to undercut these through international lobbying on excise tax and trade policy related to tobacco.[92] In addition, the tobacco companies prepared economic impact studies to argue to governments, especially those in developing countries, that contrary to what the Bank's analyses showed on the economic benefits of tobacco control, tobacco has a positive impact on their economies.[92] Knowing the influence of the World Bank, especially in developing countries, the tobacco companies worked individually and collaboratively to undermine the findings of *Curbing the Epidemic* and to obstruct the FCTC.[92]

## THE FRAMEWORK CONVENTION ON TOBACCO CONTROL

The Framework Convention on Tobacco Control (FCTC) is the first health treaty to be developed by the WHO under its constitution. It was implemented on February 1, 2006, with the ratification by a minimum of 40 Member States; now 151 States have ratified this international agreement, and negotiations continue on binding obligations that may be developed as protocols. We now discuss global governance in tobacco control as represented by this treaty, reviewing its development, barriers, and prospects for effective global cooperation in tobacco control.

### Global governance in tobacco control

Global governance refers to rules, norms, and institutions that govern public and private behavior across national boundaries; it does not refer to world government or world federalism.[97] Governance occurs at different levels – national, regional and global – within the international system, [98] and it connotes a complex set of structures and processes in both public and private arenas.[99] In many cases, global governance refers to collective actions to establish international institutions and norms to cope with the causes and consequences of adverse supranational, transnational, or national problems. [100] Global governance is characterized by the need for greater collaboration among governments and nongovernmental actors as the result of states being faced with new and growing demands on the one hand and shrinking resources on the other.[101] The inability of states to deal with transnational issues such as tobacco use demands collaboration.

An important area for global governance is health because many of the issues involved transcend national boundaries.[102] Global health is directly or indirectly associated with transnational economic, social, and technological changes taking place in the world. [103] The main determinant of this phenomenon is globalization, a process of increasing economic, political and social interdependence, and global integration that occurs as capital, traded goods, people, concepts, images, ideas and values diffuse across national boundaries.[104] Globalization has merged the domestic and international spheres of public health. This phenomenon has on one hand diminished countries' capacity to effectively deal with domestic health threats, and on the other hand has increased the need for international cooperation and collaboration as well as international law to deal with global health issues such as tobacco control.[103] Global health requires multilateral membership organizations such as WHO and World Bank to play a greater role in international health cooperation; it requires new forms of governance that permit public-

private partnerships, non-governmental organization involvement, and intersectoral collaboration.

Globally, tobacco consumption resulted in an estimated 4.83 million premature deaths in 2000, half of which occurred in developing countries.[71, 105] There are more than 1.3 billion smokers worldwide, over 1 billion of which live in developing countries. Tobacco-related deaths are estimated to reach 10 million by the 2020s, 70% of which will occur in developing countries. Tobacco use and the diseases caused by tobacco are not confined to developed economies; these are now global issues requiring global redress. One of the most hopeful interventions in this setting is the FCTC.

## Development of the Framework Convention on Tobacco Control (FCTC)

The FCTC is a global regime to combat the health problems due to tobacco use.[106, 107] The FCTC follows Article 19 of the WHO Constitution[108]and is principally a collection of effective tobacco control policies that we have discussed previously that could be adopted in different political and geographic jurisdictions.[109] The FCTC is a framework convention/protocol approach that allows countries to proceed incrementally after they have ratified the basic treaty.[110]

Knowledge on the economic and social costs of tobacco (supplied by the World Bank) and extension of tobacco industry activities into developing countries (pointed out by the advocacy community) galvanized governmental and non-governmental organizations in their approach to the negotiations.[111] The WHO also integrated recommendations from the International Conference on Illicit Trade in Tobacco in the FCTC,[112] stating that:

> The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The spread of tobacco epidemic facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as global marketing, transnational tobacco advertising, promotion and sponsorship, and international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use.[113]

