Original Investigation

Tobacco Packaging and Labeling Policies Under the U.S. Tobacco Control Act: Research Needs and Priorities

David Hammond, Ph.D.[1]

[1] *Department of Health Studies and Gerontology, University of Waterloo, Waterloo, Canada*

Corresponding Author: David Hammond, Ph.D., *Department of Health Studies and Gerontology, University of Waterloo, 200 University Avenue West, Waterloo, Ontario, N2L 3G1, Canada. Telephone: 519-888-4567 (ext.36462); Fax: 519-886-6424; E-mail: dhammond@uwaterloo.ca*

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Abstract

Introduction: The Family Smoking Prevention and Tobacco Control Act (the "Act"), enacted in June 2009, gave the U.S. Food and Drug Administration authority to regulate tobacco products. The current paper reviews the provisions for packaging and labeling, including the existing evidence and research priorities.

Methods: Narrative review using electronic literature search of published and unpublished sources in 3 primary areas: health warnings, constituent labeling, and prohibitions on the promotional elements of packaging.

Results: The Act requires 9 pictorial health warnings covering half of cigarette packages and 4 text warnings covering 30% of smokeless tobacco packages. The Act also prohibits potentially misleading information on packaging, including the terms "light" and "mild," and provides a mandate to require disclosure of chemical constituents on packages. Many of the specific regulatory provisions are based on the extent to which they promote "greater public understanding of the risks of tobacco." As a result, research on consumer perceptions has the potential to shape the design and renewal of health warnings and to determine what, if any, information on product constituents should appear on packages. Research on consumer perceptions of existing and novel tobacco products will also be critical to help identify potentially misleading information that should be restricted under the Act.

Conclusion: Packaging and labeling regulations required under the Act will bring the United States in line with international standards. There is an immediate need for research to evaluate these measures to guide future regulatory action.

Introduction

The Family Smoking Prevention and Tobacco Control Act of 2009 (the "Act") represents an important landmark for tobacco control in the United States. The Act granted the U.S. Food and Drug Administration (FDA) authority to regulate tobacco products, including packaging and labeling regulations (Deyton, Sharfstein, & Hamburg, 2010). Internationally, packaging and labeling regulations have emerged as an important component of tobacco control policy, both as a vehicle for governments to warn about the risks of tobacco use and to restrict misleading descriptors and design. Article 11 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC)—the world's first public health treaty—has served as an impetus for the rapid uptake of packaging and labeling regulations among many of the 170 countries that have ratified the Framework (WHO, 2003). Article 11 includes recommendations for large pictorial health warnings and encourages more effective forms of disclosure for product constituents and emissions. Article 11 also recognizes the importance of the package as a promotional vehicle for tobacco companies and requires the removal of potentially misleading packaging information, including the terms "light" and "mild." Article 11 advises that Parties to consider broader restrictions on other descriptors and promotional elements of pack design (WHO, 2008).

Packaging regulations have changed very little in the United States since 1984, when packages began displaying one of four mandatory text warnings printed on the side of packages (see Figure 1). However, the Act gives the FDA authority to regulate three primary areas of packaging and labeling: health warnings, the disclosure of product constituents or chemical "yields," and prohibitions on potentially misleading packaging information with respect to reduced health risk. The current paper will examine regulatory provisions in each of these areas, review evidence on best practices, and identify research priorities to help guide regulatory practice.

The United States is a critical market for global tobacco control. The United States is the largest retail market in the world in terms of value, at more than $70 billion in annual sales, and is home to the world's largest private tobacco company, Philip Morris International (PMI; Euromonitor International, 2007; Physicians for a Smoke-free Canada, 2009). PMI has 7 of the top 15 global brands, including Marlboro, the most valuable tobacco

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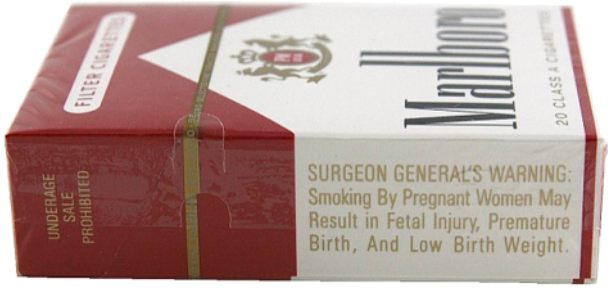

Figure 1. U.S. health warnings implemented in 1984.

brand in the world. The United States is also notable in that it is one of the few high-income countries not to ratify the FCTC and has lagged in several key areas of tobacco control, particularly with respect to federal level policy and labeling regulations. Despite the soft regulatory environment, the United States produces a vast amount of the tobacco control research and funding for international tobacco control efforts. As a consequence, the Tobacco Control Act has important implication both for domestic and for international tobacco control efforts.

