

**Chapter 3: FDA Regulation of
Tobacco Products Will Protect
Consumers and Save Lives**

Tobacco products are unique. Even though tobacco use is the leading preventable cause of death in this country, tobacco products are not regulated by any public health agency. Tobacco companies, unlike the manufacturers of food, drugs, cosmetics and many other products, remain free to market and manipulate their products to attract children, make them even more dangerous and addictive, and mislead consumers who are concerned about their health. Their powerful addictive agent nicotine is regulated in every form except the one that kills people – tobacco products.

Pending bipartisan legislation, S.625/H.R.1108, would give the U.S. Food and Drug Administration (FDA) broad authority over tobacco products and their marketing, and would empower the FDA to take actions that no other federal agency has the expertise to undertake.

The marketing restrictions and provisions in the pending FDA legislation to help prevent tobacco sales to kids have received considerable attention, but just as important are the provisions in the bill regarding FDA authority over the products themselves. Key provisions allow the FDA to:

- require companies to disclose ingredients and other information about their products;
- require changes to both new and existing products;
- prohibit misleading claims such as “light” and “low-tar”; and
- review new products and prohibit even more dangerous products from being sold.

These provisions will allow the FDA to limit the industry’s ability to use product design to recruit youth, create and sustain addiction, and discourage smokers from quitting, and are outlined in more detail below.

Authority to Require Information about Every Aspect of Products

Currently, only the tobacco companies know the true details of their products, including product features that appear deliberately designed to enhance the addictive nature of cigarettes. S.625/H.R.1108 would give the FDA access to current and future tobacco industry information and research on its products. For the first time a public health agency would have as much information about deadly tobacco products as the tobacco companies. This information would allow the FDA, researchers and the public to gain a more complete picture of past and current industry behavior. But perhaps most importantly, this knowledge will inform the FDA about what changes should be required in existing products and how to prevent product changes that make them more enticing to the young and more deadly and addictive.

While millions of tobacco company documents have already been made public as a result of lawsuits, much of this information is often dated and incomplete. The pending legislation specifically requires tobacco companies to give the FDA a listing of all

ingredients for each brand including compounds added to the tobacco, paper, filter or other parts of the product, the level and form of nicotine, and a listing of constituents in cigarette smoke, as well as all future research, including marketing research. This is consistent with what is required for food and drugs, and no less should be expected for tobacco products. In addition, the FDA will have the authority to require information in a format that is most usable in order to prevent the companies from dumping millions of documents with the hope that the sheer volume will prevent the agency from finding useful information – a tactic that the industry has often employed in litigation.

Authority to Require Changes to Both Current and Future Products Including Changes in Flavoring and Other Features that Attract Kids, Make Products More Addictive, and Harder to Quit

Currently, profit is the only factor considered in tobacco product design decisions. For the first time ever, the pending FDA legislation would allow a public health agency to oversee changes to tobacco products so that decisions would not be driven solely by tobacco company profits. To date, all decisions regarding every aspect of tobacco products have been made by the tobacco companies, and as this report makes clear, the motivation for those decisions is to make their products more appealing to children, more addictive, and harder to quit.

As has been previously described, the tobacco companies have made their products more attractive to kids by adding candy flavorings and sugars, and more addictive and harder to quit, and possibly even more toxic, by adding ammonia, glycerin and other ingredients. Under this legislation, the FDA would have the authority to establish product standards that would put an end to these harmful practices.

The pending legislation would give the FDA broad authority to establish standards regarding nicotine yields, constituents, construction, ingredients, additives, and all other properties of the tobacco product including the form and content of the labeling. The agency would also have authority to establish standards to restrict the sale and distribution of the product.

Under the proposed legislation, product standards would apply to products already on the market as well as to new products. For example, if the FDA were to determine that adding ammonia to cigarettes is harmful because it is a carcinogen when burned and enhances the absorption of nicotine, the agency could issue a standard prohibiting the addition of ammonia to any cigarette. Other possible standards could include a requirement to eliminate the use of menthol and eugenol, which numb the throat and make smoking easier.

The legislation also includes a specific standard regarding flavorings in cigarettes. Three months after enactment, it would prohibit the use of a variety of candy-like flavorings as the characterizing flavors. This would put an immediate end to outrageous products that have appeared in recent years such as strawberry, vanilla, lime and mint flavored

cigarettes. The bill would give the FDA authority to adopt product standards in the future regarding menthol and other artificial or natural flavors, herbs or spices. The FDA could also extend the standard regarding specific flavorings in cigarettes to other products including smokeless tobacco, cigars, and cigarillos.

