

January 11, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: Required Warnings for Cigarettes Packages and Advertisements
Docket No. FDA-2010-N-0568
RIN 0910-AG41

Dear Commissioner Hamburg:

The Tobacco Control Legal Consortium (“the Consortium”), America’s legal network for tobacco control policy, is pleased to submit these comments to assist the FDA (“the agency”) in designing more effective cigarette warning labels as part of the agency’s responsibilities under Section 201 of the Family Smoking Prevention and Tobacco Control Act (“FSPTCA” or “the Act”).¹ Specifically, we address the agency’s proposed rule of November 12, 2010,² proffering 36 potential images to accompany the 9 warning statements that will appear on cigarette packages and in cigarette advertisements beginning in 2012.

Since 2003, the Tobacco Control Legal Consortium has been the leading source of legal technical assistance on tobacco control in the United States. The Consortium promotes evidence-based and legally sound approaches to tobacco control policy, and provides technical assistance to federal, state, and local public health advocates, officials, and attorneys across the country. Drawing on experts at its affiliated legal centers, the Consortium assists states and localities with tobacco law-related issues ranging from smoke-free policies to tobacco taxation to regulation of tobacco products. The Consortium’s team of attorneys, based at the Public Health Law Center in St. Paul, Minnesota, provides legislative drafting and policy assistance, prepares educational materials relevant to the regulation of tobacco products, including materials about the FSPTCA and its implications, and files legal briefs as *amicus curiae* in key cases before the highest courts of the nation.

A. The FDA’s Authority to Act & its Opportunity to Set a Leading Global Standard

1. Sections 201 & 202 of the Family Smoking Prevention & Tobacco Control Act

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201, 123 Stat. 1776 (2009) (codified as amended at 15 U.S.C. § 1333).

² Proposed 21 C.F.R. § 1141; Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69524.

The FSPTCA grants the FDA explicit legal authority to regulate tobacco products,³ giving the agency a number of tools to accomplish the Act’s declared objectives of reducing tobacco use among young people, “impos[ing] appropriate regulatory controls on the tobacco industry,” and “promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases.”⁴ More specifically, the FSPTCA requires certain textual warning statements to appear both on cigarette packages and in cigarette advertisements, and directs the agency to adopt regulations prescribing graphic images to accompany these textual warning statements, amending the Federal Cigarette Labeling and Advertising Act (“FCLAA”) to give the agency the necessary rulemaking authority.

Beginning in September 2012, the FSPTCA will require cigarette warnings to be larger – covering 50% of the upper front and back of cigarette packs and 20% of ad space – and more visual, in order to more effectively communicate the health risks associated with smoking. Section 201 of the Act modifies the FCLAA to require that 9 new warning statements appear on cigarette packages (packs and cartons) and in cigarette advertisements. Although the FSPTCA specifies the language of the 9 new warning statements, it also empowers the FDA to modify the text of any of the label statements through the rulemaking process. The Act also requires the Secretary of Health and Human Services to “issue regulations that require color graphics depicting the negative health consequences of smoking to accompany these new warning statements.”⁵ Additionally, Section 202 of the Act expressly provides that graphic cigarette warning regulations promulgated pursuant to Section 201 are not preempted by FCLAA, and that the FDA may further adjust the format, color graphics, and text of any of the label requirements (or other disclosures required under the Food Drug and Cosmetic Act) “if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.”⁶ These provisions empower the agency to continually regulate cigarette packages and advertisements as necessary to ensure that the warning statements and images remain effective in communicating the consequences of smoking.

On November 10, 2010, as a major step toward implementing these new requirements, the Department of Health and Human Services and the FDA announced a proposal to require larger and more prominent health warnings on all cigarette packages and advertisements. The agency proposed a series of possible graphic warning labels to accompany the new textual warning statements, offering 36 possible images for public comment.

As explained in more detail below, the FDA should look to research from other countries demonstrating that the inclusion of larger and more vivid graphic health warnings better conveys the negative health consequences of smoking, and suggesting that the proposed graphic warnings could be strengthened to serve their intended purpose of educating all Americans about the grave consequences of smoking.

³ It could be argued that the agency possessed this power before the passage of the FSPTCA, but given the U.S. Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), it was necessary for Congress to make this authority explicit.

⁴ Pub. L. No. 111-31, § 3, 123 Stat. 1776.

⁵ *Id.* § 201(a) (amending the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. § 1333, to create a new subsection (d), Graphic Label Statements).

⁶ *Id.* § 202(b) (amending 15 U.S.C. § 1333).

2. Efficacy of Graphic Warning Labels

The agency has already established a clear record that the cigarette labels used in the United States today are ineffective, and it is unnecessary to recite that record at length. Unchanged since the amendment of the FCLAA by the Comprehensive Smoking Education Act of 1984,⁷ today's warning statements are almost laughably inconspicuous and appear on only one side panel of cigarette packages and in the lower portion of cigarette advertisements. As the FDA has stated: "there is considerable evidence that the current warnings are given little attention or consideration by [American] viewers."⁸ The warnings have been described as "invisible"⁹ and clearly fail to impart the grave health risks associated with smoking in an effective manner. Because the current labels have lost what limited effectiveness they may have once had, Americans do not understand and tend to underestimate the dangers of smoking cigarettes.¹⁰

Each year, cigarette smoking kills an estimated 443,000 Americans, the vast majority of whom were under the age of eighteen when they began smoking. Tobacco use is the leading preventable cause of death in the United States, killing more Americans than AIDS, alcohol, illicit drug use, suicides, motor vehicle accidents, and homicides combined. Each day, an estimated 6,600 Americans begin smoking; roughly two-thirds of these new smokers (about 4,000 Americans) are under the age of eighteen. As the agency has noted in its notice of proposed rulemaking, "each year cigarettes are responsible for approximately 5.1 million years of potential life lost, direct health care expenditures of approximately \$96 million, and at least \$96.8 billion in annual productivity losses."¹¹ It is critically important to the health and economic vitality of our nation that this epidemic be halted, by discouraging young people from ever picking up this deadly habit and by helping current smokers to quit.

The new graphic warnings selected by the FDA will be tremendously important in achieving this goal. Considerable research demonstrates that graphic images are more effective than text-only warnings, and have significant potential to prevent smoking initiation and promote cessation. "Pictorial warnings are more effective than text-only warnings, likely because they are more emotionally arousing and present the harms of smoking in vivid and memorable ways."¹² Studies of other countries' graphic warning labels consistently demonstrate that the greater

⁷ Comprehensive Smoking Education Act of 1984, Pub. L. 98-474, 98 Stat. 2200 (1984).

⁸ Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69525.

