Food and Drug Law Institute’s Introduction to Tobacco Law Seminar
October 20, 2014

Product Standards, Menthol and FDA’s Deeming Regulation

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Preliminary Word

• This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depends on many factors. This presentation is not intended to provide legal advice.

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Presenter

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Agenda

• Tobacco Product Standards
  – Special Rules: Flavors and Pesticides
  – Types of Standards, Considerations, Standard-Setting Procedure, Appellate Review

• Menthol
  – TPSAC and Industry Recommendations
  – Advanced Notice of Proposed Rulemaking

• FDA’s Proposed Deeming Regulation
  – What’s Included and What’s Not
**Tobacco Product Standards**

- Section 907 of the Tobacco Control Act authorizes FDA to establish product standards relating to the composition, design, labeling or marketing of tobacco products, so long as FDA finds that such a standard is “appropriate for the protection of the public health”.

- The failure or refusal to comply with a tobacco product standard is a prohibited act. See FDCA Section 301(q)(1).
Tobacco Product Standards: Special Rules

• Section 907 contains a number of self-executing “special rules” to which certain types of tobacco products are immediately subject.

• The special rule for cigarettes prohibits a cigarette or any of its components from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor or an herb or spice that is a “characterizing flavor” of the product or smoke, other than tobacco or menthol.
Tobacco Product Standards: Special Rules

• Prohibited characterizing flavors include: strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee. See Section 907(a)(1)(B).

• This applies to all tobacco products that meet the definition of a “cigarette” in Section 900(3) of the Act, even if that product is not labeled or marketed as a cigarette.
Tobacco Product Standards: Special Rules

• Tobacco flavor is permanently exempt from the characterizing flavor ban, but Section 907(a)(1)(A) permits FDA to ban menthol cigarettes.

• FDA is required to consider the public health impact of the use of menthol in cigarettes and determine what regulatory action, if any, should be taken. More on this later.
Tobacco Product Standards: Special Rules

• Special rule for pesticide residues: tobacco product manufacturers are prohibited from using tobacco, including foreign grown tobacco, that contains a pesticide chemical residue at level greater than is specified by any federal tolerance applicable to domestically grown tobacco. See Section 907(a)(1)(B).

• No such tolerance has been promulgated.
Tobacco Product Standards: Special Rules

• Until such a tolerance is established, manufacturers are *not* prohibited from using domestic or imported tobacco that contains pesticide residue.

• But under the literal interpretation of the FDCA, FDA does *not* actually have the authority to establish pesticide chemical residue tolerances on imported tobacco.
**Tobacco Product Standards: Special Rules**

- FDCA Section 201(q)(2) defines “pesticide chemical residue” as a residue of a pesticide chemical…“in or on raw agricultural commodity (RAC) or processed food.”

- Tobacco is not a processed food, and RAC is defined in Section 201(r) as “any **food** in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.”
Tobacco Product Standards: Types of Standards

- Section 907(a)(4) provides examples of standard provisions that may be appropriate for safeguarding the public health, including (but not limited to):
  - Nicotine yields of tobacco products;
  - Reduction/Elimination of HPHCs;
  - Product Construction;
  - Components, ingredients, additives, constituents and product properties;
  - Product testing and measuring of characteristics;
  - Sale/distribution and labeling form and content.
Tobacco Product Standards: Types of Standards

• FDA is expressly prohibited from establishing any standard that bans all cigarettes, smokeless tobacco products, cigars (including little cigars), pipe tobacco, or roll-your-own tobacco products, or requires the reduction of nicotine yields of a tobacco product to zero. See Section 907(d)(3).

• This prohibition does not extend to other categories of products “deemed” to be regulated, as we will discuss.
Tobacco Product Standards: Considerations

• To establish a new standard, FDA must justify that it is “appropriate for the protection of the public health.”

• FDA must consider scientific evidence of risks and benefits of the standard to users and non-users, as well as the increased or decreased likelihood that existing users will stop and non-users will start using such tobacco products.

• Technological achievability and countervailing (or negative) effects on public health and demand for contraband products.
Tobacco Product Standards: Standard Setting Procedure

- Section 907(c) sets forth FDA procedures when proposing to set, amend or revoke a tobacco product standard.
- FDA must publish a Notice of Proposed Rulemaking in the Federal Register and go through the notice and comment rulemaking process to promulgate a tobacco product standard.
- Section 907(d) contains factors for FDA to consider when establishing the effective date for a final rule for a product standard.
Tobacco Product Standards: Appellate Review

• Section 912(a) provides for judicial review of the establishment, amendment or revocation of a tobacco product standard by the U.S. Court of Appeals pursuant to Section 706(2)(a) of the Administrative Procedure Act.

• Standard for setting aside agency actions: “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”
Menthol

• Menthol (and tobacco) flavors are exempt from the cigarette characterizing flavor ban in Section 907.

• Mentholated cigarettes represent ¼ of all cigarettes sold in U.S.; because of its long history of use in cigarettes, Congress did not include menthol in the characterizing flavor ban.
Menthol

- Menthol is used in foods, drugs and OTC health and cosmetic products such as chewing gum, cough drops, mouthwash, lip balms, etc.
- Generally Recognized as Safe (GRAS) for direct addition to food in 21 C.F.R. §§ 172.515 and 182.20 of FDA’s food additive regulations.
- Impact on toxicity of cigarette smoke?
Menthol

• As with anything tobacco related, FDA’s concern is not the substance’s toxicity (after all, tobacco is inherently unsafe) but the potential impact on the public health.

