Introduction to Tobacco Law and Regulation:
Overview of the Tobacco Control Act and Deeming Regulation

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October 18, 2022

Agenda

- Brief history of tobacco and nicotine product regulation in the United States
- Overview of Family Smoking Prevention and Tobacco Control Act (TCA)
- Overview of the Deeming Regulation
- The Consolidated Appropriations Act, 2022 (Synthetic Nicotine)

Brief History of Tobacco & Nicotine Regulation

- **1995:** FDA issued a Proposed Rule to regulate nicotine-containing cigarettes and smokeless tobacco.
- **1996:** FDA published a Final Rule to regulate the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents ("1996 Rule").
  - FDA's assertion of jurisdiction over tobacco products was based on the conclusion that nicotine is a "drug" under the FDCA and that cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body.
- **2000:** Supreme Court struck down the 1996 Rule.
  - In *FDA v. Brown & Williamson*, the Court ruled that FDA lacked the authority to regulate customarily marketed tobacco products without congressional approval.

Family Smoking Prevention and Tobacco Control Act (TCA)

- Signed into law in 2009, created a new Chapter IX within the FDCA.
- Granted FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products.
- Created the Center for Tobacco Products (CTP) within FDA to administer the TCA.
- Relevant provisions include:
  - Establishment registration and product listing
  - Harmful and potentially harmful constituent testing and reporting
  - Ingredient reporting
  - Label requirements
  - Sales and marketing restrictions

TCA Sections

TCA	21 U.S.C.	Title
§ 101	§ 321(rr)	Amendment of the Federal Food, Drug, and Cosmetic Act *[definition of "tobacco products"]*
§ 900	§ 387	Definitions
§ 901	§ 387a	FDA Authority Over Tobacco Products
§ 902	§ 387b	Adulterated Tobacco Products
§ 903	§ 387c	Misbranded Tobacco Products
§ 904	§ 387d	Submission of Health Information to the Secretary
§ 905	§ 387e	Annual Registration
§ 906	§ 387f	General Provisions Respecting Control of Tobacco Products
§ 907	387g	Tobacco Product Standards
§ 908	387h	Notification and Other Remedies
§ 909	§ 387i	Records and Reports on Tobacco Products
§ 910	§ 387j	Application for Review of Certain Tobacco Products

TCA Sections (Cont.)

TCA	21 U.S.C.	Title
§ 911	§ 387k	Modified Risk Tobacco Products
§ 912	§ 387l	Judicial Review
§ 913	§ 387m	Equal Treatment of Retail Outlets
§ 914	§ 387n	Jurisdiction and Coordination with the FTC
§ 915	§ 387o	Regulation Requirement
§ 916	§ 387p	Preservation of State and Local Authority
§ 917	§ 387q	Tobacco Products Scientific Advisory Committee
§ 918	§ 387r	Drug Products Used to Treat Tobacco Dependence
§ 919	§ 387s	User Fees
§ 920	§ 387t	Labeling, Recordkeeping, Records Inspection

TCA - Definitions

"**Tobacco product**"

- Any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product), but is not a drug or device
- *Note: the underlined "or containing nicotine" language was recently added by the Consolidated Appropriations Act, 2022.*

TCA § 101(a), amending § 201(rr) of the FDCA (21 U.S.C. § 321(rr))

TCA - Definitions (cont.)

"**Cigarette**"

- Tobacco product that meets the definition in the term "cigarette" in the Federal Cigarette Labeling and Advertising Act and includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

"**Roll-Your-Own Tobacco**"

- Any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

TCA § 900 (21 U.S.C. § 387)

TCA - Definitions (cont.)

“Smokeless Tobacco”

- Any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

“Little Cigar”

- A type of tobacco product comprised of any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than a tobacco product rolled in paper or non-tobacco product) and as to which one thousand units weigh not more than three pounds.

TCA § 900 (21 U.S.C. § 387)

TCA - Definitions (cont.)

“Tobacco Product Manufacturer”

- Any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product or imports a finished tobacco product for sale or distribution into the United States.

“Small Tobacco Product Manufacturer”

- Tobacco product manufacturer that employs fewer than 350 employees (including the employees of each entity that controls, is controlled by, or is under common control with such manufacturer).

