



**Testimony of Matthew Myers
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Before the Committee on Health, Education, Labor and Pensions
United States Senate
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Chairman Kennedy, Senator Enzi, and members of the HELP Committee, thank you for this opportunity to testify in support of S.625, a bill to provide the U.S. Food and Drug Administration (FDA) with the authority to effectively regulate tobacco products and their marketing and to reduce the harms associated with tobacco use. My name is Matthew Myers, and I am President of the Campaign for Tobacco-Free Kids, the nation's largest non-profit, advocacy organization solely devoted to reducing the harm caused by tobacco use and exposure to secondhand smoke.

S.625 has the potential to save many lives. Today, America's most dangerous consumer product – tobacco – is also the one consumer product that no federal agency oversees for health and safety purposes. This carefully crafted, thoughtfully balanced legislation would correct that glaring problem and bring the type of government oversight to the manufacture, marketing and sale of tobacco products that is already provided to other consumer products.

As you know, S.625 was introduced on February 15, 2007, but the need for legislation giving FDA authority over tobacco has been discussed for years, and

legislation similar to S.625 has been before the Senate for close to a decade. A bill virtually identical to S.625 was debated and overwhelmingly approved by the full Senate in 2004.

It is essential for Congress to act if the public is to be protected. In 1996, after a two-year investigation, the U.S. Food and Drug Administration asserted jurisdiction over tobacco under current law. Then, in March 2000, the U.S. Supreme Court ruled that the FDA did not have the statutory authority to regulate tobacco products, and that only Congress could grant FDA this authority. In a highly unusual commentary, the Court urged Congress to act given the seriousness of the public health problem.

Thus, it is no surprise that S.625 has broad bipartisan support including liberals and conservatives and Senators from every geographic region of the country. It has been endorsed by every major national public health organization, many organizations representing health care providers (see attached letter), and representatives of a wide range of faith groups. Virtually identical legislation was also previously endorsed by every major tobacco-farming group.

The Campaign for Tobacco-Free Kids has measured voter support for FDA regulation of tobacco products and, not surprisingly, it has broad support across the country, with 69 percent of voters in a national poll favoring. State surveys from around the country have consistently found similarly high levels of support, crossing party and ideological lines. It even has majority support among smokers. Voter support is particularly strong for the specific provisions of FDA regulation. When asked if tobacco companies should be required to take measures to make cigarettes less harmful; if tobacco companies should be prevented from making claims that some products are

less harmful than others unless FDA determines those claims are true; or if FDA should restrict tobacco marketing aimed at children, voter support for each of these elements exceeds 75 percent.

It is truly time for Congress to act.

Why This Bill Is Needed

S.625 is essential for the protection of the public health. More than five decades after the Surgeon General's historic 1964 report, more than 400,000 Americans die prematurely every year from tobacco, roughly 1200 people every day. The critical word is "prematurely." Fifty percent of the people who die from tobacco die in middle age, and almost every one of those deaths is a person who started smoking and became addicted before they were old enough to be sold tobacco products legally.

Death from tobacco is almost always the last chapter of a book that begins in childhood. Every day, approximately 4,000 kids will try a cigarette for the first time. Another 1,000 will become new, regular daily smokers, and one-third of these kids will eventually die prematurely as a result.

While some hoped that the 1998 Master Settlement Agreement (MSA) would end tobacco marketing to children, Federal District Court Judge Gladys Kessler found last July that the tobacco manufacturers continue to market in ways that appeal to young people and continue to recruit children as new tobacco users. The MSA, while helpful, addressed less than 20 percent of the marketing and promotional expenditures by the tobacco companies, and it did not completely eliminate even those practices. The tobacco companies have easily overcome these restrictions by dramatically increasing

marketing expenditures and constantly finding new and sophisticated ways to market their products, many of which impact kids. Between 1998, the year of the MSA, and 2003, the latest year for which data are available, the major cigarette companies more than doubled their marketing and promotional expenditures from \$6.73 billion to a staggering \$15.15 billion – more than \$40 million each and every day – much of it aimed at kids. As Judge Kessler concluded in her opinion: “In fact, the overwhelming evidence set forth in this Section – both Defendants’ internal documents, testimony from extraordinarily qualified and experienced experts called by the United States, and the many pictorial and demonstrative exhibits used by the Government – prove that, historically, as well as currently, Defendants do market to young people, including those under twenty-one, as well as those under eighteen. Defendants’ marketing activities are intended to bring new, young, and hopefully long-lived smokers into the market in order to replace those who die (largely from tobacco-caused illnesses) or quit.” It’s no wonder that our surveys continue to show kids are almost twice as likely as adults to remember tobacco advertising.