During the FCTC negotiations (1999-2003) civil society organizations seeking to influence the process mobilized under a common umbrella organization, the Framework Convention Alliance (FCA), which used strategies such as provision of expert information for delegates, briefing of delegates, publication of a daily newsletter (*Alliance Bulletin*), and shaming delegates for supporting tobacco industry positions.[114] Even though participation of civil society organizations was limited by WHO rules, the FCA succeeded in incorporating Article 4: Guiding Principle No.7 of the FCTC that states: "The participation of civil society is essential in achieving the objective of the Convention and its protocols."[106] As a result, civil society organizations have become participants in the FCTC Conference of Parties (the governing body for the FCTC) discussions. This involvement of civil society in the FCTC implementation was important in its passage and may have implications for the future of global tobacco control. We

have certainly seen this in the US experience, where grassroots efforts and other political advocacy were critical to the successes enjoyed over the last five decades.

## The WHO and the FCTC

Between 1970 and 1995, WHO concentrated primarily on providing expert policy advice for Member States to control tobacco use within their jurisdictions.[71] In the early 1990s, analyses by experts in international law and tobacco control encouraged WHO to use its constitutional powers to develop an international convention on tobacco control.[115] The idea of a Framework Convention was raised at the 9th WCTOH at Paris, France in 1994, and resulted in a conference resolution, "International Strategy for Tobacco Control."[116] Subsequently the World Health Assembly adopted Resolution WHA48.11, "An International Strategy for Tobacco Control."[117] This resolution requested that the WHO Director General report to the 49th World Health Assembly in 1996 on the feasibility of an international legal instrument. In 1996, The World Health Assembly adopted resolution WHA49.17, "International Framework for Tobacco Control,"[118] which requested the Director-General to initiate the development of a WHO FCTC in accordance with Article 19 of its constitution.

Progress on the FCTC was slow until a change in leadership in 1998.[113, 116] Tobacco control was elevated to a cabinet level position by creating the WHO Tobacco Free Initiative (TFI) to accelerate the FCTC process and focus on global tobacco control. In January 1999, the WHO Executive Board adopted resolution EB301.R11 that recommended that the World Health Assembly initiate formal negotiation of the FCTC.

A Working Group process first prepared the draft elements (substantive and procedural) for the FCTC and technical background information for the International Negotiating Body (INB). These used recommendations from WHO technical consultations in Kobe, Japan, New Delhi, India and Oslo, Norway.[119] The Working Group submitted a draft convention (that reflected many elements of *Curbing the Epidemic*) to the 53rd World Health Assembly in May 2000. The Assembly adopted resolution WHA53.16 to begin negotiations with active civil society involvement.[120]

The formal negotiation of the FCTC began with the work of the International Negotiating Body (INB) in October 2000. A contentious issue during the first meeting of the INB was whether civil society organisations would be allowed to participate in the INB sessions.[121] In spite of a 1996 ECOSOC resolution [122] calling for broad participation of civil society organisations in decision-making processes of UN agencies, the INB decided that only NGOs with formal relations with the WHO could participate in its proceedings. As a result, the FCA could only be an observer. Formal participation in the FCTC negotiation was limited to FCA member organisations that had official relations with WHO, such as the International Union Against Cancer, World Federation of Public Health Associations, and the International Union Against Tuberculosis and Lung Disease (IUATLD). The WHO also solicited public comment,[109] with two days of public hearings in Geneva to provide civil society organisations (and tobacco companies) with an opportunity to make interventions about the proposed FCTC text.[123] Over 500 written submissions were received, and representatives of 144 organisations testified before the

hearing panel; 20 percent of the submissions were from the tobacco industry and affiliated groups[114]

WHO also conducted regional and sub-regional FCTC preparatory meetings and inter-session consultations in which countries could formulate policy positions on the specific components of the FCTC[119] For example, the WHO African region (AFRO) issued declarations on tobacco control supporting the FCTC after the meetings in Lome, Togo,[124] Nairobi, Kenya,[125] Johannesburg, South Africa [126]and Algiers, Algeria,[127]. This resulted in the creation of the first regional voting block in the negotiation.[128] The AFRO countries cited public health concerns as a reason for strong support of the FCTC. Other regions [128] subsequently emulated this block approach. The regional and sub-regional preparatory and consultation meetings on the FCTC made a global phenomenon – the development of the FCTC – into a regional and sub-regional issue. Such actions helped assure mutual cooperation among Regional members and provided more specific outlets for voicing concerns by Member States. Thus, the process of preparation for negotiation may have been one of the main benefits to date of the FCTC: the level of discussion about tobacco control and international cooperation in health was raised to a new level.

