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Federal Regulation of Tobacco: Legal Framework and Issues for the 116th Congress

The Family Smoking Prevention and Tobacco Control Act (TCA), P.L. 111-31, establishes the central federal regulatory regime for the manufacture, marketing, and distribution of tobacco products. The statute aims to balance competing interests in protecting the public's health against the harmful effects of smoking and youth tobacco use, while preserving access to lawfully marketed tobacco products for adult consumers. The TCA largely amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants the Food and Drug Administration (FDA) "primary Federal authority" over tobacco product regulation. This In Focus summarizes the TCA's legal framework and discusses key TCA-related issues in the 116th Congress.

Overview of the TCA

The TCA regulates "tobacco products," which generally are any products made or derived from tobacco and intended for human consumption, including the product's components, parts, or accessories. While the TCA explicitly applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the statute also permits FDA to deem other tobacco products subject to the law. FDA has exercised this authority over additional tobacco products, including electronic nicotine delivery system (ENDS) products (e.g., e-cigarettes and vape pens) and cigars. Key components of tobacco product regulation under the TCA include the following:

Premarket Review

A marked change to federal tobacco regulation, the TCA establishes a premarket review process for new tobacco products (i.e., products not commercially marketed as of February 15, 2007, or products marketed after that date, but later modified). "Grandfathered products" on the market before February 15, 2007, may be sold without prior authorization. In general, to market a particular new product, a manufacturer must submit a premarket tobacco product application (PMTA) and receive a PMTA marketing order from FDA, unless the manufacturer can successfully show that the product is either substantially equivalent to a predicate product or may be exempt from this substantial equivalence demonstration.

- **Premarket Tobacco Product Application:** To receive a marketing order from FDA, manufacturers must submit a PMTA, which includes information on health risk investigations; the composition, ingredients, and operation of the tobacco product; and the product's manufacture, processing, and proposed product labeling. To issue a PMTA marketing order, FDA must determine whether, among other things, allowing the new tobacco product to be on the market would be appropriate to protect public health.

- **Substantial Equivalence (SE):** Nearly all new tobacco products are marketed through the SE pathway. As a less rigorous alternative to a PMTA submission, FDA may permit a new tobacco product to be marketed based on a demonstration that it is "substantially equivalent" to an existing product marketed as of February 15, 2007, and complies with other federal tobacco-related requirements. A tobacco product is substantially equivalent to its earlier counterpart if, in general, it has the same characteristics (e.g., ingredients, design, heating source, or other features) of the reference product or does not raise different public health questions. Additionally, certain new tobacco products commercially marketed after February 15, 2007, but before March 22, 2011 ("provisional SE tobacco products"), may be marketed unless FDA issues an order that the new product is not substantially equivalent.
- **Substantial Equivalence Exemption:** FDA may exempt certain new tobacco products with minor modifications from having to show substantial equivalence. Products eligible for an exemption are those "modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive."

Manufacturer Requirements

The TCA creates several requirements that tobacco product manufacturers must meet to market a product. For example, the act directs FDA to issue regulations related to tobacco product manufacturing practices, to protect public health, and ensure that tobacco products are in compliance with federal law. FDA can grant exemptions and variances from such regulations under specified circumstances.

The TCA also generally directs manufacturers to maintain records, issue reports, and provide other information to FDA, as the agency may require by regulation. For instance, the TCA compels manufacturers to submit a report listing all product constituents, including smoke constituents identified as harmful or potentially harmful by FDA. The statute also authorizes FDA to conduct or require testing and reporting of tobacco product constituents, ingredients, and additives that the agency determines need testing to protect the public health.

Tobacco Product Standards

To reduce the allure of flavored tobacco products to minors, the TCA bans flavors (other than tobacco and menthol) in traditional cigarettes and components. The TCA also empowers FDA to adopt certain tobacco product standards if the agency determines that a standard is appropriate to protect the public health. Such standards may relate to

reducing nicotine levels, harmful components of a product, or other features, such as further restrictions on the sale of flavored products. That said, the TCA prevents FDA from banning all cigarettes and other specified types of tobacco products, and the agency cannot compel nicotine yields to be zero in certain products.