⁹ In testimony to Congress, the Chair of the IOM's Committee on Reducing Tobacco Use described the warnings on cigarette packs as "invisible." H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th Cong. 42 (2007) (testimony of Richard Bonnie).

¹⁰ David Hammond *et al.*, *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, 15 TOBACCO CONTROL 19, 23 (2006) (explaining that an International Tobacco Control (ITC) study aimed at assessing health knowledge and warning labels in Canada, the U.S., Australia, and the UK found that knowledge of the health harms of smoking was greatest among Canadian smokers (where prominent, graphic cigarette warning labels had been required since 2001), and lowest among U.S. smokers (where small, text-only warnings had been in place since 1984)).

¹¹ Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69526.

¹² INT'L TOBACCO CONTROL POLICY EVALUATION PROJECT, FCTC ARTICLE 11 TOBACCO WARNING LABELS, EVIDENCE & RECOMMENDATIONS FROM THE ITC PROJECT 10 (May 2009).

emotional response triggered by images illustrating the harmful effects of tobacco use leads to greater awareness and better recollection of the health risks of smoking.¹³ “The rationale for the potentially greater effectiveness over text-only, is that they provide more information (a picture tells a thousand words) including the evoking of emotional responses to the images, and that together this is more likely to stimulate concerns.”¹⁴ In other words, to help ensure that the new warning labels do not become “invisible” to American viewers, it is important that the graphic warnings vividly demonstrate the harms of smoking and be emotionally striking, so as to spur viewers to quit smoking or to refrain from smoking in the first place.

Further, graphic warning labels are particularly effective because of the frequency of their messaging. Package warnings reach smokers every time they take a cigarette from a pack, buy a pack, or otherwise notice one.¹⁵ This means that a typical pack-a-day smoker is exposed to the warnings 7,300 times in a year.¹⁶ Nonsmokers could be exposed to the warnings every time they pass a cigarette display or otherwise notice a pack of cigarettes. In fact, in countries with strong graphic warning labels (e.g., Canada), nonsmokers (including children and teens) report high exposure and awareness of the health warnings on cigarette packages.¹⁷ For these reasons, if the agency selects appropriate images, they will have a significant impact.

In fact, given their extensive reach and frequency of exposure, graphic health warnings are arguably the single most cost-effective method for communicating the facts about smoking.¹⁸ They are relatively inexpensive for the government to implement and enforce, as confirmed by data from other countries and research conducted by the International Tobacco Control Policy & Evaluation Project.¹⁹ From a regulatory perspective, graphic cigarette warnings are a low-cost, high-efficacy solution. Additionally, while complying with the new, and any revised, graphic cigarette warning label requirements is not without cost to cigarette manufacturers, the costs of compliance are modest.²⁰ Tobacco companies change their packaging constantly, whether to

¹³ David Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages: Findings from the Int’l Tobacco Control Four Country Study*, 32 AM. J. PREV. MED. 210, 215 (2007).

¹⁴ Geoffrey T. Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, 87 BULL. WORLD HEALTH ORG. 2 (2009).

¹⁵ R. Borland *et al.*, *Impact of Graphic and Text Warnings on Cigarette Packs: Findings From Four Countries Over Five Years*, 18 TOBACCO CONTROL 358, 358 (2009).

¹⁶ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 2; Geoffrey T. Fong *Evidence on the Effectiveness of Large, Graphic Warning Labels (FCTC Article 11): Findings from the ITC Project*, Presentation at the Society for Research on Nicotine and Tobacco Conference, Portland, Or. (Feb. 29, 2008) (on file with author).

¹⁷ Geoffrey T. Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, *supra* note 14, at 1.

¹⁸ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 2.

¹⁹ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13. However, it should be noted that implementation of graphic cigarette warning labels is essentially cost-free to FCTC-ratifying nations and their governments, because FCTC Article 11 guidelines stipulate that all costs are to be borne by the tobacco industry. WORLD HEALTH ORG., GUIDELINES FOR IMPLEMENTATION OF ARTICLE 11 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL 42 (2009). The U.S. has not ratified the FCTC, and it is unclear whether some of the costs associated with implementing the new FDA requirements will be borne by U.S. taxpayers.

²⁰ The FDA has estimated the cost of cigarette label redesign to be somewhere between \$28 and \$78 million, depending on variable labor, printing, and expediting charges. Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69548. However, given that the tobacco industry spent \$12.5 billion on marketing and promotional expenditures alone in 2006, 74% of which was spent to reduce the price of cigarettes at

update brand images or to promote brand extensions, new products, and flavors. It is no more difficult or expensive to add or change graphic warning labels.²¹ There is no evidence that introduction of imagery will impose excessive costs or unreasonable economic hardship on tobacco manufacturers. In any event, it is reasonable to require manufacturers to bear the modest costs involved, given the toll their products take on our nation's physical and economic health.

Finally, as a federal district court has found,²² requiring graphic cigarette warning labels is legally sound. The FSPTCA amends the FCLAA and expressly grants the FDA, pursuant to the authority of the Secretary of Health and Human Services, the power to require color graphics to depict the health consequences of smoking, and to revise those requirements, as appropriate. Although the agency's proposed regulations will require tobacco manufacturers to redesign their labels, they will not impede manufacturers' ability to communicate with their customers, both through packaging and through advertising and other channels. Requiring clear, prominent warnings does not offend manufacturers' First Amendment rights under the Supreme Court's commercial speech jurisprudence. The graphic warning labels under consideration are factual disclosures – imparting “purely factual and uncontroversial information”²³ – that accurately depict the real consequences of smoking cigarettes and the benefits and importance of quitting. Graphic warning labels *add* to the sum total of truthful information in the marketplace about these commercial products, and thus support the public interest in giving consumers information that is helpful to making informed purchasing decisions. The government constitutionally regulates the advertising and labeling of products in a wide variety of industries, in the interest of providing consumers with accurate information about products that affect their health – and no product affects consumers' health more than cigarettes, which kill about half of all their users. It is difficult to imagine information more relevant to consumers, when the product in question is inherently dangerous to human health.

In conclusion, the evidence base indicates that graphic warning labels on cigarettes:

- are more likely to be noticed and discussed than text-only warnings;²⁴
- effectively inform the public about the health hazards of smoking;²⁵

the point-of-sale, tobacco manufacturers are well-positioned to bear these costs. FED. TRADE COMM'N, CIGARETTE REPORT FOR 2006 (2009), available at <http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf>.

²¹ CAMPAIGN FOR TOBACCO-FREE KIDS, INT'L RESOURCE CTR., WARNING LABELS: COUNTERING INDUSTRY ARGUMENTS, at 2 (June 2009), available at http://tobaccofreecenter.org/files/pdfs/en/WL_industry_arguments_en.pdf.

