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Ending the Tobacco Problem: A Blueprint for the Nation
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ENDING THE TOBACCO PROBLEM

A BLUEPRINT FOR THE NATION

Committee on Reducing Tobacco Use:
Strategies, Barriers, and Consequences
Board on Population Health and Public Health Practice

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choices—runs into serious difficulty when the underlying product creates serious long-term individual and societal harms, has addictive properties, and is usually chosen by young people who fail to appreciate the associated risks.

TOBACCO PRODUCTS ARE INHERENTLY DANGEROUS

As they are now designed, tobacco cigarettes are inherently dangerous products that would not be allowed to enter the marketplace if their effects were known and if they were being introduced for the first time. For example, the nicotine in tobacco products would meet the criteria for classification of a Schedule 1 drug under the Controlled Substances Act, tobacco smoke could be classified as a "toxic substance" posing an "unreasonable risk" under the Toxic Substances Control Act, and tobacco cigarettes (and perhaps other tobacco products) could be characterized as "unreasonably dangerous product[s]" under the Consumer Product Safety Act, if tobacco products were not exempted from regulation by the specific exclusionary language in each of these statutes. If tobacco products were within FDA jurisdiction under the Federal Food, Drug, and Cosmetics Act, pre-market approval from the FDA would be required, and it could safely be predicted that such approval would not be forthcoming in light of the addictive properties of nicotine and the multitude of dangerous constituents in tobacco smoke.

However, tobacco products were introduced into the marketplace not only before their adverse effects were understood but also before any modern consumer protection or environmental health legislation had been enacted. The early efforts to suppress the sale of cigarettes, largely on moral and hygienic grounds, occurred at the state level, but most of the early bans had been repealed by 1925. The advent of mass production capabilities in the late 19th century, waning opposition from temperance groups during the first third of the 20th century, and the explosion of smoking during and after World War II catapulted the cigarette to the status of one of the most successfully marketed consumer products in the nation's history. Given such a deep entrenchment in the cultural, social, and commercial life of the country, it is hardly surprising that the burden of demonstrating the need for any substantial regulatory restriction has rested on the proponents of regulation. As indicated in Chapter 3, however, this burden has now been convincingly met. The harmfulness of cigarettes is no longer disputed, even by the manufacturers; and the rhetoric of personal freedom has been softened by a general recognition of the powerful grip of nicotine addiction, the purposeful manipulation of that addictive potential by the manufacturers, and the hazardous effects of secondhand smoke on nonsmokers. Hence the burden has been shifting to the tobacco companies to explain why they

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should be permitted to continue to promote and market this admittedly dangerous product.

The central point is that cigarettes and other tobacco products are not ordinary consumer products. For no other lawful consumer product can it be said that the acknowledged aim of national policy is to suppress consumption. For alcohol, the generally accepted aim of national policy is to suppress underage drinking and excessive or otherwise irresponsible use by adults; reducing adult consumption per se is not the nation's goal. Indeed, in many respects, state and federal governments aim to facilitate alcohol consumption, such as by liberalizing access (IOM/NRC 2004). Similarly, although firearms are indisputably dangerous products, and their unlawful sale, possession, and use is suppressed, their lawful use is widely regarded as a valued constitutional right, and many aspects of recent changes in state law have been designed to facilitate access to weapons by lawful purchasers and owners. In terms of its goal, tobacco policy has more in common with the nation's policy toward marijuana and other illegal drugs than it does with policies pertaining to alcohol or firearms.

It has become commonplace for critics of aggressive tobacco control measures to invoke the classic slippery slope argument, claiming that restrictions on tobacco will lead down the slope to measures taking away food and drinks that people like on the ground that they are not healthy enough. After all, it is said, if the "nanny state" is empowered to suppress tobacco use, it will go after the Big Mac® next. This argument underappreciates the extent to which tobacco products are unlike ordinary consumer products. Tobacco is a highly addictive, carcinogenic, and deadly product. Foods rich in fats or carbohydrates may lead to overweight and increase disease risks if consumed in excess, but they are not addictive or inherently dangerous. It therefore bears repeating that tobacco is the only lawful consumer product for which the nation's unequivocal aim is to suppress consumption altogether—rather than promoting informed, healthy choices and moderation.

That being the case, governments at all levels must play a central role in the effort to overcome and reverse the forces that create and sustain tobacco use. Governments have both the authority and the obligation to establish and sustain conditions under which people can be healthy while respecting the constitutional liberties and other important values (IOM 1988, 2003). People trust and expect the government to protect children from hazards such as poisons, lead, and tobacco; to prevent the tobacco industry from misleading people and drawing them into or sustaining an addictive behavior that they will regret; to counteract industry efforts to stimulate and sustain demand for its dangerous products; and to help people quit if they want to do so.

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nicotine yields and reduction or elimination of other constituents, wherever such a standard is found to be appropriate for protection of the public health, taking into consideration the risks and benefits to the population as a whole, including users and non-users of tobacco products; and

- **to develop specific standards for evaluating novel products that companies intend to promote as reduced-exposure or reduced-risk products, and to regulate reduced-exposure and reduced-risk health claims, assuring that there is a scientific basis for claims that are permitted.**

These recommendations are generally compatible with Articles 9-11 of the WHO Framework Convention on Tobacco Control (WHO 2003).

