The Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009 gave the United States Food and Drug Administration (FDA) authority to regulate tobacco products in several ways, including restricting cigarette packaging, requiring the inclusion of graphic warning labels (section 201 d), banning misleading descriptors such as “light” and “low tar” (section 911 a-b) that imply the product is less harmful, setting standards for nicotine content in cigarettes, and banning flavorings [1, 2]. The graphic warning labels were released in June 2011 with an original implementation date of September 2012. However, recent litigation by several tobacco companies (e.g., RJ Reynolds Tobacco Co. v. United States Food and Drug Administration [3]) has delayed the initiation of the graphic warning labels, on the grounds that the graphic warning labels violated the companies’ First Amendment rights and would be too costly and that the shocking color graphics did not deliver factual, noncontroversial messages [4, 5].

Cigarette descriptors such as “low tar,” “light,” and “mild” were successfully banned in June 2010 under the FSPTCA (section 911 a-b), although the effectiveness of this initiative remains unclear [6, 7]. Prior to the descriptor ban taking place, the tobacco industry manipulated package coloring, and supplied informational materials to retailers, so that the color coding implicitly replaced them [7, 8]. Many smokers did not notice the descriptor ban [6] and appear to have adopted the tobacco industry’s use of package colors as a way to infer “risk” level [6, 7]. These types of countermeasures and the challenges to graphic warning labels raise questions of how far the FSPTCA will actually be able to advance tobacco control for the protection of public health.

One can anticipate other possible challenges to forthcoming regulations. For example, a provision within the law formally discourages the adoption of product standards that would create significant demand for contraband or other tobacco products. Some of the most significant possible changes to tobacco products could be challenged by this provision. For example, the Tobacco Products Scientific Advisory Committee notes that banning menthol may be of benefit to the public health, yet also acknowledges that contraband markets of menthol cigarettes would likely exist and the origin and safety of these products would be difficult to determine and monitor [9].

Cigarette smoking remains the largest single, preventable cause of death and disability in the United States [10], and, from the perspective of discouraging this
deadly activity, a classic skull and crossbones-type poison symbol along with graphic images of the disease effects would seem warranted on packaging. The tobacco industry knows the utility of cigarette packages as a communication vehicle about its product. As noted by Philip Morris executive Mark Hulit in May 1994 to the Corporate Affairs Conference in Manila,

Our final communication vehicle with our smoker is the pack itself. In the absence of any other Marketing messages, our packaging—comprised of the trademark, our design, color and information—is the sole communicator of our brand essence. Put another way—when you don’t have anything else—our packaging is our Marketing. Therefore, regulations that infringe upon and distort our fundamental packaging designs must be fought with all the resources and energy Corporate Affairs can muster. 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. The size, type weight and number of countries requiring such warnings seems to be concentrated particularly here in Asia—and this is a very big concern not only in our Region but right around the world [11].

The cigarette package is clearly an excellent channel for information and has been used to mitigate smokers’ risk and harm perceptions, formulate product expectations, and convey brand image by the tobacco industry [12-14]. Mutti and colleagues [15] reported that, in an international survey of over 8,000 smokers, those whose cigarettes came in light-colored packs (e.g., gold, silver, blue) were more likely to believe their cigarettes to be less harmful than were smokers of cigarettes in dark-colored packages, such as red or black.

There is also ample evidence that the cigarette pack is an opportunity to improve smokers’ decisions about smoking and risk beliefs. Research spanning several countries and regulatory environments that measured warning label salience on cigarette packages generally supports the hypothesis that labeling increases knowledge of smoking harms and intent to quit and more negative and emotional thoughts about continued smoking [16, 17]. And an empirical study on the effect of graphic warnings and package features on cigarette preference indicates that both graphic warnings and plain packaging can reduce the appeal of a cigarette brand [18]. A recent review by Hiilamo and colleagues observed that, as the salience of health warnings on packs increased, the tobacco industry response moved from a position of “relatively innocuous” to increasingly litigious [19].

Graphic warning labels elicited negative responses to smoking in U.S. smokers [20], increased reported intention to quit smoking when Canada adopted graphic warnings [21, 22], and increased perceptions of smoking dangers in a four-country survey [23]. Some researchers have found population-level effects of graphic warning labels on smoking behaviors. Azagba and Sharaf [24] found decreased smoking prevalence and increased quit attempts; Hammond and colleagues [22] found that 20 percent of
smokers self-reported smoking less. Of course, some of these effects could be complicated by concurrent tax increases or antismoking media campaigns that coincide with the introduction of new warning labels [17, 21]. However, the results of two experimental studies designed to examine the effectiveness of FDA-approved graphic warnings are supportive of the labels [25-27]. Increased emotional and cognitive responses, high recall of the graphic warnings, and improved beliefs about the dangers of smoking were reported in a survey of over 10,000 respondents [25]. More recent research conducted by the Annenberg Public Policy Center added insight into how specific features of the warnings increase efficacy (color, phrasing consistency) and identified individual characteristics associated with responsiveness to graphic warnings [26, 27].

A recent laboratory study examined how smokers viewed a graphic warning label embedded into a print advertisement. In that study, how quickly viewer attention was drawn to the text and duration of viewer attention to the graphic image were significant predictors of their ability to recall the content of the warning [28]. Those randomly assigned to the graphic warning were significantly more likely to recall the content of the warning than those who viewed the text-only version, suggesting that graphic warning labels are superior to text warnings at conveying information by both drawing and sustaining attention. In this study, the graphic warning label was embedded in a Marlboro print advertisement. Of relevance to this discussion, those who were Marlboro brand smokers, verified by presenting their own packs to investigators, were less likely to correctly recall the warning label than smokers of other brands. This difference in recall and viewing patterns could be influenced by brand preference and indicative of how branding- and health-relevant information may battle for consumer attention in the advertisement arena. Research conducted in the United Kingdom by Munafo [29] supports this observation, as removal of brand information improved viewing and attention of the graphic warning label.

Summary
The FSPTCA ostensibly provides a means to enact important health policy improvements to a significant health problem, but the legal challenges to the implementation of the graphic warning provisions raise questions about the future of regulatory tobacco control in the United States. Graphic warning labels have been shown to be effective, low-cost, and capable of conveying important information at the relevant times—purchase and use. Several lines of empirical research conducted by the tobacco industry and health researchers provide converging results to support that cigarette packaging is an optimal vehicle of communicating risk. Research from around the world repeatedly demonstrates that graphic warning labels improve health by decreasing the likelihood of initiating smoking; improving understanding, beliefs, and knowledge of health risks; and increasing the likelihood of trying to quit smoking [20, 21, 30]. There are now more than 55 countries that have mandated that some version of image and text be affixed to cigarette packs to provide health information and discourage smoking [31].
Opponents to the implementation of graphic warning labels in the United States cite infringement of free commercial speech, that the health harms are already known, and that including graphic warnings on cigarette packs is costly. It is imperative that these arguments are weighed against the magnitude of the problem. Nearly 20 percent of adult Americans are daily cigarette smokers [32], there are nearly 400,000 smoking-attributable deaths annually, and approximately 2 million Americans, most of whom are between 12 and 18 years of age, initiate cigarette smoking each year [33]. Cigarette smoking affects a great deal of the population, and its health consequences are significant. It is therefore crucial to better inform and routinely remind the public about the dangers of cigarette smoking, to improve the accuracy of their beliefs about the risks of smoking, and to provide support for them to seek cessation, such as through the inclusion of 1-800-Quit-Now in the warning labels. An important communication device to help achieve these goals is effective implementation of graphic warning labels on cigarette packages in the United States.

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