TCA § 900 (21 U.S.C. § 387)

TCA - Definitions (cont.)

“Distributor”

- Any person (except a common carrier, such as FedEx or UPS) who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption.

“Retailer”

- Any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

TCA § 900 (21 U.S.C. § 387)

TCA - Definitions (cont.)

"New Tobacco Product"

- Any tobacco product not commercially marketed in the U.S. as of February 15, 2007, or any modification to a tobacco product where the modified product was first commercially marketed in the U.S. after February 15, 2007.
- FDA interprets "**as of** February 15, 2007" to mean "**on** February 15, 2007."

"Pre-existing Tobacco Product"

- Tobacco products that do not qualify as "new tobacco products."
- FDA previously referred to these as "grandfathered tobacco products."

TCA § 910 (21 U.S.C. § 387j)

TCA - Definitions (cont.)

“Substantially equivalent tobacco product”

- A tobacco product that, as compared to the predicate tobacco product, has:
  - The same characteristics as the predicate tobacco product or
  - Has different characteristics than the predicate but information (including clinical data if deemed necessary by FDA) demonstrates that it is not appropriate to regulate the product under section 910 of the Act because the product does not raise different questions of public health.

“Predicate tobacco product”

- Either a tobacco product commercially marketed (other than exclusively for test marketing) in the U.S. as of (on) February 15, 2007, or a tobacco product that is the subject of a substantial equivalence order.

TCA § 910 (21 U.S.C. § 387j)

TCA - Definitions (cont.)

“Modified Risk Tobacco Product”

- Those products sold or distributed for use to reduce harm or the risk of tobacco-related disease, such as products indicating expressly or impliedly that the product presents a reduced level of risk/harm (i.e., “light,” “mild,” “low,” etc.) or reduced exposure to a harmful substance, either by labeling or advertising or other action directed at consumers.

TCA - FDA Authority Over Tobacco Products

- TCA originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and components, parts, and accessories of such products.
  - However, the TCA also allowed FDA to "deem" other tobacco products subject to Chapter IX of the TCA through regulations.
- Result – If FDA wanted to include any other tobacco products than those expressly indicated under the TCA, FDA would have to issue "deeming" regulations.
  - FDA has published a final rule "deeming" additional tobacco products subject to the TCA.

TCA § 901 (21 U.S.C. § 387a)

TCA - Adulteration and Misbranding

Both adulteration & misbranding relate to compliance with certain requirements:

- **Adulteration:** involves what is in the product or how it is manufactured
- **Misbranding:** involves what you say about the product (labeling/advertising)

TCA § 902 (21 U.S.C. § 387b), TCA § 903 (21 U.S.C. § 387c)

TCA - Adulteration

A tobacco product is deemed adulterated if:

1. It contains filthy, putrid, or decomposed substance or is otherwise contaminated by a poisonous or deleterious substance that may harm health;
2. It has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated;
3. It is package is composed of any poisonous or deleterious substance which may harm health;
4. The manufacturer or importer has failed to pay a user fee;
5. It is not in conformity with an applicable Tobacco Product Standard;
6. It is a new tobacco product marketed without a pre-market review order or is in violation of the pre-market review order;
7. There are violations of the GMP requirements; or
8. It is a modified risk tobacco product in violation of requirements imposed on such products.

TCA § 902 (21 U.S.C. § 387b)

TCA - Misbranding

A product is misbranded where:

1. The labeling is false or misleading;
2. Its package does not bear the applicable labeling requirements, including requirements that ma be imposed for a uniform system of identification or under a Tobacco Product Standard;
3. It does not comply with registration, listing, and notification requirements;
4. Its advertising is false or misleading or it is sold in violation of any advertising or marketing requirements; or
5. There is a failure to comply with disclosure, records, or reporting requirements.

TCA § 903 (21 U.S.C. § 387c)

TCA - New Tobacco Product Authorization

"**New Tobacco Products**" must have premarket authorization.

- If a tobacco product qualifies as a "new tobacco product," the manufacturer must obtain premarket authorization from FDA before it can introduce the product to the U.S. market.
- "New tobacco product" – any product not commercially marketed in the United States as of (i.e., on) February 15, 2007, or one that was "modified" after February 15, 2007.