Judge Kessler also concluded that tobacco company marketing to kids is likely to continue in the future: “Similarly, 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. Defendants are well aware that over eighty percent of adult smokers began smoking before the age of 18, and therefore know that securing the youth market is critical to their survival. There is therefore no reason, especially given their long history of denial and deceit, to trust their

assurances that they will not continue committing RICO violations denying their marketing to youth.”

In addition to allowing virtually unfettered promotion of tobacco products, the absence of any meaningful regulation continues to allow the tobacco industry to manipulate their products in ways that can make them more addictive and/or more harmful. The introduction of so-called reduced risk products, with no oversight, can also deceive consumers and undermine their efforts to reduce their risk by luring them into switching to products that they falsely believe are less hazardous rather than quitting. It can also attract new smokers with the promise of less harm.

The lesson is clear: more must be done. The status quo is not working and current efforts are inadequate. The need for FDA oversight of the tobacco industry is as great today as ever:

- The tobacco industry continues deceptive marketing that undermines prevention efforts and appeals to children.
- Tobacco products remain toxic and addictive and tobacco companies are free to manipulate products to make them more appealing and addictive.
- There continue to be unsubstantiated health claims made for new and low tar products.
- There are still critical gaps in the industry’s acknowledgement of the health effects of their products.

What This Bill Will Do

This legislation will provide the FDA with the authority it needs to appropriately oversee the marketing, manufacture and sale of tobacco products. This authority will benefit public health by reducing illegal sales of tobacco to kids, by limiting marketing that targets kids to begin smoking and misleads smokers to discourage them from

quitting, by ensuring that new products that purport to reduce harm actually do so, and by requiring tobacco companies to make changes in the products that make them less harmful to smokers unable to quit.

Key principles of the legislation include:

- Ensures that oversight of tobacco is based on sound science and conducted by an agency and personnel with scientific expertise and the ability to make adjustments based on new scientific evidence;
- Requires the tobacco industry to make the type of disclosures to FDA that other manufacturers are already required to make and that are essential to enable the agency to make well-informed decisions and take effective action;
- Establishes common-sense standards for product regulation and agency action that are practical, achievable and directed towards a single common goal – to protect the public health and reduce the number of Americans who die prematurely as the result of their use of tobacco products;
- Recognizes that how a product is marketed can also have a major impact on the number of people who needlessly die from tobacco use and establishes marketing standards that are both consistent with the First Amendment and the FDA's public health mission; and
- Provides the FDA with the resources to do the assigned job capably and without detracting from FDA's other important missions.

I want to highlight just a few key provisions of the bill and also address some of the concerns that have been raised about the legislation.

Marketing: Since the Master Settlement Agreement, the tobacco industry has more than doubled its marketing expenditures with knowledge of the impact of its marketing on children; continued marketing “light” and “low tar” cigarettes despite the evidence that they do not reduce the risk of disease and the public is misled by how they are labeled and sold; and introduced new tobacco brands backed by new unsubstantiated and unproven health claims that mislead the public. It has become even clearer that state lawsuits, prior voluntary codes, and current laws have not prevented the tobacco industry from marketing to children or misleading the public.

This bill would put in place a number of specific advertising restrictions that FDA previously determined, after a two-year investigation, impact tobacco use by children; would require the elimination of the use of the terms “light,” “low tar” and similar terms unless the industry could scientifically demonstrate that products labeled “light” and “low tar” actually reduce the risk of disease; and would otherwise prevent the use of other health claims unless a manufacturer presents scientific evidence to support those claims. These are not radical concepts. Manufacturers of other products regulated by FDA are not allowed to make claims without adequate scientific substantiation because of the adverse impact on the health of potential consumers. This bill would finally force the tobacco industry to play by these reasonable rules.

