September 28, 2009

In Regards To: "Regulation of Tobacco Products Docket No. FDA-2009-N-0294"

Food and Drug Administration
Division of Dockets Management [HFA-305]
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To the Commissioner of the Food and Drug Administration,

The American Cancer Society Cancer Action Network[SM] (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem. ACS CAN supports legislative, regulatory, and policy efforts that will make cancer a top national priority.

Lung cancer is the leading cause of cancer deaths in the United States today, and tobacco use is responsible for 87 percent of all lung cancer deaths[1]. ACS CAN has established aggressive goals to reduce cancer – including lung cancer incidence and mortality – that we are pursuing with the cooperation and collaboration of the public, private, and nonprofit sectors. ACS CAN strongly supported the passage of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) which granted the Food and Drug Administration (FDA) the authority to regulate tobacco products and their marketing. ACS CAN strongly believes that FDA regulation is critical to reducing the tobacco industry's ability to addict new, young smokers and stands ready to assist the FDA in effectively implementing this new law.

While the tobacco industry has spent the last 50 years vehemently denying and misleading smokers about the dangers of tobacco use and marketing their products to youth, the American Cancer Society and more recently ACS CAN has documented the lethal consequences of smoking[2], its detrimental effects on almost every organ of the

[1] American Cancer Society. *Cancer Facts & Figures 2009.* Atlanta: American Cancer Society; 2009. Doll R, Peto R. *The Causes of Cancer.* New York, NJ: Oxford Press; 1981. US Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General.* Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1989.

[2] Thun MJ, et al. Cigarette Smoking and Changes in the Histopathology of Lung Cancer. *Journal of the National Cancer Institute.* November 6, 1997; 89(21): 1580-1586. Thun MJ, Burns DM. Health impact of "reduced yield" cigarettes: a critical assessment of the epidemiological evidence. *Tobacco Control.* 2001; 10: i4-i11. Harris JE, Thun MJ, Mondul AM, Calle EE. Cigarette tar yields in relation to mortality from lung cancer in the Cancer Prevention Study II prospective cohort, 1982-8. *BMJ.* 2004; 328(7431): 72-76. Smith RA, Glynn TJ. Epidemiology of Lung Cancer. *Radiologic Clinics of North America,* 2000, 38(3): 453-470.

body[3], and has instituted comprehensive public policies to effectively reduce tobacco use and exposure to secondhand smoke in this country. In fact, the reductions in overall cancer mortality the nation has experienced over the past few years can be partially attributed to our work in tobacco control to prevent youth from ever starting to use tobacco products and helping current users quit. Despite our efforts, tobacco use remains the number one preventable cause of death in the United States, responsible for more than 443,000 deaths each year[4]. Tobacco use accounts for at least 30 percent of all cancer deaths and an increased risk of at least 15 different types of cancer, as well as heart disease, stroke, and several lung diseases[5]. The new authority granted to the FDA to regulate tobacco products and their marketing provides new tools that will complement existing proven policies, to further combat the strategies of an industry that has worked hard to mislead the public about the dangers of its products.

The tobacco industry has a long history of altering product design and using marketing strategies to quell concern about the health risks of its products and addict new, young smokers as replacement users for those who have died prematurely from using tobacco. In 2006, U.S. District Court Judge Gladys Kessler concluded in the landmark Department of Justice case against the tobacco companies, in which they were found guilty of racketeering, "Knowing that advertising and promotion stimulated the demand for cigarettes, Defendants used their knowledge of young people, gained through tracking youth behavior and preferences, in order to create marketing campaigns (including advertising, promotion, and couponing) that would appeal to youth, in order to stimulate youth smoking initiation and to ensure that young smokers would select their brands." Priority areas for action for the FDA as it asserts its new authority must include addressing product design and ingredients that encourage initiation and increase addictiveness, such as flavorings and additives like menthol; false health claims; deceptive tobacco industry marketing, especially those targeted at youth; and, improving the warning labels on tobacco products.