Methods

Given the scope of the topic addressed in this paper and the evolving nature of the field, this paper used a narrative review approach. Narrative reviews summarize comprehensive areas with a diversity of research designs using the reviewer's own experience, along with existing theories and models (Collins & Fauser, 2005). Articles were identified using electronic searches of MEDLINE and Web of Science databases. The following key words were used to identify relevant articles: health warning, health message, health communication, emission, chemical, tar, light, mild, label, and labeling in conjunction with at least one of the following terms: smoking, tobacco, cigarette, product, package, and pack. Electronic searches were also conducted to identify relevant "grey literature," including unpublished research commissioned by governments and information related to the Act. Additional searches using reference lists of key articles were also conducted. The review was limited to articles that were available for review prior to January 2011.

Results

Health Warning Labels

The Act requires health warning labels to appear on cigarette and smokeless tobacco packages. Cigarette packages are required to display color graphic (i.e., pictorial) warnings depicting the negative health consequences of smoking (see Section 201 of the Act). One of nine health warnings are required to cover the top 50% of the "front" and "rear" of cigarette packages—see Figure 2. The warnings must be implemented no later than 39 months after enactment of the Act, September 2012. The Secretary of Health

Figure 2. Pictorial health warnings to appear on US cigarette packages.

and Human Services has the authority to revise the health warnings if the change would " . . . promote greater public understanding of the risks associated with the use of tobacco products." (Section 202)

The Act also requires one of four health warnings on smokeless tobacco products covering 30% of the front and rear of packages and appearing with contrasting background colors. Packages of smokeless tobacco products were required to display the new warnings as of July 2010. The Secretary has the authority to revise the smokeless health warnings, including increases in size to 50% and the use of color graphics if such a change would "promote greater public understanding of the risks associated with the use of smokeless tobacco products." (pp. 193–94)

The Act neither requires nor restricts the inclusion of other information, such as displaying a toll-free telephone quitline or links to online cessation resources. Nor does the Act specify timelines for revising or "rotating" new health warnings, although this presumably falls within the Secretary's mandate to make changes to the warnings should they promote greater understanding of the health risks.

Existing Evidence on Health Warnings

To date, more than 30 countries have implemented pictorial warnings on cigarette packages—see example in Figure 2 (Hammond, 2009). A wide range of study designs and measures have been used to evaluate health warnings on cigarette packages. A full discussion of these methodological issues are beyond the scope of this paper but have been reviewed elsewhere (Hammond, 2011; International Agency for Research on Cancer, 2008).

Large health warnings displayed on the principal display faces of tobacco packages are a prominent source of health information (Hammond, Fong, et al., 2006). Findings from Canada, Thailand, and elsewhere also indicate that considerable proportions of nonsmokers report awareness and knowledge of package health warnings (Brown, Diener, Ahmed, & Hammond, 2005; Environics Research Group, 2005; European Commission, 2009; Shanahan & Elliot, 2009).

Several studies demonstrate that increases to the size of text warnings enhance their impact (Environics Research Group, 1999). For example, in experimental studies where youth and adults are asked to rate the effectiveness of different health warnings, the largest warnings are most likely to be rated as effective, including among more vulnerable nonsmokers (AGB Spectrum Research Ltd., 1987; Centre for Behavioral Research in Cancer, ACCV, 1992; Environics Research Group, 1999; Les Études De Marche Createc, 2008a, 2008b; Linthwaite, 1985). Warnings that appear on the "front" or principal display area of packages are also likely to have greater impact (Rootman & Flay, 1995). Features that distinguish the warning messages from the package design have also been found to increase the salience and recall of warnings, including contrasting colors, such as black lettering on a white background (Laugesen, 1990; Nilsson, 1991).