## Barriers to engagement and new resources

The civil society groups involved in the FCTC were dominated by well-resourced organizations from developed countries. The Conference of the Parties has now made the FCA a formal participant, and the FCA has subsequently embarked on capacity building programs to train civil society groups on the implementation of the FCTC and development of tobacco control programs.[129] Despite these efforts, the civil society base for tobacco control is still weak in developing countries, and this presents a challenge to the future of tobacco control. The FCTC negotiations itself garnered interest and enthusiasm in tobacco control in many developing countries, but this governmental interest will wane without strong civil society advocacy; this is a lesson to be learned from the United States and elsewhere: without civil society involvement, tobacco control activities will neither be implemented nor enforced. Thus, the lack of civil society development is a barrier to the full implementation of the FCTC particularly in low- and middle-income countries where there are few resources or historical experiences to support civil society involvement on any issue.

## Tobacco industry tactics in the global arena

The tobacco industry has used its resources and political connections to deny the health dangers of tobacco use and to undermine tobacco control policies nationally, regionally, and globally.[130-136] During the FCTC negotiations, the industry continued to question the scientific evidence on addiction and the health effects of tobacco. A 1999 letter from the British American Tobacco (BAT) Chairman to the WHO Director-General maintained that tobacco was addictive in the same sense as chocolate. [137] This claim contradicts the tobacco industry's internal documents, which reveal that tobacco companies have been aware that nicotine is addictive since the 1960s.[138]

The tobacco industry has a long history of working covertly to undermine international tobacco control efforts.[139] Efforts included: staging of events to divert attention away from tobacco as a public health problem, attempting to reduce budgets for scientific and policy activities carried out by WHO, pitting other UN agencies against WHO, distorting the results of scientific studies on tobacco, working to discredit WHO as an institution through third party critics, and using surrogates to influence WHO decisions.[131] In developing countries, the industry used trade liberalization and smuggling to open markets and aggressive marketing tactics to increase consumption.[134, 140] The tobacco companies also attempted to create controversy over the health effect of exposure to SHS,[141, 142] used 'corporate social responsibility' programs such as youth smoking prevention voluntary codes to obfuscate their intentions,[143, 144] and engaged in lobbying and economic impact studies to thwart tobacco control programs.[92, 145, 146]

Tobacco companies that had provided written submissions and verbal testimony during the FCTC public hearings[114, 126] complained in these documents about their limited involvement in the FCTC process and claimed that WHO ignored them and their allies in the negotiations. At the same time, the industry worked directly (individually and jointly) and indirectly through country delegations[114, 146-148] and other third parties[149-152] to influence and undermine the FCTC. Members of the industry participated in the process as national delegates of China, Japan, Malawi, Russia, and Turkey.[114]

The trans-national tobacco companies also directly lobbied Member States to influence the composition of national delegations to include people from trade, finance, and agricultural ministries.[152-156]They hired consultants to engage in public relations and design strategies for undermining the FCTC,[157-160] and worked to undercut World Bank publication *Curbing the Epidemic: Governments and Economics of Tobacco Control.*[92] One particularly troublesome tactic was to infuse the "North-South" (developed-developing world) controversy into the negotiation,[114] whereby the treaty was accused of supporting the health interests of developed countries at the expense of developing countries infectious disease priorities. They developed the International Tobacco Products Marketing Standards, a global tobacco industry self-regulatory regime as an alternative to the FCTC, by internationalizing the tobacco companies' strategies of youth smoking prevention and voluntary codes.[144]

The most important third party group the tobacco industry used to lobby against the FCTC was the International Tobacco Growers' Association (ITGA). The ITGA was established in 1984, and as of September 2007, was made up of organisations from 25 countries. It claimed to represent tobacco growers during the FCTC public hearings by opposing the FCTC on economic grounds and disagreeing with the FCA members over the need for the FCTC. The tobacco industry funded the ITGA public relations program that promoted the industry's point of view[92, 114, 161]

