The Family Smoking Prevention & Tobacco Control Act

What the Law Does

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) – signed into law by President Obama in 2009 - grants the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products.

The Tobacco Control Act gives the FDA authority to regulate:

- **Manufacture;**
- **Marketing; and**
- **Distribution of tobacco products**

Prior to the law, tobacco products were largely unregulated outside of required warning labels. In sharp contrast to foods and drugs, there was no federal agency with authority to require basic disclosure of tobacco product ingredients or good manufacturing practices. This lack of oversight likely contributed to the tobacco industry's ability to mislead the public about the harms of its products and target youth and other vulnerable populations with its marketing and promotions. FDA tried to regulate tobacco products in 1996, but that attempt was struck down in 2000 by the U.S. Supreme Court, which ultimately ruled that it was necessary for Congress to grant FDA the authority over tobacco products. Almost a decade later, the Tobacco Control Act was passed by Congress and signed into law.

FDA's Authority

The Tobacco Control Act established the Center for Tobacco Products at the FDA to regulate the manufacture, marketing, and distribution of tobacco products. The Center is funded by user fees from tobacco product manufacturers. The law also created the Tobacco Products Scientific Advisory Committee to advise the FDA on key issues including menthol, dissolvable tobacco products, and modified risk tobacco products.

The other key provisions of the Tobacco Control Act include:

Requiring tobacco industry registration, product listing, and disclosure of contents of tobacco products, research, and marketing information to the FDA: Tobacco product manufacturers are required to disclose all product and smoke ingredients, additives, and byproducts. In addition, the industry is required to disclose any documents related to the health, toxicological, behavioral, or physiological effects of their products, and marketing information. The FDA has published the list of harmful and potentially harmful constituents that tobacco product manufacturers must report if they are in their products.

Prohibiting characterizing flavors, other than menthol, in cigarettes: The law specifically prohibits fruit and candy flavorings in cigarettes, but the FDA would have to issue new regulations to prohibit the use of flavors in other tobacco products. The law required the Tobacco Products Advisory Committee to complete a report the use of menthol in tobacco products, which it did, and FDA subsequently completed its own preliminary scientific evaluation and held an open comment period for the submission of data, research and information, but no other action is required by the law.

Restricting tobacco industry marketing to youth and enforcement of sales restrictions to youth: Tobacco brand sponsorships of sports and entertainment events are now prohibited, as is the sale or distribution of

any promotional items, such as hats or shirts with tobacco brands or logos. FDA has contracted with most states to enforce sales restrictions to youth, including issuing penalties to retailers who sell to minors.

Requiring new, larger, more effective health warnings on tobacco products: The law requires specific changes to existing warning labels and gives FDA the authority to require changes to warning labels on any regulated product. For cigarettes, the law mandates nine rotating warnings on packages and in advertising. The warning must occupy 50 percent of the top front and rear panel of the cigarette package. Additionally, the law requires FDA to issue a rule mandating color graphic warnings on cigarette packages. For smokeless tobacco products, the law mandates four rotating warnings on packages and in advertising. The warning must occupy 30 percent of the two principal display panels of the package.

Court Action on Warning Labels:
In 2011, the FDA issued a regulation requiring color graphic warnings on cigarettes, but unfortunately those specific warnings were struck down. The FDA has indicated it intends to issue a new rule for improved warning labels on cigarettes.

Prohibiting the use of terms such as "light," "low," and "mild" and all unsubstantiated health claims: Tobacco product manufacturers are required to prove any so-called modified risk or reduced-harm claim for a tobacco product through an application to FDA prior to using the claim in marketing and advertising. Additionally, misleading descriptors such as "light," "low," and "mild" are prohibited.

Establishing a new "public health standard" for tobacco product regulation: Because the FDA's traditional standard of making foods and drugs "safe and effective" cannot apply to tobacco products, the law established a new standard of "appropriate protection of public health." The standard must take into account the risks and benefits to the population as a whole, as well as individuals, including tobacco product users and nonusers, whether current users would be discouraged from quitting and whether current non-users would be encouraged to start. The FDA will use the standard for:

- **Premarket approval of new tobacco products:** For new tobacco products that are not substantially equivalent to a product already on the market, the manufacturer must receive approval from FDA before the product can go to market.

- **Requirements for tobacco product changes:** The FDA can require changes to tobacco products, such as the removal of harmful ingredients, prohibition on the use of flavors, or the reduction of nicotine levels, in order to make tobacco products less harmful, addictive, or appealing.

Preserving states' and localities' authority: The law also retains the authority of states and localities to implement smoke-free policies, tobacco taxes, and to further restrict the time, place, and manner, but not the content, of tobacco advertising and promotions in their communities.

Other key activities:
The Center for Tobacco Products is also funding multi-million dollar research initiatives and a youth tobacco prevention campaign called "The Real Cost," targeting at-risk teens.

Tobacco Products Covered and the Deeming Rule

At this time, only cigarettes, roll-your-own-tobacco, and smokeless tobacco are subject to regulation under the Tobacco Control Act. The law allows the FDA to "deem" other tobacco products under its authority, and subject those products to the provisions of the Tobacco Control Act.

FDA Deeming Rule

On April 25, 2014, the FDA issued a proposed rule to bring all other categories of tobacco products, including certain dissolveables, gels, hookah tobacco, electronic cigarettes, cigars, and pipe tobacco, under its authority. Several of the provisions of the law will automatically apply to these products once the rule is finalized, including registration, product listing and disclosure requirements, prohibition on unsubstantiated health claims, and pre-market approval requirements for new products. In addition, FDA is proposing three specific provisions be applied to newly deemed tobacco products:

(1) Prohibiting retailers from selling newly deemed tobacco products to persons under the age of 18 and requiring photo identification;
(2) Prohibiting the sale of newly deemed tobacco products in vending machines, except in adult-only facilities; and
(3) Requirements for warning statements on products and advertisements.

These provisions already apply to cigarettes, roll-your-own-tobacco, and smokeless tobacco under the Tobacco Control Act. More information on FDA's proposed rule can be found here.