



FEDERAL TOBACCO REGULATION

An Introduction



On June 22, 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act. The law gave the U.S. Food and Drug Administration comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products.

This brief summary provides a basic overview of what the Tobacco Control Act (“Tobacco Control Act,” “TCA,” or “Act”) does (and does not) do, what the Food and Drug Administration (FDA) is authorized to do under the law, and how various products fit into the FDA’s regulatory authority. The overarching goal is to provide a framework to assist advocates in participating in and influencing the federal regulatory process.



I. Background

Comprehensive regulation of tobacco products by the FDA might seem like a relatively new phenomenon, because it is. In fact, before the Tobacco Control Act's enactment, tobacco products were largely exempt from regulation under the nation's federal health and safety laws. Although the FDA has regulated food, drugs, and cosmetics for over a century, tobacco products largely fell outside the FDA's regulatory authority until 2009. The Tobacco Control Act amended the existing Food, Drug, and Cosmetic Act to give the FDA extensive powers to issue rules and carry out the mandates contained in the law.

II. What does the Tobacco Control Act do?

In the Act itself, Congress implemented some policies immediately and required the FDA to take certain actions by specific dates. One of the most significant immediate policies was Congress's prohibition of what the Act calls "characterizing flavors" in cigarettes — think flavorings like candy, fruits, and desserts (but not menthol). The Act also required the FDA to develop specific graphic warning labels to replace the existing text-only warning labels. In addition, the Act prohibited the sale of "modified risk" tobacco products that make claims that they are less harmful without prior authorization from the FDA. The Act also stopped illegal sales of tobacco products to people under age 18 (this was changed to 21 in late 2019). Tobacco industry sponsorships and advertisements also faced new limitations under the Tobacco Control Act.

III. What does the Tobacco Control Act *not* do?

Most notably, as is mentioned above, Congress specifically exempted menthol from the prohibition on flavored cigarettes. While the FDA has the authority to prohibit menthol in cigarettes, as it stands currently any regulation or prohibition of the sale of menthol cigarettes is left to the states and local governments. The Act also prevents the FDA from banning cigarettes, smokeless tobacco, and cigars entirely, or from reducing the amount of nicotine in tobacco products to zero. Importantly, the Act does not preempt state and local governments from enacting their own sales restrictions, prohibiting products entirely, or setting standards like those for fire safety. Federal law also does not prohibit localities from imposing restrictions on the time, place, or manner (but not the content) of cigarette advertising or promotion.

IV. What is the FDA's role under the Tobacco Control Act?

The Tobacco Control Act also created a new arm of the FDA called the Center for Tobacco Products (CTP). CTP is charged with establishing tobacco product standards, restricting manufacturing and marketing, and strengthening health warning labels, among other things. When it was enacted in 2009, the Act gave the FDA regulatory authority over cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco, but it also gave the FDA authority to “deem” other tobacco products subject to its authority under the Act, which it did, “deeming” all products containing nicotine to be subject to its authority in 2016.

Importantly, the FDA's guiding principle under the entire Tobacco Control Act is whether the actions that it takes are “appropriate for the protection of the public health,” meaning that public health should be the single guiding principle when the FDA is making rules or enforcing the law. When CTP was first established, public health advocates were hopeful that a significant reduction in the death and disease caused by tobacco products would follow, given this public health-oriented framework.

Today, however, the agency is still grappling with what “appropriate for the protection of the public health” means. The Act provides some general guiderails for this term — specifically that the agency should consider:

- 1 the risks and benefits to the population as a whole, including users and nonusers of tobacco products;
- 2 the increased or decreased likelihood that existing users of tobacco products will stop using the products; and
- 3 the increased or decreased likelihood that those who do not use tobacco products will start using them.

When it comes to advocating for policies that advance health equity, the “appropriate for the public health” standard should serve as a starting point but the agency has wide latitude in interpreting the meaning of that term beyond the general considerations outlined in the Act.

IV. Where do e-cigarettes and hookah fit into all of this?

When the Tobacco Control Act was initially enacted, it did not cover products like e-cigarettes or hookah, dissolvable products, cigars, or any other products made or derived from tobacco. As mentioned above, in 2016, the FDA issued what it called the “deeming rule” that effectively

“deemed” all products tobacco products, and their components and parts to be subject to FDA regulation. The tobacco industry, which has a long history of using litigation as a weapon, filed a number of lawsuits challenging this rule. Most of the challenges have failed and the rule itself has mostly been left intact.

V. How can public health advocates play a role in urging the FDA to do a better job to advance health equity?

The prospect of spending precious time, energy, and resources pushing for change at the federal level — particularly when the tobacco industry is extremely well-funded, well-connected, and can pay for lobbyists and law firms to exert pressure on the FDA — can seem like a futile effort. That said, public health groups can have a meaningful impact, particularly when it comes to helping the agency implement its guiding principle of protecting public health. As noted above, the FDA has wide latitude to interpret the public health standard. This means that citizen participation and involvement, particularly through the citizen petition process, commenting on rulemakings, and litigation, can push the FDA in a direction that takes into account disproportionate impacts on groups that are the most severely affected by its actions or inaction.

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