1400 EYE STREET, N.W. • SUITE 1200 • WASHINGTON, DC 20005
PHONE (202) 296-5469 • FAX (202) 296-5427

December 17, 2009

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

Re: Docket No. FDA-2009-N-0294

To Whom It May Concern:

When the U.S. Food and Drug Administration (FDA) attempted to assert jurisdiction over tobacco products in 1996 and issue the related tobacco rule (which was blocked by the courts), it took those actions based on a comprehensive analysis of available data and research on the effectiveness of the various measures available to prevent and reduce tobacco use and its harms. Since then, tobacco use levels in the United States have declined somewhat, but the problem remains unacceptably large and, despite extensive government efforts, is not being reduced sharply or rapidly enough.

Since 1996, substantial amounts of new research and data have appeared regarding the character of the problem, the inadequacy of existing efforts to reduce it, and how tobacco use and its harms can be addressed more effectively. In particular, this new research and information provide additional support not only for the reinstitution of the 1996 tobacco marketing rule, but for all the provisions in the new FDA tobacco law.

These comments provide a summary of some of this new research and data because Congress relied on much of this new data in enacting the Act and because the new data provides substantial objective scientific support for the remedial measures in the Act.

Tobacco Use is a Unique Public Health Problem

Smoking and other tobacco use cause more premature deaths than alcohol, AIDS, suicides, murders, traffic accidents, fatty foods, and illegal drugs, combined.[1] One reason for that disproportionately large toll of death and disease is that tobacco products are unlike any other products that are marketed and sold in the United States for human consumption. Besides being highly addictive, personal use typically begins before a user reaches legal age. Tobacco products are also unique in that they are the only consumer product that kills one out of two users *when used exactly as intended*.[2] Unlike other consumer products, there is no beneficial or safe way to use or consume tobacco products – and there is no way to educate or instruct consumers so that they can smoke or otherwise use tobacco products safely.

The Remedial Measures Contained in the Family Smoking Prevention and Tobacco Control Act are Necessary because Tobacco Use Continues to be a Major Public Health Disaster

While progress has been made over the past several decades in the United States in terms of reduced smoking rates among both adults and children, that progress has been too small and too slow.

- Currently, approximately forty-six million adults (20.6%) are addicted smokers, and approximately three and a half million high-school age youth (one out of every five) are current smokers.

- More than 8.5 million people currently suffer from smoking-caused illness and disease.

- More than 400,000 people die prematurely each year because of their own smoking, with tens of thousands of additional unnecessary deaths from exposure to secondhand smoke.

- If current trends are not improved, approximately six million youth alive today will grow up to die prematurely from smoking.

- Smoking-caused healthcare costs total close to $100 billion each year, with government health programs (e.g., Medicaid) accounting for roughly half of those smoking-caused health expenditures.

- Productivity losses just from useful worklives being shortened by smoking-caused early death also total approximately $100 billion, with massive additional economic losses from productive worklives curtailed even further by smoking-caused illness or disability, from smokers taking more sick days than nonsmokers, and from smokers being less productive when on the job, thanks to cigarette breaks and their generally worse health.

- Social Security Survivors Insurance payments to support the more than 300,000 youth who have lost at least one parent to smoking-caused death totals more than $2.5 billion per year.

- Every day, on average, another 1200 people die from smoking. But on that same day, more than 3500 young children try their first cigarette, and another thousand youths become new addicted smokers.[3]

As detailed in the 2004 United States Surgeon General's Report, *The Health Consequences of Smoking*, "Smoking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general," causing at least ten different types of cancer, four different types of cardiovascular disease, numerous respiratory diseases and harms, pregnancy complications and reproductive disorders (including stillbirths and fetal deaths), as well as a host of additional disorders ranging from peptic ulcers to hip fractures, and cataracts, and also contributing to or exacerbating numerous other diseases and medical conditions.[4]

Adding to this burden are the costs, suffering, disease, and premature deaths caused by other forms of tobacco use besides cigarette smoking. A 1986 Surgeon General's report documented the health risks from smokeless tobacco use, and since then, many subsequent studies have reached the same conclusion – despite not being smoked, smokeless tobacco in all its varying forms cause several types of cancer and other cardiovascular problems.[5]

While the trends in smoking rates have been generally positive over the past several decades, some recent trends are quite worrisome. Adult smoking prevalence has been on the decline since the mid-1990s, but the trend has leveled out in the last few years and actually increased, although not statistically significantly, in 2008.[6] Similarly, youth smoking declines have also flattened in recent years, showing no significant change between the last two years of the survey.[7]

Trends in taxed sales show that while cigarette consumption is on the decline, sales of other tobacco products, particularly smokeless (snuff) tobacco, cigars, and roll-your-own (RYO) tobacco, have been increasing. In 2008, national sales of cigarettes declined by 4.2% while snuff tobacco sales increased by two percent, small cigar sales increased by 14.6%, large cigar sales increased by 4.8%, and RYO tobacco sales increased by 14.9% compared to the year before.[8] According to the 2008 National Survey on Drug Use and Health, more than 3,500 kids under 18 years old try cigars *each day* – only slightly lower than the number of under-18 kids who try smoking cigarettes each day (roughly 3,800).[9] The increase in cigars and smokeless tobacco products available in flavors attractive to kids, such as cherry, grape, and chocolate, also make the growing trends in use more troublesome.[10]

Tobacco Use and Harms Could Be Quickly and Sharply Reduced Well Below Current Levels

While the nationwide smoking rate is slightly above 20 percent among adults, and the prevalence of past month smoking among high school students is 20 percent, state-specific smoking rates for adults are as low as 9.2% (Utah) and 14.8% (New Jersey) and go as low as 7.9% (Utah) and 10.6% (Washington, DC) among high-school-age youth. In addition, some cities have even lower rates, such as New York City, with an adult prevalence rate of 15.8% in 2008. Similarly, while smokeless tobacco use ranges as high as 27% among male youth in West Virginia, smokeless rates go as low as 6.6% for male youth in Nevada.[11]

There is substantial evidence that tobacco use rates can be reduced substantially below the current level. For example:

- The National Cancer Institute concluded in 2003 that there has been no epidemiological evidence that the annual quit rate in the U.S. is falling or that levels of dependence have increased.[12]

- CDC's National Health Interview Survey (NHIS) shows a steady increase in smoker quit intentions despite ongoing smoking declines. For example, in 2001, 40.6% of current adult smokers reported that they had stopped smoking for at least one day during the previous 12 months because they were trying to quit smoking. In 2005, 42.5% of current smokers reported such quit attempts, and in 2006 that measure of smoker quit attempts increased to 44.2%. While the percentage of current smokers who stopped for at least one day dropped to 39.8% in 2007,[13] it increased again to 45.3 percent in 2008.[14]

- In California, the adult smoking rate has steadily declined to only 14.0% – well under the national adult smoking rate of 20.6% and lower than any other state but Utah.[15] But there has been no related decrease in the percentage of California smokers who are interested in quitting. In fact, between 2000 and 2005, the proportion of CA smokers who were thinking about quitting in the next 30 days *increased* from 38% to 44%, and three-quarters of California smokers said in 2005 that they were thinking about quitting in the next six months.[16]

- The infrastructure for providing smokers who want to quit with assistance is much stronger today than it was even just a few years ago. For example, each and every state now has a quitline in place with a single nationwide number (1-800-QUIT-NOW) that adult smokers who want to quit can call to get free cessation guidance and assistance. While the cessation infrastructure has appeared only recently, it is well-established that quit lines help to increase adult quit rates.[17] In addition, the number of states providing some smoking cessation assistance through Medicaid programs has grown from 34 states plus DC in 2000 to 44 states plus DC in 2007, and many of the states offering cessation coverage in 2000 now offer much more comprehensive assistance.[18] More private insurers are also covering cessation assistance.[19] For example, the Addressing Tobacco in Managed Care survey found that from 1997 to 2002 the percentage of plans providing face-to-face cessation counseling increased from 26.6 to 41.1 percent and the number providing full coverage for any cessation pharmacotherapy tripled from 25 percent to nearly 89 percent – and these gains have continued.[20] This expansion of cessation coverage through Medicaid and private insurers has further strengthened the cessation infrastructure in the United States, making it more likely than in past years that adults prompted to quit will be able to do so.

As the California data suggest, it is likely that interest in quitting among the smoking population actually increases as smoking becomes less prevalent, less visible, and less acceptable. Lower smoking rates means fewer smoking role models, fewer smoking peers, fewer smoking cues, and thereby less support for continued smoking. In addition, state cigarette tax increases and the growing number of smoke-free laws have already made smoking more costly and less convenient for many smokers. These combined initiatives not only provide a strong statement about smoking's social unacceptability but create additional pressures to make more smokers more likely to quit.