Cigarette warning labels can have a significant impact on smokers' understanding of the risks of tobacco use. Research has shown that large text-based warnings are associated with increased perceptions of risk (Borland & Hill, 1997; Environics Research Group, 2007a, 2007b; Tandemar Research Inc., 1996). For example, several studies have evaluated the enhancement of text warnings in European Union member states in 2003 to a minimum of 30% of the front and back of packages (Borland et al., 2009; Fong et al., 2008; Hammond, Fong, et al., 2006; Portillo & Antonanzas, 2002). Collectively, these studies indicate that smokers have increased awareness of warnings, and many report thinking about health risks and quitting smoking as a result of the large text warnings.

A wide variety of studies have demonstrated the superiority of using pictures and imagery in health communications rather than text-only messages (Braun, Kline, & Silver, 1995; Leventhal, 1970; Sherman, Cialdini, Schwartzman, & Reynolds, 1985; Strahan et al., 2002). Experimental research on cigarette pack warnings has also found that picture-based warnings are more likely to be rated as effective versus text-only warnings, both as a deterrent for new smokers and as a means to increase cessation among current smokers (Liefeld, 1999; O'Hegarty et al., 2006). Extensive focus group testing and market research commissioned by government health agencies also underscores the importance of using pictures in package health warnings (BRC Marketing & Social Research, 2004a; Clemenger BBDO, 2004; Corporate Research Associates, 2005; Elliott and Shanahan (E&S) Research, 2003; Environics Research Group, 2000; Les Études de Marche Createc, 2006). This research consistently demonstrates that health warnings with pictures are rated by smokers and nonsmokers as more effective and associated with greater impact and recall for health risks than text-only warnings.

A series of population-based surveys have compared the effectiveness of text and pictorial warnings. These findings are consistent with both the experimental and the government commissioned research: Graphic warnings are more likely to be noticed and read by smokers, are associated with stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking (Clemenger BBDO, 2004; Corporate Research Associates, 2005; Elliott & Shanahan (E&S) Research, 2003; Environics Research Group, 2000; Hammond, Fong, McDonald, Brown, & Cameron, 2004; Hammond, Fong, McDonald, Cameron, & Brown, 2003; Hammond & Parkinson, 2009; Hammond, Fong, et al., 2006, 2007; Les Études de Marche Createc, 2006; Thrasher, Hammond, Fong, & Arillo-Santillan, 2007; White, Webster, & Wakefield, 2008).

Picture warnings appear to be especially effective among youth (Environics Research Group, 1999; Moodie, Mackintosh, & Hammond, 2009; White et al., 2008). In Canada, more than 90% of youth agreed that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive (Environics Research Group, 2007b). Pictorial warnings may be particularly important in communicating health information to populations with lower literacy rates (CRÉATEC + Market Studies, 2003; Malouff, Gabrillowitz, & Schutte, 1992; Millar, 1996). This is particularly important considering that, in countries such as the United States, smokers have lower levels of education than the general population.

Evidence from a range of sources suggests that large comprehensive warnings reduce consumption levels, increase cessation behavior, and support former smokers in remaining abstinent (Borland & Hill, 1997; Canadian Cancer Society,

2001; Environics Research Group, 2007a, 2007b; Hammond et al., 2003, 2004; Hammond, Fong, et al., 2007; Hill, 1988; Koval, Aubut, Pederson, O'Hegarty, & Chan, 2005; O'Hegarty et al., 2006; Thrasher et al., 2007; Willemsen, 2005). At least three longitudinal studies—two with adults and one with youth—have demonstrated an association between reading and thinking about health warnings and subsequent cessation behavior, one of which was conducted with nationally representative samples of smokers in Canada, Australia, the United Kingdom, and the United States (Borland et al., 2009; Hammond et al., 2003; White et al., 2008). Increases in the use of cessation services have also been associated with health warnings. Research conducted in the United Kingdom, the Netherlands, Australia, Brazil, and New Zealand has examined changes in the use of national telephone "helplines" for smoking cessation after the contact information was included in package health warnings. Each of these studies reports significant increases in call volumes (Cavalcante, 2003; Miller, Hill, Quester, & Hiller, 2009; U.K. Department of Health, 2006; Willemsen, Simons, & Zeeman, 2002; Wilson, Li, Hoek, Edwards, & Peace, 2010). Overall, while it is not possible to precisely quantify the impact of health warnings on smoking prevalence or behavior, evidence to date suggests that health warnings can promote cessation behavior and that larger pictorial warnings are most effective in doing so.