Equally as important, this bill recognizes that the tobacco industry has often circumvented rules designed to curtail both marketing to children and misleading of the public and provides FDA the needed authority to adopt new rules to address new conditions as they arise.

Any advertising regulations must be consistent with the First Amendment. The bill states that the authority to develop regulations that impose restrictions on the advertising and promotion of tobacco products must be consistent with, but can be exercised to the full extent permitted by, the First Amendment. Given the history of the tobacco industry's aggressive and misleading marketing, strong authority to restrict marketing is justified.

The kinds of federal restrictions on tobacco marketing contained in S.625 are consistent with the Supreme Court's analysis in *Lorillard Tobacco Company v. Reilly*. They would survive constitutional challenge because they are carefully tailored, scientifically proven measures to protect the recognized legitimate interests of the government in protecting 1) children from marketing that contributes to tobacco addiction and 2) adults from misleading marketing that encourages tobacco use and discourages quitting. Federal action is clearly needed because over 50 years of voluntary and state governmental efforts to change the tobacco industry's behavior have not solved the problem.

Establishing Appropriate Standards for the Content of Tobacco products: Today, tobacco products contain more than 60 known cancer-causing substances, and the incidence of disease among smokers has actually increased, not decreased, over the years, according to the National Cancer Institute.¹ Even as the tobacco industry touted that it had reduced tar and nicotine levels in its products, the level of potent

¹ Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October, 2001. <http://cancercontrol.cancer.gov/tcrb/monographs/13/>.

carcinogens, like nitrosamines, increased without any public agency having any authority to evaluate the impact of that change.

No federal agency currently has the authority to require tobacco companies to disclose, in a meaningful way, what is in each product;² to require manufacturers to provide evidence of the impact of product changes; or to require manufacturers to make technologically feasible changes to products to reduce the number or quantity of harmful substances in tobacco products and the smoke of tobacco products. S.625 would address this gap in a practical and reasonable way. It recognizes that the standard FDA normally applies to many products under its jurisdiction – whether the product is “safe and effective” – does not make sense for tobacco products because there is no such thing as a “safe cigarette.” A “safe and effective” standard would thus dictate a total ban on tobacco products, and with close to 50 million Americans addicted to tobacco use, virtually all public health experts recognize this as infeasible and unproductive. S.625 recognizes that the goal is therefore to reduce the number of people who needlessly die prematurely from tobacco use. Thus, the standard in the bill is one based on what actions are “appropriate to protect the public health,” taking into account the impact of any proposal on the health of the “population as a whole, including users and non-users” of tobacco products. The bill puts in place measures to prevent kids from starting to smoke and to ensure that smokers are not dissuaded from quitting by misleading claims, and it establishes a process to reduce the harm from tobacco products to those who are unable to quit.

² The ingredient disclosure requirements of the 1984 Comprehensive Smoking Education Act have proven wholly inadequate for this purpose. They do not provide the government with information to identify what chemicals and other ingredients are in each brand of cigarettes, the quantity of the different chemicals, in each cigarette or the type of information that is needed to understand or evaluate or warn the public about what is in each brand of cigarette.

The standard in S.625 recognizes the unique issues raised by the regulation of tobacco products. This standard looks at the overall impact on the number of people who will die needlessly from tobacco and allows the FDA to broadly consider all factors that will affect whether a proposed product change will increase or decrease the death and disease caused by tobacco. It instructs the FDA to look at how a mandated product change will impact individual tobacco users but also look at its impact on the number of tobacco users by examining its effect on discouraging smokers from quitting or encouraging non-smokers to start. The goal is protecting the public and saving lives, and the standard set forth in S.625 is right on the mark.

