Global Economic and Health Benefits of Tobacco Control: Part 2

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Although the risks of tobacco smoking have been known for decades, the pandemic of tobacco use continues. There are an estimated 1.3 billion smokers worldwide, along with millions more using various oral tobacco products. Recent global estimates place the mortality burden from tobacco use at over 6 million annually, with nearly two-thirds of these deaths occurring in developing countries. If current patterns persist, there will be an estimated 1 billion deaths from tobacco during the twenty-first century. Part 1 of this two-part paper provides an overview of the tobacco pandemic, the scope of the pandemic, and its economic and health consequences. Part 2 reviews the history of tobacco control to date and addresses the current global strategy, based on the World Health Organization's (WHO's) Framework Convention on Tobacco Control and the MPOWER package of interventions. Part 2 ends with a consideration of scenarios for the future of the pandemic.

TOBACCO CONTROL

Historical perspective

Modern tobacco control efforts largely date back to the 1962 Royal College Report in the United Kingdom and the first US Surgeon General's report in 1964, both titled "Smoking and Health."[1,2] These reports provided a solid scientific foundation for the need to control the use of tobacco. These comprehensive reports concluded that cigarette smoking is causally related to lung cancer, and recommended legislative action to control its use.[1,2] The compilation of data provided the critical rationale for effective legislative action to control tobacco use, including the initiation of health warnings on all cigarette packages and advertising restrictions on radio and television. The US publication and resulting legislative action marked the turning point in regard to smoking prevalence in the United States (**Figure 1**).

Elsewhere in the world, too, this scientific consensus was heard. For example, in 1963, following the UK report, the *South African Medical Journal* called on the South African government to take urgent steps to ban smoking in public places and in public transport, eliminate tobacco advertising, mandate health warnings, and increase taxation on cigarettes.[3] It would take decades, however, before even one of these recommendations was implemented in South Africa.

Decades passed before the irrefutable evidence that tobacco kills when used as directed was translated into effective public health policies. Throughout the history of tobacco control, the tobacco industry has tried to diminish the impact of such controls. In the early 1950s, as the causal role of smoking in lung cancer became apparent, the industry began to aggressively discredit the evidence and to sustain apparent controversy about the findings. Tobacco companies colluded in these actions and used the same general tactics a few decades later when evidence of the dangers of secondhand smoke (SHS) became convincing. These and other tactics were the basis for the litigation by the US Department of Justice against the industry, as well as the subsequent decision that the companies were guilty of fraud and racketeering. Judge Kessler's opinion in the Department of Justice case[4] and Brandt's book *The Cigarette Century* cover this history in depth.[5]

Pioneers in tobacco control include Finland, Norway, Singapore, and the United States. Shortly after the release of the 1964 Surgeon General's Report, the United States implemented the first health warnings on cigarette packages and began public education programs on the harms of smoking. Other countries quickly followed. Early tobacco control strategies differed among countries in ways that reflected their unique political, social, and economic situations. Singapore and Finland successfully instituted comprehensive national tobacco control legislation in the 1970s, including advertising bans, health warnings on all cigarette packages, indoor-smoking prohibitions, and tobacco taxes. Norway passed a comprehensive national advertising ban in 1975 but did not consistently increase tobacco taxes. Sweden focused on continually raising the prices of cigarettes and also launched public

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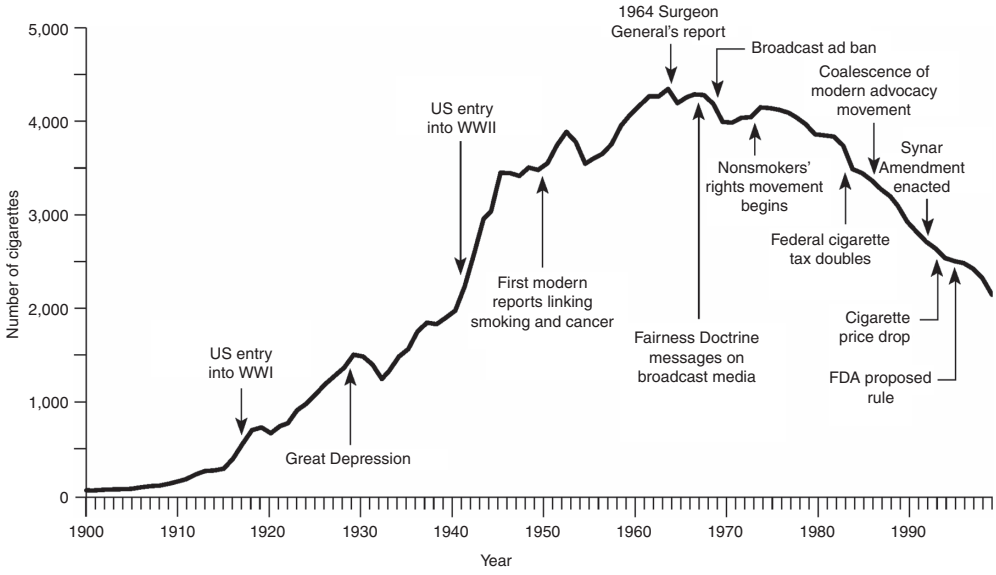