The tobacco companies also sought to weaken the influence of civil society organisations in the FCTC process by monitoring the activities of tobacco control advocates and trying to infiltrate them to promote discord[114, 162] For example, Philip Morris and RJ Reynolds used a Washington, DC-based public relations firm to gather intelligence and provide strategic advice concerning the activities of tobacco control NGOs during the

negotiation.[162] The tobacco companies were specifically interested in weakening the FCA by engaging member organisations individually at the national and local levels[162-165].

Since the FCTC was adopted, the tobacco companies have continued to work at the national level to thwart the ratification and implementation of the FCTC, especially in developing countries where governments and policymakers are vulnerable to industry influence.[144, 166, 167] For example, in 2004, the tobacco companies entered a voluntary agreement with the Ministry of Health of Mexico, the first country to ratify the FCTC in the Americas. In this agreement, Mexico has agreed on tobacco control measures with the tobacco industry in return for contributions to a public health fund. The controls are less restrictive than those in the FCTC, and the agreement makes it difficult for Mexico to enact stricter controls. This pre-emption of proposed legislation associated with the FCTC raises concern about another new tobacco industry model for counteracting its effects through voluntary agreements.[166] The tobacco companies are also aggressively promoting their International Tobacco Products Marketing Standards, the codified efforts to develop an alternative voluntary tobacco control regime in a way that could undermine the implementation of FCTC.[144]

## Enforcement issues for the FCTC

As of December 2007, 151 parties have ratified the FCTC. Because the FCTC is a framework-protocol approach, the Conference of Parties, has held meetings in Geneva, Switzerland (February 2006) and Bangkok, Thailand (June-July 2007), and South Africa (2008) to develop protocols under the FCTC. Following these meetings, the FCTC secretariat has been established at the WHO headquarters in Geneva. Thus, at the global level, the structures for implementing the FCTC have been established. The critical issue now is how to implement it at the national level.

In spite of changes in leadership, the WHO continues to play an important role in supporting Member States cooperation on some of the other critical tobacco control issues. For example, in February 2007, the WHO held a conference on crop diversification in Brazil to discuss how countries dependent on tobacco production could switch from tobacco farming to alternative sources of revenue. Tobacco farmers have been largely co-opted by the tobacco industry,[168] which has limited several countries' involvement in the FCTC process (Argentina, Colombia, Dominica and Malawi have not ratified the FCTC). Contrary to the tobacco industry argument of lack of alternatives for such segments of the economy, the FAO has identified alternative sources of income for tobacco growers in such countries.[80, 169]

A particular issue concerning the FCTC implementation is trade. Even though Article XX(b) of 1994 General Agreement on Trade and Tariffs permits trade restrictions on products for public health reasons,[108] trade was one of the most contentious issues arising during the FCTC negotiations. Many countries were against any provision which will allow public health to take precedence over trade.[114]In spite of this opposition, the Preamble of the FCTC puts public health at a par with international trade.[106] In addition, because article 30 of the Vienna Convention on the Laws of Treaties allows later treaties

to take precedence over earlier ones,[108] parties to the FCTC could challenge the trade issue. However, tobacco remains a legitimately traded product under the World Trade Organization authority.

## New financial resources in tobacco control

Lack of financial resources to develop and sustain tobacco control programs has been a key barrier to the implementation of the FCTC in developing countries. Even though Article 26 of the FCTC points out the need to provide funding for the development and strengthening of tobacco control programs in developing countries and economies in transition,[119] there has not been any institutionalized way of funding the initiation, development, and sustainability of tobacco control programs in developing countries until the recent infusion of the Bloomberg Initiative funding (See below and www.who.int/tobacco/communications/highlights/bloomberg_grants/en/index.html).