MESSAGES ON TOBACCO PACKAGES SHOULD PROMOTE HEALTH

The tobacco industry has long used cigarette packaging to identify and market its products, and governments have long used cigarette packaging to convey messages about tobacco risk and exposure. As legal restrictions have increasingly reduced or eliminated media advertising, the importance of the package as a vehicle for promotion has increased (Slade 1997). The packages carried by smokers serve as mobile advertisements for particular products. Promotional displays of packages in retail outlets are also key marketing tools. In response to the increasing importance of the package in promotion, governments have begun to exert more control over packaging characteristics for the dual purposes of reducing this form of marketing and communicating directly with consumers.

Among the reasons for regulatory interest in tobacco packaging are

- communicating product information to consumers and potential consumers,
- warning consumers about hazards and thereby discouraging consumption,
- communicating other health information (e.g., cessation hotline numbers),
- preventing smuggling (by requiring documentation of excise tax payment),
- preventing misleading messages by tobacco companies and providing corrective information to counteract previous deceptions,
- preventing promotional messages by tobacco companies as other avenues of advertising are curtailed, and
- "denormalizing" tobacco products.

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The use of packages to convey tobacco-related health risks has a number of potential advantages over other forms of communication. The frequency of exposure is high. The messages are delivered at the moment a smoker desires another cigarette. The messages on packages also communicate information to the public at large, and not merely the consumer.

Package Warnings Regarding Tobacco-Related Health Risks

Congress first required health warnings on cigarette packages in 1966 and in advertisements in 1972. By 1985, four rotating warnings were required on both packages and in advertisements. However, U.S. package warnings are still not prominent and are located on the side of the package in small print (see Figure 6-1). In 1994, a previous IOM committee made the following observation about this country's tobacco health warnings:

> The adequacy of the current cigarette warnings has been repeatedly questioned by public health specialists. Moreover, in the committee's view federal cigarette labeling legislation has reflected an unsatisfactory compromise between the public's health and the tobacco industry's desire to avoid concurrent state regulation and to reduce its exposure to tort liability. Negotiations in the legislative process have tended to favor the industry. . . . The inadequacy of current labeling policy is clearly revealed in the declaration of congressional purpose in the Comprehensive Smoking Education Act of 1984: It is the purpose of this Act to provide a

FIGURE 6-1 An example of U.S. government's warning on cigarette packages.

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> new strategy of making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings, and to enable individuals to make informed decisions about smoking. It is time to state unequivocally that the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products, especially by children and youths, as a means of reducing tobacco-related death and disease. Even though tobacco products are legally available to adults, the paramount public health aim is to reduce the number of people who use and become addicted to these products, through a focus on children and youths. The warnings must be designed to promote this objective. In the committee's view, the current warnings are inadequate even when measured against an informed choice standard, but they are woefully deficient when evaluated in terms of proper public health criteria" (IOM 1994, p. 236-237).

This committee agrees. Although federal law has remained unchanged for more than 20 years, evidence regarding the ineffectiveness of the prescribed warnings has continued to accumulate. As Krugman and colleagues note, the U.S. package warnings have served the tobacco industry well by reducing their liability exposure while communicating ineffectively with smokers and potential smokers (Krugman et al. 1999). The basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way. In contrast to the messages used in other countries, the United States requires one of four text messages in black and white that occupy only 50 percent of the side of a pack. These messages have not changed in 20 years. They therefore have little effect on decision making or behavior (see Ferrence, Appendix C).

In contrast to the experience with such warnings in the United States, the experiences with these warnings in Canada and other countries have been more promising.

The Canadian Experience

Voluntary health package warnings were introduced in Canada in 1972 but were first imposed by federal law in 1989. Initially, they included four text messages. Five years later, eight stronger messages were introduced, and these messages occupied the top 35 percent of the front and back panels of the pack. These messages clearly specified the diseases and conditions caused by smoking and confirmed that "cigarettes are addictive." These messages were soon adopted in Australia, Thailand, and Poland.

The most important innovation in package regulation is requiring companies to print graphic messages with pictorial content. Graphic warnings were first introduced in Canada in 2001. The manufacturers of cigarettes for sale in Canada are now required to print 1 of 16 health warnings on each pack of

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FIGURE 6-2 Example of one of Health Canada's 16 graphic warnings.
SOURCE: (Health Canada 2005) *http://www.hc-sc.gc.ca/ahc-asc/media/photogal/label-etiquette/img0010_e.html*. Licensed under Health Canada copyright.

cigarettes (see Figure 6-2 for an example of such a warning). The new warning system extends to carton wrappers, which now include a warning on each of their six surfaces. The top 50 percent of each main panel on the package (as opposed to the side panel) must be used for the outside warning. These warnings include a photograph or other illustration, a marker word "Warning," a short summary statement of the warning, and a brief explanation. Inside each pack, there must be 1 of 16 other detailed messages that provide information about quitting or health damage. Warning labels also include information on damage to nonsmokers exposed to smoke from cigarettes. Other tobacco products have similar requirements for warning labels.

Other Countries

Since 2001, several other countries have adopted graphic package warnings including Brazil, Singapore, Thailand, Australia, and Venezuela. Members of the European Union are now permitted, but not required, to prescribe graphic warnings, and the European Union has also developed a standard set of pictorial warnings for consideration by its members. Several other countries (Bangladesh, Hong Kong, India, Malaysia, New Zealand, South Africa, and Taiwan) are currently considering graphic warnings. The World Health Organization Framework Convention for Tobacco Control (FCTC) requires that warnings cover 30 percent of the front and the back of the package and recommends package coverage of 50 percent or more. A series of messages must be rotated. Graphic warnings are permitted but are not required.

Package warning size and placement vary considerably by country. The front of the package is considered the most prominent location

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(Cunningham 2005), and it is probably important to have some health message on all sides, since retailers may position packages to hide the warnings if all sides are not covered.