Scientific Advisory Committee

ACS CAN would like to commend the FDA for swiftly establishing the Center on Tobacco Products, appointing a Director, and establishing the Tobacco Products Scientific Advisory Committee (hereon referred to as the "Advisory Committee"). These actions display a commitment to implementing the FSPTCA expeditiously and as

[3] US Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General.* Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1989.

[4] Centers for Disease Control and Prevention. Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000-2004. *MMWR*. 2008; 57(45): 1226-1228. Centers for Disease Control and Prevention.

[5] US Department of Health and Human Services. *The Health Consequences of Smoking - A Report of the Surgeon General.* Rockville, MD: US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2004.

effectively as possible. The establishment of the Advisory Committee is particularly critical because its responsibilities include providing information, advice and recommendations to the Secretary of Health and Human Services (hereon referred to as "the Secretary") on several key issues including menthol in cigarettes, the nature and impact of dissolvable tobacco products, the effects of alterations of nicotine yields in tobacco products, as well as tobacco industry applications for modified risk products.

Menthol

Under the FSPTCA, the Advisory Committee is required to provide the Secretary with a report and recommendations "on the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities" within the first year of its existence. Addressing menthol in cigarettes is critical to reducing youth initiation of smoking and equally important, could substantially impact the unequal health burden experienced by certain populations, including African-Americans, because of aggressive industry marketing in minority communities.

Long before cigarette companies started adding fruit, candy, and alcohol flavorings to cigarettes, they were manipulating levels of menthol to addict new, young smokers. Menthol acts to mask the harsh taste of tobacco with a minty flavor and reduce irritation at the back of the throat with a cooling sensation. Additionally, menthol may enhance the delivery of nicotine. Knowing that youth who experience less negative physiological effects of smoking are more likely to continue on to smoking regularly, the tobacco industry has spent decades manipulating its menthol brand-specific product line to appeal to youth. For example, Lorillard's brand Newport was introduced in the late 1950s as a low-level menthol cigarette and its success in the market has been attributed to its appeal to young smokers[6]. It wasn't long before other tobacco companies recognized the use of lower menthol levels to appeal to young smokers and soon decreased the menthol levels in their own brands or created new, low-level menthol brands. Newport remains the second most popular brand among youth with approximately a quarter of all youth smokers reporting Newport as their brand of choice. Additionally, the preference for Newport among youth is dramatically different when race and ethnicity is taken into account – 78.6 percent of African-American high school smokers reported Newport as their brand of choice compared to 17.3 percent of their white counterparts[7].

[6] Kreslake JM, Wayne GF, Alpert HR, Koh HK, Connolly GN. Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults. *American Journal of Public Health*. September 2008, Vol. 98, No. 9: 1685-1692.

[7] Centers for Disease Control and Prevention. Cigarette Brand Preference Among Middle and High School Students Who Are Established Smokers – United States, 2004 and 2006. *MMWR*, February 13, 2009, 58(05): 112-115.

The majority of all African-American smokers (80.9%) report smoking menthol cigarettes compared to only a quarter of white smokers[8]. Internal tobacco industry documents show that the tobacco companies were intentionally targeting African-Americans and other minorities through advertising in magazines with high readership by these populations, including youth, and by targeting specific neighborhoods with higher Hispanic and African-American populations with more advertising and promotions[9]. This targeting is especially disturbing given that tobacco-related cancers remain disproportionately higher among lower-income and minority communities. The lung cancer deaths rate in African-American men was 30 percent higher than for white men from 2001-2005[10]. In order to reduce youth initiation and decrease health disparities, it is critical that the Advisory Committee comprehensively and scientifically address the issue of menthol in its report and recommendations, including the appropriateness of a complete ban, and that the FDA use its new authority to act swiftly in implementing the recommendations made by the Advisory Committee.

Dissolvable Tobacco Products

In addition to the report and recommendations on menthol, the Advisory Committee is tasked by the FSPTCA to complete a report and recommendations on "the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children" within the first two years of its existence. These new tobacco products are unique and may pose additional harms to youth.