Preventing Unsubstantiated Health Claims While Encouraging Real Scientific

Innovation to Reduce the Harm Caused by Tobacco Products: For decades, tobacco manufacturers have been marketing “light” and “low tar” products with claims that these cigarettes are less risky, leading millions of consumers to switch to these products thinking they are actually reducing their risk of disease or that they were taking a first step towards quitting. The National Cancer Institute, the U.S. Surgeon General and other credible scientific bodies have subsequently concluded that “light and “low tar” products did not reduce the risk of disease and did deter millions of smokers from quitting. Subsequent to the release of the scientific evidence demonstrating that “light” and “low tar” products have not reduced the risk of disease, tobacco companies have continued to mislead consumers and have come out with new products whose advertising includes even more specific claims of reduced risk.

The absence of any regulatory body to review health claims has led to a public health tragedy that has thwarted the well-intended personal efforts of tobacco users who have attempted to reduce their risk of disease. This bill would address that problem in a manner consistent with sound scientific standards. It requires FDA to prevent unsubstantiated and unproven claims, while permitting a manufacturer who produces a genuinely less hazardous product, and develops sound scientific evidence of its impact, to responsibly make claims about any such innovative product.

This provision by itself has the potential to save many lives. Before a manufacturer can make a health claim for a product, the legislation simply requires that manufacturer to demonstrate to FDA that the product significantly reduces the risk of disease when compared to other tobacco products, and when used in the manner a consumer will actually use the product. It also requires the manufacturer to show that any public health benefit for individual users will not be offset by the harm caused by marketing of the product resulting in increased tobacco use or decreased cessation.

This section will benefit manufacturers who develop a genuinely safer product and will adversely impact only those manufacturers who have been making unproven claims or marketing their products in ways that encourage non-tobacco users to start or discourage potential users who would otherwise quit.

Concerns of Tobacco Product Retailers: Convenience store owners have expressed concerns about provisions in the bill, including those that require retailers to check the ID of young persons seeking to purchase tobacco products. The youth access provisions of the original FDA regulations in place from 1996 to 2000 were effective in

reducing illegal sales to youth. Congress appropriated funding for this program, and FDA enforced the youth access restrictions, not by employing federal agents, but by contracting with state and local officials, such as health departments and police departments. By 2000, the FDA had contracts with every state to conduct the compliance checks and had an extensive outreach program that provided resources and information to retailers. This was a program that was producing solid results in reducing illegal youth access to tobacco in a manner sensitive to state and local interests.

Although this bill does hold store owners responsible for illegal tobacco sales to children, it establishes detailed procedures to protect retailers who diligently require young people to show government-issued IDs, including procedural protections that were not in place between 1996 and 2000. In addition, no fines are incurred until repeated violations occur, and retailers are warned after the first violation that additional compliance checks will be conducted. The only retailers who will be punished will be those who repeatedly sell tobacco to kids illegally.

Impact on FDA's Ability to Regulate Food, Drugs, Devices and Other Products

Currently Under Its Jurisdiction: We recognize that there are concerns about FDA's resources and whether it is successfully carrying out its current responsibilities. The expectation is that FDA would create a new office and hire additional staff to carry out the activities required by this legislation. The new responsibilities would be funded through a user fee on the tobacco industry, so it would have no impact on the funding provided to FDA to carry out its other important activities. The user fees are allocated

among the manufacturers of tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S. tobacco product market. Many of the groups that support this legislation care deeply about the many important tasks of the FDA including drug and device approval and the work the agency does to protect our food supply. But we also believe that a key to improving the nation's health is reducing the harm caused by tobacco products.

Impact on Tobacco Companies: Some tobacco companies have argued that this bill will give an advantage to one tobacco manufacturer over others, claiming that certain tobacco companies can more easily comply with stringent FDA regulations and that industry leaders will benefit by the bill's restriction of tobacco marketing. Neither argument has any merit.

When the FDA sets safety standards for foods and drugs, its focus is on safety and efficacy, not the size of the manufacturer or the impact on market share. For those other products, the only manufacturers who are hurt are those who can't meet FDA's public health standards. This bill does the same for tobacco products and creates a level playing field for all manufacturers. The bill's marketing restrictions are also fair and balanced. Today, close to 90 percent of all new long term smokers are children. It is a strength of this legislation, not a weakness, that it provides a comprehensive attempt to restrict marketing that appeals to children. The tobacco industry claims its marketing is about brand competition among smokers; the industry's own documents and Judge Kessler's decision last August reflects powerful evidence that the industry's advertising is a major contributor to tobacco use by youth. What is of paramount

importance to public health is the size of the overall market for tobacco products, NOT the market share of any particular company. We believe that this legislation will significantly reduce the number of people who use tobacco and who become sick and die as a result.