"**Pre-existing Tobacco Products**" do not require premarket authorization.

- If the tobacco product does not qualify as a "new tobacco product" (i.e., is considered a "pre-existing Tobacco Product"), then no premarket authorization required.

TCA § 910 (21 U.S.C. § 387j)

TCA - New Tobacco Product Authorization (Cont.)

Three premarket review pathways:

1. **Substantial Equivalence Report ("SE Report")**
   - For "new tobacco products" that are "substantially equivalent" to a "predicate product."
2. **Exemption from Substantial Equivalence**
   - For "new tobacco products" that have been modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive.
3. **Premarket Tobacco Product Application**
   - For "new tobacco products" that do not fit under the first two pathways.

TCA § 910 (21 U.S.C. § 387j)

TCA - Modified Risk Tobacco Products

- The TCA prohibits tobacco products from bearing any claims that a product:
  1. is less harmful or presents a lower risk of tobacco-related disease than other commercially marketed tobacco products;
  2. reduces exposure to a harmful substance;
  3. does not contain or is free of a substance; or
  4. is “low,” “light,” or “mild” (or has other similar attributes), unless FDA has specifically authorized the claim via a modified risk tobacco product (MRTP) order.
- Two types of MRTP orders:
  - Risk modification orders
  - Exposure modification orders

TCA § 911 (21 U.S.C. § 387k)

TCA - Health Information

- Manufacturers and importers must submit the following health information to FDA:
  - **Ingredient Listing**: List of all ingredients, compounds, substances, and additives that are added to the tobacco, paper, filter, or other part of the product; and a description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams.
  - **Harmful and Potentially Harmful Constituents**: List of constituents, including smoke constituents, identified by FDA as harmful or potentially harmful.
  - **Health Documents**: All documents generated after June 22, 2009, relating to health, toxicological, behavioral, or physiological effects of current or future tobacco products.
- *Note: FDA has current guidance documents that indicate how and to what extent FDA currently enforces the above requirements (i.e., products, ingredients, types of documents, etc.).*

TCA § 904 (21 U.S.C. § 387d)

TCA - Registration & Listing Requirements

- **Establishment Registration**
  - All [domestic] establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product marketed in the U.S. must register with FDA by December 31 of each year
  - Currently only domestic establishments are required to register (but the TCA contemplates that foreign establishments may also be required to register in the future through rulemaking)

- **Product Listing**
  - At the time of registration, registrants must also submit to FDA a list of all tobacco products manufactured, prepared, compounded, or processed by the establishment
  - Registrants must also file a biannual report of certain changes to their product lists

TCA § 905 (21 U.S.C. § 387e)

TCA - Sale & Distribution Restrictions

- The TCA required FDA to issue regulations to restrict youth access to tobacco products and related advertising.
- Manufacturers, distributors, and retailers of cigarettes and smokeless tobacco products are responsible for complying with Part 1140 restrictions.
- Key restrictions include:
  - **Sample ban** – ban on free cigarette samples; samples of smokeless products permitted in qualified adult-only facilities.
  - **Event sponsorship** – athletic, musical, artistic, or other social or cultural events, or an entry or team in any event, cannot be sponsored in the brand name, logo, motto, etc. of a cigarette or smokeless tobacco product.
  - **Advertising and other restrictions** – e.g., warning statements on advertisements.

TCA - Tobacco Product Standards

- The TCA established a tobacco product standard for flavored (non-menthol) cigarettes and provided that FDA may adopt additional tobacco product standards in the future.
- Tobacco product standards are provisions “appropriate for the protection of public health,” such as those relating to:
  - Nicotine yields
  - Reduction or elimination of HPHCs.
- As of the date of this presentation, there are two Tobacco Product Standards in effect (arguably one), and two proposed Tobacco Product Standard.

TCA § 907 (21 U.S.C. § 387g)

TCA - Tobacco Product Standards - Current

- **Cigarettes – Ban on characterizing flavors (other than menthol)**
  - As of September 29, 2009, cigarettes may not contain any artificial or natural flavor, or any herb or spice (except for tobacco or menthol)
- **Pesticide Chemical Residue**
  - As of June 2011, manufacturers may not use foreign grown tobacco that contains a pesticide chemical residue that exceeds applicable U.S. tolerances.
  - However, there are currently no such established tolerances in effect.