Earlier this year, R.J. Reynolds introduced several new smokeless, dissolvable tobacco products for test marketing in various cities around the country. These products include Camel Orbs, which are mint-sized pellets, Camel Strips, a film strip (similar to Listerine Strips) and Camel Sticks, which are similar in appearance to toothpicks[11]. These products are composed of finely ground, flavored tobacco and are meant to dissolve in the mouth within 3 to 30 minutes. These products are highly attractive to youth – they look and dissolve like candy, the packaging is brightly colored and resembles the size and shape of products youth are already familiar with, such as mint tins or cell phones, and the use and packaging of these products are easily concealed from

[8] National Survey on Drug Use and Health, 2007.
[9] U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 1998
[10] American Cancer Society. *Cancer Facts & Figures for African Americans 2009-2010.* Atlanta, GA: American Cancer Society, 2009.
[11] Winston-Salem Journal. "Reynolds Moves To Be On Top When Smoke Clears." October 8, 2008.

parents and teachers. Additionally, each Camel Orb is believed to contain at least as much nicotine as a cigarette and potentially up the three times more nicotine. This is concerning because more than one Orb can be placed in the mouth at a time, greatly increasing the intake of nicotine and other harmful ingredients and research shows that youth are more susceptible to nicotine addiction than adult.

The tobacco industry claims to be marketing these products to adults as an alternative to cigarettes. Yet, there is no evidence that cigarette smokers in the U.S. actually switch entirely to any kind of smokeless tobacco product[12]. In fact, smokers are more likely to continue smoking, as well as use a smokeless product, thereby increasing their risk for oral cancers in addition to lung cancer. This dual use could become more popular as more and more places become smoke-free around the country. Given these products' unique ability to initiate and sustain nicotine addiction and their attractiveness to youth, it is important that the Advisory Committee determine the effect of having these products on the market and that the FDA use its new authority to implement the recommendations of the Advisory Committee regarding dissolvable tobacco products.

Nicotine

"Nicotine is not addictive." Seven tobacco company executives testified to this statement to Congress in 1994. Twelve years later, in her opinion in the landmark Department of Justice case against the tobacco companies, U.S. District Court Judge Kessler concluded that the tobacco companies not only knew nicotine was addictive, they were actively deceiving the public about the addictiveness of their products and they "Researched, Developed, and Utilized Various Designs and Methods of Nicotine Control to Ensure that All Cigarettes Delivered Doses of Nicotine Adequate to Create and Sustain Addiction."

Under the FSPTCA, the FDA has the authority to order the alteration of nicotine levels in tobacco products in order to make them less addictive, while Congress retains the sole power to eliminate nicotine completely in tobacco products. Industry documents indicate that tobacco companies have been adjusting nicotine levels in their products since the 1960s, realizing that the more addictive their product, the more likely a new user will continue to use and the less likely current users will quit. Most recently, one study showed that tobacco companies have been increasing the nicotine levels in their

[12] Zhu S-H, Wang JB, Hartman A, Zhuang Y, Gamst A, Gibson JT, Gilljam H, Galanti MR. Quitting cigarettes completely or switching to smokeless tobacco: do US data replicate the Swedish results? *Tobacco Control*. 2009, 18: 82-87. Carpenter CM, Connelly GN, Ayo-Yusuf OA, Wayne GF. Developing smokeless tobacco products for smokers: an examination of tobacco industry documents. *Tobacco Control*. 2009, 18: 54-59.

products by an average of 1.6 percent a year between 1998 and 2005 across all brands of cigarettes[13]. The study also concluded that increases in nicotine yield in smoke are partially due to new design features intended to increase the dose of nicotine in a single puff. In addition to product redesign, tobacco companies have used additives, including menthol, in their products to enhance nicotine delivery to promote addiction. One study found more than 100 additives in cigarettes that can enhance or maintain nicotine delivery, increase the addictiveness of cigarettes, and mask negative physical symptoms associated with smoking[14].

The FSPTCA requires that the Advisory Committee provide advice, information and recommendations to the Secretary on "the effects of the alteration of the nicotine yields from tobacco products" and "whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved." ACS CAN encourages the FDA to propose regulations to make tobacco products less addictive by reducing nicotine levels, as well as taking into consideration the role of product design and additives in enhancing the delivery of nicotine.