Labeling Requirements and Marketing Restrictions

A complex legal landscape governs the labeling, promotion, and other marketing of tobacco products. As a central part of this landscape, the TCA altered and expanded upon existing federal restrictions relating to labeling, advertising, and other marketing of cigarettes and other tobacco products. Among other things, the act instructs FDA to largely reissue a 1996 rule containing several restrictions on the sale, distribution, and advertisement of tobacco products (in 2000, the Supreme Court invalidated the rule on grounds that at that time, Congress had not authorized FDA to regulate tobacco products). The TCA also permits FDA to impose additional marketing restrictions based on a determination that such restrictions are appropriate to protect the public health. Current TCA-related statutory and regulatory requirements include the following:

- **Health Warnings:** Mandatory warnings on cigarette packages and advertisements must be a specific size and format and bear graphic images that portray the negative consequences of cigarette use, under FDA regulations. Other types of tobacco products must include warning statements, and statements vary based on product.
- **Advertising and Promotion Restrictions:** FDA regulations limit manufacturers of cigarettes and smokeless tobacco from sponsoring athletic, musical, artistic, and other events in the tobacco brand's name. These entities may not offer gifts or items in consideration of a tobacco purchase, and there are limits on advertising in certain audio and video formats.
- **Sales and Distribution Limitations:** FDA regulations prohibit the sale of tobacco products to persons under age 18 (the TCA limits the agency's ability to establish a higher age), and retailers must verify a purchaser's age using photographic identification for persons younger than age 27. Subject to exceptions, regulations also ban distribution of free samples of tobacco products and the sale of products through vending machines and self-service displays.

Preservation of State, Local, and Tribal Authority

Under the TCA, states, localities, and tribal governments retain authority to regulate tobacco products in certain ways. For example, the TCA states that these governmental entities may generally maintain additional (or more stringent) requirements on the sale or distribution of tobacco products. Under this language, states may, for instance, enact their own minimum age restrictions for the purchase of tobacco products. Yet, the TCA limits state and local governments from adopting, among other things, their own tobacco product standards, requirements for premarket review, or manufacturing practices.

Enforcement

Persons who violate tobacco-related provisions of the FD&C Act, as amended by the TCA, may be subject to sanctions, including civil monetary penalties. Retailers that violate FDA regulations on selling tobacco products to minors (as well as other FDA regulations) may be liable for a special civil monetary penalty. FDA may impose a No-Tobacco-Sale Order (NTSO) against retailers that have five or more repeated violations of these FDA regulations within 36 months. NTSOs prohibit retailers from selling tobacco products for a specified time.

Current Legal Considerations

Issues related to the TCA and its implementation have been of interest to the 116th Congress. These issues include the following:

- **Age Restrictions:** While the TCA generally permits FDA to issue regulations creating a federal minimum age for the sale of tobacco products, the agency lacks authority to establish an age restriction beyond age 18. As noted above, the TCA allows states and localities to establish stricter age requirements. To help curb adolescent tobacco use, some Members of Congress have expressed support for federal legislation that would alter FDA's existing authority and prohibit the sale of tobacco products to individuals under the age of 21.
- **Graphic Warnings:** Several of TCA's labeling and marketing restrictions have been challenged in court on First Amendment grounds. For example, in 2012, a federal appeals court vacated FDA's mandatory health warnings rule because aspects of the rule violated free speech protections of the First Amendment. FDA recently reissued a proposed rule on these warnings, and it remains to be seen whether the rule will be subject to further litigation.
- **Flavored ENDS Products and Enforcement:** Some Members of Congress have raised concerns about the popularity of ENDS products with minors, particularly flavored products. Newly regulated ENDS products are subject to premarket review, but FDA has delayed enforcement of these requirements, providing manufacturers more time to prepare for the review process. In September 2019, FDA announced plans to prioritize enforcement of the premarket authorization requirements for some flavored e-cigarettes and other flavored ENDS products. Accordingly, while it appears that FDA does not seek to "ban" these products, manufacturers may soon need to obtain a PMTA or other FDA authorization to remain on the market, or risk enforcement action.

For information on the TCA and policy considerations, see CRS Report R45867, *FDA Regulation of Tobacco Products*, by Victoria R. Green.

Jennifer A. Staman, Legislative Attorney

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