There are considerable variations in the types of graphics used and in potential emotional impacts of particular graphics. In Brazil, for example, the warnings are more colorful and more dramatic than the Canadian warnings, most showing smokers with obvious health conditions (see Figure 6-3).

FIGURE 6-3 Examples of Brazil's graphic warnings.
SOURCE: See *www.anvisa.gov.br/eng/informs/news/281003.htm*.

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Evidence Regarding Effectiveness

Ferrence and colleagues (Appendix C) have reviewed the scientific evidence regarding the effectiveness of tobacco package warnings in getting the attention of consumers and potential consumers (salience), influencing their awareness of tobacco-related health risks (risk perception), and affecting their self-reported smoking intentions and behaviors. In general, the evidence shows that the salience of warnings is affected by their placement, sizes, and other design features, and that salient warnings affect the consumer's awareness of risks. Although few studies have been able to parse out the effects of warnings on smoking behavior, the available data suggest a beneficial effect on consumption and cessation.

For the committee's present purposes, the question of greatest importance is what is known about the effects of pictorial warnings. Given that Canada was the first country to introduce pictorial warnings, all of the available evidence derives from Canadian smokers. A study conducted with Canadian smokers in 2001 found that more than half reported that the pictorial warnings have made them more likely to think about the health risks of smoking (Hammond et al. 2004). National surveys conducted on behalf of Health Canada also indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information (Health Canada 2005a; Health Canada 2005b).

The International Tobacco Control Policy Evaluation Survey—a cohort survey of a representative sample of more than 8,000 adult smokers from Canada, Australia, the United States, and the United Kingdom—also provides suggestive findings. When smokers were asked to cite the sources of smoking-related health information, approximately two-thirds of all smokers cited cigarette packages; this proportion was more than radio, print, and electronic sources, and cigarette packages were the second most common source after television (Hammond et al. 2005) However, the results varied substantially by country: respondents living in countries with more comprehensive warnings were more likely to cite packages as a source of health information. For example, 85 percent of Canadian respondents cited packages as a source of health information; in contrast, 47 percent of U.S. smokers cited packages as a source of health information. In addition, specific health warnings were associated with knowledge about specific diseases. For example, in Canada, where package warnings include information about the risks of impotence, smokers were more than twice as likely as smokers from the other three countries to agree that smoking causes impotence. Overall, the study found that warnings that are graphic, larger, and more comprehensive in content were associated with greater health knowledge.

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Finally, there is evidence that smokers with less education are less likely to recall health information in text-based messages than people with more education (Millar 1996). Given the inverse association between smoking and educational status, pictorial warnings may be particularly important for communicating with those most at risk. Indeed, preliminary evidence suggests that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels (Siahpush et al. 2006). Pictorial warnings may also be particularly effective in educating people who are illiterate, and could have a significant population impact in developing countries with low literacy rates, as well as regions where numerous languages and dialects are used.

In a series of papers, Hammond and colleagues (2004) have examined the impact of Canadian graphic warning labels on smoking behavior. Smokers who had read, thought about, and discussed the new labels were more likely to have quit, tried to quit, or reduced their smoking at the 3-month follow-up, after adjustment for intention to quit and smoking status at baseline (Hammond et al. 2004). One-fifth of Canadian smokers said that they smoked less because of the labels, whereas only 1 percent said that they smoked more and one-third said that they were more likely to quit because of the warnings. In addition, former smokers identified the pictorial warnings as important factors in their quitting and in subsequently maintaining abstinence (Hammond et al. 2004). Results from the International Tobacco Control Policy Evaluation Survey are consistent with these findings: at least one quarter of respondents from Canada, Australia, the United Kingdom, and the United States reported that package warnings have made them more likely to quit, although Canadian smokers were significantly more likely to report cessation benefits from the warnings than smokers in the other three countries that have text-only warnings (Fong et al. 2004).

As recommended in Growing Up Tobacco Free (IOM 1994) the proposed Tobacco Control legislation would strengthen the required package warnings immediately and would confer authority on the FDA to revise these requirements upon finding "that such a change would promote greater public understanding of the risks associated with tobacco." (The 1994 committee stated that the agency should also be authorized to modify the warnings upon finding that so doing would reduce consumption, such as by making the risks more salient or strengthening the resolve of smokers to quit, and this committee agrees.) The bill would specifically authorize the agency to increase the required label area up to 50 percent of the package and to require color graphics. On the basis of the evidence accumulated thus far, graphic warnings of the kind required in Canada, Brazil, and Thailand "would promote greater public understanding of the risks" of using tobacco and would help reduce consumption.

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Recommendation 26: Congress should strengthen the federally mandated warning labels for tobacco products immediately and should delegate authority to the FDA to update and revise these warnings on a regular basis upon finding that doing so would promote greater public understanding of the risks of using tobacco products or reduce tobacco consumption. Congress should require or authorize the FDA to require rotating color graphic warnings covering 50 percent of the package equivalent to those required in Canada.

Using Packages to Convey Other Health Information

Aside from printed health warnings, regulatory authorities can use the tobacco package to convey health-related information in other ways. For example, so-called package onserts (printed matter that is affixed to the package, and that is equivalent to inserts in drug product packaging) provide an appropriate vehicle for supplementing the health warnings printed on the package with information on ingredients and details regarding specific health hazards. In addition, the package can be used creatively to promote smoking cessation by displaying a quitline number and by including coupons for nicotine replacement products (e.g., patches and gum).