Tobacco Ingredients and Documents Disclosure

The FSPTCA requires tobacco product manufacturers to provide a list of all ingredients, as well as a description of content, delivery, and form of nicotine in its products to the Secretary. With this information disclosure, the FDA can start to use its authority to require changes to tobacco products to make them less harmful and less addictive.

After the 1998 Master Settlement Agreement, thousands of internal tobacco industry documents were released to the public. These documents have subsequently been used in highly effective public education campaigns,[15] to counteract the false claims tobacco companies' have made about their products, as well as provide evidence for their egregious marketing practices and public deception on the harms of their products[16]. Beginning next year, tobacco product manufacturers must provide all documents (developed after June 22, 2009) related to health, toxicological, behavioral, and physiological effects of its current and future products, their ingredients, constituents and additives. In addition to using these documents to issue appropriate product regulations for the protection of public health, with its new authority, the FDA should assess whether

[13] Connolly GN, Alpert HR, Wayne GF, Koh H. Trends in nicotine yield in smoke and its relationship with design characteristics among popular US cigarette brands, 1997-2005. *Tobacco Control*, 2007, 16(e5).
[14] Rabinoff M, Caskey N, Rissling A, Park C. Pharmacological and Chemical Effects of Cigarette Additives. American Journal of Public Health. November 2007, Vol. 97, No. 11, 1981-1991
[15] Farrelly MC, Nonnemaker J, Davis KC, Hussin A. The Influence of the National truth® Campaign on Smoking Initiation. *American Journal of Preventive Medicine*. 2009, 36(5): 379-384.
[16] Rabinoff M, Caskey N, Rissling A, Park C. Pharmacological and Chemical Effects of Cigarette Additives. American Journal of Public Health. November 2007, Vol. 97, No. 11, 1981-1991

public release of tobacco industry documents, including listing ingredients and additives on tobacco packaging, would be beneficial to the public health.

Characterizing Flavorings

In addition to its marketing strategies, tobacco companies have targeted youth with the use of new ingredients and product design. Altering tobacco product ingredients and design can improve the ease of use of a product by masking harsh effects, facilitating nicotine uptake and increasing a product's overall appeal. Candy and fruit flavorings in tobacco products were a promotional tool to lure new, young smokers. Clearly flavors such as "Twista Lime" and "Winter MochaMint" were not aimed at established adult smokers. In fact, one study found that as many as 20 percent of smokers 17 to 19 years of age have smoked flavored cigarettes compared to only 6 percent of smokers over the age of 25[17]. Tobacco companies aggressively market these new products with creative campaigns such as "scratch and sniff" marketing tactics, DJ nights, ads in magazines with a high proportion of youth and young adults readers, and specially-themed packs.

These new flavors in cigarettes and new tobacco industry marketing tactics were successful – after high school smoking rates declined from 1997 to 2003, progress stalled with high school smoking rates showing no change between 2003 and 2007[18]. Similar trends are occurring with the use of smokeless tobacco, cigars (in particular little cigars), and other tobacco products, and in fact, may be increasing among some populations of youth[19]. Additionally, in terms of overall sales, while cigarette sales declined by 18 percent from 2000 to 2007, sales of other tobacco products, including little cigars, loose tobacco and moist snuff, increased by 115 percent, 91 percent and 33 percent respectively[20]. Smokeless tobacco companies have a long history of using flavorings, such as cherry, apple and honey, and other product manipulation as part of a graduation process to get new, young users addicted to "starter" products, keep them using and even move them on to more potent products. Little cigars have the look and feel of a cigarette, yet are often sold individually and are available in a variety of flavors. A new trend popular among youth and young adults in the U.S. is the use of hookahs or waterpipes, in which moist tobacco, available in such flavors as apple and mint, is smoked[21]. Because of the tobacco flavoring, the sweet aromas, and use of water, hookah users perceive this practice as less harmful than cigarette smoking. In fact, hookah tobacco and smoke are as dangerous as cigarettes and contain carcinogens and other substances that can cause