Figure 1 Adult per capita cigarette consumption and major smoking and health events in the United States from 1900 to 1999. FDA, Food and Drug Administration. Reprinted from ref. 49.

education campaigns. In the United States, aggressive national action was impossible because of the longstanding influence of the tobacco industry on the federal government. Therefore, advocates of tobacco control in the United States combated the tobacco industry by focusing on state and local action.

Policy approaches to controlling tobacco use shifted in the late 1980s with the rise of new evidence that SHS causes death and disease in nonsmokers. The industry extensively criticized the science used to make the link between SHS and disease and attempted to extend controversy regarding the health effects of SHS, the extent of exposures, and the effectiveness and minimal cost of controlling it.

Consequently, the industry aggressively fought national and local clean indoor air measures (often working through surrogates with undisclosed links to the tobacco industry, such as "Hospitality Associations") throughout the world. In Latin America, for example, Philip Morris and British American Tobacco, working through the US law firm Covington & Burling, developed the "Latin Project" to counter regulations aimed at creating smoke-free workplaces and public places.[6,7] This is only one instance of the widespread use of tactics that were intended to reduce the credibility of the scientific evidence of SHS's effects on health, and to promote strategies other than bans.

Industry documents now reveal that, as early as the 1970s, the industry anticipated that policies restricting or ending smoking in public places would severely undermine the social acceptability of smoking, create an environment that would make it easier for smokers to stop smoking, and discourage young people from starting the habit.[8] Subsequent scientific research has validated this foresight; smoke-free workplaces, for example, are associated with a 29% reduction in cigarette consumption.[9]

The consolidation of scientific evidence and the shift toward the protection of nonsmokers led to a major new legislative agenda for tobacco control, and substantial declines in smoking prevalence followed (**Figure 1**). Initially, actions were taken to separate smokers and nonsmokers within the same space (nonsmoking sections); this was followed by creating separated smoking sections, and then by a complete ban on smoking. The movement toward a complete ban was largely motivated by evidence that ventilation and air cleaning could not remove cigarette smoke toxins from the air.[10]

In 1999, California became the first state to become completely smoke free in all public places and workplaces, including restaurants and bars. Other states, such as Massachusetts, Nevada, and New York, have since followed suit. In fact, more than 70% of the US population is now covered by comprehensive legislation for a smoke-free environment.[11] In 2005, Ireland became the first country to become completely smoke-free. Momentum has continued to grow in support of legislation for a smoke-free environment. By 2007, Italy, Norway, Sweden, Uruguay, England, Scotland, France, the Bahamas, and Uganda were all smoke free, and many other countries had expanded the number of public places in which smoking was completely banned. Up-to-date information on the global status of legislation for smoke-free environments can be found on the Global Smokefree Partnership website.[12]

The role of media in promoting addiction and, alternatively, in reducing tobacco use, has become a major issue in tobacco control. The industry has been successful at resisting moves to restrict the use of media for promoting tobacco products and in evolving alternative strategies to reach current and potential smokers with media messages that promote the product. In 2005, the tobacco industry spent $13.5 billion (in 2006 dollars) on cigarette advertising and promotion. On the other hand, there is strong evidence to indicate that media campaigns can reduce tobacco use, thereby underscoring the need for adequately funded mass media campaigns. The US National Cancer Institute's Tobacco Control Monograph 19 has the most current and comprehensive review of the scientific literature on media communications for both promotion and control of tobacco use.[13]

In the United States, litigation has also proven valuable in advancing tobacco control. Miura and colleagues[14] provide an overview of this complex topic. Three waves of litigation have taken place in the United States, the first beginning in the 1950s with the recognition that smoking causes disease and premature death. This first wave proved unsuccessful because the foundation of causation had not yet been firmly established and because the plaintiffs' lawyers had insufficient resources to deal with the industry. The second wave began in the 1980s with a more secure scientific foundation, shifting societal norms, and the use of the industry's failure to issue warnings as to the dangers of tobacco products. The *Cippolone* case is the best known of the second-wave series.[15] This was the first case in which jurors saw the industry's conduct through its own documents and consequently found the industry to be at fault, although a lengthy appeal process followed.