The benefits from reducing smoking and other tobacco use rates well below current levels are enormous. For example, each additional percentage point decline in adult, youth, and pregnant women smoking rates that government efforts are able to achieve produces enormous public health and economic benefits including:

- More than 600,000 adults prevented from dying prematurely from smoking.
- More than 55,000 high school age youth – and more than one hundred thousand younger kids – saved from growing up to die early from smoking.
- More than 40,000 fewer smoking-affected births each year.
- More than $35 billion in reduced future smoking-caused healthcare costs.[21]

Conversely, each percentage point decline in smoking rates that government efforts fail to achieve, or that is significantly delayed, allows similarly massive public health harms and costs to continue unnecessarily.

Government Efforts to Prevent and Reduce Tobacco Use and Its Harms Have Been Substantial, But Much More Aggressive and Comprehensive Government Action is Needed.

Over the years the federal and state governments have made significant efforts to reduce tobacco use. They have raised taxes. They have implemented strong new laws to prohibit smoking in workplaces and other public places, including restaurants and bars. As a result, more than half of the U.S. population now lives under strong state or local smoke-free laws.[22]

Prevention efforts have also paid dividends, but have left much to be accomplished. Since 1996, government spending on tobacco prevention has also increased, with state funding rising from almost nothing in 1996 to more than $500 million per year after the states began receiving tobacco settlement payments from U.S. cigarette companies.[23]

The US has also tried to better inform the public and to discourage tobacco use through three different variations of increasingly strong warning labels. In 1965, the federal government first established federally required warning labels on cigarette packages; revised them in 1969 and revised them again in 1984. Similar text-only warning labels on smokeless tobacco products were first established in 1986. Yet, multiple studies have shown that the current warning labels are no longer effective.

Prior efforts to reduce tobacco marketing have also been tried and have paid some dividends but have repeatedly been shown to be inadequate. In 1971, Congress passed the federal law making advertisements of cigarettes on television or radio illegal, and a similar law relating to smokeless tobacco products passed in 1986. In 1998, the states entered into a binding agreement (the Master Settlement Agreement) with the major tobacco manufacturers to settle lawsuits that the states had brought against them. These settlement agreements also required payments to the states and to a new tobacco control foundation (The American Legacy Foundation). The payments to the states have led to some increased funding for new tobacco prevention efforts, but have not brought about fundamental change because the agreements do not require that any of the funds be used for tobacco prevention.[24]

Many states have also passed tobacco control laws since 1996 in an effort to reduce tobacco use among children, ranging from total or partial bans on free samples and vending machines, to requirements that cigarettes not be sold loose or in packs of less than 20.[25] Despite these efforts, court findings and recent studies have demonstrated that these efforts have been inadequate to stop the tobacco companies from marketing in ways that attract and appeal to children and that children are still exposed to tobacco marketing on a regular basis.

The evidence presented to Congress on the need for more aggressive action to address tobacco use was clear and overwhelming. This is why Congress passed the new FDA tobacco law, re-implemented the 1996 Tobacco Rule, and gave FDA authority to take additional action to regulate tobacco products and restrict their marketing. Indeed, some of the resilience of tobacco use rates in the United States over the past decades is not only a result of the highly addictive nature of tobacco products, but from the massive increases in tobacco

company marketing and promotional efforts and the tobacco companies' ability to get around existing marketing restrictions to promote smoking and other tobacco use.

Tobacco Product Marketing Continues to be a Major Problem Despite Prior Government Efforts

There is compelling evidence that tobacco industry marketing and advertising increases tobacco use initiation among youths and young adults, increases overall consumption, is misleading and reduces cessation among youth and adult users. While the MSA placed some restrictions on tobacco marketing and promotion, the MSA has been limited in its effectiveness because it does not address many important matters, and some of the matters it does address are not covered adequately. Some tobacco companies have even been found to violate some of the MSA's marketing restrictions.[26]

The evidence regarding the impact of tobacco marketing has grown significantly beyond that cited by the FDA in support of its 1996 Tobacco Rule. Numerous studies have demonstrated that exposure to tobacco marketing impacts potential new users, the majority of whom are young people, to try tobacco and become long-term addicted customers.[27] While there are many important new sources, the conclusions of the National Cancer Institute (NCI) Monograph that summarized the evidence on tobacco use and tobacco marketing merit particular attention. The comprehensive report, released by NCI in 2008, found that "the evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption" and that even brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking as well as their intentions to smoke.[28]

This 2008 report adds to findings from an earlier NCI report from 2001 which concluded that "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable."[29] Additional findings regarding the relationship between tobacco marketing and smoking initiation include:

- A study published in the December 2006 issue of *Archives of Pediatrics and Adolescent Medicine* found that exposure to tobacco marketing more than doubles the odds that children under 18 will become tobacco users. The researchers also found that pro-tobacco marketing and media depictions lead children who already smoke to smoke more heavily, increasing the odds of progression to heavier use by 42 percent.[30]
- A 2002 study in the *Archives of Pediatric and Adolescent Medicine* found that receptivity to tobacco advertising had a significant impact on each step of the progression from non-smoking to established regular smoking. The biggest impact was on influencing non-susceptible youth to becoming susceptible to smoking.[31]
- A longitudinal study of teenagers in the *Journal of the American Medical Association* showed that tobacco industry promotional activities influenced previously non-susceptible non-smokers to become susceptible to or experiment with smoking.[32]

While the tobacco industry claims that it does not market to children, many of the colors, images and themes used in tobacco advertisements and promotional materials appeal to youth. In 1994, the Institute of Medicine (IOM) concluded that images used in tobacco product advertising and promotion convey the message that tobacco use is desirable and create positive feelings towards smoking. Tobacco marketing often includes young, physically active, and attractive models which suggest that tobacco use is safe, healthful and a widely practiced behavior and falsely associates tobacco use with youth, energy, and sex appeal.[33] These themes and images resonate with youth and can satisfy adolescents' need to be popular, feel attractive, take risks and avoid or manage stress. As a result, according to the IOM, "tobacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and to become addicted to them." [34]

In addition to increasing youth smoking initiation, the evidence indicates that the amount of advertising actually impacts tobacco consumption. While the tobacco industry has argued that the primary purpose of its advertising is to maintain brand loyalty and keep current consumers from switching to another tobacco product, data show that there is a positive correlation between the amount of advertising and overall tobacco

consumption.[35] Tobacco company internal documents also indicate that their advertising does more than just influence brand loyalty and brand switching.[36] In addition, research suggests that brand switching by itself justifies only a small percentage of a cigarette company's advertising and promotion expenditures.[37]

Tobacco marketing also maintains and increases tobacco use among current tobacco users by providing smoking cues for current smokers. Studies show smokers of all ages have an increased desire to smoke when presented with smoking-related images, such as someone smoking or a cigarette pack, or other items associated with smoking.[38,39] Studies have also found that tobacco advertisements may reduce current smokers' willingness to quit and provoke former smokers to resume their habit.[40]

The evidence clearly demonstrates that exposure to the type of images that the tobacco industry's marketing continues to project is associated with a greater likelihood of smoking initiation and increased tobacco consumption. The limitations on advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-text on white background is a reasonable and necessary approach that promotes the government's interest in reducing tobacco use based upon the available evidence. The IOM specifically endorsed the black-and-white, text only approach in its 2007 report.[41]

Specific types of tobacco industry marketing, such as advertising and promotion in the retail environment, tobacco brand sponsorships, and tobacco promotional items, increase tobacco use initiation and overall tobacco consumption. It is clear that the tobacco industry recognizes the importance of influencing consumers at the moment of purchase by the amount spent on product packaging and marketing in the retail environment. In recent years, tobacco companies have significantly stepped up their marketing efforts in the retail environment, or point-of-purchase. Point-of-purchase tobacco advertising consists of cigarette and smokeless tobacco ads located inside, outside, and on the property of convenience stores, drug stores, gas stations, and other retail sales outlets. The tobacco companies significantly increased their point-of-sale advertising after the state tobacco settlements' ban on tobacco billboards went into effect in April 1999.[42] In 2006 (the latest year for which data are available), the cigarette companies spent over $242 million on point-of-sale advertising, a 33.1 percent increase from 2005. In 2006, smokeless tobacco companies spent over $20.8 million on this type of advertising.[43]

Several studies have documented the increasing pervasiveness of tobacco promotion in retail outlets. For example, in one survey, eighty percent of retail outlets had interior tobacco product advertising, 60 percent had exterior tobacco product advertising, and over 70 percent had tobacco product functional items, such as display racks, counter mats, entrance and exit signs, and change cups; and forty percent of retailers that also sell gas had tobacco product advertising in the driveway and parking lot area.[44] Another survey found that the average retail outlet had 25 pieces of in-store cigarette advertisements, alone; and another found more than 3,000 cigarette ads in just 184 stores, with nearly one-third of those stores being within 1,000 feet of a school.[45]