TCA § 907 (21 U.S.C. § 387g)

TCA - Tobacco Product Standards – Proposed/Pending

- On May 4, 2022, FDA issued two proposed rules to establish product standards.
- **(1) Tobacco Product Standard for Menthol in Cigarettes** (87 Fed. Reg. 26,454)
  - Establishing a tobacco product standard prohibiting a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper) from containing, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.
- **(2) Tobacco Product Standard for Characterizing Flavors in Cigars** (87 Fed. Reg. 26,396)
  - Establishing a tobacco product standard prohibiting a cigar or any of its components or parts (including the tobacco, filter, or wrapper) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including but not limited to strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke.

TCA § 907 (21 U.S.C. § 387g)

The "Deeming Rule"

- On May 10, 2016, FDA published the final "Deeming Rule," which deemed all products meeting the definition of "tobacco product," including components and parts, but not including accessories, to be subject to the TCA.
  - Examples of tobacco products previously regulated include cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco.
  - Examples of newly regulated tobacco products include electronic nicotine delivery systems (ENDS), pipe tobacco, cigars, hookah/waterpipe tobacco, e-liquids.
- The Deeming Rule took effect on August 8, 2016.

81 Fed. Reg. 28,974 (May 10, 2016)

The "Deeming Rule" (cont.)

- The Deeming Rule distinguished between components or parts and accessories.
  - Components and parts of the newly deemed tobacco products are included under the Deeming Rule, but accessories are not.

- **"Components and Parts"**
  - Any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.
  - Examples: E-liquids; atomizers; batteries; cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems; electric heater or charcoal used for prolonged heating of waterpipe (i.e., maintaining combustion of the tobacco).

21 C.F.R. § 1143.1

The "Deeming Rule" (cont.)

- **"Accessories"**
  - Any product intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:
    - (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
    - (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.
  - Examples: Ashtrays, spittoons, hookah tongs, cigar clips and stands; pipe pouches; humidors or refrigerators that solely control the moisture and/or temperature of a stored product; conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion.

21 C.F.R. § 1143.1

The "Deeming Rule" (cont.)

Components & Parts (included under Deeming Rule)	Accessories (*not* included under Deeming Rule)
Intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.	(1) Not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.
E-liquids; atomizers; batteries; cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems,; electric heater or charcoal used for prolonged heating of waterpipe (i.e., maintaining combustion of the tobacco)	Ashtrays, spittoons, hookah tongs, cigar clips and stands; pipe pouches; humidors or refrigerators that solely control the moisture and/or temperature of a stored product; conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion

21 C.F.R. § 1143.1

The "Deeming Rule" – The "Compliance Policy"

- When it issued the Deeming Rule, FDA recognized that many products in the newly deemed categories that were already on the market qualified as new tobacco products (i.e., they were not grandfathered under the statute because they were not on the market on February 15, 2007).
- Rather than requiring removal of all new deemed tobacco products from the market on the Deeming Rule's effective date (August 8, 2016) and FDA authorization to return them to the market at some future date, FDA announced a compliance policy (the "Compliance Policy") applicable to new tobacco products in the newly deemed categories that were already on the U.S. market on the Deeming Rule's effective date, August 8, 2016.

The "Deeming Rule" – The "Compliance Policy" (cont.)

- Under the Compliance Policy, such newly deemed products that were on the market as of August 8, 2016, could remain on the market without an FDA marketing authorization until specified deadlines for submitting marketing applications (which changed over time) and during at least some period of FDA's review of timely filed marketing applications for such products.
- FDA initially announced staggered compliance periods depending on the complexity of the submission:
  - 12 months for substantial equivalence (SE) exemption requests;
  - 18 months for SE reports; and
  - 24 months for PMTAs.

The "Deeming Rule" – Changing Compliance Deadlines

- **July/August 2017:** FDA releases new "Comprehensive Plan" for tobacco and nicotine regulation" and modified the Compliance Policy to permit the continued marketing of certain deemed products that were on the market on August 8, 2016 .
  - Announces approach to tobacco regulation focused on nicotine levels and addition.
  - Modified the Compliance Policy to permit the continued marketing of the following products that were on the market on August 8, 2016:
    - Combusted products (i.e., cigars) until August 8, 2021
    - Non-combusted products (ENDS) until August 8, 2022
  - The revised Compliance Policy also permitted a product to remain marketed beyond the applicable 2021 date during FDA's review of a timely-filed marketing application.