The philanthropic community has been involved in global tobacco control activities for a number of years. The United Nations (Turner) Foundation, the Soros Foundation, and the Rockefeller Foundation provided modest funding for global tobacco control in the 1990s and early 2000s. However, in January 2007, Michael R. Bloomberg, philanthropist and Mayor of New York City, launched a US$125 million global tobacco control initiative in partnership with WHO, the Campaign for Tobacco Free-Kids, the CDC Foundation, the Johns Hopkins Bloomberg School of Public Health, and the IUALTD to reduce tobacco use in low- and middle-income countries. [170] Such private sector involvement in global tobacco control signals that the FCTC process may have, as a secondary effect, attracted the attention of new partners who can help signatory countries implement its obligations. This funding will be critical in helping to overcome many national barriers to tobacco control for poor countries, helping build capacity, and leveraging other international sources to contribute to the global efforts.

## The future of the FCTC

The FCTC does not solve the global tobacco problem. The critical element of the FCTC is implementation at the country level; otherwise "the FCTC could turn out into yet another treaty gathering dust in ministries and academic institutions around the world."[171] Even though countries such as Ireland, the United Kingdom, France, Uganda, and Uruguay have adopted smoke-free policies, and others such as India and Sri Lanka have enacted stricter legislation, more work needs to be done at the country level to secure compliance with the FCTC. Its implementation still faces daunting economic, political and socio-cultural challenges in developing countries especially, despite their vocal support for the treaty during negotiations. Lack of financial resources poses one of the largest threats to the implementation of the FCTC in these countries.

The FCTC is an evidence-based treaty that establishes the "baseline" for the developing and sustaining tobacco control programs at the national level. The adoption of the FCTC does not imply that tobacco control is "done" because tobacco consumption continues to be a global epidemic. Even if tobacco control efforts succeed in reducing smoking prevalence by one percentage point annually in every country from 2003, there will still

be over 1.3 billion smokers in 2010, and 1.45 billion in 2025. [95, 172] It has been estimated that between one-half and two-thirds of long-term smokers around the world will eventually die prematurely of tobacco-related diseases.[173]

The FCTC as global governance may strengthen multinational cooperation on tobacco control in the future. In order to do so, Article 26, securing financial resources to build tobacco control structures, to strengthen civil society, and to encourage scientific research in developing countries as well as to continue collaboration among the members of the UN Ad Hoc Task Force on Tobacco Control is needed. This poses a moral dilemma for countries such as the United States where so much of the research on what works in tobacco control has been done. Donor nations should, if not ratifying the FCTC, at least provide resources to address tobacco control as the global public health problem that it is.[174] These nations have a stake in health as well as in the economic stability that may result from healthier global populations.

# PART IV - HOW CAN THESE LESSONS FROM THE PAST INFORM CURRENT AND FUTURE INVESTMENTS IN GLOBAL TOBACCO CONTROL?

## LESSONS LEARNED FROM THE ANALYSIS OF THE POLITICAL ECONOMY OF TOBACCO CONTROL

The main points presented in this review of the political economy of tobacco control are:

- The tobacco industry has worked for decades to embed tobacco use in culture, national economies, national and local political structures, and personal behavior; tobacco control can only be successful if this situation is de-normalized at multiple levels. The political economy of tobacco control is influenced not only by the direct actions of the tobacco industry, but also by industry surrogates from related industries and the agricultural sector. Understanding the interrelationship among these disparate sectors, the tobacco industry, and government is necessary for successful tobacco control programs.

- The social norms supporting tobacco use can be changed, but only slowly and with multi-dimensional interventions that depend not only on strong government support and financing, but on strong grassroots efforts and partnerships. These efforts have been a key component of the tobacco control successes in the United States and in other developed countries. Such activities may be unfamiliar territory in the developing world, and thus investment in civil society development is a critical component of tobacco control efforts.

- Tobacco control is increasingly important for economic development and poverty reduction in low and middle-income countries. The World Bank's research on this in the late 1990's provided the analytical basis for gathering evidence in these economies. However, as smoking rates increase in some developing economies, additional evidence is needed to understand the direct impact of smoking on these developing economies and the potential benefits of reducing the burden of tobacco-attributable diseases within health systems.