²² Commonwealth Brands, Inc. et al., v. U.S. Food & Drug Admin., No. CV-000117 (W. D. Ky. Jan. 5, 2010), at *21-28 (granting plaintiffs' motion for summary judgment concerning the FSPTCA's “tombstone advertising” requirements on First Amendment grounds, but denying plaintiffs' motions in all other respects, including their challenge to the law's graphic cigarette warning label requirements; concluding that the law's new graphic labeling requirements are sufficiently tailored to advance the government's substantial interest under *Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980)).

²³ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

²⁴ INT'L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 5 (noting that after Canada introduced large graphic warning labels in 2001, 91% of smokers in Canada said they had read the warnings and 84% of nonsmokers viewed health warning labels as a source of health information, compared with 47% of U.S. smokers, where text-only labels are required); David Hammond *et al.*, *Showing Leads to Doing: Graphic Cigarette Warning Labels Are an Effective Public Health Policy*, 16 EUR. J. PUB. HEALTH 223, 224 (2006).

- encourage smokers to quit, and help sustain the motivation to remain tobacco-free;²⁶
- may prevent nonsmokers from starting to smoke;
- are relatively easy and cost-effective for government entities to implement;²⁷ and
- are likely to withstand legal challenge.²⁸

3. The U.S. Has Fallen Behind in Regulating Cigarette Labeling and Advertising

Over the past decade, the United States has fallen behind much of the international community in regulating cigarette labeling and advertising. This failure was the result of Congress' inaction in leaving the miniscule side-of-pack-only warning labels unchanged for 25 years prior to adoption of the FSPTCA in 2009, combined with the U.S. Supreme Court's 2000 determination that Congress had retained exclusive regulatory authority to itself.²⁹ In the meantime, the rest of the world has moved forward, with some 172 countries – representing 87 percent of the world's population – ratifying the World Health Organization's Framework Convention on Tobacco Control ("FCTC"),³⁰ the first international treaty for the protection of public health. The United States has not ratified the FCTC, a fact that attests to the powerful influence the tobacco industry has over the political process in this country.

The FCTC, among other things, requires ratifying parties to implement policies protecting the public from exposure to tobacco smoke (Article 8); regulating tobacco advertising, promotion, and sponsorship (Article 13); and, of relevance here, regulating tobacco packaging and labeling (Article 11). FCTC Article 11 encourages Parties to adopt warning labels covering a minimum of 50% of the front and back of the pack,³¹ as the U.S. will soon do. Moreover, the official Guidelines for implementation of this provision, adopted unanimously by the Parties to the treaty, urge that, in light of the evidence of the effectiveness of large graphic warnings, Parties should "aim to cover as much of the principal display areas as possible."³²

²⁵ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13; Ahmed I. Fathelrahman *et al.*, *Smokers' Responses Cigarette Pack Warning Labels in Predicting Quit Intention, Stage of Change, and Self-Efficacy*, 11 NICOTINE & TOBACCO RESEARCH, 248, 249 (2009).

²⁶ Hammond *et al.*, *Showing Leads to Doing*, *supra* note 24, at 224; Hammond *et al.*, *the Impact of Cigarette Warning Labels and Smoke-Free Bylaws on Smoking Cessation*, 95 CAN. J. PUB. HEALTH 201, 201 (2004) (finding that study participants who quit smoking after introduction of graphic warning labels on cigarettes in Canada were nearly 3 times more likely to cite the warnings as a motivation to quit than smokers who quit before the graphic warnings were introduced). *See also* R. Borland *et al.*, *supra* note 15; M. O'Hegarty *et al.*, *Reactions of Young Adult Smokers to Warning Labels on Cigarette Packages*, 30 AM. J. PREV. MED. 467 (2006).

²⁷ Hammond *et al.*, *Showing Leads to Doing*, *supra* note 24, at 224 (stating "pictorial warnings are free to governments and ... are among the most cost-effective public health interventions available").

²⁸ *See* Commonwealth Brands, Inc. *et al.*, v. U.S. Food & Drug Admin., No. CV-000117 (W. D. Ky. Jan. 5, 2010).

²⁹ FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

³⁰ WHO Framework Convention on Tobacco Control (adopted by World Health Assembly on May 21, 2003). *See* World Health Org., Framework Convention on Tobacco Control (FCTC), <http://www.who.int/fctc/en/> (last visited Jan. 9, 2011).

³¹ WHO Framework Convention on Tobacco Control (FCTC), Art. 11.1(b)(iv).

³² WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, GUIDELINES FOR IMPLEMENTATION: ARTICLES 5.3; ARTICLE 8; ARTICLE 11; ARTICLE 13, at 35 (2009), *available at* http://whqlibdoc.who.int/publications/2009/9789241598224_eng.pdf.

Until now, the United States has failed to keep up with the international community's movement towards requiring larger, more vivid graphic warnings on cigarette packages and in cigarette advertisements. The FDA now has the opportunity to exercise its strengthened cigarette labeling authority in a bold and decisive manner, and to bring the United States up to speed with the rest of the international tobacco control community.

4. The FDA Should Act Decisively

As one of the few nations failing to ratify the FCTC, the United States has lagged behind many other nations in adopting effective health warnings for cigarettes. Dozens of countries – including Canada (2001), Brazil (2002), Singapore (2004), Thailand (2005), Venezuela (2005), Jordan (2005), Australia (2006), Uruguay (2006), Panama (2006), Chile (2006), Belgium (2006), New Zealand (2008), and the United Kingdom (2008)³³ – have now leapfrogged the U.S. in conveying critical health information through graphic cigarette warning labels. In fact, as of late 2010, 39 jurisdictions had adopted graphic warning requirements; many more are in the process of doing so.³⁴ Further, many countries that have already implemented graphic warning labels are now on their second, third, or even fourth round of warnings.³⁵

Our nation's delay is unfortunate, but it can be overcome if the FDA acts decisively. The agency now has the opportunity to exercise its unprecedented authority under the FSPTCA to redefine global best practices, and to set the standard for others to follow. It remains to be seen whether this opportunity will be realized.

The measure of the FDA's success in implementing the Act will not be whether the agency acts to create a stable system for the perpetual oversight of tobacco sales to tens of millions of consumers, as though cigarettes were a normal and legitimate consumer product to be used indefinitely by a large segment of the population. On the contrary, the only meaningful test of the agency's success, and of the success or failure of the Act itself, will be whether the agency begins from the premise that continued widespread use of cigarettes is not an acceptable outcome for the nation over the long term. The FDA should use its authority to move with all practicable speed towards making smoking a minor problem involving a very small fraction of the population, by using every available regulatory measure to discourage initiation and make quitting easier and more attractive.