Opportunities for Future Research

Perhaps the greatest challenge confronting regulators is the selection of message content for pictorial warnings—the specific images and text to appear on packages. There is a need for research to examine the most effective types of "message content" for pictorial warnings, including the use of fear-arousing graphic depictions of disease, images that highlight human suffering, symbolic imagery, and the use of personal testimonials. Pictorial warnings implemented in different countries reveal a wide variety of themes and executional styles; however, there is relatively little evidence to indicate which approach is most effective other than the general finding that graphic depictions of disease appear to be reliably effective. Additional research is also needed to explore the most effective way to design addiction messages as well as supportive cessation-oriented messages—two of the nine "label statements" to be featured in the U.S. warnings. To date, messages depicting these themes have performed poorly in testing relative to other themes (Corporate Research Associates, 2005; Decima, 2009).

Research is required to examine features other than the pictorial and text elements that would "promote greater public understanding of the risks" of cigarettes to guide the Secretary's mandate to revise the warnings. Research opportunities include the potential of impact of integrating cessation services within health warnings, such as telephone "quitline" numbers and web-based cessation services (Li & Grigg, 2009; M. A. Wakefield, Loken, & Hornik, 2010). Research should also examine how pack shape and size interacts with the effectiveness and legibility of health warnings. Packages with irregular shapes and tall narrow cigarette packs—occasionally referred to as "lipstick" packs—alter the dimensions and surface area of warnings. This is particularly important for smokeless tobacco products, many of which do not have rectangular shapes and clearly defined "front" and "rear" sides. Research could also inform novel warning practices, such as the feasibility and impact of requiring "inserts" or "onserts" that would contain additional information on health effects or cessation resources. Research on the international precedent set by Canada with respect to "inserts" should be considered a priority (Health Canada, 2010).

Following implementation of health warnings, there is a need to monitor the impact of warnings over time and among various subpopulations. For example, to what extent does the impact of health warnings vary across socioeconomic status or other subgroups of smokers? What types of health messages or health effects are most effective among youth and young adults? Research is also required to monitor the "wear out" of warnings over time and the ideal period for "revising" the warnings. Finally, the impact of warnings may be enhanced through linkages to other media campaigns and tobacco control policies. Research is required to examine these opportunities to leverage the potential public health benefit.

One challenge confronting work in this area is the vagueness of the key provision in terms of updating the warnings based on promoting "greater public understanding of the risks associated with the use of tobacco products." It is not clear what threshold or criteria should be used to establish greater understanding. Although this threshold will presumably be defined by the Secretary or the FDA, researchers can help to frame this threshold. In particular, research should consider the implications for the types of measures used to assess understanding not only in terms of basic health knowledge but also in terms of the broader concept of perceived risk, which includes perceived severity and likelihood.

Disclosure of Product Constituents and Emissions on Packs

The Act gives the Secretary the discretion to determine whether quantitative information in the form of tar and nicotine "yields" should be displayed on packs. The Secretary can also require that the level of any cigarette or other tobacco product or smoke constituent be disclosed on the pack if the Secretary determines that disclosure would be of benefit to the public health or otherwise would increase consumer awareness of the health consequences of the use of tobacco products. Product constituents other than tar and nicotine will not appear on the face of any cigarette package but could appear elsewhere.

Evidence

Disclosure of tobacco constituents and emissions has presented a unique challenge to regulators. Cigarette smoke contains approximately 4,000 chemicals, including more than 60 carcinogens and toxins such as polonium 210, benzene, and arsenic (Hoffmann & Hoffmann, 2004). Although there is general agreement that cigarette packages should include some information on the toxic and addictive properties of tobacco products, regulators continue to struggle with how best to communicate this information in a feasible and meaningful way to consumers.

