

# The Need for FDA Regulation of Tobacco Products

Senator Edward M. Kennedy\*

Smoking is the number one preventable cause of death in America. Empowering the Food and Drug Administration (FDA) to regulate tobacco products is the most important action we can take to substantially reduce the number of men and women who suffer and die from smoking-induced disease each year.

We cannot, in good conscience, continue to allow the federal agency most responsible for protecting the public health to remain powerless to deal with the enormous risks of tobacco—the most lethal of all consumer products. That is why Senator Mike DeWine and I introduced legislation expanding the FDA’s jurisdiction to cover tobacco products and why twenty other senators have already co-sponsored it.<sup>1</sup> That is also why we are confident that the Senate will pass legislation granting the FDA the necessary authority to take on this enormously important task.

The provisions of this bill track the bipartisan compromise on the terms of FDA jurisdiction that was reached during Senate consideration of comprehensive tobacco control legislation in 1998. Fifty-eight senators supported the comprehensive bill at that time. That legislation was never enacted because of disputes over tobacco taxation and litigation, not over FDA authority.

The legislation is a fair and balanced approach to FDA regulation. It creates a new section in FDA jurisdiction for the regulation of tobacco products, with standards that allow for consideration of the unique issues raised by tobacco use. It is sensitive to the concerns of tobacco farmers, small businesses, and nicotine-dependent smokers. Nevertheless, it clearly gives the FDA the power it needs in order to prevent youth smoking and to reduce addiction to this highly lethal product. The FDA would be given broad authority to consider all the relevant factors related to tobacco use, and to take such action as it determines “is appropriate for the protection

---

\* Senator Edward M. Kennedy is the Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions, which has jurisdiction over the Department of Health and Human Services and tobacco issues.

<sup>1</sup> S. 2626, 107th Cong. (2002).

of the public health.”<sup>2</sup> The agency is expressly directed to analyze the impact of a proposed rule “with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product.”<sup>3</sup>

I believe that any attempt to weaken the 1998 language would undermine the FDA’s ability to deal effectively with the enormous health risks posed by smoking. This concern is shared by a number of independent public health experts. The bipartisan compromise agreed to in 1998 is still the best opportunity for senators to come together and grant the FDA the regulatory authority it needs to substantially reduce the number of children who start smoking and to help addicted smokers quit. Nothing less will do the job.

Within the past year, some tobacco companies have even acknowledged the need for FDA regulation of their products. However, the proposals presented by the industry and its allies in Congress would only create a toothless regulatory tiger. While giving the agency nominal jurisdiction, their legislation would erect serious legal barriers to the FDA’s ability to effectively regulate tobacco products in the public interest. Such a statute would create a false sense of security amongst smokers and potential smokers that tobacco products were being made safer to use, while, in fact, the FDA would be handcuffed in its ability to meaningfully protect the public. As the legislative debate moves from whether tobacco products should be regulated by the FDA to what kind of authority the FDA should have, those who are genuinely concerned with public health must be vigilant against such industry-inspired ploys.

The stakes are vast. Every day, another five thousand children try their first cigarette, and two thousand of them become daily smokers. Nearly a thousand of them will die prematurely from tobacco-induced diseases. Cigarettes kill well over four hundred thousand Americans each year. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, suicide, and fires combined. Our response to a public health problem of this magnitude must consist of more than halfway measures.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The FDA needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco. The tobacco industry currently spends over nine billion dollars a year to promote its products. Much of that money is spent in ways designed

---

<sup>2</sup> *Id.* § 906(d).

<sup>3</sup> *Id.*

to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risks. The industry knows that more than ninety percent of smokers start smoking as children and are addicted by the time they reach adulthood.<sup>4</sup>

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 products. Recent studies by the Institute of Medicine and the Centers for Disease Control and Prevention show the substantial role of industry advertising in decisions by young people to use tobacco products. If we are serious about reducing youth smoking, the FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. The proposed legislation will give the FDA the ability to stop tobacco advertising that glamorizes smoking from appearing where it will be seen by significant numbers of children.

Contrary to industry claims, the major tobacco companies have not abandoned their aggressive marketing strategy aimed at children. The Master Settlement Agreement (MSA) entered into between the major tobacco companies and forty-six states in 1998 contained an industry promise not to "take any action, directly or indirectly, to target youth."<sup>5</sup> Within months of making that commitment, the industry massively increased the amount it spent on marketing. In 1999, expenditures on tobacco advertising and promotion rose by 22.3% to \$8.24 billion. In 2000, they rose by an additional 16.2% as cigarette manufacturers spent a record \$9.57 billion on marketing.<sup>6</sup> According to the Federal Trade Commission, this was the highest level of spending which had ever been reported by the industry.