Tobacco is not like other products. "Tobacco is a very unusual consumer product, given that it is highly addictive and kills around half of its long-term users."³⁶ There is no other similar consumable product that, when used as intended, kills its users. For that reason, the FDA should exercise its rulemaking authority to require graphic cigarette warnings that are aimed at the eventual elimination of smoking in the United States, like the countries mentioned above, and to revise those requirements as appropriate to ensure their continued efficacy. Although the

³³ Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, *supra* note 14, at 1. The year noted in parentheses is the year of implementation, not passage of the enabling legislation.

³⁴ CANADIAN CANCER SOCIETY, CIGARETTE PACKAGE HEALTH WARNINGS: INTERNATIONAL STATUS REPORT (2010), available at http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_en.pdf.

³⁵ *Id.* at 3. See also Fong *et al.*, *supra* note 14, at 1.

³⁶ Borland *et al.*, *supra* note 15, at 358.

FSPTCA is apparently intended to “continue to permit the sale of tobacco products to adults,”³⁷ the agency should exercise its discretion boldly to create an environment that dissuades nonsmokers from starting and that makes it as easy as possible for smokers to quit. Powerful warning labels will assist significantly with both of these goals.

B. FDA’s Proposed Graphic Cigarette Warning Labels Should be Strengthened

1. The Proposed Warnings Do Not Create As Strong of an Impression as They Should

We are not experts in consumer or behavioral psychology. Nor are we in a position to critique the methodology underlying the experimental study commissioned by the Center for Tobacco Products.³⁸ And yet we cannot escape the observation that many of the 36 possible images offered for comment by the agency appear less strong, and perhaps less effective, than many of the images already in use in other countries. The Act gives the agency extensive authority to require whatever label statements and images will best prevent smoking initiation and promote cessation. To achieve this end, we believe the final graphic warning labels should be stronger than those initially proposed, for the reasons explained below.

a. The Evidence Base in Brief: What Works in Graphic Cigarette Warning Labeling

A significant body of research on graphic cigarette warning labels has led to the development of a conceptual model, consistent with theories of message processing and health behavior change that explains their efficacy.³⁹ Research has measured short- and long-term responses to graphic cigarette warning labels (both hypothetical/proposed warnings, and those actually used in other countries), ranging from initial emotional responses (e.g., worried, disgusted) to more sustained cognitive impressions (e.g., informative, memorable).⁴⁰ Although there is some debate about whether more explicit or “gruesome” graphic warnings are more effective in promoting sustained behavior change around smoking,⁴¹ on balance, the research indicates that:

- warning size is related to warning effectiveness;⁴²
- more vivid, explicit images tend to elicit stronger emotional responses;⁴³
- eliciting strong emotional reactions to graphic cigarette warning labels aids cognitive processing and enhances recall of the health warning, thereby ensuring that the health message is better understood and remembered;⁴⁴ and

³⁷ Pub. L. No. 111-31, § 3(7), 123 Stat. 1776.

³⁸ James Nonnemaker *et al.*, RTI International, *Experimental Study of Graphic Cigarette Warning Labels: Final Results Report* (Dec. 2010).

³⁹ *Id.* at 1-2 (citations omitted).

⁴⁰ *See sources cited id.*

⁴¹ *See* G. Hastings & L. MacFadyen, *The Limitations of Fear Messages*, 11 TOBACCO CONTROL 73-75 (2002); *cf.* L. Biener & T.M. Taylor, *The Continuing Importance of Emotion in Tobacco Control Media Campaigns: A Response to Hastings & MacFadyen*, 11 TOBACCO CONTROL 75-77 (2002). *See also generally* Borland *et al.*, *supra* note 15, at 358.

⁴² Borland *et al.*, *supra* note 15, at 363.

⁴³ *See* Glenn Leshner *et al.*, *Scare ‘Em or Disgust ‘Em: The Effects of Graphic Health Promotion Messages*, 24 HEALTH COMM. 447, 457 (2009).

⁴⁴ *Id.*

- immediate or “gut” reactions influence short-term outcomes, such as subsequent recall of the message;⁴⁵
- subsequent recall of the health message leads to changes in knowledge, attitudes, and beliefs about the dangers of tobacco use and secondhand smoke exposure;⁴⁶ and
- as attitudes and beliefs about tobacco use are modified, changes in intentions to stop (or not start) smoking change, and, over time, smoking initiation is lowered and successful cessation is achieved.⁴⁷

In sum, research indicates that graphic cigarette warnings that prompt a strong emotional response (e.g., fear, alarm, disgust, repulsion) in the viewer are most effective;⁴⁸ warning size increases warning effectiveness; and stronger, more vivid warnings tend to sustain their effects for longer periods of time.⁴⁹ Graphic warnings are effective because “they elicit greater emotional engagement with the information,” and this engagement “drives much of the subsequent quitting-related activity.”⁵⁰ Decades of research studies indicate that fear appeals are effective in motivating health behavior change (i.e., quitting smoking), especially if warnings include information about how to avoid fearful consequences (e.g., cessation information, quit lines).⁵¹ In sum, graphic, fear-inspiring or disturbing warning labels are associated with increased motivation to quit smoking, and reduced propensity to start smoking. All of these research findings support the argument that governments should *exceed* FCTC Article 11 minimum requirements and strive to follow or exceed FCTC Guidelines, explained below, for graphic cigarette warning labels.

b. Our Impressions of & Recommendations for FDA’s Graphic Warning Labels

We have three primary observations of the FDA’s proposed graphic cigarette warning labels: (1) the warnings should be larger than 50% of the principal display areas (front and back of pack); (2) the proposed photographic images could be more vivid, and thus elicit a stronger emotional response; and (3) the cartoon images are not visceral enough and should be rejected.

1. The Warnings Should be Larger

First, we recommend that the FDA exercise its authority under Section 201(a) of the FSPTCA⁵² to require warnings that exceed the 50% of front and rear principal display panel threshold.

⁴⁵ Nonnemaker *et al.*, *supra* note 38, at 1-2.

⁴⁶ *Id.*

⁴⁷ Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, *supra* note 14.

⁴⁸ David Hammond, *Graphic Canadian Cigarette Warning Labels and Adverse Outcomes: Evidence from Canadian Smokers*, 94 AM. J. PUB. HEALTH 1442, 1444 (2004).

⁴⁹ Borland *et al.*, *supra* note 15, at 363 (concluding that the evidence base indicates that larger cigarette warnings are more effective; graphic warnings are more effective than text-only warnings in producing sustained cognitive and behavioral reactions; and, given their benefits, governments should exceed FCTC recommendations on graphic cigarette warning labels rather than just meeting its minimal requirements).