The "Deeming Rule" – Changing Compliance Deadlines (cont.)

- **March 2018**: Several public health organizations and individual physicians filed a lawsuit challenging FDA's 2017 Comprehensive Plan.
  - *American Academy of Pediatrics v. FDA*, U.S. District Court for the District of Maryland
- **May/July 2019:** Court order moved up the compliance deadlines to May 2020.
  - The Maryland District Court agreed with plaintiffs, issued remedy order as follows for all deemed new tobacco products on the market on August 8, 2016:
    - Marketers must file premarket submissions within 10 months (by May 2020).
    - Products covered by timely-filed applications may remain on the market for a period not to exceed one year after submission of the application.
    - FDA may exercise its discretion to enforce the premarket review requirements if no application submitted within 10 months.
    - Gives FDA the ability to exempt deemed products on the market on August 8, 2016, from these requirements for good cause and on a case-by-case basis.

The "Deeming Rule" – Changing Compliance Deadlines (cont.)

- **January 2020**: FDA issues final compliance policy adopting May 2020 compliance deadline.
  - Flavored ENDS remain enforcement priorities; flavored cigars not referenced.
- **March 2020**: FDA files a motion with U.S. District Court for the District of Maryland requesting a 120-day extension of the premarket application deadline based on the impact of the COVID-19 pandemic.
- **April 2020:** District Court grants the requested extension and moves the deadline for filing premarket submissions for new deemed tobacco products on the market on August 8, 2016, to September 9, 2020.
  - For products subject to applications filed by September 9, 2020, FDA will continue to exercise enforcement discretion and the products could generally continue to be marketed for up to one year from the deadline unless negative action is taken by FDA.

The "Deeming Rule" – Changing Compliance Deadlines (cont.)

- **April 2020**: Consistent with the District Court order, FDA issues amended compliance policy extending premarket compliance deadline to September 9, 2020, with the following enforcement priorities:
  - Flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored ENDS).
  - All other ENDS for which manufacturer has failed to take adequate measures to prevent minors' access.
  - Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.
  - Any ENDS for which premarket submission was not filed by Sept. 9, 2020.
- For products subject to applications filed by September 9, 2020, FDA indicated it would continue to exercise enforcement discretion and the products could generally continue to be marketed for up to one year from the deadline (September 9, 2021) unless negative action is taken by FDA.

Consolidated Appropriations Act, 2022 (Synthetic Nicotine)

- On March 15, 2022, President Biden signed into law the Consolidated Appropriations Act, 2022, which expanded CTP's jurisdiction to synthetic nicotine products.
  - Closed the "loophole" for synthetic nicotine products.
- The Act revised the definition of "tobacco product" to read:
  - "any product made or derived from tobacco or **containing nicotine from any source** that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

Consolidated Appropriations Act, 2022 (Synthetic Nicotine) (cont.)

- The Act established a "transition period" for compliance with the FFDCA's premarket review requirements for synthetic-nicotine containing "new tobacco products" on (or introduced to) the U.S. market during the 30-day period between the law's enactment and effective date.
  - For 60 days following its enactment (i.e., until May 14, 2022), synthetic nicotine products on the market within 30 days of the bill's enactment would not violate the FFDCA's premarket review requirements for "new tobacco products."
  - To continue marketing such a synthetic nicotine product after this 60-day period, the manufacturer must have submitted a PMTA for the product by May 14, 2022, which allowed the manufacturer to market the product for up to another 60 days (until July 13, 2022) during FDA's review of the PMTA.

Consolidated Appropriations Act, 2022 (Synthetic Nicotine) (cont.)

- After July 13, 2022, synthetic nicotine products without a marketing authorization are technically noncompliant.
- However, FDA has not taken enforcement action against synthetic nicotine products covered by a still pending PMTA.
- FDA's enforcement action thus far appears to have been limited to products not covered by a PMTA or those that received negative determinations.

Questions?

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