Recommendation 27: Congress should empower the FDA to require manufacturers to include in or on tobacco packages information about the health effects of tobacco use and about products that can be used to help people quit.

Restricting Misleading Messages on Tobacco Packages

Tobacco manufacturers have traditionally used the words and trademarks on the package as a channel for conveying messages about product characteristics. Some of these messages are misleading and are not protected by the First Amendment, because they falsely imply that smoking a particular brand of cigarette is less harmful than smoking other brands.

As Wakefield and colleagues (Wakefield et al. 2004) have noted, package design can help to shape perceptions of a tobacco product's performance and its sensory attributes, even among experienced smokers. This phenomenon is best illustrated by the use of brand descriptors and colors to promote perceptions that the tobacco product is safer than other tobacco products. Tobacco manufacturers commonly pair brand descriptors such as "light" and "mild" with cigarettes that generate low tar yields under the machine testing protocols. Although the industry has argued that these terms refer only to the "taste" of a product, these descriptors help to promote these brands as "healthier" products (Pollay 2001; Pollay

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C

Warning Labels and Packaging

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INTRODUCTION

Cigarette packages are an important medium for communicating with smokers, both for the tobacco industry and for governments seeking to convey the health risks of smoking. As restrictions have increasingly reduced or eliminated traditional forms of tobacco advertising, the importance of the package as a marketing vehicle has increased. At the same time, governments have begun to exert more control over tobacco labeling, including the introduction of more prominent health warning messages. This appendix reviews the effectiveness of tobacco labeling policies and health warnings on cigarette packages.

THE CIGARETTE PACKAGE AS A MARKETING TOOL

Packaging is an important component in the overall marketing strategy of consumer goods (Shapiro et al. 1999). Packaging helps to establish brand identity in competitive markets and serves as an effective form of promotion both at the point of purchase and while the product is being used (Slade 1997). Packaging is particularly important for consumer products such as cigarettes, which have a high degree of social visibility (Pollay 2001). Unlike many other consumer products, cigarette packages are displayed each time the product is used and are often left in public view between uses (Wakefield and Letcher 2002). As John Digianni, a former cigarette package designer noted: "A cigarette package is unique because the consumer carries it around with him all day . . . It's a part of a smoker's clothing, and when he saunters into a bar and plunks it down, he makes a statement about himself" (Koten 1980). As a result, the package serves as a "badge product" and an important form of advertising in its own right (Pollay 2001).

Cigarette packages also serve as an important link to other forms of tobacco advertising (Wakefield et al. 2002a). Package designs help to reinforce brand imagery that is communicated through other media and play a central role in point-of-purchase marketing, which now accounts for a majority of the industry's promotional spending in Canada and the United States (Dewhirst 2004). Indeed, cigarette "power walls"—rows of cigarette packages prominently displayed be-

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hind retail counters—have been shown to be an effective form of marketing, particularly among youth and young adults (Wakefield et al. 2002a). Moreover, marketing value of the cigarette package increases as other forms of marketing are restricted (Celebucki and Diskin 2002; Wakefield et al. 2002b). The following quote from a Phillip Morris executive highlights the importance of the package under increasingly restrictive advertising environments: "Our final communication vehicle with our smoker is the pack itself. In the absence of any other marketing messages, our packaging . . . is the sole communicator of our brand essence. Put another way—when you don't have anything else—our packaging is our marketing" (Hulit 1994).[1] Internal documents from British American Tobacco also indicate that packages have been designed to compensate for restricted forms of advertising: "Given the consequences of a total ban on advertising, a pack should be designed to give the product visual impact as well as brand imagery . . . the pack itself can be designed so that it achieves more visual impact in the point of sale environment than its competitors" (Miller 1986).

Beyond the retail environment, packages also help to increase the reach of "below-the-line" marketing activities (Carter 2003). For example, cigarette packages in Malaysia contain specific references to the sponsorship of Formula 1 racing series, while packs in other countries carry images and information for concert and nightclub promotions. As Pollay (2001) noted, "The package is the last and most critical link in an integrated chain of promotional communications" (Pollay 2001). Overall, the cigarette package is the cornerstone of tobacco marketing strategy and an effective means of targeting key subgroups of smokers, including young adults and women (Carpenter et al. 2005; Chapman and Carter 2003; Chapman and Carter 2003; Cummings et al. 2002; Pollay 2001).

WARNING LABELS

Background

In addition to serving as a marketing vehicle for the tobacco industry, cigarette packages also provide governments with a direct means of communicating with smokers. Warning labels are primarily intended to communicate the health risks of smoking and to fulfill the government's responsibility as regulators to warn consumers about these hazardous products. To date, warnings labels have been introduced on cigarette packages in virtually every jurisdiction; the size and general strength of these warnings, however, vary considerably (Aftab et al. 1999). In most countries, the first warnings to appear on packages were introduced by tobacco manufacturers in response to growing pressure from health authorities and in an attempt to avoid liability for their products (Chapman and Carter 2003). By 1974, government-mandated warnings were required on packages in several countries, including Canada, Costa Rica, Ecuador, Ireland, New Zealand, Japan, Panama, Peru, the United Kingdom, the United States, and some areas of Australia. In the United States, health warnings were first included on cigarette packages in 1966 and in advertisements in 1972. Since 1984, U.S. cigarette packages have carried one of four government-mandated text warnings on the side panels of packages.

The United States is one of the few countries in the developed world that has not updated its warnings in the past 20 years. In contrast, most countries have increased the size, number, and general prominence of package warning labels. Most notably, several countries have introduced pictorial warnings labels. Canada was the first country to require pictorial warnings when they

[1] Originally cited by (Alechnowicz and Chapman 2004).