Tobacco manufacturers have communicated tar and nicotine numbers directly to smokers ever since the health risks of smoking became publicly known (Pollay & Dewhirst, 2001). These early forms of "product disclosure" were motivated less by consumer protection than by a marketing strategy intended to capitalize upon widespread misperceptions of tar and nicotine

levels (Pollay & Dewhirst, 2001). As early as 1955, the U.S. Federal Trade Commission (FTC) issued voluntary guidelines requesting that cigarette manufacturers avoid unsubstantiated or ambiguous claims about tar and nicotine levels. According to the FTC, tar and nicotine levels represented unsubstantiated health claims and were confusing to the public (Tobacco: End of the Tar Derby, 1960). However, 4 years after the FTC brokered a voluntary ban on the use of tar and nicotine numbers in advertising, the 1964 Surgeon General's report on smoking concluded that lower tar cigarettes were likely to be less harmful (U.S. Department of Health, Education, and Welfare, 1964). As a result, the FTC reversed course and took steps to provide consumers with comparative information about the tar and nicotine levels of different products as well as to set guidelines on how manufacturers communicate this information if they chose to do so (Federal Register, 1970; Peeler, 1996). In the absence of any legal requirement, many manufactures voluntarily printed tar and nicotine levels on packs, albeit in a highly selective fashion. In 2004 and 2005, tar levels were printed on more than 90% of U.S. brands with less than 3 mg of tar compared with fewer than 2% of brands with 8–11 mg of tar (FTC, 2007).

Research has repeatedly shown that many smokers are not able to recall the specific tar level of their brand; nevertheless, a substantial proportion equate lower numbers with a reduction in exposure and risk, and many use these numbers to guide their choice of brands (Chapman, Wilson, & Wakefield, 1986; Cohen, 1996; Devlin, Eadie, & Angus, 2003; Gori, 1990; Health Canada, 2003b; O'Connor, Kozlowski, Borland, Hammond, & McNeill, 2006; Pollay & Dewhirst, 2001). Recent findings suggest that smokers even in the most affluent and educated countries continue to hold false beliefs about emission numbers (Bansal-Travers, Hammond, Smith, & Cummings; 2011; Hammond & Parkinson, 2009).

The underlying premise for communicating tar and nicotine numbers directly to consumers—that "low-tar" cigarettes are less harmful—has since been rejected. Not only has the epidemiological data failed to detect differences in risk but the serious limitations of emission testing methods have also become apparent (Benowitz, 1996; Hammond, Collishaw, & Callard, 2006; U.S. Department of Health and Human Services [U.S. DHHS], 2001). Scientific consensus is that tar, nicotine, and carbon monoxide emission numbers "do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette or on the relative amounts of tar and nicotine exposure they are likely to receive from smoking different brands of cigarettes." (U.S. DHHS, p. 10)

In the United States, the FTC issued a consumer alert about the consumer use of tar and nicotine numbers in 2000 (FTC, 2000), and in 2008, the FTC rescinded its original guidance on the use of tar and nicotine yields established in 1966 and concluded that "tar and nicotine yields as measured by this test method are confusing at best, and are likely to mislead consumers who believe they will get proportionately less tar and nicotine from lower-rated cigarettes than from higher-rated brands." (FTC, 2008, p. 12)

In light of these findings, some jurisdictions have supplemented the International Organization for Standardization numbers with additional emission information. In 2000, Canada increased the list of emissions that must be reported and added a second set of emission numbers generated under the "Health Canada" method, a more intensive machine smoking method. Subsequent research conducted on behalf of Health Canada found that four of five smokers did not understand the emission information; nevertheless, more than half reported that they would use these numbers to find a less harmful brand (Health Canada, 2003b). Changing the metric of cigarette emissions by using more intensive testing methods provides little insurance against the likelihood that consumers will interpret brands with lower numbers as lower risk. These findings are consistent with research from Australia, indicating that the disclosure of quantitative information and product constituent reports is ineffective (Australia Department of Health and Ageing, 2009).

Given the current scientific consensus that emissions data do not accurately reflect meaningful differences in risk between conventional cigarette brands, the WHO has called for the removal of emission numbers from packages (WHO Study Group on Tobacco Product Regulation, 2004). The "Elaborated Guidelines" for FCTC Article 11 also state that "Parties should prohibit the display of figures for emission yields, such as tar, nicotine, and carbon monoxide, on packaging and labeling, including when used as part of a brand name or trademark" (WHO, 2008). A growing number of countries have removed emission information from packages and replaced it with descriptive information about toxic constituents and their effects on health (see example from Australia in Figure 3). Preliminary research suggests that this information is more meaningful to consumers and less likely to result in misperceptions about the relative risk of different cigarette brands (Health Canada, 2003a). Research commissioned by Health Canada also suggests that messages on specific toxic constituents with an explanation of their health effect were rated as most effective (Health Canada, 2007).