Unfortunately, the massive amount of tobacco product advertising and marketing at retail outlets maintains tobacco use rates among adults and increases youth initiation. For example, a study published in the May 2007 *Archives of Pediatrics and Adolescent Medicine,* the first national study to examine how specific marketing strategies in convenience stores and other retail settings affect youth smoking, concluded that the more cigarette marketing teens are exposed to in retail stores, the more likely they are to smoke. Specifically, the study found that retail cigarette advertising increased the likelihood that youth would initiate smoking, and cigarette promotions increased the likelihood that youth will move from experimentation to regular smoking.[46]

An earlier study of middle-school youth concluded that those who visited convenience stores and similar retail outlets at least weekly and were, therefore, more exposed to retail tobacco marketing, had a 50 percent greater odds of ever smoking compared to kids who went to such retail stores less frequently.[47] Similarly, a 2009 study found that more frequent visits to stores selling tobacco and greater awareness of cigarettes sold in stores increased the likelihood of teenagers being susceptible to initiating, experimenting, or becoming current smokers.[48] These findings, corroborated by other studies, are especially troubling given past findings that three out of four teenagers shop at a convenience store at least once a week.[49]

More generally, point-of-purchase tobacco product advertising and displays have been found to increase average retail tobacco product sales by as much as twelve to twenty-eight percent.[50] A recent study found that

cigarette pack displays at retail outlets stimulate impulse purchases among smokers and that those trying to avoid smoking commonly experience urges to purchase cigarettes when confronted with these displays, suggesting that cigarette pack displays undermine intentions to quit among established smokers.[51] That same study also found that 25 percent of the surveyed smokers had at least sometimes made an unplanned purchase of cigarettes in the last 12 months as a result of seeing point-of-purchase tobacco product displays. Similarly, a study based on interviews with persons having just bought cigarettes at retail outlets with point-of-purchase displays found that more than one out of five of the purchases were unplanned.[52]

In addition to point-of-purchase advertising, research suggests that tobacco promotional items and tobacco brand sponsorships impact youth smoking.[53] According to one study, adolescents who own a tobacco promotional item and can name a cigarette brand whose advertising attracted their attention are twice as likely to become established smokers as those who do neither.[54] Another study found that that exposure to tobacco brands via event and sport sponsorships can increase initiation."[55] While the Master Settlement Agreement limits tobacco brand-name sponsorships of concerts, events in which any contestants are under 18, and specific sporting events, it permits each tobacco company to continue a single tobacco-product brand-name sponsorship of an event not specifically prohibited such as auto racing or rodeo events.

The new requirements in the Family Smoking Prevention and Tobacco Control Act are critically necessary because Congress properly found that the tobacco industry has a long history of irresponsible advertising and marketing practices that have not been stopped by the prior efforts of government

The tobacco industry continues to market their products in ways that appeal to kids. In fact, in August 2006, U.S. District Court Judge Gladys Kessler released her final opinion in the U.S. Government's case against tobacco companies, describing how the tobacco companies continue to target youth with sophisticated marketing campaigns. According to Judge Kessler," … Defendants continue to engage in many practices which target youth, and deny that they do so. Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents."[56]

Here are two recent examples of tobacco industry marketing targeting to kids:

- In January 2007, R.J. Reynolds (RJR) launched a new version of its Camel cigarette, called Camel No. 9, packaged in shiny black boxes with hot pink and teal borders. The name evoked famous Chanel perfumes, and magazine ads that featured flowery imagery and vintage fashion ran in magazines popular with both young women and girls, including *Vogue*, *Glamour*, *Cosmopolitan*, *Marie Claire* and *InStyle*. Promotional giveaways included flavored lip balm, cell phone jewelry, tiny purses and wristbands, all in hot pink.
- Also in 2007, RJR ran a multi-page ad in *Rolling Stone* magazine (1.5 million youth readers) that featured numerous cartoon drawings of animals, monsters and images from outer space. Shortly thereafter, eight state Attorneys General sued the company for violating the MSA. RJR then took down a website that featured images from the ad and announced that it would cease any advertising of its cigarettes in magazines.

In addition, according to Federal Trade Commission (FTC) reports on tobacco industry marketing, industry spending on advertising and promotion has almost doubled since the 1998 Master Settlement Agreement. The major cigarette companies, alone, now spend about $12.5 billion per year (or more than $34.2 million every day) to promote their products; and many of their marketing efforts directly reach kids.[57] In fact, cigarette company spending to market their deadly products increased by more than 85 percent from 1998 to 2006 (the most recent year for which complete data are available).[58] Much of the increase in spending is for strategies that reach and influence vulnerable underage populations. For example, the cigarette and spit-tobacco companies continue to advertise heavily at retail outlets, like convenience stores where teenagers are known to frequent. Cigarette companies increased their spending on point-of-sale marketing by more than $60 million between 2005 and 2006 and spent the bulk of their marketing dollars (90 percent, or $11.2 billion) on strategies that facilitated retail sales, such as price discounts and ensuring prime retail space.[59]

In her August 2006 Opinion, Judge Gladys Kessler concluded, "As Defendants' senior executives took the witness stand at trial, one after another, it became exceedingly clear that these Defendants have not, as they claim, ceased their wrongdoing or, as they argued throughout the trial, undertaken fundamental or permanent institutional change."[60] Given the tobacco industry's history of irresponsible marketing, there is little doubt that left unchecked the industry will continue these egregious marketing practices. As Judge Kessler concluded, "there is a reasonable likelihood that Defendants' RICO violations will continue…"[61]

Congress acted appropriately and included restrictions based upon a careful examination of the latest evidence regarding the amount of tobacco industry marketing and its impact on initiation and continued use of tobacco products. After reviewing the science, Congress accurately concluded that: (1) tobacco marketing has increased since the 1996 Tobacco Rule and the 1998 MSA; (2) tobacco marketing continues to be effective at getting kids to smoke and increase overall tobacco consumption; (3) the industry's egregious and irresponsible tobacco marketing practices will continue unless further restrictions are implemented; and (4) there is a serious and substantial need for reinstatement of the1996 Rule.

The restrictions in the Family Smoking and Tobacco Prevention Act directly advance the government's legitimate interests because its restrictions and mandates will curtail tobacco product marketing that has the greatest impact on youth and that misleads consumers and will ultimately reduce tobacco use

Research indicates that restrictions on the advertising and promotion of tobacco products lead to reductions in the number of children who use and eventually become addicted to these products. Congress found specifically that the advertising and promotion of tobacco products contained in the 1996 regulation will lead to a significant decrease in the number of children using and becoming addicted to tobacco products. Recent research on the impact of marketing restrictions reaffirms the evidence cited by the FDA in support of the 1996 regulation. The previously noted study in the *Archives of Pediatrics and Adolescent Medicine* found that retail cigarette advertising increased the likelihood that youth would initiate smoking AND that reducing or eliminating these retail marketing practices would significantly reduce youth smoking.[62] In addition, while the World Health Organization (WHO) has concluded that a comprehensive ban on tobacco advertising, promotion, and sponsorship is one of the most effective policy measures to reduce tobacco use, it also found that partial bans impact tobacco consumption.[63]

The 2008 NCI Monograph on tobacco marketing, "The Role of the Media in Promoting and Reducing Tobacco Use", the 2007 Report of the President's Cancer Panel, "Promoting Healthy Lifestyles: Policy, Program and Personal Recommendations for Reducing Cancer Risk", and the 2007 Report of the Institute of Medicine on tobacco, "Ending the Tobacco Problem: A Blueprint for the Nation", all found that more needs to be done to reduce the influence of tobacco industry marketing. The President's Cancer Panel recommended that, "…the influence of the tobacco industry – particularly on America's children – be weakened through strict Federal regulation of tobacco products sales and marketing."[64]

Stronger Warning Labels on Tobacco Products Will Also Help Reduce Use and Harms

The warning label provisions included in the Family Smoking Prevention and Tobacco Control Act reflect the current state of the science regarding warning labels, including best practices from other countries and recommendations from the World Health Organization (WHO), Institute of Medicine, and other health experts. The body of research supporting strong warning labels as effective tools for helping to prevent and reduce tobacco use and its harms is large and continues to grow.[65]

Research and real-world experience with cigarette pack warning labels has established that warning labels consistent with those required by the Act are noticed more, increase knowledge about tobacco use harms, increase concern abut the health effects of smoking, and increase both the intention to quit and the likelihood of quitting. The research shows that the most effective warnings are large, prominently located and include colorful images that portray the health effects of tobacco use, and are changed periodically to avoid becoming worn out.[66]

As of June 2009, twenty countries and jurisdictions in the Americas, Eastern Mediterranean, Europe, South-East Asia and Western Pacific regions have passed legislation to require pictures or images on cigarette packs. Within the Europe region, the European Parliament and Council directive gives its twenty-seven member countries the option of adding pictures to warnings as a way to educate smokers about the risks of smoking. These actions reflect the growing expert consensus that warning labels are effective at communicating health messages and discouraging tobacco use.