Much of the spending increase has been on marketing that is known to appeal to youths. A March 2002 survey found that while only twenty-seven percent of adults had seen tobacco advertisements in the preceding two weeks, sixty-four percent of teenagers recalled seeing tobacco ads during that period.<sup>7</sup> The industry is still promoting cigarettes in the ways most likely to reach children.

One study documented a twenty-five percent increase in tobacco advertising in magazines with more than fifteen percent youth readership

---

<sup>4</sup> U.S. DEP'T HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL (1994).

<sup>5</sup> Master Settlement Agreement 15 (1998), *available at* <http://www.naag.org/issues/tobacco/index.php?smod=919>.

<sup>6</sup> FED. TRADE COMM'N, CIGARETTE REPORT FOR 2000 (2002).

<sup>7</sup> INT'L COMMUNICATIONS RESEARCH, TEEN EXCEL STUDY FROM MARCH 6-10 2002 (2002).

in the first year after the MSA was signed.<sup>8</sup> The industry spent \$120 million dollars in the nine-month period covered by the study, most of it promoting the five brands favored by underage smokers. The following year, an analysis of advertising penetration found that magazine ads for fifteen youth-oriented brands of cigarettes reached eighty percent of children between twelve and seventeen years of age at least seventeen times during 2000.<sup>9</sup> The increased level of tobacco advertising in youth-oriented magazines following the MSA received a great deal of public attention. The adverse publicity and the threat of new litigation from state Attorneys General led several of the major tobacco companies to reduce the level of magazine advertising. Last year, a California judge fined R.J. Reynolds \$20 million for its advertising in youth-oriented magazines, which the court found to be a violation of the MSA's prohibition on targeting youth.<sup>10</sup>

The greatest increases in spending have occurred in the areas of in-store marketing and promotion, known to be particularly effective in reaching children. Discount promotions such as "buy one, get one free" make cigarettes more affordable to kids, who are particularly price sensitive. Payments to retailers for prime shelf space at children's eye level make cigarettes more visible to kids in convenience stores. Free promotional gifts such as hats, jackets, and mini-radios have a strong appeal for teens. The evidence clearly demonstrates that the tobacco industry has not given up on its efforts to seduce a new generation of children into smoking. When one form of marketing to youth becomes too transparent and controversial, the industry merely moves its dollars to another, subtler, way of reaching kids. Only a comprehensive set of enforceable marketing standards developed by the FDA can prevent continued industry efforts to make nicotine addicts of our children.

The proposed legislation will give the FDA full authority to regulate tobacco advertising "consistent with and to the full extent permitted by the First Amendment."<sup>11</sup> The Supreme Court has repeatedly stated that for commercial speech to come under the cloak of First Amendment protection, it must promote lawful activity and not be misleading. There is a voluminous record of evidence documenting the fact that tobacco

---

<sup>8</sup> Diane Turner-Bowker & William L. Hamilton, *Cigarette Advertising Expenditures Before and After the Master Settlement Agreement: Preliminary Findings*, at <http://www.tobaccofreekids.org/reports/addicting/magazines/connolly.pdf> (May 15, 2000).

<sup>9</sup> Charles King & Michael Siegal, *The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines*, 345 NEW ENG. J. MED. 504, 504 (2001).

<sup>10</sup> *People ex rel. Lockyer v. R.J. Reynolds Tobacco Co.*, No. GIC 764118, 2002 WL 1292994 (Cal. Super. Ct. June 6, 2002).

<sup>11</sup> S. 2626, 107th Cong. § 906(d) (2002).

companies target much of their advertising at children, even though it is unlawful to sell cigarettes to minors in nearly every state. Tobacco ads designed to encourage kids to smoke are not promoting a lawful activity. Much of the industry's advertising is grossly misleading on the critical health consequences of smoking. Substantial limitations can be constitutionally imposed on tobacco advertising, as long as the restrictions are narrowly tailored to prevent these evils.

The FDA's authority must also extend to the sale of tobacco products. Most states make it illegal to sell cigarettes to children under eighteen, but surveys show that these laws are rarely enforced and are frequently violated. The 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 most 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 eighteen are not able to buy cigarettes.