- Tobacco control is now addressed through a new global health governance vehicle, the Framework Convention on Tobacco Control, which lends hope for multi-lateral cooperation against a trans-border health threat. Tobacco use is a true global health threat in which the State's sovereign responsibility for health is impugned by multi-national image marketing, trade agreements, and information asymmetry that supports tobacco use. However, the FCTC is a top-down approach that may not achieve the same historical successes without concomitant efforts at the grassroots level.

- Private-public partnerships and non-governmental funding may have new global influence in the prevention and control of tobacco use. These present challenges to global health governance, but at least there is now interest among some donors to take on tobacco's growing disease burden. Governments have the lion's share of responsibility to control tobacco as a global public 'bad', but grassroots and community efforts have been shown to stimulate governments and to help carry out government programs with less than adequate funding. New funding sources may need to address the need to develop civil society in order to achieve success in global tobacco control.

- The World Bank should continue to contribute analytic capacity, country assistance and financing, and leadership through partnerships in support of global tobacco control; the Bank has produced some of the most important documents to date on the economic basis for tobacco control, and thus its analytic role in this field should be sustained. However, the Bank deals primarily with governments, and thus the interactions between government and civil society may need to be explored further in the Bank's investment strategies for tobacco control.

## POLICY INFLUENCES FOR GLOBAL TOBACCO CONTROL

We have attempted to show several major policy influences that can lead to a collective approach to tobacco control at the global level. These by necessity affect local levels, extend to sub-national-level programs, and affect national governments. In addition, these policy drivers have influenced the efforts of multinational organizations and new multinational structures in tobacco control. They include:

- *Science* to inform the public and policymakers about health risks, economic costs, program effectiveness, and clinical interventions regarding tobacco use;

- *Information* strategies to educate consumers and potential consumers, motivate advocates, and support behavior change among smokers;

- *Advocacy* to stimulate interventions and hold accountable decision-makers who do not support or enforce evidence-based policy;

- *Legal actions* to develop regulations on SHS, product contents, advertising, packaging, and labeling; hold the tobacco industry accountable through litigation; and stimulate global tobacco control through multinational agreements;

- *Collaboration* now codified by the FCTC, to work across borders, including national governments, multi-national organizations, and the private sector. Most importantly the FCTC requests that countries provide information to monitor it implementation.

These may all be thought of as critical components of a comprehensive approach to global tobacco control. Without science and continued exploration of evidence on what works, the tobacco control community would not be able to formulate policy. Without the dissemination of information, tobacco as a major cause of the current and future global burden of disease will not be recognized. Without advocacy to disseminate information and cause policies to be implemented, not enough will happen in tobacco control through government. Without regulations and legislative approaches, governments will not be able to intervene against tobacco use as a public health problem. Without collaboration, the multi-national community of nations will be divided by the multi-national tobacco industry. This industry has the resources, economic motivations, and fiduciary responsibility to its stakeholders to do all that is possible to subvert international agreements such as the FCTC as well as national programs to protect the public's health. The evidence for these efforts has been relatively well documented in developed countries such as the United States, but there is still need for additional evidence to support developing countries' tobacco control programs.

## BUILDING COALITIONS AT COUNTRY LEVEL AND THE ROLE OF CENTRAL GOVERNMENT

Within each nation, partnerships and intersectoral cooperation is critical to the success of comprehensive programs; these types of cooperative efforts are not necessarily a natural response, as there are political silos, sectoral competition for funding, and cultural differences that may prevent effective cooperation. While government has the responsibility for implementation of most comprehensive activities, these have been shown to be most effective if supported by grassroots efforts as well as central financial resources. Stakeholders are important in the political process at multiple levels. For example in Brazil, small farmers, including tobacco growers, are an important part of the political base of the current government. Hence, any major modifications to tobacco policies will have to consider this group as a central actor.

With the ratification of the FCTC, government must implement national policies in accord with the binding obligations of the treaty. To do this, key stakeholders are essential to contribute to the policy development needed for this compliance. These may include representatives from the ministry of agriculture, the trade office, the ministry of security (to address smuggling), the ministry of education, the ministry of consumer protection, ministry of youth and/or sport, the media, the business community, and health NGOs. Health ministries, especially public health institutions, are not necessarily the strongest of the stakeholders, and thus the contributions of these related ministries and actors must be assured from top down as well as from the bottom up.