Current warning labels used in the United States are ineffective. Since the U.S. first mandated the use of warning labels in 1984, their effect on smokers has drastically weakened, and the current labels are now virtually meaningless. Using the same parameters and the same four messages approved by Congress more than 20 years ago, today's labels are small and easily overwhelmed by the designs on cigarette packages and fail to effectively convey relevant information. Moreover, smokers have become habitualized to the style of labels, to the point that the labels are seldom-noticed.[67] According to the Institute of Medicine,

> "Even though tobacco products are legally available to adults, the paramount public health aim is to reduce and become addicted to these products, through a focus on children and youths. The warnings must be designed to promote this objective. In the committee's view, the current warnings are inadequate even when measured against an informed choice standard, but they are woefully deficient when evaluated in terms of proper public health criteria."[68]

Consumer misperceptions and misunderstandings about tobacco use persist. Despite the numerous public reports on the risks of smoking, studies show that a large number of smokers have inadequate knowledge of the health effects of smoking.[69] While some smokers generally know that tobacco use is harmful, they underestimate the severity and magnitude of the health risks.[70] A 2007 study found that two in three smokers underestimate the chance of developing lung cancer compared to a non-smoker, and four in ten incorrectly believe that developing lung cancer depends more on genes than anything else. Furthermore, the survey found that up to a third of smokers think that certain activities such as exercise and taking vitamins could "undo" most of the effects of smoking.[71] An earlier study found that 65 percent of smokers either incorrectly thought that low tar and filter cigarettes are less dangerous than full-flavored cigarettes or did not know whether these features made cigarettes less dangerous. In the same study, when asked about health risks of smoking, 39 percent of respondents either answered incorrectly or said they did not know.[72] Knowledge of the health risks of smoking is even lower among people with low income and fewer years of education because of limited access to information and lower literacy rates.[73]

Strong warning labels inform smokers about the health hazards of smoking. Numerous studies have found that warning labels are effective at informing smokers about the health hazards of smoking and increasing knowledge about tobacco use harms. Warning labels on tobacco products are an ideal way of communicating with smokers. Since the intervention is delivered at the time of smoking, nearly all smokers are exposed to warning labels, and pack-a-day smokers could be exposed to the warnings more than 7,000 times per year.[74] Research shows that effective warning labels increase knowledge about risks associated with smoking and can influence future decisions about smoking.[75] Further, two-thirds of all smokers indicate that the package is an important source of health information, and health knowledge is strongly associated with an intention to quit smoking.[76] Smokers report that they receive more information about the risks of smoking from the tobacco product package than from any other source except television.[77]

According to an international comparative study by Hammond et al., "Large, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers [and] may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information." Hammond and colleagues also found that smokers in countries where a warning depicts a particular health hazard of smoking are much more likely to know about that hazard, and smokers who reported noticing warnings were 1.5 to 3.0 times more likely to believe in each health hazard.[78] This is important because smokers who perceive greater health risk from smoking are more likely to intend to quit and quit smoking successfully.[79]

Strong warning labels encourage smokers to quit and discourage nonsmokers from starting to smoke. Numerous studies indicate that health warnings discourage tobacco use and promote cessation. Adult and youth smokers report that large comprehensive warning labels increase motivation to quit and increase the likelihood that they will remain abstinent following a quit attempt.[80] Evidence from several countries suggests that large warnings with photos are particularly effective in discouraging smoking and increasing public awareness of the health effects of smoking.[81]

A four-country study indicated that text-only labels (as seen in the U.S.) were associated with lower levels of awareness about the health risks of smoking than prominent, pictorial warning labels (as seen in Canada and Australia). Furthermore, the study indicated that pictorial warning labels were more effective than text-only labels in leading people to think about quitting and deterring them from having a cigarette.[82] A follow-up investigation of the four-country study revealed that larger, pictorial warning labels were associated with increased quit attempts.[83]

Additional research regarding the effectiveness of warning labels is summarized below.

- After new, large pictorial warnings were introduced in 2000, 91% of Canadian smokers surveyed reported having read the warning labels and demonstrated a thorough knowledge of their content. Further, smokers who read, thought about, and discussed the warning labels in greater depth at baseline were significantly more likely to either quit, attempt to quit, or reduce their smoking at follow-up.[84]
- The introduction of new pictorial warning labels in 2006 in Australia made 57% of smokers report thinking about quitting, helped 36% of smokers smoke less, helped 34% of smokers try to quit, and helped 55% of recent quitters remain abstinent.[85]
- After Brazil introduced new pictorial warnings in 2002, 73% of 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. The impact was particularly strong among less educated, lower income people.[86] Brazil introduced a second set of warning labels in 2004. In a study evaluating both sets of warning labels, researchers found the most graphic and threatening warning labels increased intentions to avoid smoking.[87]
- After Singapore introduced their pictorial warning labels in 2004, a Health Promotion Board survey found that 28% of the smokers surveyed reported smoking fewer cigarettes because of the warnings; 14% of the smokers surveyed said that they made it a point to avoid smoking in front of children; 12% said that they avoided smoking in front of pregnant women; and 8% said that they smoked less at home.[88]
- Since Thailand introduced their second set of pictorial labels in 2006, 53% said the pictorial warning labels made them think "a lot" about the health risks, and 44% of smokers said the warnings made them "a lot" more likely to quit over the next month.[89]
- An investigation of the impact of the text-only Chinese labels compared to other text and pictorial labels from around the world found that larger pictorial labels were perceived to be more effective at informing about the dangers of smoking, convincing youth not to start and motivating smokers to quit.[90]

There is evidence that graphic warnings are especially effective among youth. More than 90 percent of Canadian youth agree that picture warnings on Canadian cigarette packages have provided them with information about the health effects of smoking and make smoking seem less attractive.[91] Studies suggest that picture warnings that include graphic, fear-arousing depictions of smoking's effect on the body are the most effective because they are associated with increases in motivation to quit smoking, thinking about health risks and engaging in cessation behavior.[92]

- Following the introduction of Australia's graphic health warning labels, adolescent experimental and established smokers were more likely to think about quitting, and intentions to smoke were lower among those students who discussed the new warning labels.[93]
- A Greek study of adolescents indicates that proposed European Union pictorial warning labels were more effective at informing about the health effects of smoking and preventing initiation than the previous text-only labels. Approximately 84% of non-smoking adolescents reported that the proposed

EU pictorial labels were more effective than the old EU text labels in preventing smoking initiation.[94]

In addition, studies show that intentions to quit smoking improve when a quitline number is provided with the pictorial label. After Australia introduced pictorial labels with quitline information in 2006, the rate of quitline callers doubled from the previous two years.[95] After New Zealand introduced pictorial labels with quitline information in 2008, the number of new quitline callers increased. (The rate doubled from 12% to 27% the first month and then remained at 30% thereafter.)[96]

Characteristics of effective tobacco warning labels. The World Health Organization's Framework Convention on Tobacco Control and the Institute of Medicine have identified several characteristics that enhance a warning label's effectiveness. The Act's warning label provisions incorporate these recommendations.

According to the World Health Organization, the components of an effective warning label are as follows:

COMPONENT	DESCRIPTION	IMPACT
Location	Labels should appear on the top of the principal display areas (front and back—the largest panels of the package).	If the message is in a prominent location, it is more likely to be noticed.
Size	Should cover at least 50% of the package's principal display areas.	Large messages are more likely to be noticed. Label effectiveness increases with size. Large labels provoke emotional responses and increase motivation to quit.
Pictorials	Pictures and/or pictograms should illustrate the ill-effects of tobacco use.	Photos and strong graphics help smokers visualize the nature of a tobacco-caused disease better than words alone. Pictures are more likely to draw attention and are more likely to be remembered when an individual makes decisions about whether or not to smoke or cut back on smoking. Pictures are especially important in regions with low literacy or where research shows smokers are ignoring text-only warning labels. Pictorial warnings are likely to reach children and adolescents, especially the children of smokers, who are particularly vulnerable.
Color, Background, and Font	Use full color. Contrast colors with the background and the text.	Maximizes visibility and ease of comprehension.
Rotation	Multiple health warnings and messages can appear on all tobacco products concurrently or be rotated periodically.	Prevents overexposure.
Text	List risk factors by highlighting harmful effects and impact of exposure to	Messages highlight the harmful effects of tobacco and provide important public

	tobacco. Include the magnitude of specific risks. Provide cessation advice and local quit line information. Identify the addictive nature of tobacco. Elicit unfavorable emotional association with tobacco use.	health information to the public which may not be otherwise accessible. Messages eliciting unfavorable emotional associations about tobacco use are more believable and convincing.
Language	Label should be in the country's principal language(s).	Messages in all principal languages ensures a broader reach.
Source attribution	Label should identify a source such as a national health authority (e.g., Minister of Health) that recommends the health messages.	Depending on the culture, attribution can add credibility to the message.