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were implemented in 2000. The top 50 percent of each main panel on the package features one of 16 warnings. Each includes a photograph or other illustration, a marker word ("Warning") and a short summary statement. Inside each pack, one of 16 text messages provides additional information on the health risks of smoking, as well as cessation-related information.

Since 2000, Brazil, Singapore, Thailand, and Venezuela have also introduced pictorial warnings. Australia is set to do so in 2006, and the European Union (EU) has developed a standard set of pictorial warnings for EU member states to consider. Several other countries, including Bangladesh, India, Hong Kong, Malaysia, New Zealand, South Africa, and Taiwan are also considering implementing pictorial warnings on packages. Indeed, the coming years promise an unprecedented degree of change in labeling policies as countries prepare to meet the standards set out in the Framework Convention for Tobacco Control (FCTC). Article 11 of the FCTC requires that warnings: (1) be approved by the competent national authority; (2) be rotating; (3) be large, clear, visible, and legible; (4) should be 50 percent or more of the principal display areas and no less than 30 percent of the principal display areas; and (5) may be in the form of or include pictures or pictograms. Given that the FCTC recommends—but does not require—pictorial warnings, policy makers in a number of countries will be forced to choose between the minimal and the recommended standards. The following section reviews the evidence on the effectiveness of text and pictorial warning labels that should guide these policy decisions.

Evidence

Salience of Package Warning Labels

Package warnings are unique among tobacco control interventions in that they are delivered at the time of smoking and have a high frequency of exposure that increases with the number of cigarettes per day. Nevertheless, warning labels must be noticed to be effective, and the extent to which smokers attend to warnings depends upon various content and design features. The salience of warnings is enhanced when information is presented in a vivid manner that evokes an emotional reaction (Strahan et al. 2002). Specific, unambiguous warnings (e.g., "cigarettes cause lung cancer") are also more likely to be noticed and less likely to be discounted than vague, equivocal warnings (e.g., "cigarettes are hazardous to your heath") (Linthwaite 1985; Loken and Howard-Pitney 1988; Wegrzyn 1992). Warnings that are attributed to a specific source (e.g., the Surgeon General) have also been shown to be more credible than unattributed warnings (Guttman and Peleg 2003; Wogalter et al. 1999). In addition, text-based warnings should also target an appropriate literacy level (CREATEC Market Studies 2003). The United States warnings, for example, require a college reading level and may be inappropriate for youth and Americans with poor reading abilities (Malouff et al. 1992). This is particularly important considering that, in most countries, smokers report lower levels of education than the general public.

Several design features are also associated with greater salience, including the size and position of the warning on the package (Fong 2005; Willemsen 2005). For example, smokers are more likely to recall larger warnings, as well as warnings that appear on the front of packages as opposed to on the sides (AGB Spectrum Research Ltd. 1987; Health Canada 2005b; Linthwaite 1985; Strahan et al. 2002; Wegrzyn 1992). Several studies indicate that the U.S. text warnings on the side of packages demonstrate low levels of salience among smokers (Crawford et al. 2002; Fischer et al. 1989; Fox et al. 1994). In a comparative study of students in Canada and the United States carried out in 1995, at a time when Canadian packages carried text warnings on the front

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of packages, 83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages, compared to only 7 percent of U.S. students (Northrup and Pollard, 1995). A Phillip Morris document also highlights the importance of positioning on the front of packages: "Government required warnings placed on the largest packaging panel, often called the front and/or back, are the biggest marketing threat to all of us in Asia . . . " (Hulit 1994). Smokers have also been found to equate the size of the warning with the magnitude of the risk (Cragg Ross & Dawson Ltd. 1990). Support for these findings comes from a series of 56 focus groups, conducted across seven European countries, which explored reactions to more prominent warnings in the E.U. (Devlin et al. 2005).

Features that distinguish the warning messages from the package design have also been found to increase the salience and recall of warnings (Laugesen 1990). Messages with black lettering on a white background are the easiest to read, whereas the legibility of silver or gold text messages is comparatively poor (Nilsson 1991; Wegrzyn 1992). Warnings that include pictures or graphics are also more noticeable and more likely to be recalled than text messages (Health Canada 1999). This is consistent with research demonstrating that viewers perceive a greater likelihood of occurrence when presented with graphic depictions of disease (Laugesen 1990).

The salience of warnings labels is not constant over time. Rather, the effectiveness of health communications decreases with repeated exposures (Bornstein 1989; Henderson 2000), and the salience of tobacco warnings has been found to lessen as smokers become desensitized to the warnings over time (Health Canada 1999). For example, more than half of Canadians surveyed in 1999 agreed that warnings introduced in 1994 were "worn out" and had lost their effectiveness (Mahood 1999). It is important therefore to ensure that warnings are revised on a regular basis. Short of introducing new labels, any feature that enhances the vividness of the warnings should prolong their effectiveness (Strahan et al. 2002). In other words, color warnings, pictures, and increases in the number of rotating warnings should delay the wear-out of warnings. Indeed, approximately 4 years after their introduction, Canadian youth and adult smokers report only a moderate decrease in the frequency of reading the labels, with little or no decrease in reports of their effectiveness (Health Canada 2005a; Health Canada 2005b), and 95 percent of youth smokers reported that pictorial warning labels provided them with important information about the health effects of smoking. In addition, a comparative study of smokers in Canada and the United Kingdom found that the 4-year-old pictorial warnings in Canada were more likely to be rated as effective than the large text warnings that were introduced in the United Kingdom in 2003, only months prior to the survey (Fong et al. 2004).