Opportunities for Future Research

Although there is extensive evidence that quantitative information is misleading, there is relatively little research indicating whether alternative approaches to communicating emission and constituent information are effective. There is an urgent need for evidence on nonnumeric or "descriptive" emission statements. Would consumers be best served by a long list of toxic chemicals, a subset of the most hazardous chemicals, or perhaps the most recognizable toxicants, such as arsenic and benzene? Research should also examine the most effective way of communicating the addictive constituents from tobacco products and whether it is possible to design these messages to

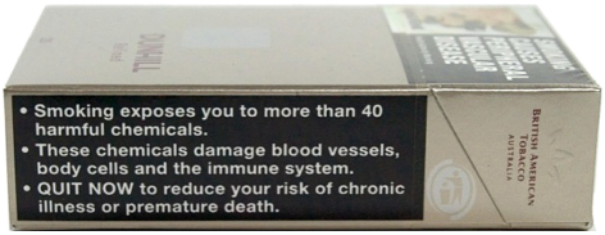

Figure 3. Example of "descriptive" nonnumerical constituent warning (Australia, 2009).

increase awareness of the highly addictive nature of tobacco products without undermining self-efficacy for quitting among current users. Finally, in contrast to the "main" health warnings, there is a need to examine whether descriptive emission statements could be enhanced by using graphics or symbols. For example, widely recognized symbols, such as a skull, have been found to be especially effective in diverse populations, including among individuals with low literacy and education (Banda & Sichilongo, 2006).

Prohibition on Misleading Packaging Information

Unless a product meets the requirements of being a "modified risk" product (see Section 911 for criteria), the Act prohibits labeling that (a) "represents explicitly or implicitly that the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other tobacco products; (b) contains a reduced level of a substance or presents a reduced exposure to a substance; (c) the tobacco product or its smoke does not contain or is free of a substance; or (d) uses the descriptors 'light', 'mild', 'low', or similar descriptors."

As of June 22, 2010, tobacco products were prohibited from being labeled or advertised as "light," "low," or "mild." A U.S. Federal District Court had previously ruled in 2006 that these terms are deceptive, and a Court Order prohibited their use; however, the terms remained on packages pending appeal until June 2010 (U.S. District Court for the District of Columbia, 2006). To date, no other elements of packaging have been prohibited under this area of the Act.

Existing Evidence

Tobacco companies have made extensive use of cigarette packages to reassure consumers about the potential risks of their products (Freeman, Chapman, & Rimmer, 2008; Pollay & Dewhirst, 2001). A central feature of this strategy has been to use misleading brand descriptors—words and numbers incorporated in the name of a brand. Words such as "light" and "mild" are ostensibly used to denote flavor and taste; however, "light" and "mild" brands have also been promoted in advertisements as "healthier" products (Pollay & Dewhirst, 2001, 2002; M. Wakefield, Morley, Horan, & Cummings, 2002). "Light" and "mild" descriptors are also applied to brands with higher levels of filter ventilation—small holes in cigarette filters. Not only does filter ventilation dilute cigarette smoke to produce deceptively low tar and nicotine numbers under machine testing but it also produces "lighter" tasting smoke, which reinforces the misleading descriptors on packages. As a result, considerable proportions of adult smokers believe that "light," "mild," and "low-tar" cigarette brands lower health risk and are less addictive than "regular" or "full flavor" brands (Ashley, Cohen, & Ferrence, 2001; Etter, Kozlowski, & Perneger, 2003; Gilpin, Emery, White, & Pierce, 2002; Ling & Glanz, 2004; Pollay & Dewhirst, 2001; Shiffman, Pillitteri, Burton, Rohay, & Gitchell, 2001; Weinstein, 2001). Indeed, many health-concerned smokers report switching to these brands as an alternative to quitting (Gilpin et al., 2002; U.S. DHHS, 2001). "Light" and "mild" descriptors may also promote smoking initiation among youth: One study found that U.S. youth believe "light" and "mild" cigarettes have lower health risk and lower levels of addiction than "regular" brand varieties similar to adults (Kropp & Halpern-Felsher, 2004). Overall, synergistic but subtle effect of brand descriptors, lower emission numbers, and the "lighter" tasting smoke have undermined perceptions of risk among smokers, leading many to delay or put off quitting altogether.