Moving Forward

The new Tobacco Products Center of the U.S. Food and Drug Administration has the potential to have a dramatic impact on tobacco use and the toll it takes on the health and economy of the United States. The Family Smoking Prevention and Tobacco Control Act gives the new Center at the Food and Drug Administration strong and broad authority to finally address tobacco use – the leading preventable cause of death in the United States.

While it is essential that the FDA pay close attention to all of the deadlines in the legislation, we urge the FDA to think long term. Many of the Act's provisions can be implemented effectively and quickly based on existing knowledge. Other provisions will require careful deliberation, a review of documents and information provided to the Agency by the tobacco industry and outside experts to address complex scientific issues.

For these reasons, it is absolutely critical that, in addition to acting to implement the specific provisions of the law, the Center be built carefully and methodically to take on the tobacco issue in the long term as well as in the short run. Preparing for the long term will entail a number of dimensions, including placing a priority on:

- Building a first-rate Center with exceptional staff
- Carefully putting in place a process for setting priorities based upon which actions will have the greatest impact
- Identifying the type of information that will be necessary to make evidence-based decisions and establishing procedures to guarantee that the critical information the Agency receives can be fully evaluated, including by outside researchers,
- Establishing a process for collaborating with partners and other agencies (e.g., NIH, CDC, SAMHSA) to identify and build the science base for potential agency action

The tobacco industry is unlike any other industry regulated by the FDA in that it has a long history of opposing regulation and thwarting government oversight. The Center must be prepared to act forcefully when the industry violates the law and to react quickly and flexibly when the industry engages in attempts to get around it. To this end, the Center should put in place monitoring systems to monitor the industry's marketing practices and other actions relevant to its compliance with both the letter and the spirit of the law.

Lastly, given the tobacco industry's history of misleading the public, it is important for the FDA to put in place procedures for carefully evaluating consumer perceptions to guide its own communications with the public and to guide its regulation of the tobacco industry's communications with the public. It will be critical to conduct consumer research to develop this understanding. The Center should establish a mechanism for conducting

consumer perception research quickly and efficiently. Only by understanding how consumers react will the agency be able to determine what indeed benefits the overall public health – not just individual consumers.

Sincerely,

Matthew L. Myers
President
Campaign for Tobacco-Free Kids

---

[1] U.S. Centers for Disease Control and Prevention (CDC), "Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004, *Morbidity and Mortality Weekly Report (MMWR)* 57(45):1226-1228, November 14, 2008 http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf. (AIDS) CDC, "Table 7. Estimated numbers of deaths of persons with AIDS, by year of death and selected characteristics, 2001–2005 and cumulative—United States and dependent areas," HIV/AIDS Surveillance Report, Volume 17, Revised Edition, June 2007, http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/pdf/table7.pdf; (Alcohol) Mokdad, AH, et al., "Actual Causes of Death in the United States, 2000," *Journal of the American Medical Association (JAMA)* 291(10):1238-1245, March 10, 2004 [with correction in *JAMA* 293(3):298, January 19, 2005]; (Motor vehicle) National Highway Traffic Safety Administration's National Center for Statistics and Analysis, *2006 Traffic Safety Annual Assessment – A Preview*, DOT HS 810 791, July 2007, http://www.nhtsa.gov/portal/nhtsa_static_file_downloader.jsp?file=/staticfiles/DOT/NHTSA/NCSA/Content/RNotes/2007/810791.pdf; (Homicide, Suicide, Drug-Induced) Kung HC, et al., "Table 2. Deaths, death rates, and age-adjusted death rates for 113 selected causes, injury by firearms, drug-induced deaths, alcohol-induced deaths, and injury at work: United States, final 2004 and preliminary 2005," *Health E-Stats*, National Center for Health Statistics, September 2007, http://www.cdc.gov/nchs/data/hestat/preliminarydeaths05_tables.pdf#2.

[2] U.S. Department of Health and Human Services (HHS), CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, *The Health Consequences of Smoking: A Report of the Surgeon General* (2004) [quote from Chapter 1, page 25], http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

[3] For sources for all of this bulleted information, see the Campaign for Tobacco-Free Kids (CFTFK) factsheet, *The Toll of Tobacco in the USA*, and the sources cited therein, http://tobaccofreekids.org/research/factsheets/pdf/0072.pdf.

[4] HHS, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, *The Health Consequences of Smoking: A Report of the Surgeon General*, 2004 [quote from Chapter 1, page 25], http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

[5] HHS, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, Bethesda, MD 20892, NIH Publication No. 86-2874, April 1986, http://profiles.nlm.nih.gov/NN/B/B/F/C/. NCI, *Monograph 2: Smokeless Tobacco or Health: An International Perspective*, September 1992, http://cancercontrol.cancer.gov/tcrb/monographs/2/index.html. See also, CFTFK factsheet, *Health Harms from Smokeless Tobacco Use*, and the sources cited therein, http://www.tobaccofreekids.org/research/factsheets/pdf/0319.pdf.

[6] CDC, National Center for Health Statistics, National Health Interview Survey.

[7] CDC, Youth Risk Behavior Surveillance System.

[8] Alcohol and Tobacco Tax and Trade Bureau Tobacco Statistics, http://www.ttb.gov/tobacco/tobacco-stats.shtml.

[9] Substance Abuse and Mental Health Services Administration (SAMHSA), *Results from the 2008 National Survey on Drug Use and Health: National Findings,* Office of Applied Studies, NSDUH Series H-36, DHHS Publication No. SMA 09-4434, Rockville, MD, 2009, http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm.

[10] A trade publication for convenience stores recently quoted one retailer stating, "In the case of smokeless tobacco, you get a new flavor once every quarter." ["Flavors Add New Dimension to Tobacco," *Convenience Store News*, October 1, 2007.]

[11] CDC, Behavioral Risk Factor Surveillance System; 2007 Youth Risk Behavior Surveillance. New York City Department of Health and Mental Hygiene, *New York City Smoking Rates Fall to Lowest Rate on Record*, Press Release, May 5, 2009, http://www.nyc.gov/html/doh/html/pr2009/pr023-09.shtml.

[12] NCI*, Those Who Continue to Smoke: Is Achieving Abstinence Harder and Do We Need to Change Our Interventions?,* Smoking and Tobacco Control Monograph No.15, NIH Pub. No. 03-5370, April 2003.

[13] CDC, "Cigarette Smoking Among Adults—United States, 2001," *MMWR* 52(40):953-956, October 10, 2003, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5240a1.htm. CDC, "Tobacco Use Among Adults—United States, 2005," *MMWR* 55(42):1145-1148, October 27, 2006, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5542a1.htm. CDC, "Cigarette Smoking Among Adults—United States, 2006," *MMWR* 56(44):1157-1161, November 9, 2007, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5644a2.htm.

[14] CDC, "Cigarette Smoking Among Adults and Trends in Smoking Cessation—United States, 2008," *MMWR* 58(44): 1227-1232, November 13, 2009, http://www.cdc.gov/mmwr/PDF/wk/mm5844.pdf

[15] CDC, Behavioral Risk Factor Surveillance System. Thanks to the large number of non-smoking Mormons in its population, Utah has an adult smoking rate of only 9.3%.

[16] Tobacco Control Section, California Department of Health Services, *California Tobacco Control Update 2006: Social Norm Change Approach*, 2006.

[17] Zhu, S-H, et al., "Evidence of Real-World Effectiveness of a Telephone Quitline for Smokers," *New England Journal of Medicine* 347(14):1087-1093, October 2002. Zhu, S-H, et al., "A Centralised Telephone Service for Tobacco Cessation: The California experience," *Tobacco Control* 9:48-55, 2000. An, L, et al., "Benefits of Telephone Care Over Primary Care for Smoking Cessation," *Archives of Internal Medicine* 166:536-542, 2006. Swartz, S, et al., "Use and Effectiveness of Tobacco Telephone Counseling and Nicotine Therapy in Maine," *American Journal of Preventive Medicine* 29(4): 288-294. Cummins, SE, et al., "Reaching Young Adult Smokers Through Quit Lines," *American Journal of Public Health* 97(8):6-9, 2007. U.S. Centers for Disease Control & Prevention, *Telephone Quitlines: A Resource for Development, Implementation, and Evaluation*, September 2004. See also, CFTFK factsheet, *Quitlines Help Smokers Quit,* http://tobaccofreekids.org/research/factsheets/pdf/0326.pdf.