⁵⁰ *Id.* at 362.

⁵¹ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, AT 6.

⁵² Pub. L. 111-31, 123 Stat. 1776 (codified at 15 U.S.C. § 1333(d)).

The FCTC states that cigarette warning labels should cover 50% or more, but no less than 30%, of the principal display areas (the front and back of the cigarette package).⁵³ Although the treaty *mandates* only that the warning occupy at least 30% of the display areas, the official Article 11 Guidelines state: “Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that *cover more than 50% of principal display areas and aim to cover as much of the principal display areas as possible.*”⁵⁴

The Article 11 Guidelines, adopted at the Third Conference of the Parties in November 2008, LAO provide that graphic warning labels should:

- appear on both front and back of cigarette packages;
- appear at the top of the principal display areas;
- include full color pictures, not black-and-white images;
- provide accurate information about the harms of smoking and risks of exposure to secondhand smoke; and
- include a range of warnings and messages;
- provide information about cessation; and
- be revised and rotated regularly.⁵⁵

Article 11 stipulates that each party shall adopt and implement effective packaging and labeling measures within three years after the FCTC obligations come into force for that party.⁵⁶

In light of these recommendations, many Parties have exercised their authority to exceed the minimum requirements of the FCTC.⁵⁷ Many countries – 14, to be precise – require graphic cigarette warning labels to exceed 50% of the package’s principal display areas. Uruguay, currently the international leader in graphic cigarette warning labels, has required graphic labels to cover 80% of both the front and back panels of cigarette packages since 2006. (Furthermore, Uruguay has prevented “message burnout” by rotating its graphic warnings; new images were required in 2006, 2008, 2009, and 2010).⁵⁸ Honduras has also adopted legislation to require picture-based warnings to cover 80% of the front and back of cigarette packages; implementing regulations are required to be adopted by August 21, 2011.⁵⁹ Mauritius requires graphic warnings to cover 60% of the front of pack, and 70% of the back of pack. Australia and New Zealand require graphic warnings to cover 30% of the front of pack, and 90% of the back of pack, for 60% combined principal display coverage. Mexico requires graphic warnings to cover 30% of the front of pack, and 100% of the back of pack, resulting in combined principal display coverage of 65%.⁶⁰

⁵³ World Health Org., Framework Convention on Tobacco Control, Art. 11.1(b)(iv).

⁵⁴ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, GUIDELINES FOR IMPLEMENTATION: ARTICLES 5.3; ARTICLE 8; ARTICLE 11; ARTICLE 13, at 35 (2009) (emphasis added).

⁵⁵ *Id.* See also INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 2.

⁵⁶ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, GUIDELINES FOR IMPLEMENTATION: ARTICLES 5.3; ARTICLE 8; ARTICLE 11; ARTICLE 13 (2009).

⁵⁷ See CANADIAN CANCER SOCIETY, *supra* note 34, at 8.

⁵⁸ *Id.* at 2-3.

⁵⁹ *Id.* at 2.

⁶⁰ *Id.* at 4. There is some debate about whether the 30/100 (65% total coverage) versus 50/50 approach is more effective.

Recently, Canada announced that it will modify its graphic warning label requirements, which have been unchanged since 2001, to cover 75% of the front and back of cigarette packages.⁶¹ (Although a regulatory process needs to be completed, the Minister of Health has stated that the new warnings will appear on packages in 2011.)⁶² Canada was the first country to require graphic warnings in 2001, but had not rotated the images or otherwise changed its warnings since then. The new warnings were initiated in recognition of the fact that the previous 50% warnings had reached their maximum potential, and stronger warnings were needed to keep young people from smoking and encourage existing smokers to quit.⁶³ The new warnings will feature new diseases and, for the first time, testimonials from individuals affected by tobacco use. (Chile also utilizes testimonials featuring “real people” in its graphic cigarette warning labels, which are required to cover 50% of the front and back of cigarette packages.)⁶⁴ Canada’s new graphic warning labels will also include a toll-free quit line number and a web address to readily connect Canadian smokers with cessation information.

Although Article 11 does not prescribe the size of the graphic warning labels to be used by the FCTC Parties, a significant number of Parties have exercised their authority to exceed FCTC minimum requirements, as noted above.⁶⁵ Research from other countries suggests that graphic warning labels that exceed FCTC minimum size requirements are more effective at reducing tobacco use.⁶⁶ Findings from the International Tobacco Control (ITC) Four Country Study indicate that “more prominent health warnings are associated with greater levels of awareness and perceived effectiveness among smokers.”⁶⁷ In particular, this study found that new health warnings that were enhanced to meet or exceed minimum international (FCTC) size standards were significantly more likely to be noticed and read, viewers of such warnings were more likely to think about the health risks of smoking and contemplate quitting, and viewers more often reported that such warnings had deterred them from having a cigarette.⁶⁸ The ITC study findings provide strong support for the effectiveness of warnings that meet the minimum FCTC size standards; “however, the findings also suggest that larger pictorial warnings ... are likely the most effective means of communicating the full range and severity of health risks to smokers.”⁶⁹

⁶¹ HEALTH CANADA, STRONGER HEALTH WARNING MESSAGES ON CIGARETTE AND LITTLE CIGAR PACKAGES (Dec. 2010). The full set of 16 warnings has not yet been released, but examples may be seen here: <http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/fact-fait/fs-if/stronger-bonifiees-eng.php>.

⁶² *Id.*; Rob Cunningham, Canadian Cancer Society, Canada Announces New Picture Warnings to Cover 75% of Package Front and Back (Dec. 30, 2010) (on file with author).

⁶³ HEALTH CANADA, *supra* note 61.

⁶⁴ Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, *supra* note 14, at 3; CANADIAN CANCER SOCIETY, *supra* note 34, at 6.

⁶⁵ See CANADIAN CANCER SOCIETY, *supra* note 34, at 6-8.

⁶⁶ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 8 (comparing warning labels used in Thailand against those used in Malaysia, and concluding that “enhancing warning labels beyond TCTC minimum standard increases effectiveness”).

⁶⁷ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13, at 215.

⁶⁸ *Id.*

⁶⁹ *Id.* at 216.