International guidelines under FCTC Article 11 state that:

> . . . tobacco product packaging and labelling [shall] not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. (WHO Framework Convention on Tobacco Control, 2008, p. 9)

To date, more than 50 countries have prohibited the terms "light," "mild," and "low tar." The list of prohibited terms has been expanded in countries such as Malaysia to include "cool," "extra," "special," "full flavor," "premium," "rich," "famous," "slim," and "grade A." However, recent research conducted in Canada, the United Kingdom, and Australia suggests that prohibiting "light" and "mild" terms may be insufficient to significantly reduce false beliefs about the risks of different cigarette brands (Borland et al., 2008; Mutti & Hammond, 2011). One potential explanation for these findings is the wide range of other descriptors that remain in use, including words such as "smooth," color descriptors such as "gold" and "blue," as well as "tar" numbers that are incorporated into brand names or printed on the sides of packs (Hammond & Parkinson, 2009; King & Borland, 2005; Mutti & Hammond, 2011).

The persistence of false beliefs may also be due to other promotional aspects of the pack, including brand imagery and color. Tobacco industry documents describe this phenomenon: "Lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean healthy association" (Philip Morris, 1990). Different shades of the same color and the proportion of white space on the package are commonly used to manipulate perceptions of a product's strength and potential risk. Indeed, a number of industry studies have shown that the color and design of the package are effective to the point where they influence sensory perceptions from smoking a cigarette, a process known as "sensory transfer" (Aubin, 1989; McBride, 1987; M. Wakefield et al., 2002). Research from other health domains underscores the effect of color on consumer perceptions: The color of pharmaceutical pills, for example, has been shown to influence their effectiveness, presumably through a potent placebo effect (de Craen, Roos, de Vries, & Kleijnen, 1996).

The removal of color and other elements of package design—so-called "plain packaging"—has emerged as one regulatory option for reducing potentially misleading package designs. Plain packaging would standardize the appearance of cigarette packages by requiring the removal of all brand imagery, including corporate logos and trademarks. Packages would display a standard background color, and manufacturers would be permitted to print only the brand name in a mandated size, font, and position. Other government-mandated information, such as health warnings, would remain. Australia is currently

developing plain packaging regulations scheduled for implementation in 2012.

Plain packaging has three potential effects. First, plain packaging has the potential to reduce false beliefs about the harmfulness of different cigarette brands (Doxey & Hammond, 2011; Hammond, Doxey, Daniel, & Bansal-Travers, 2011; Hammond & Parkinson, 2009). Second, plain packaging may also enhance the effectiveness of health warnings by increasing their noticeability, recall, and believability (Beede & Lawson, 1992; Goldberg, Liefeld, Madill, & Vredenburg, 1999; Goldberg et al., 1995; Hammond, 2009). Third, plain packaging regulations also have the potential to reduce the appeal of tobacco products, particularly among youth and younger adults (Chapman, 2007; Cummings, Morley, Horan, Steger, & Leavell, 2002; DiFranza, Eddy, Brown, Ryan, & Bogojavlensky, 1994; Pollay, 2001). For example, packaging for female-oriented brands, including tall narrow "slim" packs, are particularly effective at promoting brands to young females (Doxey & Hammond, 2011; Hammond et al., 2011). Research to date suggests that plain packages are less attractive and engaging and may reduce the appeal of smoking among youth and adults (Bansal-Travers et al., 2011; Doxey & Hammond, 2011; Hammond, 2009; Hammond et al., 2011; Hoek, Wong, Gendall, Louviere, & Cong, 2010; Northrup & Pollard, 1995; Rootman & Flay, 1995; Trachtenberg, 1987; M. A. Wakefield, Germain, & Durkin, 2008).

Finally, references to product design also have the potential to mislead consumers. Products that are positioned as "low-yield" brands often carry images or references to product design on the package (Pollay & Dewhirst, 2001). References to filtration are among the oldest and most common examples of this strategy. For more than 50 years, tobacco companies have communicated filter properties to consumers as tangible evidence of emissions reduction and lower risks (Pollay & Dewhirst, 2001). Indeed, the rise of filtered cigarettes in the United States paralleled the rise in health concerns among consumers. From Kent's Micronite filter, to Barclay's ACTRON filter, to the charcoal filters currently being test marketed in Marlboro Ultra Smooth—whatever the filtration properties of these designs may be, they reassure smokers when displayed on the package (Kozlowski et al., 2005). As Myron Johnston and W.L. Dunn of Philip Morris stated in 1966, "the illusion of filtration is as important as the fact of filtration" (Dunn & Johnston, 1966). Leading brands from China provide a contemporary example of this packaging strategy, where packs feature images of "high-tech" filters and references to "color cellulose particles." Packages with pictures and references to special cigarette filters such as these are rated by a majority of smokers as having less tar and lower health risk (Hammond & Parkinson, 2009).