[17] Giovino GA, Yang J, Tworek C, et al. Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004. *Nicotine & Tobacco Research*, Vol. 10 Issue 7, July 2008: 1209 – 1214.
[18] Cigarette Use Among High School Students – United States, 1991-2007. *MMWR.* 2008 57(25): 689-691.
[19] Centers for Disease Control and Prevention. NYTS and YRBS data.
[20] Connelly GN,Alpert HR. Trends in the use of cigarettes and other tobacco products, 2000-2007. *JAMA.* 2008; 299(22): 2629-2630.
[21] Primack BA, Sidani J, Agarwal AA, Shadel WG, Donny EC, Eissenberg TE. Prevalence of and Associations with Waterpipe Tobacco Smoking among U.S. University Students. *Ann Behav Med.* August 22, 2008. Wedglick LS, Templin TN, Rice VH, Jamil H, Hammad A. Comparison of cigarette and water-pipe smoking by arab and non-arab-american youth. *Am J Prev Med.* October, 2008; 35(4): 334.339.

cancer and other diseases[22]. The use of other tobacco products is concerning because it exposes youth to a lifetime of nicotine addiction and often youth move from these other tobacco products onto cigarette smoking.

Under the FSPTCA, characterizing flavors, other than tobacco and menthol, are banned in cigarettes as of this month. The FDA should exert its new authority over other tobacco products to issue the same ban on flavorings in cigarettes onto all other tobacco products, including little cigars, smokeless tobacco products, loose tobacco and hookah tobacco for the same reason the FSPTCA banned flavorings in cigarettes – they are used to appeal to young smokers, mask the harshness of using tobacco, and ease them into a lifetime of addiction.

Health Claims

The public health community provides the public with information on the harms of tobacco products but the overwhelming communications from an unregulated tobacco industry has stifled the effectiveness of these efforts. The tobacco industry aggressively marketed cigarette filters and "low-tar" yield cigarettes to the public as implied health claims, despite no proven reduced risk from these new product designs. In fact, despite the decrease in machine-measured tar yields between the 1950s and 1980s, lung cancer death rates increased during this period[23]. By the mid-1990s it became clear that lung cancer risk in current smokers had nearly doubled in men and had increased more than five-fold in women in the time between the first American Cancer Society Cancer Prevention Study (CPS-I, 1959-1965) and the second Cancer Prevention Study (CPS-II, 1982-1988). It has now been proven that these so-called "low-tar" cigarettes can provide the smoker with the same levels of tar and nicotine as regular cigarettes (while still producing low machine-measured tar yields) because of the cigarette's redesign and because of compensatory behavior by smokers.

The FSPTCA bans the use of misleading terms such as "light, "low" and "mild" as descriptors as of the middle of next year, but it is imperative that the FDA monitor and aggressively take action on the tobacco industry's use of descriptors, packaging (such as special coloring to designate different brands), and advertising for use of any implied or explicit, false health claim about their products.

Marketing Restrictions

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[22] Knishkowy, B., Amitai, Y. Water-Pipe (Narghile) Smoking: An Emerging Health Risk Behavior. *Pediatrics*. 2005:116:113–119. WHO study group on tobacco product regulation. Advisory note on water pipe tobacco smoking: health effects, research needs and recommended actions by regulators, 2005. El-Hakim Ibrahim E., Uthman Mirghani AE. Squamous cell carcinoma and keratoacanthoma of the lower lips associated with "Goza" and "Shisha" smoking. *International Journal of Dermatology*. 1999:38:108-110.

[23] Thun MJ, Burns DM. Health impact of "reduced yield" cigarettes: a critical assessment of the epidemiological evidence. *Tobacco Control.* 2001; 10: i4-i11. National Cancer Institute. *Changes in Cigarette-Related Disease Risk and Their Implication for Prevention and Control* (Thun et al, Chapter 4). Smoking and Tobacco Control Monograph No. 8. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 97-4213, February 1997.