According to ITC researchers, there are substantial benefits to in changing from the FCTC minimum (30% of principal display areas), to the FCTC recommendation (50% or more of principal display areas).⁷⁰ Based on a study comparing the impact of graphic cigarette warning labels in Thailand (where the labels were changed in 2006 from the FCTC minimum (30%) to the FCTC recommendation (50% or more)) and those in Malaysia (where the labels did not change), ITC researchers concluded that enhancing warning labels beyond the FCTC minimum standard increased their effectiveness.⁷¹ The ITC Thailand Survey found that increasing the label size and adding powerful graphic images to warning labels resulted in significant increases in the percentage of smokers who thought about the health risks of smoking and contemplated quitting.⁷² By contrast, the ITC Malaysia Study conducted during the same period found no such increases.⁷³ According to one expert, based on this research, it is reasonable to infer that even greater increases would occur if the labels were made even more prominent (more than 50% of principal display areas).⁷⁴ These conclusions indicate that the FCTC's requirements and Guidelines for image size should be considered a *floor*, rather than a ceiling.

In sum, the United States can do better. It should require the graphic cigarette warning labels to cover more than 50% of the front and back of cigarette packages, as many other countries have done.

2. The Photographic Images Should be More Vivid

Second, we recommend that the photographic images used in the graphic warning labels be more vivid and visual. While some of the proposed photographic images are compelling (“Hole in Throat,” “Deathly Ill Woman,” “Healthy/Diseased Lungs”),⁷⁵ others are not that gripping or emotionally arousing (“White Cigarette Burning,” “Woman In Rain”), or are simply confusing (“Woman Blowing Bubble”).⁷⁶ When compared with many of the images used in other countries, the FDA’s proposed photographic images do not pack much of a punch. Because a picture speaks louder than words, we submit Brazil’s graphic cigarette warning labels as an example of more effective photographic images:

⁷⁰ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 8.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.* Malaysia has since modified its cigarette warning labels to include graphic images; since 2009, such warnings have been required to cover 40% of the front of pack, and 60% of the back of pack. CANADIAN CANCER SOCIETY, *supra* note 34, at 6.

⁷⁴ Geoffrey T. Fong *Evidence on the Effectiveness of Large, Graphic Warning Labels (FCTC Article 11): Findings from the ITC Project*, Presentation at the Society for Research on Nicotine and Tobacco Conference, Portland, Or. (Feb. 29, 2008) (on file with author).

⁷⁵ Here, we use the referential names given to the proposed images in the Center for Tobacco Products’ experimental study. Nonnemaker *et al.*, *supra* note 38.

⁷⁶ The desired messaging effect of this proposed image is not clear. What is this image supposed to depict? Stronger lung capacity? Is the viewer supposed to discern that the woman pictured is a nonsmoker? We also note that the research commissioned by the agency concluded that this image did not resonate with the study sample. *See* Nonnemaker *et al.*, *supra* note 38.



Brazil has implemented some of the most vivid and emotionally arousing graphic cigarette warning labels in the world. The Brazilian approach is based on research showing that stimuli that are very negative and emotionally arousing cause an avoidance response.⁷⁷ After Brazil introduced new warnings in 2002, and again in 2004, 73% of Brazilian smokers said they approved of them, 54% said they had changed their opinion about the health consequences of smoking, and 67% said the new warnings made them want to quit.⁷⁸ Evaluation of the Brazilian approach has demonstrated that such graphic, visceral – arguably gruesome – warnings are most effective in increasing intentions to quit smoking.⁷⁹

Images like those used in Brazil may be difficult to look at, but they accurately depict the very real dangers of smoking, and have been shown to resonate with viewers. The point of these warnings is not to scare, but to accurately inform existing and potential smokers about “the full range, likelihood, and severity of smoking-related disease.”⁸⁰ As one leading international expert has explained:

*[T]he health risks of smoking are inherently frightening: warnings of lung cancer that fail to contain arousing information also fail to communicate these risks in a truthful, forthright manner.*⁸¹

⁷⁷ Research shows that anti-smoking signs “which elicit strong emotional arousal ... [and] portray the adverse consequence of smoking” are associated with an “increased intention not to smoke” among both adults and teenagers. Wakefield *et al.*, *Effects of Anti-Smoking Advertising on Youth Smoking: A Review*, 8 J. HEALTH COMM. 229, 240 (2003).

⁷⁸ CAMPAIGN FOR TOBACCO-FREE KIDS, INT’L RESOURCE CTR., WARNING LABELS: ESSENTIAL FACTS 1 (July 2009) (citing Presentation to EU Commission on Enforcement of Health Warnings in Brazil (2002)).

⁷⁹ B.E. Nascimento *et al.*, *Avoidance of Smoking: The Impact of Warning Labels in Brazil*, 17 TOBACCO CONTROL 405, 409 (2008) (a study of the initial round of Brazil’s graphic cigarette warning labels (issued in 2002) and the second, more vivid round (in 2004) found that the most graphic and threatening warning labels more effectively increased smokers’ intentions to avoid smoking). See also CAMPAIGN FOR TOBACCO-FREE KIDS, INT’L RESOURCE CTR., WARNING LABELS: EVIDENCE 2 (June 2009).

⁸⁰ Hammond *et al.*, *Showing Leads to Doing*, *supra* note 24, at 224.

⁸¹ *Id.*

The primary intent of graphic cigarette warning labels is to communicate health risks that are “manifestly frightening and harsh.”⁸² Graphic warning labels depicting lung cancer, for example, that fail to contain arousing, arguably brutal, images also fail to communicate the health risks of smoking in a truthful manner.⁸³ Cancer is not a pretty or pleasant disease, and images depicting its devastating effects on the human body should be hard to look at and emotionally arousing. “In this context, emotional reactions should be interpreted as a measure of effectiveness.”⁸⁴

We encourage the FDA to consider utilizing more vivid, visceral photographic images, like the Brazilian examples above, in its final graphic warnings. We note that the experimental study commissioned by the agency concluded that “cigarette warning labels that are most graphic or emotional elicit the strongest emotional reactions,” and that “images that evoke the strongest ... emotional responses are likely to be most effective in promoting increased awareness of ... the health risks of smoking and in turn promoting behavior change.”⁸⁵

3. Cartoons Should be Avoided

Third, we encourage the FDA to consider not using cartoon or pictogram-based images. We acknowledge that some research has shown that cartoon-based graphic labels may resonate with youth, and that Article 11 specifically allows the use of pictograms. However, on balance, it seems that they are largely ineffective in impressing adults and young adults.⁸⁶ Moreover, they seem to parody rather than accurately depict the “real” consequences of smoking. Cartoons can easily be perceived as fictitious or satirical. Using images that accurately depict the real impact that tobacco use has on the human body – such as actual photographs of diseased lungs or persons dying of cancer – have proven to be more effective in warning labels used in other countries, such as Canada, Australia, Brazil, and Thailand.