The third wave has proved to be the most significant for tobacco control. This litigation began in the 1990s as the public became aware of the industry's misleading behavior and manipulation of nicotine delivery to sustain addiction. The third wave included individual cases, class-action cases involving large groups of individuals injured by tobacco smoke (such as flight attendants exposed to SHS), cases brought by state agencies for recovery of tobacco-related health expenditures, and fraud cases relating to the claims of products being "light" and "low-yield." The litigation, particularly the Minnesota litigation, led to the eventual release of the industry's internal documents. These documents have proven to be a rich source of insight into the industry's tactics for marketing and promoting its products, its level of understanding of the risks of cigarettes, its focus on delivering nicotine and maintaining addiction, and its tactics aimed at maintaining controversy regarding scientific evidence on tobacco.[16]

The states initiated litigation to recover expenditures for health-care costs by state assistance systems (Medicaid). Several of the first states to bring such litigation settled independently with the tobacco industry, but most were participants in the Master Settlement Agreement. This agreement brought the states a total of $20 billion and created the American Legacy Foundation.[17] However, the Master Settlement Agreement has done little for tobacco control because the states have used the funds largely as a general revenue stream, rather than following the best practices for state tobacco control programs as recommended by the Centers for Disease Control and Prevention.[17]

Litigation is less common outside the United States, but, increasingly, advocates have been bringing innovative lawsuits in other countries as well.[18] Australia, India, and Uganda have seen major rulings on the dangers of SHS. In 1992, an Australian state court made the first award outside the United States on behalf of a worker harmed by SHS. The Supreme Court of India granted a public interest writ filed by the President of the Mumbai Regional Congress Committee against the Union of India and major Indian tobacco companies. The court ordered Indian states to immediately ban smoking in many public arenas, such as hospital buildings, educational institutions, libraries, court buildings, public conveyances, and public offices. However, in many countries, litigation has proven extremely difficult to sustain. Britain, for example, has not been hospitable to anti-tobacco litigation, with negative judicial decisions forcing group action to be abandoned.[19]

The FCTC

Not until the late 1980s and early 1990s did tobacco control advocates in developed countries begin to share successful tobacco control programs and technical expertise with public health colleagues in developing countries.[20–23] This communication was driven by the realization that the increasing international activities of the major tobacco companies were creating a public health crisis in developing countries. By the mid-1990s, a small number of developing countries, including Poland, Thailand, and South Africa, were successful in pushing through tobacco control policies based on experiences in more developed countries.

In 1994, at the 9th World Conference on Tobacco or Health in Paris, Ruth Roemer, an academic and a tobacco control advocate from California, and Allyn Taylor, then a doctoral student from Columbia, drafted a resolution encouraging the development of a framework convention for tobacco control to respond to the increasingly trans-border nature of tobacco use. The resolution marked the first international forum in which the idea of the Framework Convention on Tobacco Control (FCTC) was formally discussed. Only 2 years later, in 1996, the World Health Assembly endorsed the idea of the FCTC and, in 1998, the World Health Organization (WHO) Member States adopted, by consensus, a resolution leading toward accelerated multilateral negotiations on an FCTC and possible related protocols.[24] The initiation of the FCTC process marked the first time that the Member States of the WHO enacted the Organization's power under Article 19 of its constitution to negotiate and sign a binding treaty aimed at protecting and promoting public health. It was also the first time that states cooperated worldwide in a collective response to the causation of avoidable chronic disease.

The FCTC was developed as an evidence-based treaty. As such, an expert working group was created in 1998 to consolidate the scientific evidence for the WHO convention and possible protocols. The FCTC Working Group met twice as it developed its technical report to the World Health Assembly. The formal FCTC negotiations took place between 2000 and 2003. Six formal negotiating sessions, each lasting for ~1 week, were held in Geneva during that period, in addition to numerous regional negotiating sessions and technical conferences. More than 170 states participated in at least one of the negotiating sessions.

