

EXECUTIVE SUMMARY

Even though tobacco use is the leading cause of preventable death in the United States, killing more than 400,000 people and costing the nation nearly \$100 billion in health care expenditures each year, tobacco products are virtually unregulated to protect public health.

This lack of government regulation has allowed the tobacco industry free rein to design and market their products. Tobacco manufacturers can introduce new products, secretly modify existing products with new designs and ingredients, and make unproven health claims without regard for the impact on public health.

This combination of highly engineered products with no oversight is deadly. Flavors and product modifications not only make the product more appealing to kids, but often produce additional carcinogens. Manipulation of nicotine and other chemicals increases addictiveness and harm. Misleading claims discourage smokers from quitting and have cost countless lives.

Because of this lack of government oversight, the tobacco industry has been able to counter declining smoking rates and growing restrictions on smoking by unleashing a new generation of tobacco products. Just like in the past, product design features, fully understood only by the industry, play a huge role. Key trends include:

- Flavored products: Cigarettes, smokeless tobacco products, and so-called “little cigars” have been introduced in an array of candy, fruit, and alcohol flavors that mask the harshness of the products and make them more appealing to children.
- Novel smokeless products: Facing growing restrictions on where smoking is allowed, tobacco companies have introduced novel smokeless tobacco products that are marketed as a way for smokers to sustain their addiction in places where they cannot smoke.
- Controlling nicotine levels: Tobacco companies have been trying to maintain addiction among smokers and addict a new generation of replacement smokers by increasing nicotine levels in their products over time.
- Unproven health claims: To discourage smokers from quitting, and possibly entice former smokers or those who have never smoked, increasing numbers of products have been marketed with unproven and misleading claims that they are less harmful than traditional cigarettes.

Tobacco products once were limited to cigarettes, cigars, pipe tobacco and chewing or spit tobacco. Today, tobacco products come in more flavors, forms, shapes and sizes, and with more unproven health claims than ever before, all with the goal of facilitating the consumption of – and addiction to – nicotine.

This reports details how the companies manipulate their products to recruit new youth users, create and sustain addiction, and discourage users from quitting. It then describes the new generation of tobacco products designed to achieve these goals. Finally, it outlines how effective regulation by the U.S. Food and Drug Administration (FDA), as exemplified by legislation currently under consideration in Congress, can curtail the tobacco industry's harmful practices and save lives. Until the FDA is given such authority, the American public will continue to be human guinea pigs in the tobacco industry's deadly science experiment.

The Critical Role of Product Design

While advertising icons like the Marlboro Man and Joe Camel have rightfully been blamed for attracting and addicting millions of kids to a lifetime of smoking, they are only part of the story of tobacco industry success – and public health disaster.

Few people realize how the tobacco companies design the product itself to achieve the objectives of recruiting new youth smokers, creating and sustaining addiction, and discouraging smokers from quitting. Tobacco products are far from simple tobacco leaf rolled in paper or other packaging. They are highly engineered nicotine delivery devices, finely tuned to appeal to the taste, feel, smell, and other sensations of new and addicted smokers. For example, common methods used by the tobacco industry to optimize nicotine delivery include the addition of chemicals such as ammonia and the manipulation of smoke particle size.

With no government regulation, these design decisions are based solely on the business interests of the tobacco companies, with no regard for public health. The public simply has no way of knowing what the companies are doing to their products and how that affects health. While we have learned a lot from the tobacco companies' internal documents, what is really alarming is what we do not know and will not know until tobacco products are regulated like other consumer products.

Designing Products to Recruit New Youth Smokers

Tobacco companies know that almost all new smokers begin their addiction as children. They also know that smoking is unpleasant for new smokers, so they carefully design the product, including the delivery of nicotine, for this vital market. Their internal documents describe methods of reducing harshness to overcome the problem that new smokers often don't like the taste of smoke. These methods improve the "mouth feel" by reducing negative sensations like hotness and dryness. They even address how the cigarette should be designed so that the novice smoker can light it more easily.