4. Cessation Information Should be Included

Fourth and finally, we recommend that the FDA add cessation information to the proposed graphic warning labels. The FCTC recommends that graphic cigarette warning labels include cessation information and resources. As the health risks depicted on cigarette packages become more explicit, providing cessation information may become increasingly important to helping smokers change their behavior.⁸⁷ “International experience shows that calls to quit lines increase substantially when a toll-free number is added prominently to the package.”⁸⁸ Several FCTC-ratifying countries have opted to prominently feature national quit lines on their warning labels, resulting in increased use of these resources.⁸⁹ For example, in the Netherlands, calls to the

⁸² Hammond *et al.*, *Graphic Canadian Cigarette Warning Labels and Adverse Outcomes*, *supra* note 48, at 1444.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Nonnemaker *et al.*, *supra* note 38, at 4-2.

⁸⁶ *See, e.g., id.* at 3-22.

⁸⁷ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13, at 15.

⁸⁸ Canadian Cancer Society, *Society Applauds New Cigarette Package Health Warnings* (Dec. 30, 2010).

⁸⁹ Hammond *et al.*, *Showing Leads to Doing*, *supra* note 24, at 223.

national quit line increased dramatically after its inclusion on cigarette packages.⁹⁰ The United Kingdom Department of Health estimates that the UK warnings have prompted an additional 2,000 to 4,000 calls per month to the National Health Services smoking helpline.⁹¹ Research from Australia and New Zealand also demonstrates that including a quit line number as part of a graphic cigarette warning label increases the demand for cessation services.⁹² As noted above, Canada's new graphic warning labels, to be implemented later this year, will include a toll-free national quit line number and a web address to provide smokers with easy access to cessation information and resources.⁹³ The new Canadian warnings will also be accompanied by a social media campaign, designed to complement the warnings as part of an integrated cessation promotion plan.⁹⁴

The FDA could learn from the experience of these other countries in requiring cessation resources to be included in graphic cigarette warning labels. For instance, the U.S. Department of Health and Human Services' national toll-free portal number – 1-800-QUIT-NOW – could be included in the warning labels. This number would route calls to the national network of U.S. state and territorial quit lines, and put smokers quickly in touch with cessation resources in their communities.

In sum, when compared with the graphic warnings used in other countries, a number of the FDA's proposed graphic warning labels appear relatively mild and even timid, and we believe other images would be more effective in reducing tobacco use. We encourage the FDA to review the graphic cigarette warning labels that have already been used and tested in other countries, and to select final warnings that are more vivid and emotionally powerful than the 36 graphic warnings initially proposed. The FDA should benefit from the international community's experience and follow the example set by nations who have pioneered graphic cigarette warning label requirements. We recommend that the agency:

- require graphic warnings that cover more than 50% of the front and back of cigarette packages;
- utilize more vivid photographic images;
- avoid the use of cartoons; and
- add cessation information (e.g., a toll-free nationwide quit line number, as well as a web address referring smokers to online cessation resources) to the new warning labels.

2. The Proposed Graphic Warnings May Suffer From Cultural Biases

Previous research and recommendations have raised concerns about how to select graphic warning labels in a way which reaches the broadest swath of a diverse nation's population, taking into account differences in educational attainment and other socio-economic indicators.

⁹⁰ M.C. Willemsen *et al.*, *Impact of the New EU Health Warnings on the Dutch Quit Line*, 11 TOBACCO CONTROL 382 (2002).

⁹¹ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13, at 215.

⁹² C.L. Miller *et al.*, *Impact on the Australian Quitline of New Graphic Cigarette Pack Warnings including the Quitline Number*, 18 TOBACCO CONTROL 235 (2009); J. Li *et al.*, *New Graphic Warnings Encourage Registrations with the Quitline*, 18 TOBACCO CONTROL 72 (2009).

⁹³ HEALTH CANADA, *supra* note 61.

⁹⁴ Canadian Cancer Society, *supra* note 88.

For example, the Institute of Medicine has expressed concern about the ability of consumers with less education to recall the information included in textual cigarette warning statements.⁹⁵ Graphic warnings have greater impact than text-only labels because they can be recognized and understood by the groups most susceptible to tobacco initiation and addiction, such as juvenile, low socio-economic, and low literacy populations.

Graphic warning labels on cigarettes are an important public health intervention because they can more effectively reach “low-income or low-literacy individuals who may not have access to other mediums of health information.”⁹⁶ Research consistently indicates that the pairing of graphic images with textual warnings increases comprehension and recall. Even if the text cannot be comprehended by the viewer, the images will help to underscore the warning’s intended message. The FDA acknowledges that because the current U.S. smoking population consists of persons with varied educational attainment (including, notably, a high percentage of individuals with low educational attainment) and includes a large number of teenagers who have yet to complete their education, text-only warnings are inadequate to discourage smoking in this country.⁹⁷

Graphic warnings may be particularly important in communicating health information to populations with lower literacy rates. This is critically important, because in the United States, smokers generally report lower levels of education than nonsmokers.⁹⁸ We applaud FDA’s effort to implement graphic cigarette warning labels. However, care should be taken in the selection of images for use in low-literacy or non-English-speaking/English as a Second Language (ESL) populations because, without supporting text, images that are not strong enough may inadvertently suggest approval of tobacco use, rather than warning of its harms.⁹⁹ “Although pictures may say a thousand words, it is critical to select those that say the correct thousand words.”¹⁰⁰

We question whether the proposed graphic warning labels will be effective in reaching the broadest number of Americans, or whether cultural and linguistic biases will impede their effectiveness. Additionally, open questions remain about how to select images which resonate

⁹⁵ INST. OF MED. OF THE NAT’L ACAD., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 295 (2007).

⁹⁶Hammond *et al.*, *Showing Leads to Doing*, *supra* note 24, at 224.

⁹⁷ Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69531.

⁹⁸ U.S. Ctrs. for Disease Control & Prevention (CDC), *Cigarette Smoking Among Adults—United States, 2004*, 54 MORBIDITY & MORTALITY WEEKLY REPORT (MMWR) 1121, 1121 (Nov. 2005) (stating: “By education level, current smoking prevalence was highest among adults who had earned a General Educational Development (GED) diploma (39.6%) and among those with a 9th-11th grade education (34.0%) and generally decreased with increasing years of education”). *See also* American Lung Ass’n, Facts & Figures: African Americans (Feb. 2010), <http://www.lungusa.org/stop-smoking/about-smoking/facts-figures/african-americans-and-tobacco.html> (last visited Jan. 9, 2011) (noting that, in the African American population, the prevalence of smoking declines as education level increases; “In 2008, smoking rates were over 3.4 times higher among African American males over age 25 who had less than a high school education (34.5%) compared to those with a college education (10.1%). Smoking rates are also much higher in African American females over age 25 years old who have less than a high school education (23.2%) compared to those with a college education (9.5%).”).