[18] CDC, "State Medicaid Coverage for Tobacco-Dependence Treatments—United States, 2007," *MMWR* 58(43):1199-1204, November 6, 2009, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5843a1.htm. CDC, "State Medicaid Coverage for Tobacco-Dependence Treatments—United States, 1998 and 2000," *MMWR* 50(44):979-982, November 9, 2001, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5044a3.htm.

[19] Thompson, D, "More HMOs, insurers offering smoking cessation programs," *The Business Journal,* March 3 2000, http://triad.bizjournals.com/triad/stories/2000/03/06/focus2.html?page=4. See also, American Lung Association (ALA), "Helping Smokers Quit: State Cessation Coverage," Tobacco Policy Trend Report, 2008, http://www.lungusa.org/atf/cf/%7B7a8d42c2-fcca-4604-8ade-7f5d5e762256%7D/HELPING_SMOKERS_QUIT_FULL_REPORT.PDF.

[20] McPhillips-Tangum, C, et al., "Addressing Tobacco in Managed Care: Results of the 2002 Survey," *Preventing Chronic Disease* 1(4):A04, October 2004, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1312309. University of Wisconsin Center for Tobacco Research and Intervention Report, Coverage of Tobacco Cessation Treatments, Wisconsin 2004, http://www.ctri.wisc.edu/Employers/Insurance_Coverage_WI.doc. Zwillich, Todd, "Report: Smokers Need More Help to Quit," *WebMDHealth,* June 14 2006, http://www.medscape.com/viewarticle/536431.

[21] For sources for all of this bulleted information, see CFTFK factsheet, *Benefits & Savings from Each One Percentage Point Decline in Adult and Youth Smoking Rates in the United States*, and the sources cited therein, http://tobaccofreekids.org/research/factsheets/pdf/0235.pdf. See, also, CFTFK factsheet, *The Daily Toll of Tobacco Use in the USA*, http://tobaccofreekids.org/research/factsheets/pdf/0300.pdf.

[22] See, e.g., American Nonsmokers' Rights Association materials at http://www.no-smoke.org/goingsmokefree.php?id=519#venues.

[23] See, e.g., Robert Wood Johnson Foundation et al., A Decade of Broken Promises: The 1998 State Tobacco Settlement Ten Years Later, November 18, 2008, http://www.tobaccofreekids.org/reports/settlements/.

[24] CFTFK factsheet, *Summary of the Multistate Settlement Agreement (MSA)*, and other related factsheets available at http://tobaccofreekids.org/research/factsheets/index.php?CategoryID=8.

[25] American Lung Association, *State of Tobacco Control 2008*, 2009, http://www.stateoftobaccocontrol.org/2008/ALA_SOTC_08.pdf. See, also, prior year editions available at http://www.lungusa.org/about-us/publications.

[26] USDOJ-Findings of Fact Volume V pg.2251, V.A.(3)(a) Para. 59.

[27] Kaufman, N., et al., "Predictors of Change on the Smoking Uptake Continuum Among Adolescents," *Archives of Pediatric and Adolescent Medicine,* 156: 581-587, 2002; Choi, W, et al., "Progression to Established Smoking, The Influence of Tobacco Marketing," *American Journal of Preventive Medicine*, 22(4):228-233, 2002.

[28] National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use,* Smoking and Tobacco Control Monograph No. 19, NIH Pub. No. 07-6242, June 2008, http://cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete.pdf.

[29] National Cancer Institute, *Changing Adolescent Smoking Prevalence,* Smoking and Tobacco Control Monograph No.14, NIH Pub. No. 02-5086, November 2001, http://cancercontrol.cancer.gov/tcrb/monographs/14/index.html.

[30] Wellman RJ, et al., "The extent to Which Tobacco Marketing and Tobacco Use in Films Contribute to Children's Use of Tobacco: A Meta-Analysis," *Archives of Pediatrics and Adolescent Medicine* 160(12):1285-96, 2006.

[31] Kaufman, N, et al., "Predictors of Change on the Smoking Uptake Continuum Among Adolescents," *Archives of Pediatric and Adolescent Medicine,* 156:581-587, June 2002.

[32] Pierce, J. et al, "Tobacco Industry Promotion of Cigarettes and Adolescent Smoking," *Journal of the American Medical Association (JAMA)* 279(7):511-505, February 1998 [with erratum in *JAMA* 280(5):422, August 1998].

[33] National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use,* Smoking and Tobacco Control Monograph No. 19, NIH Pub. No. 07-6242, June 2008, http://cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete.pdf.

[34] Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children*, National Academy of Sciences, 1994.

[35] HHS, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General*, 1989; See also, HHS *Reducing Tobacco Use Among Young People, A Report of the Surgeon General*, 1994. Smee C. Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence. London: Department of Health, Economics and Operational Research Division, 1992; Andrews RL, Franke GR. The determinants of cigarette consumption: A meta-analysis. *Journal of Public Policy and Marketing, 10,* 81-100, 1991; Lynch BS, Bonnie RJ. (eds) *Growing up tobacco free: Preventing nicotine addiction in children and youths.* Washington, D.C: Institute of Medicine, National Academy Press, 1994; Roemer R. *Legislative action to combat the World Tobacco Epidemic* (2e ed.). Geneva: World Health Organization, 1993.

[36] Pollay, RW. "Targeting youth and concerned smokers: evidence from Canadian tobacco industry documents," Tobacco Control, June 9(2), 2000.
[37] Siegel M, et al., "Tobacco Survey" *American Journal of Preventive Medicine*, Jan-Feb;12 (1),1996. Comment in: *American Journal of Preventive Medicine* , Jan-Feb;12(1), 1996.
[38] U.S. Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No. (CDC) 89-8411. 1989.
[39] Upadhyaya HP, Drobes DJ, Thomas SE. Reactivity to smoking cues in adolescent cigarette smokers. Addictive Behaviors. 2004; 29: p.849-856.
[40] Warner, KE. Selling Smoke: Cigarette Advertising and Public Health, Washington, DC American Public Health Association, 1986; Chaloupka FJ and Warner, KE. "The Economics of Smoking. National Bureau of Economic Research, Working Paper No. W7047. Available at: www.nber.org/papers/w7047.
[41] Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation*, National Academy of Sciences, 2007.
[42] Wakefield, M, et al., "Changes at the point of purchase for tobacco following the 1999 tobacco billboard advertising ban," University of Illinois at Chicago, Research Paper Series, No. 4, July 2000.
[43] FTC Reports, 2009, http://ftc.gov/os/2009/08/090812cigarettereport.pdf, http://ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf.
[44] Wakefield, M, et al., *Changes at the point of purchase for tobacco following the 1999 tobacco billboard advertising ban*, University of Illinois at Chicago, Research Paper Series, No. 4, July 2000.
[45] Feighery, EC, et al., "An examination of trends in amount and type of cigarette advertising and sales promotions in California stores, 2002-2005," *Tobacco Control* (published online), February 26, 2008; Glanz, K, Sutton, NM, & Jacob Arriola, KR, "Operation storefront Hawaii: Tobacco advertising and promotion in Hawaii stores," *Journal of Health Communication* 11(7):699-707, 2006. See also, Cummings, KM & Sciandra, R, "Tobacco Advertising in Retail Stores," *Public Health Reports* 106(5):570, September 1991; Feighery, E, et al., "Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California," *Tobacco Control* 10L:184-188, 2001.
[46] Slater, SJ, et al., "The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake," *Archives of Pediatrics and Adolescent Medicine* 161:440-445, May 2007. See also, Feighery EC, et al. "Seeing, wanting, owning: the relationship between receptivity to tobacco marketing and smoking susceptibility in young people." *Tobacco Control* 1998;7:123-28; Feighery, E, et al. "Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California." *Tobacco Control*, 10L:184-188, 2001; Henriksen L. "Effects on youth of exposure to retail tobacco advertising." *Journal of Applied Social Psychology* 2002;32:1771-1789. Henriksen, L. et al. "Association of Retail Tobacco Marketing with Adolescent Smoking." *American Journal of Public Health*, December 2004, 94(12): 8-10.
[47] Henriksen, L, et al., "Association of Retail Tobacco Marketing with Adolescent Smoking," *American Journal of Public Health* 94(12): 8-10, December 2004. See, also, Henriksen, L, et al., "Reaching youth at the point of sale: Cigarette marketing is more prevalent in stores where adolescents shop frequently," *Tobacco Control* 13: 315-318, 2004; Donovan RJ, et al., "Tobacco point of sale advertising increases positive brand user imagery," *Tobacco Control* 11(3):191-4, September 2002.
[48] Paynter J, et al., "Point of sale tobacco displays and smoking among 14-15 year olds in New Zealand: a cross-sectional study," *Tobacco Control*, 18:268-274, 2009.
[49] Feighery, E, et al., "Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California," *Tobacco Control* 10L:184-188, 2001 [citing Point of Purchase Advertising Institute, *The point-of-purchase advertising industry fact book*, Englewood, New Jersey, 1992]. For corroborating studies on increased retail exposure increasing likelihood of smoking, see the Henricksen and Paynter studies cited above.
[50] Feighery, E, et al., "Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California," *Tobacco Control* 10L:184-188, 2001 [citing *The 1999 annual report of the promotion industry, a PROMO magazine special report,* Overland Park, 1999; and Point of Purchase Advertising Institute, *The point-of-purchase advertising industry fact book*, Englewood, New Jersey, 1992].
[51] Wakefield M., et al., "The effect of retail cigarette pack displays on impulse purchase," *Addiction* 103: 322-328, 2008. See, also, Wakefield M & D Germain, "Adult smokers' use of point-of-sale displays to select cigarette brands," Australia New Zealand Journal of Public Health 30(5):483-4, 2006.
[52] Carter OBJ, et al., "The effect of retail cigarette pack displays on unplanned purchases: results from immediate postpurchase interviews," *Tobacco Control* 18: 218-221, 2009. For more information about the key role of retail outlets in tobacco product marketing and promotion, see the Campaign for Tobacco-Free Kids factsheet, *Tobacco Company Marketing that Reaches Kids: Point of Purchase Advertising and Promotions,* http://tobaccofreekids.org/research/factsheets/index.php?CategoryID=23.
[53] HHS, *Reducing Tobacco Use, A Report of the Surgeon General*, 2000; Eriksen, MP. Social forces and tobacco in society. Paper presented at the Robert Wood Johnson Foundation Conference, New Partnerships and Paradigms for Tobacco Prevention Research; May6-9, 1997.
[54] Biener, L & Siegel, M, "Tobacco Marketing and Adolescent Smoking; More Support for a Causal Inference," *American Journal of Public Health* 90(3):407-411, March 2000.
[55] Rigotti, NA, et al., "US College Students' Exposure to Tobacco Promotions: Prevalence and Association With Tobacco Use," AJPH 95(1):138-144, 2005. See also, Vaidya SG, Vaidya JS, Naik UD. Sports sponsorship by cigarette companies influences the adolescent children's mind and helps initiate smoking: results of a national study in India. *Journal of the Indian Medical Association*. 1999;97:354-356
[56] *U.S. V. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, http://www.tobaccofreekids.org/reports/doj/FinalOpinion.pdf. Pages 1607-1608.
[57] U.S. Federal Trade Commission (FTC), *Cigarette Report for 2006*, 2009, http://ftc.gov/os/2009/08/090812cigarettereport.pdf. See also, FTC, *Smokeless Tobacco Report for the Years 2006*, 2009, http://ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf. Data for top 5 manufacturers only.

