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**STATEMENT OF SENATOR EDWARD M. KENNEDY IN SUPPORT OF FDA
REGULATION OF TOBACCO PRODUCTS**

United States Senate Health, Education, Labor, and Pensions Committee Executive Meeting

As Entered into the Record

Today, the Senate begins the final steps toward passage of legislation that should have been enacted years ago – authority for the FDA to regulate tobacco products, the most lethal of all consumer products.

It has been a long and arduous path with many political obstacles. Fortunately, the legislative journey is nearing a successful conclusion. The House of Representatives overwhelmingly passed a nearly identical bill last month. Once approved by this Committee, the FDA Tobacco bill will move quickly to the Senate floor, where it has the support of a strong bipartisan majority. President Obama is anxiously waiting to sign it into law.

The need to regulate tobacco products can no longer be ignored. Used as intended by the companies that manufacture and market them, cigarettes will kill one out of every three smokers. Yet, the federal agency most responsible for protecting the public health is currently powerless to deal with the enormous risks of tobacco use. Public health experts overwhelmingly believe that passage of S. 982 is the most important action Congress can take to protect children from this deadly addiction. Without strong Congressional action, smoking will continue at its current rate, and more than six million of today's children will ultimately die from tobacco-induced disease. Smoking is the number one preventable cause of death in America. Nationally, cigarettes kill well over four hundred thousand people each year. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, and suicide combined. Congress cannot continue to ignore a public health problem of this magnitude.

And Congress will not ignore it. This legislation has broad bipartisan support. More than half the members of the Senate are cosponsoring it. They recognize that giving FDA authority over tobacco products is essential to effectively addressing the tobacco health crisis.

The American Cancer Society, the American Heart Association, the American Lung Association, the American Medical Association, the Campaign for Tobacco-Free Kids and eighty-six other national public health organizations speak with one voice on this issue. They are all supporting S. 982 because they know it will give FDA the tools it needs to reduce youth smoking and help addicted smokers quit.

A landmark report by the Institute of Medicine, released two years ago, strongly urged Congress to “confer upon the FDA broad regulatory authority over the manufacture, distribution, marketing and use of tobacco products.”

Opponents of this legislation argue that FDA should not be regulating such a dangerous product. I could not disagree more. It is precisely because tobacco products are so deadly that we must empower America's premier public health protector – the FDA – to combat tobacco use. For decades the federal government has stayed on the sidelines and done next to nothing to deal with this enormous health problem. The tobacco industry has been allowed to mislead consumers, to make false health claims, to conceal the lethal contents of their products, to make their products even more addictive, and worst of all – to deliberately addict generations of children. The alternative to FDA regulation is more of the same. Allowing this abusive conduct by the tobacco industry to go unchecked would be terribly wrong.

Under this legislation, FDA will for the first time have the needed power and resources to take on this challenge. The cost will be funded entirely by a new user fee paid by the tobacco companies in proportion to their market share. Not a single dollar will be diverted from FDA's existing responsibilities.

Giving FDA authority over tobacco products will not make the tragic toll of tobacco use disappear overnight. More than forty million people are hooked on this highly addictive product and many of them have been unable to quit despite repeated attempts. However, FDA action can play a major role in breaking the gruesome cycle that seduces millions of teenagers into a lifetime of addiction and premature death.

What can FDA regulation accomplish?

- It can reduce youth smoking by preventing tobacco advertising which targets children.
- It can help prevent the sale of tobacco products to minors.
- It can stop the tobacco industry from continuing to mislead the public about the dangers of smoking.
- It can help smokers overcome their addiction.
- It can make tobacco products less toxic and less addictive for those who continue to use them.
- And it can prohibit unsubstantiated health claims about supposedly “reduced risk” products, and encourage the development of genuinely less harmful alternative products.

Regulating the conduct of the tobacco companies is as necessary today as it has been in years past. The facts presented in the federal government's landmark lawsuit against the tobacco industry conclusively demonstrate that the misconduct is substantial and ongoing. The decision of the Court states: “The evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity...Defendants continue to engage in conduct that is materially indistinguishable from their previous actions, activity that continues to this day.” Only strong FDA regulation can force the necessary change in their corporate behavior.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The Food and Drug Administration needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco.