State and Local Authority: The legislation achieves a reasonable balance between federal and state or local authority over tobacco. It allows the states to continue to regulate the sale, distribution, and possession of tobacco products and would expand state authority to regulate tobacco product marketing. To ensure consistent product standards nationally, however, the legislation reserves to the federal government the right to regulate the product itself, which is consistent with the way the FDA regulates other products under its jurisdiction.

We believe that states and localities ought to be able to control the time, place and manner of tobacco advertising in their communities, and this legislation will allow them to do that for the first time in almost forty years. The bill cuts back, but does not fully eliminate, the exemption for the tobacco industry passed in 1969 as part of the Federal Cigarette Labeling and Advertising Act. That act prevented the states from regulating cigarette advertising, even purely local forms of cigarette advertising. The bill returns to state and local governments the ability to impose limitations on the time, place and manner of marketing and advertising practices, but not on the content of ads. The states already have this authority for smokeless tobacco products and other products regulated by FDA, and it has not created problems for the marketplace.

The sponsors of this legislation were careful to specifically make clear that the legislation does not curtail any of the areas states have traditionally used to reduce tobacco use. Under the legislation, state and local governments would continue to be free to adopt measures regulating exposure to secondhand smoke; restricting youth access to tobacco products; and enacting fire safety standards for tobacco products. In short, the bill in no way restricts states from pursuing policies such as smoke-free laws, tobacco taxes, fire-safe measures, age requirements, identification checks, retailer licensing and fines, and other restrictions on the sale and distribution of tobacco products that have been instrumental in reducing tobacco use. States would also be able to impose additional reporting requirements on tobacco manufacturers (as Massachusetts, Texas and Minnesota have done) if there was any information FDA was not getting or not sharing that a state thought would be useful.

The bill does give the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products. States could not establish requirements in these areas. This approach is consistent with federal law regarding FDA regulation of drugs, devices, and food because it provides for a consistent national standard.

Permitting Cross Category Comparative Health Claims: The bill permits the FDA to authorize tobacco manufacturers of one type of tobacco product to make health claims comparing the risks of its tobacco to other forms of tobacco products, but only if the manufacturer has presented sufficient scientific evidence that the advertised product is

indeed safer and will reduce the user's risk of disease – in this regard, the bill is explicit. There has been a debate about whether the use of smokeless tobacco by committed, addicted smokers who can't or won't quit can be a useful harm reduction strategy. This bill sets the scientific standard for FDA making such a determination, but doesn't prejudge the scientific result. If a smokeless tobacco manufacturer provides the FDA with adequate scientific evidence that a specific product or group of products is less hazardous than a cigarette product and will reduce the risk of disease among certain tobacco users, FDA is authorized to permit the smokeless manufacturer to make an approved claim. However, in making such a determination, FDA is required to consider the population-wide impact of permitting such claims, including the impact of any claims on the number of smokers who would otherwise quit using tobacco altogether and the number of people who begin using tobacco products.

Limitations on FDA's Authority Over Tobacco Growers and Leaf Tobacco: The bill contains a number of specific prohibitions against the exercise of FDA authority on tobacco farms. The bill establishes FDA authority over tobacco manufacturers and their products and prohibits FDA from regulating leaf tobacco. Even FDA's standard-setting authority is limited to standards for manufactured tobacco products. Many tobacco growers believe American producers, much more easily than their foreign competitors, will be able to swiftly produce the quality tobacco leaf manufacturers require, and that consequently the legislation may provide American growers with a comparative advantage over foreign competition.

Conclusion

Mr. Chairman, in summary, the Campaign strongly supports this bill, and we firmly believe that it will help protect our kids from tobacco companies and their deadly products and deceptive advertising. It will help more adult tobacco users to quit, and it will greatly benefit the public health of the nation.