Impact on Health Knowledge

Cigarette warning labels have been shown to have a significant impact on smokers' understanding of the risks of tobacco use. Several studies have demonstrated that large text-based warnings are associated with increased perceptions of risk. Cross-sectional surveys conducted in Canada during the 1990s found that the majority of smokers reported that package warning labels are an important source of health information and have increased their awareness of the risks of smoking (Health Canada 2005a; Health Canada 2005b; Tandemar Research 1996). In Australia, Borland and Hill (1997) found that relative to nonsmokers, smokers demonstrated an increase in their knowledge of the main constituents of tobacco smoke and identified significantly more disease groups following the introduction of new Australian warning labels in 1995 (Borland and Hill 1997). At least two studies have evaluated the effects of the 2003 E.U. directive (2001/37/EC), which mandated that warnings in all E.U. countries meet size standards

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equivalent to the FCTC minimal requirement. First, a study of Spanish university students concluded that text warnings based upon the E.U. directive significantly increased perceptions of risk (Portillo and Antonanzas 2002). These findings were consistent with results from the International Tobacco Control (ITC) Policy Evaluation Survey—a cohort survey of a representative sample of more than 8,000 adult smokers from Canada, Australia, the United States, and the United Kingdom. This quasi-experimental evaluation examined the changes in perceptions and reactions to warnings among adult smokers in the United Kingdom, compared to those in the other three countries, where no changes in warnings had occurred (Fong et al. 2004). The findings indicated that the enhancement in labels led to significant increases in the United Kingdom—relative to the other three countries—in: (1) salience and noticeability of the warnings, (2) thinking about the health risks of smoking, and (3) forgoing a cigarette due to the label.

There is also a growing evidence base on the effectiveness of pictorial warnings in communicating risk. Since Canada was the first country to introduce pictorial warnings, all of this evidence derives from Canadian smokers. A study conducted with Canadian smokers in 2001 found that more than half reported that the pictorial warnings have made them more likely to think about the health risks of smoking (Hammond et al. 2004). National surveys conducted on behalf of Health Canada also indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information (Health Canada 2005a; Health Canada 2005b). Findings from the ITC Survey also provide evidence of the effectiveness of pictorial warnings. When asked to cite sources of health information, approximately two-thirds of all smokers cited cigarette packages—more than radio, print, and electronic sources—and the second most common source after television (Hammond et al. 2006). However, the results varied substantially by country: respondents living in countries with more comprehensive warnings were more likely to cite packages as a source of health information. For example, 85 percent of Canadian respondents cited packages as a source of health information, in contrast to only 47 percent of U.S. smokers. In addition, specific health warnings were associated with knowledge of specific diseases. In Canada, where package warnings include information about the risks of impotence, smokers were more than twice as likely to agree that smoking causes impotence compared to smokers from the other three countries (United States, United Kingdom, and Australia). Overall, the study found that warnings that are graphic, larger, and more comprehensive in content were associated with greater health knowledge.

There is also evidence that pictorial warnings may be effective in communicating health risks to nonsmokers. For example, approximately two-thirds of youth nonsmokers in Canada recently reported looking at the pictorial warnings at least once per week, and 95 percent agreed that the warnings have been effective in providing them with important information about the health effects of smoking (Health Canada 2005b).

Finally, there is evidence that smokers with less education are less likely to recall health information in text-based messages (Millar 1996). Given the inverse association between smoking and educational status, pictorial warnings may be particularly important for communicating with those most at risk. Indeed, there is preliminary evidence to suggest that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels (Yong et al. 2005). Pictorial warnings may also be particularly effective in developing countries with low literacy rates, as well as regions with numerous languages and dialects.

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Impact on Behavior

Few studies have examined the impact of warning labels on smoking behavior; however, those that have suggest a beneficial effect on consumption and cessation. Borland and Hill (1997) found that new text warnings introduced in Australia encouraged some smokers to delay smoking or smoke less of a cigarette (Borland and Hill 1997). Willemsen (2005) looked at the impact of new text warnings on motivation to quit and smoking behavior using data from the Dutch Continuous Survey of Smoking Habits. Among smokers, 14 percent said they were less likely to buy cigarettes as a result of the new warnings, 32 percent said they preferred to buy packages without the warnings, 18 percent said the warnings made them more motivated to quit, and 10 percent said they smoked less because of the warnings. Those who intended to quit within 6 months were five to six times as likely to report smoking less due to the warnings than those who did not plan to quit. In fact, smokers not motivated to quit said their motivation decreased as a result of the warnings. However, since they were not planning to quit before the warnings came into effect, it is not clear that this response represented a meaningful decrease in intent (Willemsen 2005).

In a series of papers, Hammond and colleagues have examined the impact of Canadian graphic warning labels on smoking behavior. Smokers who had read, thought about, and discussed the new labels were more likely to have quit, tried to quit, or reduced their smoking at 3-month follow-up, after adjusting for intention to quit and smoking status at baseline (Hammond et al. 2004). One-fifth of Canadian smokers said they smoked less because of the labels, whereas only 1 percent said they smoked more, and one-third said they were more likely to quit because of the warnings. In addition, former smokers identified the pictorial warnings as important factors in their quitting and in subsequently maintaining abstinence (Hammond et al. 2004). Results from the ITC Policy Evaluation Survey are consistent with these findings: at least one-quarter of respondents from Canada, Australia, the United Kingdom, and the United States reported that package warnings have made them more likely to quit, although Canadian smokers were significantly more likely to report cessation benefits from the warnings than smokers in the other three countries that have text-only warnings (Fong et al. 2004).