Public health experts and tobacco companies alike know how great a role marketing plays on youth's uptake of tobacco. Numerous studies have shown that children are more sensitive to tobacco advertising than adults and exposure to tobacco industry advertising is related to both intentions to smoke and actual initiation[24]. Awareness of tobacco product advertising, receptivity of tobacco product advertising and owning a promotional item increase the likelihood that a youth will become a tobacco user. The tobacco companies spend a substantial amount of their marketing expenditures on advertising, particularly in places youth frequent often, including convenience stores, placing ads in areas most visible to youth, such as right below the door handles, on ice cream coolers, and next to candy, and offering price discounts to make tobacco products more affordable. In 2006, the most recent year data are available, tobacco companies spent over $260 million on point-of sale advertising in retail stores, a 30 percent increase from the previous year and an additional $9.4 billion on price discounts[25]. As evidence of the success of the tobacco companies' marketing efforts, the most popular cigarettes among youth are the most heavily advertised brands – Marlboro, Camel and Newport for cigarettes and Skoal and Copenhagen for smokeless tobacco[26].

With its new authority, the FDA should aggressively take action to reduce youth exposure to tobacco marketing and advertising through restrictions of tobacco marketing at retail outlets, including point-of-sale and advertising visible outside stores, and magazines with high youth readership to the full extent permissible under the First Amendment. Prior to any marketing restrictions, including when the 1996 Final Rule takes effect next year, the FDA must work diligently to ensure these restrictions will stand up to a judicial review. In contrast to previous years, there is a substantial body of evidence of the effect of tobacco industry marketing on youth initiation and the use of deceptive healthy smoker lifestyle images to mislead consumers about the harms of their products. It is important that marketing restrictions be as comprehensive as legally possible to be most effective. It is evident from changes in marketing expenditures in the U.S. after the Master Settlement Agreement in 1998 and experiences in other countries, tobacco companies can easily adapt to restrictions and bans on marketing by investing in new, creative ways to reach youth. As important as the marketing restrictions taking effect, is the enforcement of them. The FSPTCA recognized this by requiring the Secretary to complete an enforcement action plan for advertising and promotion restrictions. The FDA must set up system working with other agencies, state and local

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[24] National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242, June 2008.

[25] Federal Trade Commission. Cigarette Report for 2006. http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf, 2009. Federal Trade Commission. Smokeless Tobacco Report for the Year 2006. http://www.ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf, 2009.

[26] Substance Abuse and Mental Health Services Administration. The National Survey on Drug Use and Health: 2005 Detailed Tables, Tobacco Brands. Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2006.

governments and nongovernmental organizations to ensure that marketing restrictions are adhered to once implemented.

Warning Labels

After the 1964 Surgeon General's Report first documented that smoking was harmful to health in numerous ways, Congress acted to require warning labels on packs of cigarettes, and eventually smokeless tobacco products, in order to inform consumers about the health harms associated with the use of these products. The location of warnings on tobacco product packages allows for the warning to be communicated at the time of deciding whether to use the tobacco product. The effectiveness of the warning label is dependent on the size, position and design of the label and additionally, warning labels are subject to viewer "wear-out." Unfortunately, the warnings on tobacco products in the U.S. have been ineffective because of their inability to attract attention due to size and placement on the packaging and inability to use messaging that highlights a compelling health danger.

Other countries, however, have required the use of larger, more explicit warning labels on tobacco product packaging that has proven effective. Since 2000, Canada has required warning labels to cover 50 percent of the front and back panels of tobacco products. Canada rotates 16 different full color warnings, some of which are graphic portrayals of the health consequences of smoking. A study assessing the impact of the graphic warning labels in Canada found that approximately one-fifth of adult smokers reported smoking less as a result of the labels, and more generally, smokers that reported a negative emotion in response to the graphic warning label, were more likely to have quit, attempted to quit or reduced their smoking[27]. An international study assessing the impact of warning labels in four different countries, U.S., United Kingdom (UK), Australia and Canada, concluded that the larger, more prominent the warning label, the greater the level of awareness of the warning and the greater the perception of effectiveness among smokers[28]. Additionally, in comparing changes to warning labels in the UK and Canada, the study concluded that while larger, more prominent text-based warnings are effective, graphic warnings may be even more effective. The U.S. had the least effective warning label among the four countries, as it only occupies part of one side panel of the packaging and rotates four warning messages that have not been changed since 1984.