[58] See, e.g., Fairclough, G, "Corporate Focus R.J. Reynolds Lowers Forecasts -- Cigarette Price War, Generic Competition to Take Toll on Earnings," *Wall Street Journal*, September 9, 2002; the companies' periodic reports to the U.S. Securities and Exchange Commission at www.sec.gov/edgar/searchedgar/webusers.htm; and Campaign for Tobacco-Free Kids Factsheet, *Increased Cigarette Company Marketing Since the Multistate Settlement Agreement Went into Effect*, http://www.tobaccofreekids.org/research/factsheets/pdf/0128.pdf.

[59] FTC, *Cigarette Report for 2006*, 2009, http://ftc.gov/os/2009/08/090812cigarettereport.pdf.

[60] *U.S. V. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, pg.1605, http://www.tobaccofreekids.org/reports/doj/FinalOpinion.pdf.

[61] *U.S. V. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, http://www.tobaccofreekids.org/reports/doj/FinalOpinion.pdf. Page 1606.

[62] Slater, SJ, et al., "The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake," *Archives of Pediatrics and Adolescent Medicine* 161:440-445, May 2007.

[63] World Health Organization (WHO) Report on the Global Tobacco Epidemic 2008: The MPOWER package. Geneva: World Health Organization, 2008.

[64] *Promoting Healthy Lifestyles: Policy, Program and Personal Recommendations for Reducing Cancer Risk,* 2006-2007 Annual Report, President's Cancer Panel.

[65] See, e.g., in addition to the previously cited studies, Beltramini, RF. "Perceived believability of warning label information presented in cigarette advertising," *Journal of Advertising*, 17(1):26-32, 1988; HHS, Preventing Tobacco Use Among Young People: A Report of the Surgeon General, 1994. http://www.cdc.gov/tobacco/sgr/sgr_1994/index.htm; Borland, Ron. "Tobacco health warnings and smoking –related cognitions and behaviours," *Addiction* Vol. 92, Issue 11, No., 1997; Garfield Mahood. "Warnings that tell the truth: breaking new ground in Canada," *Tobacco Control*;8:356-361, 1999; Duffy, SA & D Burton, "Cartoon characters as tobacco warning labels," *Archives of Pediatric and Adolescent Medicine*, 154(12): 1230-36, December, 2000; G.T. Fong. "A Review of the Research on Tobacco Warning Labels, With Particular Emphasis on the New Canadian Warning Labels, Report to Justice Canada." March, 30, 2001; Strahan EJ, et al., "Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective," *Tobbaco Control* 11(3):183-90, September, 2002; Hammond D. McDonald, PW, Fong GT, Cameron AR. "Cigarette warning labels, smoking bans, and motivation to quit smoking: Evidence from former smokers. *Canadian Journal of Public Health*, 95 (3): 201-04, 2004; Willemsen MC, "The new EU cigarette health warnings benefit smokers who want to quit the habit: results from the Dutch Continuous Survey of Smoking Habits," *Eur J Public Health* 15(4):389-92, August, 2005; Peters, E, Romer D, et al. "The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers," *Nicotine & Tobacco Research* 9(4), April 2007; Givel, M, "A comparison of the impact of U.S. and Canadian cigarette pack warning label requirements on tobacco industry profitability and the public health," *Health Policy,* 83(2-3): 343-52, October 2007; Thrasher JF, et al., "Smokers' reactions to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada," *Salud Publica Mex* 49(Suppl 2): S233-40, 2007.

[66] Borland R, et al., "Impact of Graphic and Text Warnings on Cigarette Packs: Findings from Four Countries over Five Years," *Tobacco Control*, doi:10.1136/tc.2008.028043, published online June 28, 2009; Borland R, et al., "How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey," *Addiction* 104(4):669-75, April 2009; Borland, R, "Tobacco health warnings and smoking-related cognitions and behaviours," *Addiction* 92(11)1427-35, November 1997; Duffy, SA & D Burton, "Cartoon characters as tobacco warning labels," *Archives of Pediatric and Adolescent Medicine*, 154(12): 1230-36, December, 2000; Givel, M, "A comparison of the impact of U.S. and Canadian cigarette pack warning label requirements on tobacco industry profitability and the public health," *Health Policy,* 83(2-3): 343-52, October 2007; Hammond D, et al., "Impact of the graphic Canadian warning labels on adult smoking behaviour," *Tobacco Control* 12(4):391-5, 2003; Hammond, D, "Health warnings on tobacco packages: summary of evidence and legal challenges," white paper prepared for the International Legal Consortium of the Campaign for Tobacco-Free Kids, January 2008, http://www.tobaccofreecenter.org/files/pdfs/reports_articles/India%20Labelling%20Review-Revised%20(Hammond%202008).pdf; Hammond, D, 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," *Tobacco Control* 15(suppl_3):iii19-iii25, 2006; Hammond, D, Fong GT, et al. "Impact of the graphic Canadian warning labels on adult smoking behaviour," *Tobacco Control*. 12(4): 391-95, December 2003; Hammond, D, Fong GT, et al. "Text and Graphic Warnings on Cigarette Packages: Findings from the International tobacco control four country study" *American Journal of Preventive Medicine* 32(3), 2007; Hammond, D, Fong GT, Graphic Canadian warning labels and adverse outcomes: evidence from Canadian smokers," *American Journal of Public Health* 94(8), 2004; Health Canada, *The health effects of tobacco and health warning messages on cigarette packages – survey of adults and adult smokers: Wave 9 Surveys*, prepared by Environics Research Group, January 2005; Nascimento BE, et al., "Avoidance of smoking: the impact of warning labels in Brazil," *Tobbaco Control* 17(6):405-09, December, 2008; O'Hegarty M, et al. "Reactions of young adult smokers to warning labels on cigarette packages," *American Journal of Preventive Medicine* 30(6), 2006; Peters, E, Romer D, et al. "The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers," *Nicotine & Tobacco Research* 9(4), April 2007; Romer, D, Jamieson P, "The role of perceived risk in starting and stopping smoking," in Slovic, (ed.), Smoking: Risk, Perception, and Policy (Sage, 2001) at 65-80; Strahan EJ, et al., "Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective," *Tobbaco Control* 11(3):183-90, September, 2002; Thrasher JF, et al., "Smokers' reactions to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada," *Salud Publica Mex* 49(Suppl 2): S233-40, 2007; White, V et al., "Do graphic warning labels have an impact on adolescents' smoking-related beliefs and behaviors?" *Addiction* 103(9): 1562-71, September, 2008; Willemsen MC, "The new EU cigarette health warnings benefit smokers who want to quit the habit: results from the Dutch Continuous Survey of Smoking Habits," *Eur J Public Health* 15(4):389-92, August, 2005. See, also, the Campaign for Tobacco-Free Kids International Resource Center website pages on warning labels, including factsheets with references, at http://tobaccofreecenter.org/resources/warning_labels; the online Tobacco Labeling Resource Centre at http://www.tobaccolabels.ca.