This approach is epitomized by the design considerations for the infamous Joe Camel campaign, which not only targeted teens in its marketing, but with the product itself. After extensive consumer testing and product analysis, R.J. Reynolds (RJR) introduced cigarettes that were less harsh and smoother tasting, making them easier to smoke.

Following these product changes, Camel's share among 18 year olds increased dramatically from 2.5 percent in 1985 to 14 percent in 1993. By 1993, Camel had been transformed into a brand for the young adult smoker (a tobacco industry euphemism for kids).¹

The use of flavors is also part of the process of attracting youth smokers to a lifetime of addiction, even though many make the product more harmful. Used to make the smoke less harsh and more flavorful for new smokers, additives like chocolate, when burned in a lit cigarette, produce additional toxins, including carcinogens.

New Flavored Tobacco Products

Continuing the long tradition of designing products that appeal explicitly to new users, tobacco companies in recent years have significantly stepped up the introduction and marketing of flavored products:

- Among cigarette manufacturers, RJR has been the most aggressive in this category. RJR's "Camel Exotic Blends" have come in more than a dozen flavors including Twista Lime, the coconut and pineapple-flavored Kauai Kolada, Warm Winter Toffee and Winter Mocha Mint. RJR has also marketed alcohol-flavored Camels with names like ScrewDriver Slots, Blackjack Gin and SnakeEyes Scotch. Colorful ads for these products appeared in magazines with large youth readerships such as Rolling Stone and Sports Illustrated.
- Smokeless tobacco manufacturers have also stepped up the introduction of new flavored products. In one magazine ad, U.S. Smokeless Tobacco Company (UST) touts that its Skoal brand comes in vanilla, apple, berry blend, mint and other flavors. 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."²
- There has also been a proliferation of flavored products in the small cigar category, often with names that blatantly appeal to consumers who like sweet flavors. Swisher, Inc., offers a variety of chocolate, strawberry, peach, grape, and other flavored little cigars under the name "Swisher Sweets," while Phillie Cigarillos also come in many flavors including "Sugarillos" for "when sweet isn't sweet enough." The Altria Group, parent company of Philip Morris USA, recently expanded its business to the cigar category by acquiring John Middleton, Inc., which sells Black & Mild brand little cigars in flavors that include apple, cherry, wine and cream. With their colorful packaging and sweet flavors, these cigar products are often hard to distinguish from the candy displays near which they are frequently placed in retail outlets. These products are often sold singly rather than in packs and, in the case of so-called little cigars that resemble cigarettes, at lower excise tax rates than cigarettes, increasing their affordability and appeal to children.

Designing Products to Create and Sustain Addiction

The tobacco companies have known for decades that the key to their business is the delivery of nicotine. As one RJR document put it, “In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry.”³ Two product innovations were particularly critical in increasing the delivery of nicotine:

- Adding ammonia to the tobacco changed the chemistry of the smoke in a way that resulted in nicotine reaching the brain more efficiently. This innovation by Philip Morris is cited by other tobacco companies for the incredible growth in Marlboro from a relatively small brand to the world’s best selling cigarette.⁴ Indeed, ammonia may play as important a role as the Marlboro Man in the brand’s success.
- Engineering smoke particles to achieve a size that is optimal for delivering nicotine to the lungs. While larger or smaller particle sizes may well cause less harm to the smoker, companies do not need to consider this given the lack of regulation of their products.

Increased Nicotine Levels and New Products to Sustain Addiction

Reports from the Massachusetts Department of Public Health⁵ and the Harvard School of Public Health⁶ have also documented an increase in nicotine levels in cigarettes in recent years. However, because of the lack of regulation of tobacco products, no government agency can stop tobacco manufacturers from doing this.

Another major trend has been the introduction of new and more novel smokeless tobacco products marketed to help smokers through the times they cannot smoke. These products have proliferated, and now major cigarette manufacturers have entered the smokeless market as smoking rates have declined and a growing number of states and localities have enacted smoke-free laws. In many instances, these products are advertised as ways to get a nicotine fix when smokers cannot smoke, thereby providing a disincentive for smokers to quit and truly protect their health. Tobacco companies have long known that smoke-free laws often result in more smokers trying to quit and succeeding, and this is one of their answers to a declining market for cigarettes.