Finally, internal documents from the tobacco industry also provide some indication of the effectiveness of pictorial warning labels. For example, research conducted by Rothmans Benson & Hedges in Canada on the pictorial warnings that were introduced in 2000 concluded that "the impact of the new warnings is colossal" (Pollay 2001).

Public Support and Credibility of Warning Labels

Tobacco labeling policies have received strong endorsement from both smokers and nonsmokers. In a 1992 survey, 89 percent of Canadians expressed support for government-mandated warnings, while 83 percent were in favor of more detailed warnings than the text-based messages that were on packages at the time of the survey (Insight Canada 1992). Warning labels have also received strong public support in countries such as Australia (Borland and Hill 1997) and the United States (Jordan 1993). Graphic pictorial warnings have also received public backing. A 1999 national survey of Canadians found that 74 percent of the general public and 59 percent of daily smokers were in favor of regulations requiring warning messages to include pictures and to occupy 60 percent of the front and back of each pack (Environics 2000). High levels of support have also been found in subpopulations, such as young adults (Koval et al. 2005). Focus group testing of the current Canadian warnings found that all participants, regardless of age or smoking status, felt that stronger warnings are more effective in discouraging smoking (Health Canada

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2000). A majority of smokers supported the pictorial warnings even after their introduction: in 2001, only 27 percent of smokers reported that the Canadian warnings contained "too much" health information, whereas 23 percent reported the warnings contain "about the right amount of information," and 50 percent of smokers wanted to see even more health information on packages (Hammond et al. 2004).

Research also indicates that package warnings are perceived to be a credible source of health information. For example, 97 percent of Canadian youth reported that they "believed" the 1994 text-only labels (Environics Research Group 1996), while 86 percent of adult Canadian smokers agreed that the 1994 labels were accurate (Health Canada, 2000). Findings from Australia and the United States also indicate that both smokers and nonsmokers perceive warning labels to be credible sources of information (Beltramini 1988; Cecil et al. 1996; Health Canada 2005b). Graphic pictorial warnings also enjoy high credibility ratings from smokers: in 2002, 87 percent of Canadian smokers reported that the graphic warnings accurately depicted the health risks of smoking (Hammond et al. 2004). A separate survey conducted with youth smokers found that 90 percent agreed that the messages communicated in the pictorial warnings are accurate (Health Canada 2005b).

Cessation-Related Information

In addition to warning about the risks of smoking, cigarette packages can also be used as a vehicle for communicating cessation-related information. In fact, research on public health communications indicates that health warnings are most effective when they are paired with efficacy-related information (Strahan et al. 2002; Witte and Allen 2000). In other words, cigarette warning labels that include information on the benefits of quitting and specific quit methods are most likely to result in behavior change. The Canadian warnings, which include general messages of support, as well as concrete information on ways to quit smoking, are consistent with this literature. The pictorial warnings that have been proposed by the EU include even stronger efficacy information on the outside of packs. Telephone quitline numbers appear to be a particularly important addition to recent warnings. Quitline information already appears on packs in several countries, including Holland, where calls to a national quitline increased dramatically after the number appeared on packages (Willemsen et al. 2002). Website addresses have also been printed on packages in countries such as Canada and represent another means of communicating cessation resources directly to smokers.

Labeling of Constituents

In many countries, tar, nicotine, and other mainstream smoke constituents are required by law to appear on cigarette packages. These cigarette "yields" are determined under the International Standards Organization (ISO) machine testing protocol, which is widely acknowledged to be seriously flawed. The ISO testing protocol is based upon unrealistic smoking parameters that lead to deceptively low yields and exaggerate differences between cigarette brands. Most importantly, ISO cigarette yields are not associated with individual exposure or with health risk (Shopland et al. 2001).

Nevertheless, in most countries, the ISO yields are the only source of constituent information printed on cigarette packages. Not surprisingly, a considerable proportion of smokers use the tar yields when choosing cigarette brands, under the mistaken belief that lower-tar cigarette reduce the risks of smoking (Cohen 1996; Environics Research Group Limited 2003). As a consequence, there is a growing consensus that the ISO yields should be removed from all cigarette

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packages, as will shortly be the case in Australia (WHO 2000). Although the ISO machine testing parameters used to generate the cigarette yields are currently under revision, there is no indication that the revised parameters will generate yields that are more closely associated with individual risk. Until there is persuasive evidence to indicate that the differences in cigarette yields, measured under the ISO protocol or any other protocol, reflect meaningful differences in health risk, there is no benefit to presenting them directly to consumers, who will inevitably interpret lower-yield products as less hazardous.

There is some evidence that nonnumerical constituent information may be more useful in communicating risk to consumers (Environics Research Group Limited 2003). For example, in the place of the cigarette yields, Brazil, Venezuela, and Australia have adopted more "descriptive" approaches to communicating constituents. This includes statements about the health effects of specific chemicals, as well as statements about the overall number of chemicals in tobacco smoke. Additional research is required to determine the most effective means of labeling constituent information on cigarette packages.