The lessons learned about the role of government in the United States, indicate that the information shocks produced by the 1964 Surgeon General's Report moved Congress and some agencies to take action. Thus, information dissemination by governments and governance structures is a critical component of the global and national efforts to control tobacco use. Most programmatic efforts seem to devolve to sub-national levels, which have more direct responsibility to protect the health of their residents. At a sub-national government level, civil society plays a more critical role in tobacco control in assuring

accountability from government. However, a coordinated national program effort is important for two reasons: first, the national tobacco control activities will be supported by recognized national experts and by important political actors; and second, health messages from national leadership have substantial political legitimacy at multiple levels.[175] Civil society actions, however, can be fragile, with their effectiveness depending on social and ideological conditions at a given moment. Governments, on the other hand, can implement strong policies, but without the support of civil society, enforcement of these policies may be challenging.

## ROLES OF INTERNATIONAL INSTITUTIONS

Health may be considered a global public good,[176] and the UN agencies seem to be clear in supporting this notion, embedded in the Millennium Development Goals.[95] The WHO as the main health agency of the United Nations must maintain a strong leadership role in setting standards, assuring evidence-based approaches based on regional and national perspectives, monitoring the epidemic and its interventions, and technically supporting the Conference of the Parties to the FCTC. The WHO TFI has been empowered by the infusion of the new Bloomberg funding (it is one of the Bloomberg Partners, including the Campaign for Tobacco-free Kids, Johns Hopkins Bloomberg School of Public Health, the CDC Foundation, and the IUALTD). The WHO may also look for new opportunities to work across its own agencies, for example in infectious disease control, immunization programs, mental health programs, and others to support policy cohesion on tobacco control. Further, there are likely many potential opportunities if the disciplinary and programmatic barriers inherent in the UN bureaucracy can be overcome. Tobacco control efforts cross over many sectors, and thus success in global tobacco control may be accomplished more effectively than by the work of only the health agencies. The UN Interagency Group should be revitalized to assure such multi-disciplinary collaboration. Ultimately, however, WHO will be supporting policy development at the national level, and if multiple UN sectors can be involved, this policy development is likely to be more robust at that level.

The World Bank as a knowledge development organization is well placed to provide analytic strength and country-level assistance for tobacco control. Knowledge development is central to its larger health and economic development mission.[177] Thus it is important that the Bank has a continuing role in supporting country level analyses and in evaluating economic conditions germane to the full implementation of the FCTC. Their work in this area has been shown to be critical in the lead-up to the FCTC, and there will now be additional opportunities for such research and country-level assistance as the FCTC protocols are developed.

## FUTURE RECOMMENDATIONS FOR GLOBAL TOBACCO CONTROL.

### Regulatory actions

In particular, regulatory policies regarding tobacco product contents, advertising, labeling, clean indoor air legislation, alternative tobacco products, and so forth have been identified as components of comprehensive tobacco control programs. WHO's TobReg Study Group has focused on Articles 9, 10, 11 of the FCTC to support such tobacco regulation at the country level, and additional regulatory approaches may be developed in this process as well.[178] The Study Group made the following basic recommendations:

- Tobacco product contents and designs should be evaluated from the perspective of dependence potential and emissions;
- The use of flavored additives to enhance sales should be prohibited;
- Biomarkers of exposure should be required in studies submitted for regulatory approval of tobacco-use cessation interventions and studies defining exposure reduction from different tobacco products;
- Maximum levels of carcinogenic tobacco-specific nitrosamines should be set for all brands, and those exceeding the maximum level should be prohibited from importation, exportation, distribution, and sales.

Whether and by whom these regulations may be enforced is yet to be established.

### Best Practices

Additional knowledge development on best practices in different settings is still needed; academia, especially through the network of WHO Collaborating Centers on Tobacco Control, is an essential partner in the generation of new knowledge and the evaluation of current interventions. One example for future concentration is the environmental assessment of compliance with SHS restrictions. Technology is now available to quickly assess ambient nicotine and particulate pollution in areas that should be smoke free. Such compliance research should begin with health care institutions in particular, as the vanguard of a non-smoking social norm.