Underscoring the importance of the smokeless category to traditional cigarette manufacturers, Reynolds American Inc., the parent company of RJR, in 2006 purchased the Conwood Company, the second largest manufacturer of smokeless tobacco products in the United States. Wall Street analysts have speculated that Altria may also seek to acquire a smokeless tobacco company, and Philip Morris is already test-marketing Marlboro moist smokeless tobacco in Atlanta.

Traditionally, smokeless tobacco in the United States has taken the form of chewing tobacco or moist snuff, which is loose tobacco placed between the lip and gum. Both require frequent spitting. Today, smokeless tobacco has expanded to other forms,

including teabag-like pouches and even dissolvable tablets of tobacco, some of which do not require users to spit.

- In the past year, both Philip Morris and RJR have entered the smokeless tobacco market by test marketing pouch products carrying the names of their most famous cigarette brands, Marlboro Snus for Philip Morris and Camel Snus for RJR. Marketing for these products explicitly encourage using snus where people are not allowed to smoke. Marketing for Camel Snus uses the slogan “Pleasure for wherever!” while the Marlboro Snus web site mentions “flavor anytime” and pictures an airplane, where smoking is not allowed, as a “good time to snus.” The Lorillard Tobacco Company, the third-ranking cigarette manufacturer in the United States, is also planning to test-market a new pouch product in conjunction with smokeless manufacturer Swedish Match, the company that created snus. In the absence of regulation, there is no way to know how or whether these new products differ from other smokeless products or, indeed, from each other.
- Other notable smokeless tobacco products introduced in recent years include Star Scientific’s Ariva and Stonewall Hard Snuff, both dissolvable tablets of tobacco. These types of products pose two serious problems. First, like other smokeless products, they discourage smokers from quitting by feeding their nicotine addiction in places where they cannot smoke. Second, these products appeal to children because of their candy-like form and minty taste and because they are easy to conceal.

Designing Products to Discourage Users from Quitting

As smokers grow concerned about health risks and consider quitting, tobacco companies seek to keep them smoking by developing new products that make implicit or explicit claims of reduced harm. With no regulation of the product or of claims, there is no way for consumers to know whether the claims are true and no incentive for companies to manufacture products that actually reduce harm rather than just claiming to do so.

The public health disaster of “light” and “low-tar” cigarettes exemplifies the problem. Faced with smokers concerned about their health, the tobacco companies developed products to reassure smokers about the health effects with the full knowledge that these products conferred no health advantage. The companies knowingly developed products that produced lower tar ratings on the machine test, but that neither actually reduced consumers’ exposure, nor offered any real health benefit to smokers. This resulted in untold numbers of smokers switching to “light” and “low-tar” cigarettes rather than quitting, taking an incalculable toll on public health. Even today, many smokers still consider these cigarettes to be less harmful.

New Products with Unproven Health Claims

The tobacco companies have begun introducing a variety of so-called “reduced risk” products that threaten to repeat the “low-tar” public health disaster with a new

generation of unproven, misleading and unregulated health claims. These products and their explicit and implicit health claims include:

- Test-marketed in several U.S. cities, Brown & Williamson's Advance cigarettes were advertised with the slogan, "All of the taste... Less of the toxins."
- RJR's Eclipse cigarette has been marketed with the claim that it "may present less risk of cancer associated with smoking." The company has also touted Eclipse as "a cigarette that responds to concerns about certain smoking-related illnesses, including cancer."
- Vector Tobacco's Omni cigarettes have been advertised with the slogan, "Reduced carcinogens. Premium taste."
- Vector also introduced Quest, which it claimed to be a "nicotine-free" cigarette and implied it could help smokers quit despite the lack of safety and efficacy review that is given to FDA-approved smoking cessation products.
- Introduced by Philip Morris and test-marketed in Atlanta, Tampa, and Salt Lake City beginning in 2005, Marlboro UltraSmooth cigarettes have been marketed with messaging such as "Filter Select" and "new carbon filter lets the flavor through" that consumers could easily interpret as indicating advances in filtration of harmful elements.