The tobacco industry currently spends over thirteen billion dollars each year to promote its products. Much of that money is spent in ways designed to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risk. Four thousand children have their first cigarette every day, and one thousand of them become daily smokers. The industry knows that nearly 90% of smokers begin as children and are addicted by the time they reach adulthood.

Documents obtained from tobacco companies prove, in the companies' own words, the magnitude of the industry's efforts to trap children into dependency on their deadly product. Studies by the Institute of Medicine and the Centers for Disease Control show the substantial role of industry advertising in decisions by young people to use tobacco products.

If we are serious about reducing youth smoking, FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. This legislation will give FDA the authority to stop tobacco advertising that glamorizes smoking to kids. It grants FDA full authority to regulate tobacco advertising “consistent with and to the full extent permitted by the First Amendment.”

FDA authority must also extend to the sale of tobacco products. Nearly every state makes it illegal to sell cigarettes to children under 18, but surveys show that many of those laws are rarely enforced and frequently violated. FDA must have the power to limit the sale of cigarettes to face-to-face transactions in which the age of the purchaser can be verified by identification. This means an end to self-service displays and vending machine sales. There must also be serious enforcement efforts with real penalties for those caught selling tobacco products to children. This is the only way to ensure that children under 18 are not able to buy cigarettes.

The FDA conducted the longest rulemaking proceeding in its history, studying which regulations would most effectively reduce the number of children who smoke. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the Agency promulgated rules on the manner in which cigarettes are advertised and sold. Due to litigation, most of those regulations were never implemented. If we are serious about curbing youth smoking as much as possible, as soon as possible; it makes no sense to require FDA to reinvent the wheel by conducting a new multi-year rulemaking process on the same issues. This legislation will give the youth access and advertising restrictions already developed by FDA the force of law, as if they had been issued under the new statute. Once they are in place, FDA will have the authority to modify these rules as changing circumstances warrant.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, and in all print advertisements. These warnings will be larger and more explicit in their description of the medical problems which can result from tobacco use. Each cigarette pack

will carry a graphic depiction of the consequences of smoking. The FDA is given the authority to change the warning labels periodically, to keep their impact strong.

The nicotine in cigarettes is highly addictive. Medical experts say that it is as addictive as heroin or cocaine. Yet for decades, tobacco companies vehemently denied the addictiveness of their products. No one can forget the parade of tobacco executives who testified under oath before Congress that smoking cigarettes is not addictive. Overwhelming evidence in industry documents obtained through the discovery process proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated the nicotine in their products to make it even more addictive.

An analysis by the Harvard School of Public Health demonstrates that cigarette manufacturers are still manipulating nicotine levels. Between 1998 and 2005, they significantly increased the nicotine yield from major brand name cigarettes. The average increase in nicotine yield over the period was 11%.

The tobacco industry has a long, dishonorable history of providing misleading information about the health consequences of smoking. These companies have repeatedly sought to characterize their products as far less hazardous than they are. They made minor innovations in product design seem far more significant for the health of the user than they actually were. It is essential that FDA have clear and unambiguous authority to prevent such misrepresentations in the future. The largest disinformation campaign in the history of the corporate world must end.

Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public. Over forty million Americans are currently addicted to cigarettes. No responsible public health official believes that cigarettes should be banned. A ban would leave forty million people without a way to satisfy their drug dependency. FDA should be able to take the necessary steps to help addicted smokers overcome their addiction, and to make the product less toxic for smokers who are unable or unwilling to stop. To do so, FDA must have the authority to reduce or remove hazardous and addictive ingredients from cigarettes, to the extent that it is scientifically feasible. The inherent risk in smoking should not be unnecessarily compounded.

Recent statements by several tobacco companies make clear that they plan to develop what they characterize as "reduced risk" cigarettes. Some are already on the market making unsubstantiated claims. This legislation will require manufacturers to submit such "reduced risk" products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA's satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety. Only by preventing bogus claims will there be a real financial incentive for companies to develop new technologies that can lead to genuinely and verifiably safer products.

This legislation will vest FDA not only with the responsibility for regulating tobacco products, but with full authority to do the job effectively. It is long overdue.

Enacting this bill this year is the right thing to do for America's children. They are depending on us. By passing this legislation, we can help them live longer, healthier lives.

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