Brand Descriptors on Packages

One of the most important functions of packaging is to communicate sensory properties of a brand, such as its "taste" or "lightness." As Wakefield and colleagues (2004) have noted, package design can help to shape perceptions of a product's performance and its sensory attributes, even among experienced smokers (Wakefield et al. 2004). This phenomenon is best illustrated by the use of brand descriptors and colors to promote perceptions of a safer product. Tobacco manufacturers commonly pair brand descriptors such as "light" and "mild" with cigarettes that generate low ISO tar yields under the machine testing protocols. Although the industry has argued that these terms refer only to the "taste" of a product, these descriptors help to promote these brands as "healthier" products (Pollay 2001; Pollay and Dewhirst 2002). Indeed, surveys of smokers in the United States and Canada indicate that a substantial proportion of "light" smokers believe that their cigarettes are less hazardous (Elton-Marshall et al.; Kozlowski et al. 1998; Shiffman et al. 2001). Ashley et al. (2000) report that in Ontario in 1996, one in five smokers of "lights" believed that smoking "light" and "mild" cigarettes lowered the risk of cancer and heart disease (Ashley et al. 2000). In 2000, 27 percent of Ontario smokers said they smoked "lights" to reduce health risks, 40 percent said they used them as a step toward quitting, and 41 percent said they would be more likely to quit if they knew that "light" cigarettes provided the same amount of tar and nicotine as regular cigarettes (Ashley et al. 2001). In a study of smokers' response to advertisements for potentially reduced-exposure tobacco products, "light" cigarettes, and regular cigarettes, Hamilton and colleagues (2004) found that respondents perceived "lights" as having significantly lower health risks and carcinogen levels than regular cigarettes. Adolescents have also been found to have similar misconceptions that "light" cigarettes are less hazardous.

Article 11 of the FCTC calls for the removal of any brand descriptor that "directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products," including terms such as "low-tar," "light," or "mild." Several jurisdictions have already banned deceptive descriptors. For example, in September 2003, the European Union banned the use of a number of brand descriptors, such as "low-tar," "light," "ultra-light," and "mild," in accordance with Directive 2001/37/EC. Findings from the International Tobacco Control Policy Evaluation Survey suggest that this ban has been effective in reducing misconceptions about the health benefits of "light" and "mild" brands (Fong 2005). However, as the United Kingdom experience has demonstrated, tobacco manufacturers have proven adept at substituting

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colors and numbers for the banned descriptors. For example, pale blue or the number "one" are used to indicate a "light" or "mild" cigarette. In Brazil and the United Kingdom, manufacturers openly provided translation guides for this substitution.

Plain Packaging

Plain packaging, devoid of brand logos and images, may be the only way of removing deceptive labeling from packages. Although plain packaging has yet to be mandated in any jurisdiction, it would effectively strip the industry of a critical marketing tool. Two separate studies also indicate that plain packaging would help to increase the salience of health warnings. Goldberg and colleagues (1999) found that plain packaging increased the recall of health warning messages in two of three cases (Goldberg et al. 1999). Short, simple messages appeared to be more effective on plain packages, whereas a longer technical message showed no improvement on a plain package. Beede and Lawson (1992) also found that presenting health warnings on plain packages without brand imagery resulted in a significantly greater recall rate (Beede and Lawson 1992).

Government Regulation and Industry Opposition

The tobacco industry has vigorously opposed comprehensive tobacco labeling policies, especially in the case of pictorial labels (Chapman and Carter 2003). For example, as Alechnowicz and Chapman (2004) have noted, in 1995, package warnings were identified by British American Tobacco (BAT) as one of the key issues facing the company. Protecting the pack design and "neutralizing" the controversy over pack warning labels were among the priorities listed in the document (BAT 1995). The same document goes on to state that "pictorial warnings, and those occupying a major pack face or faces (front and back) or a disproportionately large area of advertising space, should be restricted, as should moves to plain or generic packs. Every effort should be made to protect the integrity of the company's packs and trade marks" (Alechnowicz and Chapman 2004; BAT 1995).

In public, tobacco manufacturers have argued that large comprehensive warnings are not only unnecessary, but are less effective than more obscure text messages (Chapman and Carter 2003). For example, Martin Broughton, the former chairman of BAT, recently stated that "the growing use of graphic image health warnings . . . can offend and harass consumers—yet in fact give them no more information than print warnings" (Hearn 2004). Tobacco manufacturers have also argued that comprehensive warnings constitute an unreasonable and illegal expropriation of cigarette packaging (Pollay 2001).

To date, courts of law have disagreed. For example, in response to a legal challenge of the Canadian Tobacco Act, the court found that the tobacco companies' right to advertise their products could not be given the same legitimacy as the federal government's duty to protect public health (Pollay 2001). In short, the courts have ruled that even graphic warnings are warranted considering the societal costs of smoking.

RECOMMENDATIONS

The cigarette package is a key component of tobacco marketing strategy, particularly under increasing regulation of advertising and other forms of promotion. As a consequence, restrictions on package labeling are critical to reducing tobacco use and ensuring that smokers are adequately

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informed about the risks of smoking. Indeed, prominent health warnings on packages are among the most cost-effective forms of public health education available.

To achieve these dual objectives, we recommend the following:

- Large graphic health warnings are now used or proposed in many countries and should be adopted for cigarettes in the United States.
- Misleading brand descriptors such as “light” and “mild” should be eliminated. Consideration should be given to limiting the use of colors and numbers that suggest “light” and “mild” attributes.
- Misleading constituent information, such as the ISO cigarette yields, should be eliminated from packaging.
- Information on the benefits of quitting, as well as concrete cessation advice and sources of support, should be provided on cigarette packages. In particular, telephone quitline numbers should be included on all packages. This information should be displayed on the outside panels of the package, although more detailed information can also be included on the inside of the package or on an insert.
- The regulation of cigarette package labeling requires a more formal regulatory structure.
- Specific package markings can be used to indicate that federal or provincial taxes have been paid. This is particularly useful for identifying packages of cigarettes that have not been taxed and may be sold illegally.

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