In determining what regulations would most effectively reduce the number of children who smoke, the FDA conducted the longest rulemaking proceeding in its history. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the FDA 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 the FDA to reinvent the wheel by conducting a new, multi-year rulemaking process on the same issue. The proposed legislation will give the youth-access and advertising restrictions already developed by the FDA the immediate force of law, as if those regulations had been issued under the new statute. The FDA will have the authority to modify regulations in future years, as experience and new scientific developments warrant.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, as well as in all print advertisements. These warnings will be more explicit in their description of the medical problems that can result from tobacco use. The FDA is given the authority to change the text of these warning labels periodically, to keep their impact strong.

Nicotine in cigarettes is highly addictive. Medical experts say 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 as recently as 1994 that smoking cigarettes is not addictive. Overwhelming

evidence in industry documents, obtained through investigation, proves that the companies not only knew of the addictive nature of nicotine for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated nicotine in their products to make it even more addictive.

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 really are. Furthermore, they made minor innovations in product design seem far more significant for the health of the user than they actually were. The FDA must 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 health. Since over forty million Americans are currently addicted to cigarettes, no responsible public health official believes that cigarettes should be banned. A ban would leave those forty million people without a way to satisfy their drug dependency. The 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, the FDA needs the authority to reduce or remove hazardous ingredients from cigarettes, to the extent it is scientifically feasible. The inherent risk in smoking should not be unnecessarily compounded.

Modern cigarettes have become much more than shredded tobacco rolled in a paper tube; they are highly engineered products, potentially containing hundreds of ingredients. Some of these ingredients are inherent in the tobacco leaf, but many are added in manufacturing. For this reason, the tobacco companies have vigorously opposed ingredient disclosure. When cigarettes are lit, the burning process actually generates more than four thousand chemicals in the smoke. Many of them are toxic, and could be reduced or eliminated if health considerations were given appropriate weight in the cigarette design process.

The tobacco companies have deliberately made their products even more addictive than they would be naturally. Ammonia is used to convert naturally occurring nicotine to the free base form in order to enhance its addictiveness. Additives such as menthol may also make cigarettes more addictive by easing the ability to inhale smoke more deeply into the lungs. Particle physicists working for the industry have designed aerodynamic smoke particles that can reach the deepest cavities in the lungs. The FDA needs unfettered authority to analyze the impact of cigarette ingredients

and product design. This knowledge can then be used by the FDA to set performance standards that will incrementally make the product less lethal and less addictive.

Recent statements by several tobacco companies make clear that they plan to develop what the industry characterizes as “reduced risk” cigarettes. The proposed 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.

If the tobacco industry is permitted to market “reduced risk” products without strict supervision by the FDA, the companies will heavily promote minor product modifications that have no real impact on the health risks posed to smokers. This was the case with “light” and “low tar” products, presented in an earlier era as offering a safer way to smoke. Those claims have now been conclusively disproved in a number of independent studies, including one by the National Cancer Institute issued last year. Unregulated claims of reduced risk can create the false perception amongst smokers that they no longer need to quit and amongst non-smokers that it is less dangerous to start.

Claims such as “reduced carcinogens” and “less of the toxins,” currently appearing in advertisements for new products, imply much but convey little actual information about the health risks. A reduction in the level of one or two of the many different carcinogens present in cigarettes may have only a negligible impact on the risk to the smoker of developing cancer. Merely demonstrating a reduction in the level of one toxin does not establish that the new product significantly reduces the overall health risk. Only independent testing under FDA oversight can determine whether a significant reduction in risk has actually been achieved. To be genuinely “reduced risk,” a tobacco product must demonstrate a substantial net reduction in overall health risk to the public.

Congress must vest the FDA with not only the responsibility for regulating tobacco products, but also with full authority to do the job effectively. The proposed legislation will give the FDA the legal authority it needs to (1) reduce youth smoking by preventing tobacco advertising targeting children; (2) prevent the sale of tobacco products to minors; (3) help smokers overcome their addiction; (4) make tobacco products less toxic for those who continue to use them; and (5) prevent tobacco companies from misleading the public about the dangers of smoking.

We cannot allow the tobacco industry to stop us from doing what we

know is right for America's children. Empowering the nation's foremost public health agency to regulate the consumer product posing the greatest health hazard is long overdue. It will save thousands of lives each year.