In addition to their graphic portrayals of the health harms of tobacco use, Canada and the UK, as well as several other countries, provide additional health and cessation information on tobacco products. After increasing the size of their warning labels, improving the health warning message and providing quitline information on packs in

[27] Hammond D, Fong GT, McDonald PW, Brown S, Cameron R. Graphic Canadian Cigarette Warning Labels and Adverse Outcomes: Evidence from Canadian Smokers. *American Journal of Public Health.* August 2004, Vol. 94, No.8: 1442-1445.

[28] Hammond D, Fong FT, Borland R, Cummings M, McNeill A, Driezen P. Text and Graphic Warnings on Cigarette Packages – Findings from the International Tobacco Control Four Country Study. *American Journal of Preventive Medicine.* 2007; 32(3): 210-217.

2003, the UK experienced in an increase in the number people calling the national quitline. Of the smokers who call the UK quitline, between 1,500 and 4,000 a month have cited the new warning labels as a catalyst to quit[29]. Providing cessation information, such as a national quitline number and website, on tobacco products packaging, could potentially increase quit attempts and success by providing access to services at the time the user is motivated to quit due to the more effective warning labels.

Under the FSPTCA, tobacco products, other than cigarettes, must bear new warning labels as of one year after enactment and within the first 24 months of enactment, the Secretary must issue regulations on graphic warnings on cigarettes. With this new authority, the FDA has an opportunity to make an enormous, and almost immediate, impact on effectively informing the public of the actual harms of using tobacco products and inducing the desire to quit among users. ACS CAN urges the FDA to require larger, graphic warning labels that depict actual harms from use of the products by using Canada's warning labels as an example, and ensure warnings are rotated at a rate to prevent wear-out. In addition, the FDA should collaborate with nicotine dependence professionals so that warning labels effectively promote the awareness, availability and use of cessation services, including quitline programs. New, larger and even graphic warning labels should be placed on all tobacco products, including cigarettes, smokeless tobacco and cigars to accurately and effectively warn consumers of the harms of use of these products.

FDA Enforcement and Infrastructure

As the FDA begins to exert its new authority, ACS CAN believes it is vital to incorporate provisions on enforcement, including establishing collaborations with other federal agencies, states and local governments and non-governmental organizations when appropriate, for regulation to reach is maximum effectiveness. For example, the FSPTCA requires the Secretary to monitor and take action on any suspicion of the illicit trade of tobacco products. Other federal agencies, as well as many states, are concerned and already working on controlling the illicit trade of tobacco products. The FDA would benefit from creating collaborations and systems of communications between federal agencies and states to effectively prevent the illicit trade of tobacco products.

The FSPTCA requires the Secretary to work with state and local governments in two specific areas: 1) prevention of tobacco products sales to youth, and 2) new authority granted to state and local governments regarding marketing restrictions. State and local governments need to know when a new regulation has been issued, when they have the authority to enforce a regulation, and also need to have a process for reporting back to the FDA when a regulation has been ignored or violated. Additionally, the non-governmental tobacco control community has been exceptionally successful at implementing effective tobacco control policies, monitoring the industry and providing scientific expertise when

[29] Department of Health (UK). Consultation on the introduction of picture warnings on tobacco packs. May 2006. http://www.dh.gov.uk/assetRoot/04/13/54/96/04135496.pdf.

needed over the last several decades. By engaging the tobacco control community on enforcement and other regulatory issues, the FDA would be able to act quickly to address likely evasive and innovative tobacco industry activities that arise as a result of new regulations and restrictions.

With the enactment of the FSPTCA, the FDA has begun the process of implementation in a transparent way and has allowed opportunity for input from organizations who have been working in tobacco control for decades. ACS CAN encourages the FDA to continue that level of transparency and swift implementation. As the FDA begins to engage on regulating tobacco products and its marketing, ACS CAN urges the FDA to consider what actions would reduce youth initiation of all tobacco products, addiction and health disparities, as well as the morbidity and mortality caused by tobacco use. ACS CAN is ready to assist the FDA in using its new authority assertively and aggressively to truly end the enormous toll tobacco takes on our nation.

Sincerely,

Daniel E. Smith
President
American Cancer Society Cancer Action Network