Opportunities for Future Research

Much of the research conducted to date has been focused primarily on consumer perceptions of "light" and "mild." There is a need for research that helps to document other potentially misleading information, including a broader range of descriptors. It is particularly important to examine many of the "substitute" terms used to replace the terms "light" and "mild" following their removal from U.S. packages in 2010. Research should explore the role of pack color and how it interacts with descriptors and other elements of packaging specific to the U.S. market. The planned introduction of plain packaging in Australia in 2012 provides an excellent opportunity to evaluate restrictions on pack color and brand imagery. Given the litigious nature of the tobacco industry and the unique legal framework in the United States, research might also examine potential legal barriers in the United States related to the removal of brand imagery and color.

There are also opportunities to examine the extent to which references to product design, such as the filtration properties of cigarettes, mislead consumers. Additional research is required to examine whether factual statements about a product's design or constituents may prove deceptive to consumers when presented on packaging, particularly without additional context. For example, "Natural American Spirit" is popular brand of cigarettes labeled as "organic" and "additive free." These statements may be perceived as health claims by consumers in which case they would be subject to restrictions under the Act. The variety of pack shapes and sizes also presents research opportunities to examine the impact of shape and size on consumer perceptions. For example, to what extent are tall "slim" cigarettes associated with misleading perceptions among young women? Pack shape and size are particularly relevant to the smokeless tobacco market in the United States, which is characterized by a wide variety of unusual shapes and sizes.

Discussion

Tobacco packaging and labeling policies are prominent and cost-effective tobacco control measures. Although the United States has lagged behind most other jurisdictions for more than two decades, the labeling provisions in the Act will rapidly bring U.S. policies in line with most other countries.

There is a strong evidence base to support the regulations under the Act that have been specified to date: large pictorial warnings on cigarette packages and prohibitions on "light" and "mild" terms. However, labeling regulations should not be static measures. Health warnings must be periodically revised and updated to maintain their impact.

Therefore, research monitoring the impact of the new warnings to be implemented in 2012 will be critical to informing both the design and the content of future rounds of health warnings. Prohibitions on misleading packaging information also need to adapt to industry practice. Many advocates have argued that "replacement" terms such as "smooth" and the names of colors, such as "gold," simply reinforce the same false beliefs as the prohibited terms, "light" and "mild." Research on consumer perceptions is important to verify these claims and to justify further restrictions on packaging elements. Research is also critical for evaluating how consumers perceive "modified risk" products, an area of regulation in which the United States is setting new international precedents.

In some cases, new frameworks or research designs may be needed to understanding the impact of labeling regulations and to fully assess consumer perceptions of product and packaging. This research will need to draw upon a diversity of studies, ranging from experimental studies examining individual packaging elements to population-based studies monitoring new products. Given that many of the specific regulatory provisions under the Act are to be guided by public understanding of the risks of

tobacco, articulating this research framework should be considered a priority.

As regulations under the Act are implemented, international labeling practices will continue to evolve and may inform both the research agenda and the future regulations under the Act. For example, countries continue to increase the size of pictorial warnings: Pictorial warnings in Uruguay cover 80% of the principal display areas, and Canada has recently announced warnings covering 75% of the front and back of packs. These developments provide new precedents for the FDA to consider as well as new potential sources of evidence regarding their impact on consumers. Likewise, the plain packaging regulations scheduled for 2012 in Australia will establish a new international precedent and provide a unique opportunity to examine restrictions on color and brand imagery on packs as well as how the tobacco industry will respond to these regulations. As in other policy domains, it is important to examine to what extent evidence collected in other jurisdictions applies to the U.S. market.

Overall, the packaging and labeling measures included in the FDA bill should be considered the first step in an ongoing regulatory process rather than the completion of work in this critical area of tobacco control. Research will be critical to ensure that this process is guided by the best possible evidence.

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None declared.

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