The WHO Member States unanimously adopted the final text of the FCTC[25] in May 2003. Many universal elements of national tobacco control policies became core provisions of the FCTC's final text (**Table 1**). The key provisions include a comprehensive ban on tobacco advertising, promotion, and sponsorship (with an exception for countries, such as the United States, which deem such a ban to be unconstitutional); a ban on misleading descriptors intended to convince smokers that certain products are safer than "standard" cigarettes (for example, the term "lights" in Marlboro Lights); and a mandate to place rotating warnings that cover at least 30%

Table 1 Key provisions of the FCTC aimed at demand reduction

Article 6: pricing and tax measures to reduce the demand for tobacco	Recognizes that pricing and tax measures are an effective and important means of reducing tobacco consumption, especially among young people
Article 8: protection from exposure to tobacco smoke	Requires Parties to adopt and implement effective measures "providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places, and as appropriate, other public places"
Article 9: regulation of the contents of tobacco products	Obligates countries to require that manufacturers and importers of tobacco products disclose to government authorities information about product contents and emissions. Measures for public disclosure must be adopted
Article 10: regulation of tobacco product disclosures	Conference of the Parties is to develop guidelines that can be used by countries for testing, measuring, and regulating contents and emissions. Parties must adopt pertinent measures at the national level
Article 11: packaging and labeling of tobacco products	Requires Parties to adopt and implement effective measures requiring large, clear health warnings, using rotating messages approved by a designated national authority. Provides that these warnings should cover 50% or more of the principal display areas and must occupy at least 30% of tobacco packaging Requires the Parties adopt and implement effective measures to ensure that tobacco product packaging and labeling do not promote a tobacco product by any means that is false, misleading, deceptive, or likely to create an erroneous impression about the product's characteristics, health effects, hazards, or emissions
Article 12: education, communication, training, and public awareness	Requires the adoption of legislative, executive, administrative, or other measures that promote public awareness and access to information on the addictiveness of tobacco, the health risks of tobacco use and exposure to smoke, the benefits of cessation, and the actions of the tobacco industry
Article 13: tobacco advertising, promotion, and sponsorship	Requires, in accordance with constitutional limitations, a comprehensive ban on all tobacco advertising, promotion, and sponsorship
Article 14: demand-reduction measures concerning tobacco dependence and cessation	Requires creation of cessation programs in a range of settings, including diagnosis and treatment of nicotine dependence in national health programs and the establishment of programs for diagnosis, counseling, and treatment in health-care facilities and rehabilitation centers

Adapted from Framework Convention on Tobacco Control (FCTC), http://www.who.int/fctc/text_download/en/index.html (accessed 17 February 2009).

of tobacco packaging, with encouragement for even larger, graphic warnings. The FCTC also encourages countries to implement smoke-free workplace laws, address tobacco smuggling, and increase tobacco taxes.

The FCTC entered into force in February 2005 after 40 countries had ratified the treaty. By the time the first Conference of Parties (COP) was held in February 2006, 115 nations had ratified the treaty, including many of the treaty's strongest critics such as Japan, China, and Germany. Many governments around the world, signatories and nonsignatories alike, adopted new tobacco control measures during the period of the FCTC negotiations and following its entry into force so as to better align themselves with the treaty's goals. New Zealand, for example, passed a new law regarding the size of warning labels on tobacco products and is now in compliance with all articles of the FCTC. The Indian Parliament responded to the FCTC process by passing the Cigarettes and Other Tobacco Products Act, 2003 and approved ratification of the treaty. The Philippines' Tobacco Regulation Act of 2003, limiting the sale, sponsorship, and advertising of tobacco products, was a step toward the country's signing of the FCTC in October 2003. The government of Uganda signed the FCTC in March 2004 and implemented a ban on smoking in public places. This was done despite the tobacco industry being seen as bringing prosperity to the country.

The FCTC process has continued to evolve over the past 3 years. To date (early 2009), 168 countries have signed the treaty and 162 countries have ratified it. However, implementation of the treaty's text remains a challenge in many countries, especially low- and middle-income ones. Only two populous nations have yet to ratify the treaty: Indonesia and the United States. The COP has adopted guidelines for a number of the treaty's Articles, including those relating to SHS. Negotiations are also ongoing with regard to the treaty's first protocol—the Protocol on Illicit Trade of Tobacco Products.

MPOWER

Building on the FCTC process, the WHO released its first "Report on Control of the Tobacco Epidemic," titled "MPOWER," in 2008.[26] MPOWER stands for a set of six key tobacco control measures that reflect and build on the policy approaches embedded in the WHO FCTC, including monitoring the epidemic; offering assistance in quitting; protecting nonsmokers from exposure to SHS; warning smokers of the health effects of smoking with strong, effective health warnings; enforcing advertising bans; and raising taxes on tobacco products.

The report, which surveyed tobacco control policies worldwide, concludes that no country has carried out all of the antismoking measures necessary to forestall illness and that only 5% of the world's population reside in countries that fully protect their residents with any one of the crucial measures required to reduce smoking rates.