Economic analyses are being undertaken by International Tobacco Evidence Network (ITEN), among other university-based research groups, on the economics of tobacco control (http://www.tobaccoevidence.net/). ITEN was established. to maintain a formal network of economists, epidemiologists, social scientists and other tobacco control experts able to provide rapid, policy-relevant research on country-level, regional or international tobacco control issues.

## Funding

Funding, especially by donor nations and philanthropy is necessary to assure implementation of the FCTC. Technical assistance may be provided by donor countries, even those who have not signed or ratified the FCTC. Even if a country does not ratify the FCTC, this does not mean they have no national interest in global tobacco control; this is a true, cross-border global health problem, and thus even without a treaty agreement, many non-members of the Conference of Parties will have equity in the issue. The FCTC is a code of conduct, but the imperative for effective action against tobacco extends beyond this written agreement.

Increased financial resources are now evident, and it seems as though these may have important consequences for the near future; what remains to be seen is how these resources can create sustainable government-based interventions at the national level and effective grassroots activities at the local level. Government is still the responsible entity for assuring a comprehensive approach to tobacco control, but it must be supported by advocacy and science to assure implementation of national programs.

## Training and capacity development

Finally, training is a continuous need, and this may be addressed through new mechanisms such as those supported by the WHO collaborating centers, the Bloomberg Global Initiative, and national public health institutes. Capacity development for civil society is a critical need, and this has been addressed in bilateral donor activities as well as by the World Bank. One idea is establish Visitors' Programs for developing country partners that might come to countries where substantial progress in tobacco control can be observed and resources mobilized to provide training. In such a program, organized one- to two-week study tours for visiting public health workers including government officials, civil society groups, and researchers learn about best practices in tobacco control. Such programs may be conducted in various sites around the globe to take advantage of specific expertise in tobacco control interventions (such as advocacy work in California, tobacco industry document research in London, tobacco policy development at Johns Hopkins University, and regulatory approaches in New Zealand).

## The tobacco industry

Tobacco control is coming into its own in terms of funding, multinational leadership, and science, with persistent needs for these elements in developing and transitional economies. However, the tobacco industry continues to find weaknesses to exploit, through direct interference in the FCTC, lobbying and pre-emptive legislative efforts at national levels, and continued deceptive marketing practices, especially through 'corporate social responsibility' and the International Tobacco Products Marketing Standards. We can expect to see more of these behaviors, and thus continued vigilance and advocacy must be supported, including tobacco industry document research.

## Global governance for tobacco control

Global governance for tobacco control is now being consolidated through the FCTC, and this will be supported through the multi-national membership organizations in particular. However, global health is increasingly fraught with governance challenges, especially with new public-private partnerships that do not respond to existing governance structures and the new philanthropies.[179] The involvement of the private sector in non-communicable disease control activities has been advocated and engaged through private-public partnerships; such arrangements have been shown to be important in communicable disease control (witness the Global Fund for AIDS, TB, and Malaria; STOP TB; and Roll Back Malaria). How these new governance structures will work with the private sector in tobacco control remains to be seen. Guidelines on involving the private sector in public health work are needed and have been suggested in recent publications.[180] Such partnerships are broadly welcomed, but the potential for conflicts of interest is a matter of concern, especially with respect to the tobacco industry. These conflicts could affect research and public trust in science.

## Knowledge generation

The production of new knowledge and the consistent dissemination of information to the public and policy makers about the health consequences of tobacco use will remain a cornerstone of effective tobacco control. Through the production of new knowledge and research, the global burden of tobacco may be recognized as a priority for the multinational organizations such as the WHO and the World Bank, and it should be recognized as a worthy investment by philanthropy and by bilateral donors. The FCTC is a start, a baseline, and a provocative international agreement for global governance in tobacco control, but it is not the end of the battle. Civil society, governments, and multiple sectors will need continual encouragement to prevent the global health disaster that has been predicted as a result of tobacco use in the world.

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