⁹⁹ Fong *et al.*, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, *supra* note 14, at 2.

¹⁰⁰ *Id.*

with consumers of distinct cultural backgrounds, even if the images help to surmount linguistic differences and low literacy abilities.

For example, it appears that some of the proposed images may arguably carry a certain level of Western or Caucasian cultural bias. It is possible that not all of the images will resonate with, or even make sense to, Americans of African, Asian, or Latin/South American origin, who comprise an increasing segment of our population. To elucidate our concerns, we pose the following questions:

- Will all American cigarette purchasers recognize a marionette?
- What percentage of Americans will understand what a toe tag signifies?
- In an era where many Americans hail from cultures that do not mark graves with tombstones, or even bury the dead, what percentage of the public will recognize the shape intended to represent a tombstone? Of those, what percentage will understand that the letters “RIP” are an abbreviation for “Rest in Peace,” and are not intended to represent the word “rip”?

These cultural concerns are compounded by the fact that the textual warnings are required by law to be in the English language,¹⁰¹ and that those populations most vulnerable to these types of cultural confusion may have limited English proficiency.

The agency commissioned an experimental study to analyze the salience, memorability, and overall impact of the proposed 36 graphic warnings. We note that this study involved a small, random sample of participants that did not include significant numbers of individuals from racial or ethnic minority groups. According to the study’s authors:

Small sample sizes for populations of interest (e.g., African Americans, Latinos, lower income or lower educational status) prevented us from obtaining precise parameter estimates for these populations, making it difficult to assess differences in efficacy of the warning labels across these groups. Time constraints prevented us from attempting to recruit additional members of some populations of interest ... The time frame available for this study simply did not allow for such efforts to recruit additional members of these groups.¹⁰²

The omission of study participants from priority population groups is troubling, given that lower educational attainment and socio-economic class is positively associated with tobacco use, and both of these characteristics are prevalent among members of minority populations in the United States. In sum, the omission of representatives of priority populations from the experimental study may call into question the utility of its conclusions.

We would encourage the FDA to conduct further research designed to assess which graphic warnings may be most effective in reaching and resonating with priority populations. To be

¹⁰¹ 15 U.S.C. § 1333(b); proposed §1141.10(b)(2). See Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 218, at 69537.

¹⁰² Nonnemaker *et al.*, *supra* note 38.

effective, the graphic warning labels must be readily understood and have a meaningful impact on all Americans.

3. The FDA Is Not Limited to the 36 Proposed Images

From a legal perspective, the FDA is not limited to selecting from the 36 graphic warning labels that have been proposed through this rulemaking notice. The FSPTCA empowers the FDA, as the designee of the Secretary, to adjust the format, size, color graphics, and text of any of the label requirements, if it “finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.”¹⁰³

If the FDA finds, through this rulemaking process, that considerable questions have been raised about the efficacy of several or a majority of the proposed 36 graphic warning labels, then the agency should change course and consider developing new proposed graphic warnings. The purpose of this notice and comment period is to allow the agency to receive and consider comments from diverse constituents. If the FDA concludes that some or all of the proposed images may not be the most effective, then the agency should create or select better images, based on the examples already tested by the international community. As the FTC recommends: “Parties should consider the evidence and the experience of others when determining new packaging and labeling measures and aim to implement the most effective measures they can achieve.”¹⁰⁴

4. The Graphic Warning Labels Should be Revised & Rotated Regularly

Over time, all health warnings are subject to “message wear-out.” As consumers become more accustomed to viewing graphic warnings on cigarette packages and in cigarette advertisements, the images – however disturbing – lose their “punch” (although graphic warnings have been demonstrated to sustain their effectiveness longer than text-only warnings).¹⁰⁵ Graphic warning labels on cigarettes lose their impact with repeated exposure; however, research indicates that rotating the warnings increases their salience.¹⁰⁶ For this reason, whatever images the FDA selects, it should make provisions to revisit all cigarette warning labels (both the textual statements and the graphics) periodically through rulemaking. In order to sustain their efficacy, graphic cigarette warning labels should be rotated, ideally no less than every two to four years.¹⁰⁷ Rotation of graphic cigarette warning labels prevents overexposure and message wear-out.

¹⁰³ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201 (d), 123 Stat. 1776 (2009).

¹⁰⁴ WORLD HEALTH ORG., GUIDELINES FOR IMPLEMENTATION OF ARTICLE 11 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL 33 (2009).

¹⁰⁵ INT’L TOBACCO CONTROL POLICY EVALUATION PROJECT, *supra* note 12, at 6; Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13, at 15.

¹⁰⁶ Hammond *et al.*, *Text & Graphic Warnings on Cigarette Packages*, *supra* note 13, at 15.

¹⁰⁷ *See id.* (noting that decreases in salience were observed 2.5 years following the introduction of the new UK warnings, but measures of impact remained high in Canada 4 years after implementation; thereby suggesting that larger, more vivid warnings are more likely to retain their salience over time than less prominent warnings, but still suggesting that graphic warning labels should be revised and rotated regularly to prevent message wear-out).

The tobacco industry will likely raise objections to frequent rotation. However, the experience of other countries has demonstrated that warnings can be rotated annually, or every two years, without difficulty. Many of the countries that have already implemented graphic cigarette warning labels, such as Brazil, Thailand, and Uruguay, are now on the second, third, or even fourth round of graphic warnings.¹⁰⁸

We appreciate that notice and comment rulemaking takes time, and making provisions for future rulemaking will entail public expense. But the experience of the international community suggests that, in order for graphic cigarette warning labels to have the greatest efficacy, they must be rotated regularly. The FDA should learn from this experience. The United States cannot repeat history and have cigarette warnings that remain unchanged for decades. Past experience with cigarette warning labels demonstrates that failing to refresh the messages about the health risks of smoking leads audiences to cease paying attention to the messages, no matter how grave the risks. The FDA cannot allow this to happen, if it hopes to prevent youth initiation, promote cessation, and work to end the disastrous consequences of tobacco use.

Conclusion

We appreciate this opportunity to share our observations and recommendations regarding the FDA's proposed graphic cigarette warning labels. The Tobacco Control Legal Consortium would welcome the chance to provide any additional information that may be helpful. Should you have any questions about these comments, please contact Kate Armstrong via e-mail at kate.armstrong@wmitchell.edu or by calling 651-290-6339.

Respectfully,

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¹⁰⁸ CANADIAN CANCER SOCIETY, *supra* note 34.