As part of the report, the WHO also collected the best available prevalence data on tobacco use from all its Member States. The preparation of the report helped to highlight the urgent need to conduct nationally representative and comparable prevalence studies. In response to this need the WHO, in collaboration with the US Centers for Disease Control, has launched the Global Adult Tobacco Survey.[27] The survey protocol is currently being implemented, and comparable national data should be forthcoming over the next several years from the most populous developing countries.

FUTURE OF TOBACCO CONTROL

The role of harm reduction

Tobacco harm reduction is the general term used to describe the scientific, policy, legal, and communications issues raised

by products designed to promote the continued use of tobacco while holding out the promise of reduced risk of tobacco-related disease.[28] A fractious debate is in progress with regard to the role of harm-reduction strategies in tobacco control. The debate centers on how scientific investigation can establish whether novel products or methods will reduce risks to health for individual smokers, or at least reduce exposures likely to influence risks; how a determination can be made as to the likely population impacts of the introduction and marketing of these novel products; how health professionals and consumers can be made aware of the potential and limits of harm reduction; and what role is possible and desirable for governmental regulation.[29] This topic has been the focus of two committees of the Institute of Medicine, which provided influential reports and coined the term "potentially reduced exposure products."[30]

Underlying the current debate is the recognition that harm-reduction strategies in two previous generations of cigarette modifications have already ended in failure: filtered cigarettes in the 1950s and cigarettes with low tar and nicotine yields in the late 1960s and early 1970s. In both cases the products were introduced to offer smokers an ostensibly less hazardous smoking experience and, therefore, an alternative to quitting.[31] These modifications, although lowering yields as measured by a machine, had no significant consequences for doses of smoke delivered to smokers because smokers tended to compensate for the lower yield. The industry, however, marketed products under brand names that included terms such as "light" and "ultra light" with the underlying intent of implying reduced risk to health. However, there is no scientific basis for such claims, and multiple groups of experts have concluded that no benefits have been documented in smokers for so-called lower-yield products as measured by a machine.[31–33]

In her ruling,[4] Judge Kessler found that the tobacco companies had engaged in misleading conduct, and enjoined the industry to desist from further use of deceptive brand descriptors that implicitly or explicitly convey to the smoker or potential smoker that they are less hazardous to health than full-flavor cigarettes, including the popular descriptors "low tar," "light," "ultra light," "mild," and "natural." The ruling also ordered the industry to issue corrective statements in major newspapers, on the three leading television networks, on cigarette "onserts," and in retail displays, regarding (i) the adverse health effects of smoking; (ii) the addictive nature of smoking and nicotine use; (iii) the lack of any mitigation of ill effects from smoking "low tar," "light," "ultra light," "mild," or "natural" cigarettes; (iv) the industry's manipulation of cigarette design and composition to ensure optimum nicotine delivery; and (v) the adverse health effects of exposure to SHS. The tobacco industry is appealing this decision.

Regardless of this history, the tobacco industry has continued to direct substantial resources to developing products that potentially lead to less exposure to disease-causing smoke components, i.e., potentially reduced exposure products. Potentially reduced exposure products that contain tobacco have been on the market for several years.[30] These products include modified tobacco products that claim to reduce the levels of selected toxins.[28] The claimed reductions are achieved by using different curing or fermentation processes or by adding chemicals such as palladium to the tobacco leaves (e.g., Advance and OMNI cigarettes and Revel smokeless tobacco). In addition, products that are claimed to significantly reduce nicotine levels have been developed by genetically engineering the tobacco plant (e.g., Quest). There are also products that are nicotine delivery devices (e.g., Eclipse, Accord), that heat rather than burn tobacco. The industry claims that these have lower emissions of toxic combustion products. Finally, the use of oral noncombustible tobacco products in lieu of smoking has been proposed as a method of reducing health risks among cigarette smokers (e.g., Ariva, Exalt, Revel).

Oral tobacco products have long been available; they sustain addiction but are associated with a lower risk of ill effects than products involving tobacco combustion, particularly cigarettes. These oral tobacco products are causally linked to oral cancer and possibly pancreatic cancer, and concern persists about the possibility that they increase the risk of cardiovascular disease. There is a variation in risk associated with the different products. Swedish snus, a moist snuff that is low in tobacco-specific nitrosamines, has received particular attention because it is widely used in Sweden, apparently with little increase in risk of developing cancer or cardiovascular disease.[34] Among Swedish men, it is the most widely used tobacco product; observational evidence suggests that its availability has not increased tobacco use more generally.[35] However, there is concern that strategies to proactively introduce lower-risk products will diminish efforts to promote prevention and cessation. In addition, the tobacco industry in the United States is moving to introduce snus, possibly with the intent of providing a nicotine-delivering product that can be used in circumstances in which smoking is not possible, thereby sustaining addiction.