The pipeline of these new products and claims may well be growing. Philip Morris parent Altria, for example, has invested \$350 million in a Center for Research and Technology that may result in new products for which the company will seek to make health-related claims. A January 19, 2008, article in *The Wall Street Journal* detailed the many new products Philip Morris International has developed ostensibly for its overseas markets.⁷ These include Marlboro Intense, a short but strong version of the brand described as a way for smokers to get a quick nicotine hit when stepping outside smoke-free environments, and Marlboro Mix 9, a high-tar, high-nicotine product launched in Indonesia in 2007. With no government oversight in the United States, nothing prevents the introduction of these or other new products to the American market.

The Need for FDA Regulation of Tobacco Products

The ongoing product manipulation by the tobacco companies with no government oversight and without regard to health impact demonstrates just how critical it is that the FDA be given authority to regulate tobacco and its marketing, just as it has for virtually all other consumer products.

Bipartisan legislation (S.625/H.R.1108) is pending to grant the FDA authority over the manufacturing and marketing of both current and new tobacco products. This legislation addresses tobacco marketing to children, manipulation of tobacco products to make them more appealing and addictive, and use of misleading health claims by tobacco companies. Among other things, this legislation will:

- Authorize the FDA to restrict tobacco marketing to protect children and public health, and limit tobacco advertising, such as at point-of-sale and in publications with significant youth readership (as well as any remaining outdoor advertising) to black-and-white text only.
- Ban candy and fruit flavorings in cigarettes.
- Require tobacco companies to disclose detailed information about their products, including contents, changes to products, amount and form of nicotine, research on health effects, and marketing. For the first time, a public health agency will have as much information about deadly tobacco products as the tobacco companies.
- Authorize the FDA to require changes in current and future tobacco products, such as the reduction or elimination of harmful chemicals or the reduction of nicotine levels. The FDA could prohibit some of the harmful steps the tobacco companies have taken to make their products attractive to kids, more addictive or more harmful.
- Require larger, more informative health warnings on tobacco products and in advertising.
- Immediately prohibit terms such as “light,” “mild,” and “low-tar” that mislead consumers into believing that certain cigarettes are safer than others.
- Prohibit tobacco companies from making any explicit or implicit health claims, such as reduced risk of disease, without first scientifically proving to the FDA that both 1) the product, as actually used by consumers, will reduce the risk of disease and 2) the product as marketed will benefit the population as a whole (in other words, that it won’t discourage current users from quitting or encourage new users to start).

The tobacco companies have proven that they design and manipulate their products to make them more appealing, more addictive, and more deadly. The resulting carnage will only continue if their special protection from government oversight is not addressed.

¹ Wayne, GF & Connolly, GN, “How Cigarette Design Can Affect Youth Initiation Into Smoking: Camel Cigarettes, 1983-1993,” *Tobacco Control* 11:i32 - i39, March 2002.

² “Flavors Add New Dimension to Tobacco,” *Convenience Store News*, October 1, 2007.

³ Teague, C, “Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein,” April 14, 1972, Bates No. 519198977-519198985.

⁴ Bates, C, Jarvis, M, & Connolly, GN, *Tobacco additives: Cigarette engineering and nicotine addiction*, ASH UK, July 14, 1999, http://newash.org.uk/files/documents/ASH_623.pdf.

⁵ Massachusetts Department of Public Health, *Change in Nicotine Yields, 1998-2004*, 2006, http://www.mass.gov/Eeohhs2/docs/dph/tobacco_control/nicotine_yields_1998_2004_report.pdf.

⁶ Connolly, GN, et al., *Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands, 1997-2005*, A Report of the Tobacco Research Program Division of Public Health Practice, Harvard School of Public Health, January 2007.

⁷ O’Connell, V, “Philip Morris Readies Aggressive Global Push,” *The Wall Street Journal*, January 29, 2008.