[67] Krugman, DM, et al. "Do Cigarette Warnings Warn? Understanding what it will take to develop more effective warnings. " *Journal of Health Communications* 4, No. 2, 1999.

[68] Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children*, National Academy of Sciences, 1994.

[69] Ayanian JZ, Cleary PD. Perceived risks of heart disease and cancer among cigarette smokers. *JAMA*. Mar 17;281(11):1019-21, 1999.
[70] D. Hammond, GT Fong, et al. Text and graphic warnings on cigarette packages: Findings from the international tobacco control four country study. *American Journal of Preventive Medicine*, 32(3):202-9, 2007.
[71] Survey of 900 adult smokers in the U.S. conducted by American Legacy Foundation and GlaxoSmithKline Consumer Healthcare, August 2007. http://www.americanlegacy.org/304.aspx
[72] Cummings, MK, et al. "Are Smokers Adequately Informed About the Health Risks of Smoking and Medicinal Nicotine?" *Nicotine & Tobacco Research* Volume 6, Supplement 3, December 2004. See also, Cummings, MK, "Tobacco Risk Perceptions and Behavior: Implications for Tobacco Control, *Nicotine & Tobacco Research* Volume 6, December 2004.
[73] See, e.g., Davis, TC, et al., "Low literacy impairs comprehension of prescription drug warning labels," *Journal of General Internal Medicine* 21(8), August 2006; Wolf, MS, et al., "Misunderstanding of prescription drug warning labels among patients with low literacy," *American Journal of Health-System Pharmacy*, 63(11), June, 2006.
[74] D. Hammond, G.T. Fong, et al. "Impact of the graphic Canadian warning labels on adult smoking behaviour." *Tobacco Control*. Vol. 12, No. 4, p.391-395, December 2003.
[75] Hammond D, Fong GT, Borland R, Cummings KM, 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;32(3):202-9, 200; Tobacco labelling toolkit: Implementation. In: Hammond D, editor. Tobacco Labeling and Packaging Toolkit: a guide to FCTC article 11. Waterloo: University of Waterloo; 2008.
[76] D. Hammond, G.T. Fong, et al. "Effectiveness of Cigarette Warning Labels in informing smokers about the risks of smoking: Findings from the International Control Four Country Study," *Tobacco Control*. Vol. 15, Suppl III p. 19-25, June 2006; Hammond D. FCTC Article 11 Fact Sheet: Health warnings on tobacco packages. Waterloo: University of Waterloo; 2008. Available online: http://www.tobaccolabels.ca/tobaccolab/labelling
[77] D. Hammond, G.T. Fong, et al. "Effectiveness of Cigarette Warning Labels in informing smokers about the risks of smoking: Findings from the International Control Four Country Study," *Tobacco Control*. Vol. 15, Suppl III p.19-25, June 2006.
[78] Hammond D, Fong GT, McNeill A, Borland R, and Cummings KM. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tobacco Control*. 2006; Vol. 15, Suppl III p.19-25, June 2006.
[79] Romer, D., Jamieson P. The role of perceived risk in starting and stopping smoking. In: Slovic, ed. Smoking: risk, perception, and policy. Thousand Oaks, California: Sage, 65-80, 2001.
[80] Borland R, et al., "Impact of Graphic and Text Warnings on Cigarette Packs: Findings from Four Countries over Five Years," *Tobacco Control*, published online June 28, 2009; Borland R, et al., "How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey," *Addiction* 104(4):669-75, April 2009; O'Hegarty M., et al. "Reactions of young adult smokers to warning labels on cigarette packages." *American Journal of Preventive Medicine* 30 (6), 2006; D. Hammond, "Health warnings on tobacco packages: summary of evidence and legal challenges." January 2008; D. Hammond, GT Fong, et al. Text and graphic warnings on cigarette packages: Findings from the international tobacco control four country study. *American Journal of Preventive Medicine*, 32(3):202-9, 2007; Hammond D, Fong GT, McNeill A, Borland R, and Cummings KM. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tobacco Control,* Vol. 15, Suppl III p.19-25, June 2006.
[81] Hammond D, Fong GT, McDonald PW, Cameron R, Brown KS. Impact of the graphic Canadian warning labels on adult smoking behaviour, *Tobacco Control*, 12(4):391-5, December 2003.
Shanahan P, Elliott D. Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008 -- Executive Summary. Australian Government Department of Health and Ageing; 2009. Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/83F397C5993B9AA4CA2575880078FCF2/$File/hw-eval-exec-sum.pdf
[82] Hammond D, Fong GT, Borland R, Cummings KM, McNeill A, Driezen P. Text and graphic warnings on cigarette packages: Findings from the international tobacco control four country study. *American Journal of Preventive Medicine,* 32(3):202-9, 2007.
[83] Borland R, et al., "How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey," *Addiction* 104(4):669-75, April 2009.
[84] D. Hammond, G.T. Fong, et al. "Impact of the graphic Canadian warning labels on adult smoking behaviour." Tobacco Control. Vol. 12, No. 4, p.391-395, December 2003.
[85] Shanahan P, Elliott D. Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008 -- Executive Summary. Australian Government Department of Health and Ageing; 2009. Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/83F397C5993B9AA4CA2575880078FCF2/$File/hw-eval-exec-sum.pdf
[86] Costa e Silva, VL. Presentation to EU Commission on enforcement of health warnings in Brazil. Brussels 2002.
[87] Nascimento BE, Oliveira L, Vieira AS, Joffily M, Gleiser S, Pereira MG, et al. Avoidance of smoking: the impact of warning labels in Brazil. *Tobbaco Control*, Dec;17(6):405-9, 2008.
[88] Health Promotion Board -- Singapore. Graphic health warnings on tobacco packaging inspire smokers to quit the habit.
[89] International Tobacco Control Policy Evaluation Project (ITC). ITC Thailand survey summary. Waterloo: Institute for Population and Social Research, Mahidol University Salaya, and Thai Health Promotion Foundation; 2009. Available from: http://itcconference.com/ITCWorkshopResources/ITCprojectCountryBrochures/ITCThailand4PagerV115single.pdf.
[90] Fong G, Hammond D, Driezen P, Quah A, Yuan J, Qiang L. Presentation Comparing Health Warnings in China to Health Warnings in Other Countries: An Experimental Study in four Chinese Cities. International Tobacco Control Policy Evaluation Project; 2009. Available from: http://www.itcproject.org/keyfindi/chinalabel
[91] Health Canada. The health effects of tobacco and health warning messages on cigarette packages – survey of adults and adult smokers: Wave 9 Surveys. Prepared by Environics Research Group, January 2005. See also, D. Hammond, "Health warnings on tobacco packages: summary of evidence and legal challenges." January 2008.
[92] D. Hammond, G.T. Fong, et al. Graphic Canadian warning labels and adverse outcomes: evidence from Canadian smokers," *American Journal of Public Health* 94 (8), 2004.

[93] V, Webster B, Wakefield M. Do graphic health warning labels have an impact on adolescents' smoking-related beliefs and behaviours? *Addiction.* 103(9):1562-71, 2008.
[94] Vardavas CI, Connolly G, Karamanolis K, Kafatos A. Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels. *European Journal of Public Health*, 19(2):212-7, 2009.
[95] Miller CL, Hill DJ, Quester PG, Hiller JE. Impact on the Australian Quitline of new graphic cigarette pack warnings including the Quitline number. *Tobacco Control*, February, 2009
[96] Li J, Grigg M. New Zealand: new graphic warnings encourage registrations with the quitline. *Tobacco Control,* Feb;18(1):72, 2009.