The role of cessation

To reduce the burden of smoking-induced disease, both prevention and cessation are essential aspects of strategy; prevention reduces the numbers of new smokers, whereas cessation brings the benefits of reduced disease risk. To achieve an immediate impact on the smoking-attributable disease burden, tobacco control strategies need to include effective cessation modalities. Prevention initiatives directed at youth will begin to show an impact only when the birth cohorts that have benefited from prevention reach middle age, which is generally the time of life when smoking-induced diseases begin to occur.

Apelberg, Samet, and colleagues have modeled the impact of tobacco control initiatives using the relative risks reported in the American Cancer Society's Cancer Prevention Study II. They simulated the avoidable disease burden in Japan[36] and in the United States.[37] The model incorporates estimates of how relative risks decline after cessation so that the impact of an intervention can be estimated over time. The model includes most of the major tobacco-induced diseases, except for chronic obstructive pulmonary disease.

For the United States, Apelberg and Samet[37] considered various policy scenarios, including setting 100% cessation

immediately as yielding the maximum, albeit unachievable, benefit. The projections of cumulative avoidable deaths for the 20-year span 2006–2025 showed a 7% reduction in all-cause mortality in smokers under the 100% scenario; a more realistic, feasible scenario proposed by the Institute of Medicine[30] was predicted to reduce total mortality by 1%. Reductions in rates of initiation were shown to have no consequence over the 20-year span. For Japan,[36] a country-specific model gave estimates of 46,000 lung cancer deaths and 56,000 cardiovascular-related deaths that could be avoided over 20 years if cessation rates increased to the level of the United States. The use of nicotine replacement therapy was estimated to increase these figures by ~40%.

One consistent finding in tobacco users in developed countries is their desire to quit. The majority (68%) of cigarette smokers in Britain say they want to stop smoking. In the United States, the proportion of current everyday smokers who tried to quit in 2007 was 53.1% among persons aged 18–24 years, 39.9% among those aged 25–44 years, 38.1% among those aged 45–64 years, and 25.3% among those aged >65 years. In 2007, the success rate of smoking cessation among young American adults was 8.5%, as compared to 5.0% in older adults.[38] Since 2002, former smokers have outnumbered current smokers in the United States.[39]

In contrast, cessation rates in developing countries remain very low. In China, for example, <11% of smokers have ever tried to stop smoking, and only 2% have succeeded. However, Global Youth Tobacco Survey data indicate that a majority of current youth smokers in developing countries want to stop smoking and have already tried to quit, although very few students who currently smoke have ever attended a cessation program.[40]

If tobacco control programs are to have a significant impact on the global burden of disease in the short-to-medium term, they must be successful at getting current smokers to quit. In ratifying the FCTC, countries have agreed to develop and disseminate appropriate, comprehensive, and integrated guidelines based on scientific evidence and best practices, and to take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence. However, the FCTC wording is rather ambiguous and weak, and there have been calls for a specific Protocol on the Treatment of Tobacco Dependence. The most recent FCTC COP-3 agreed to establish a working group to elaborate guidelines for Article 14 (to demand reduction measures concerning tobacco dependence and cessation) that will be presented to COP-4 in 2010. Offering treatment to people who are addicted to nicotine is also one of the six basic measures advocated by the WHO in its MPOWER package.[26] Three types of treatment are recommended: (i) tobacco cessation advice incorporated into primary health-care services; (ii) easily accessible and free quit lines; and, (iii) access to low-cost pharmacological therapy.

Low-cost pharmacotherapies could play a role globally. Nicotine replacement therapy may be the most widely applicable agent. Data show higher success rates with the use of such products than for unaided quit attempts, and in some communities there is growing familiarity with the range of products and approaches available. However, there are major challenges at the global level concerning the role of nicotine replacement therapy and other pharmaceuticals. Traditional approaches to the packaging and marketing of pharmacological products for smoking cessation will not be viable for the majority of smokers who are poor, who live in developing countries, and who cannot afford the treatments that have been developed to date. Even if they could afford the products, these smokers lack awareness and understanding of how the products could help with cessation. Different cultural norms and economic realities will necessitate altered delivery mechanisms that are appropriate locally, as has been the case in developed countries (e.g., gum, lozenge, or patch). The recent global economic downturn makes it even more unlikely that governments in developed countries, let alone developing countries, will dedicate scarce public health resources to the provision of free smoking cessation products. However, the challenge of providing effective and low-cost pharmacological therapy must be met if the global burden of disease from tobacco is to be reduced in the next half century.