Authority to Prohibit Misleading Health Claims and an Immediate End to Claims such as “Light” and “Low-Tar”

Right now, tobacco companies can make implied and explicit claims about reduced risk with little, if any, regard to their truth. The proposed FDA bill gives the agency broad authority to prohibit any claim by a tobacco company that a product poses less risk or harm than other tobacco products on the market unless that claim is supported by sufficient evidence and the product is determined to be appropriate for the protection of public health.

Tobacco companies have made misleading claims for decades about the relative risks of their products. The marketing of “light” and “low-tar” cigarettes as less harmful has led many smokers to switch to these products because they believe they are reducing their risk of disease. However, a National Cancer Institute Monograph (No. 13) made clear that rather than reducing harm, these products have had a negative impact on the public’s health.¹ In recent years, tobacco companies have made a host of additional claims of reduced harm or risk such as “fewer toxins” or “reduced carcinogens,” which continue to mislead consumers.

A cornerstone of the pending legislation is the requirement that any explicit or implicit health claim must be evaluated by the FDA on a pre-market basis. This principle applies to all other products that the FDA regulates and should be applied to tobacco products. The bill prohibits such claims unless it can be proven that the product, as actually used by consumers, will significantly reduce harm and the risk of disease, and that the product, as marketed, will benefit the public health. The FDA bill would put an immediate end to the use of “light,” “mild,” and “low” and similar descriptors in the label or advertising of cigarettes. The goal of the legislation is to put an end to misleading claims and create a regulatory mechanism for the review and approval of those claims that provide meaningful and truthful information to consumers about the relative risks of various products.

Authority to Review New Products and Modifications to Existing Products

At present, tobacco companies can add or increase any ingredient or additive, change filter design, change the size of particles contained in the smoke, or make any other changes to their products with no oversight or restrictions, even when the changes make the products more addictive and possibly even more deadly.

The pending legislation would put an end to secret changes in tobacco products and give the FDA authority to review all new products and evaluate modifications to existing products to determine the impact on public health. It requires manufacturers to disclose any new additive or increases in existing additives 90 days prior to implementing the change. In addition, not only would the companies have to inform the agency of any changes to the product, the onus would be on the companies to prove that a product change would not have a negative impact on the public health.

Under the legislation, in order to introduce a new product that is not similar to other products currently on the market, a manufacturer must demonstrate to the FDA that the new product would protect the public health. In reviewing the product, the FDA would consider the risks and benefits to the population as a whole, including to both current users and nonusers of tobacco products. The FDA would examine whether existing users will quit or others will start using tobacco products as a result of the new product's introduction. For example, if R.J. Reynolds (RJR) were to try to introduce a new product such as Eclipse, a product that heated rather than burned tobacco, RJR would have to file an application for review before introducing such a product and demonstrate to the FDA that the marketing of such a product is appropriate for the protection of public health.

In recent years, state and local governments have taken a host of actions to reduce tobacco use including raising tobacco taxes, investing in tobacco prevention programs and enacting laws that require all workplaces to be smoke-free. However, the Institute of Medicine and the President's Cancer Panel have noted that state efforts alone cannot solve the tobacco problem and have concluded that Congress, long absent from the fight to reduce tobacco use, should enact legislation granting the FDA authority over tobacco products.²

Without FDA regulation, tobacco companies will continue to take advantage of the lack of government oversight and continue to design and market products that recruit new youth users, create and sustain addiction to nicotine, and discourage current users from quitting. Without FDA regulation, America's kids and consumers will continue to be Big Tobacco's guinea pigs.

¹ National Institutes of Health, *Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee*, National Cancer Institute, Smoking and Tobacco Control Monograph 13, October 2001.

² Institute of Medicine (IOM), *Ending the Tobacco Problem: A Blueprint for the Nation*, Washington, DC: National Academies Press, May 2007, http://www.nap.edu/catalog.php?record_id=11795#toc; President's Cancer Panel, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk*, August 2007, <http://deainfo.nci.nih.gov/advisory/pcp/pcp07rpt/pcp07rpt.pdf>.