The role of regulation

Although the deadly effects of tobacco were not well characterized until the 1950s, the effects of nicotine on the body were recognized much earlier. In 1890, tobacco appeared in *Pharmacopoeia*, an official US government listing of drugs.[41] However, the reference to tobacco was dropped prior to the passage of the 1906 Food and Drug Act, the legislation that created the US Food and Drug Administration (FDA), after tobacco companies threatened that tobacco-growing states would not support the law as long as tobacco was included in the list of drugs to be regulated by the new agency. Since that time, tobacco has been in a regulatory vacuum, defined neither as a food or a drug. As recently as the year 2000, the US Supreme Court cited the 1906 Pure Food and Drug Act to justify its decision that the FDA had no authority over tobacco, despite evidence that "tobacco use, particularly among children and adolescents, poses perhaps the most significant threat to public health in the U.S."[42]

The lack of regulatory mechanisms in the United States has had global consequences. By the year 2000, only a few countries required that tobacco companies disclose even the most basic information regarding the contents of their cigarettes or provide customers with basic information regarding the products they are consuming. The industry has used well-funded and sophisticated corporate lobbying to resist regulation of their products.[43] This lobbying effort, undertaken by the companies and third parties, targets governments, international institutions, and the media.[7,44] In the Middle East, for example, the major transnational tobacco companies operating in the region formed the Middle East Working Group, which later became the Middle East Tobacco Association, to promote and defend the interests of the companies in the region.[44] In Africa the industry developed the International Tobacco Growers' Association to lobby on its behalf. The International Tobacco Growers' Association, along

with other international consortiums, lobbied the United Nations Food and Agricultural Organization and WHO in particular.[45]

The US Congress has remained a vital target of the tobacco lobby. During the first half of 1998, for example, the industry reportedly spent more than US$43 million to lobby against federal tobacco legislation sponsored by Senator John McCain.[43] Nonetheless, as this article was written, legislation is under consideration in Congress that would lead to regulation of the tobacco industry by the FDA. The provisions of the bill include strengthening of advertising restrictions and prohibitions on marketing to youth; requiring new and more prominent warning labels; compelling companies to disclose all ingredients in tobacco products; and authorizing the FDA to restrict harmful additives, as well as to monitor and reduce nicotine yields. A new division of the agency, funded by user fees paid by the industry, will implement and enforce these regulations. The legislation explicitly prohibits companies from making claims that their products are approved by the FDA. The bill bans candy and fruit flavorings that have recently been used to make cigarettes more appealing to young people, but its failure to prohibit the use of menthol has drawn considerable criticism from tobacco control groups and former health officials. The bill treats menthol as it does other potentially harmful substances in cigarettes: if the FDA were to find that menthol is dangerous, it could limit or ban its use in the future. The legislation prohibits the FDA from banning tobacco sales or the use of nicotine in tobacco products, but the agency could eventually mandate the reduction of nicotine to nonaddictive levels.

Philip Morris, the dominant player among the US tobacco companies, has endorsed the bill, whereas the other major companies vigorously oppose it. Some argue that FDA regulation would cement Philip Morris's sizable market advantage in the United States. However, even as Altria (the domestic parent company of Philip Morris USA) was acceding to FDA regulation, it spun off the far more profitable Philip Morris International. Philip Morris International, well understanding that future profits in the cigarette trade will come largely from sales abroad, is currently setting up its headquarters in Lausanne, Switzerland, far from the regulatory authority of the FDA. Consequently, even if FDA regulation fulfills its promise of further reducing smoking-related morbidity and mortality in the United States, in the future it will be critical that tobacco regulation efforts take a global approach.

The FCTC outlines a global regulatory framework in Articles 9, 10, and 11. The second session of the FCTC COP decided[46] to set up a working group to further develop guidelines or a progress report pursuant to Articles 9 and 10 regarding, in a first phase, the testing and measuring of tobacco product contents and emissions. The working group's report concluded that the development and validation of guidelines setting out these methods will take several years, given the amount of work required and the complexity of the issues faced, and that this complexity calls for considerable prudence in approach. In addition to the FCTC COP process, the WHO Study Group on Tobacco Product Regulation is working on a proposed global product testing strategy.[47]

Many tobacco control advocates remain highly skeptical of the potential benefits vs. pitfalls of global regulation and product testing, especially given the diversity of products in use throughout the world. Product testing strategies might be feasibly implemented where tobacco is still largely used in the form of manufactured cigarettes, and where only a few companies sell cigarettes. Given the uniformity of the product, representative testing should be possible in countries like the United States, for example. By contrast, there are numerous products in India for which testing methods have not yet been developed and for which test compounds and biomarkers have not been established. Even the development of protocols for obtaining representative samples would be difficult, given the likely heterogeneity of the tobacco and tobacco products across the various regions of the country. Despite these challenges, science-based guidance will be needed in the future regulation of and communication about the diverse tobacco market.

The role of capacity building

The FCTC and the subsequent MPOWER report highlight a key weakness in current global efforts to control tobacco—domestic capacity. Despite national commitments to tobacco control, as evidenced by ratification of the FCTC, most developing countries do not have the national infrastructure and resources in place to effectively implement the necessary measures. Although the FCTC calls for the development of mechanisms to help countries build their capacity, specific assistance mechanisms have yet to be developed. In countries where the necessary infrastructure does exist, there is often an unwillingness to assign the resources required to prevent further tobacco-related death and disease among their own populations, let alone to help subsidize measures to control tobacco use in other countries.

Over the past 2 years, private foundations—in particular, Bloomberg Philanthropies and the Gates Foundation—have stepped up to fill the resource gap. This private funding is supporting the development of government infrastructure, public education, and policy advocacy in the countries where tobacco-related illness burden is the highest.

These private initiatives have come at a critical juncture in ongoing global tobacco control attempts. Without these investments, the momentum gained throughout the FCTC process could have been lost. However, future sustainability still depends on lasting commitments from governments to provide the necessary resources to support effective tobacco controls.

Both immediate and long-term capacity development are urgently needed in many countries. Experiences in several countries have shown that a few, or even just one, trained and committed tobacco control professional can have a substantial impact. However, in many developing countries there is not even one individual working full time on tobacco control, and research capacity in the area of public health in general is often too low to bring about the necessary changes.[48]

Research capacity in the area of tobacco control needs attention in the future. In many countries, the few researchers active

in this area work in weak institutions and have multiple demands on their time that too often crowd out research on tobacco control. In many countries, national research bodies give low priority to tobacco control in general, and policy research more specifically. Within such a largely unsupportive environment, capacity development for tobacco control research typically suffers. In the short term, there is the need to develop the surveillance infrastructure to monitor the development of the tobacco use epidemic within countries, and further research is needed in a number of countries on the applicability and effectiveness of a range of internationally promoted policies. For example, the range of low-cost tobacco products in some countries may reduce the effectiveness of traditional tax interventions. In India, for example, a tax increase may simply prompt smokers to switch from higher-cost cigarettes to far cheaper bidis.

Capacity building as regards training is also needed, both short term and long term. Developed and developing countries must build a core of tobacco control professionals and institutions that will sustain tobacco control initiatives across these countries for decades to come. A number of capacity-building programs have been carried out throughout the world, but further programs and the development of the technological infrastructure to sustain in-country programs are urgently needed. One available resource is the free training website http://globaltobaccocontrol.org, which contains more than 40 lectures from the world's leading tobacco control experts.

To avoid repeating past mistakes in building sustainable capacity, it is vital to learn the reasons for success/failure in other programs that may be applicable to tobacco control.[48] Further, the possibility of linking development of tobacco control capacity to other public health research programs needs serious consideration. The expertise within countries with strong tobacco control capabilities should be drawn on to build global capacity. In doing so, new forms of pairing between institutions at varying levels of capability should be considered and tested.

CONCLUSION

From a twentieth-century viewpoint, the current status of tobacco control could not have been anticipated: declining smoking rates in many countries, smoke-free cities, states, and countries, and an international treaty, ratified by most nations, that obligates tobacco control. This remarkable outcome was driven by credible scientific evidence, a global industry in need of regulation, strong champions, and intense information sharing between countries at multiple levels—and major shifts in international treaty making.

Despite this progress, much hard work lies ahead to continue to change behavior and social norms relating to the use of tobacco. The economic and health benefits of tobacco control will depend on the effective implementation of comprehensive policy approaches, including higher taxes that serve as an incentive for smokers to reduce their consumption or quit, bans on indoor smoking so as to protect nonsmokers and reduce the amount of time available for a smoker to indulge his or her habit, effective warning labels that refer to treatment, large mass media campaigns that educate the public and denormalize smoking behaviors, and stricter bans on tobacco advertising, including banning of television and movie scenes showing people smoking. Such policies and programs will prevent youth from starting smoking, drive the demand for effective smoking cessation products, and lead to the achievement of the full economic and health gains of effective tobacco control.

CONFLICT OF INTEREST

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