• Congress referred TPSAC to review and report on public health impact of menthol in cigarettes including use by children and racial minorities.
  – The D.C. District Court recently found that several TPSAC members have severe conflicts of interest and invalidated its March 2011 Menthol Report; FDA is not allowed to rely on findings and conclusions of that report.
Menthol:
TPSAC Report Findings and Conclusions

• TPSAC found that there was sufficient evidence to conclude that availability of menthol cigarettes:
  – Increases experimentation and regular smoking;
  – Increases likelihood of addiction and degree of addiction in youth smokers;
  – Results in lower likelihood of smoking cessation success in African Americans and minorities compared to non-menthols.
Menthol: TPSAC Report Findings and Conclusions

- TPSAC also found that smokers of menthol cigarettes inhale more smoke per cigarette and are exposed to higher levels of nicotine and other tobacco toxins.
- But evidence was insufficient to conclude that it is more likely than not that menthol smokers have an increased risk for diseases caused by smoking compared with smokers of non-menthol cigarettes.
Menthol:
TPSAC Report Findings and Conclusions

• Overall, TPSAC concluded that availability of menthol cigarettes has an adverse impact on public health and that there are no public health benefits compared to non-menthols.

• Recommended that removing menthol cigarettes from the marketplace would benefit the public health.

• Potential negative consequence: increase in illegal black market for menthol cigarettes.
Menthol: Tobacco Industry Report

• Led by R.J. Reynolds and Lorillard, the tobacco industry submitted its own report on menthol to FDA.

• According to industry, the only appropriate focus for FDA in evaluating menthol is to determine whether menthol cigarettes have a disproportionate effect on public health compared to non-menthol cigarettes.

• Scientific evidence suggests no causal relationship linking menthol to increased disease risk or biomarkers for potential harm.
Menthol: Advanced Notice of Proposed Rulemaking

- FDA published an Advanced Notice of Proposed Rulemaking in July 24, 2013 to solicit public comment and obtain more data on whether it should regulate menthol in cigarettes and other tobacco products.
- FDA posed a number of questions in the ANPRM including whether the Agency should establish a tobacco product standard for menthol in cigarettes and, if so, what level of menthol is appropriate for protecting the public health.
Menthol: Advanced Notice of Proposed Rulemaking

• The ANPRM also requested comment on the viability of sale and distribution as well as advertising and promotion restrictions on menthol, and what impact such restrictions might have on youth smoking behavior.

• The public comment period was open for 120 days and closed on November 22, 2013; nearly 175,000 comments were submitted.

• Next steps: FDA must review all comments (no timetable) and determine whether to promulgate a Notice of Proposed Rulemaking.
Menthol:  
FDA Preliminary Report and New Studies

• Along with the ANPRM, FDA also released its Preliminary Menthol Report on the available scientific evidence assessing the public health impact. FDA found that weight of evidence supports that:
  – Menthol in cigarettes is \textit{not} associated with increased or decreased smoke toxicity or exposure biomarkers, increased disease risk or altered physiological responses to smoke;
  – Minorities, females and younger people are more likely to smoke menthols; and
  – Menthol in cigarettes is likely associated with increased initiation and progression to regular cigarette smoking and reduced cessation success, particularly among African Americans.
Menthol: FDA Preliminary Report and New Studies

• But given its preliminary nature, FDA’s report was not meant to indicate what regulatory action, if any, it would take with respect to menthol.

• FDA has also commissioned three menthol-related studies to examine:
  – Genetic differences in taste perceptions in tobacco use;
  – Effects of menthol in cigarettes by assessing toxins from smoke by comparing cigarettes that are identical except for levels of menthol; and
  – Impact of menthol and non-menthol compounds in various tobacco products on addiction and toxicants of tobacco smoke.
Deeming Regulation

• Tobacco Control Act defined “tobacco product” broadly (i.e., anything made or derived from tobacco intended for human consumption), but only gave FDA immediate authority over certain types of tobacco products, e.g., cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco.

• **Not** included: other tobacco products, such as e-cigarettes, cigars, pipe tobacco and dissolvable tobacco.
Deeming Regulation

- Section 901(b) further provides that FDA may use its rulemaking authority to “deem” any other tobacco products to be regulated products subject to FDA’s authority under the Tobacco Control Act.

- The Notice of Proposed Rulemaking for FDA’s “Deeming Regulation” was finally published on April 25, 2014.

- The 105-day comment period ended on August 8, 2014. FDA has received over 80,000 comments.
Deeming Regulation

• Once FDA has reviewed all the comments it will prepare a final rule which, once completed, will be submitted to OMB for approval. Final rule must include analysis of the comments.
• If OMB approves, the final rule will become effective and will be published in the Federal Register and eventually in the Code of Federal Regulations (21 CFR).
• The entire “Notice and Comment Rulemaking” process will likely take at least 1-2 years, at least.
• Before any major federal rule goes into effect, agencies are required to forward the rule to Congress for review. See Small Business Regulatory Enforcement Fairness Act of 1996.
Deeming Regulation

• If the rule becomes effective as currently drafted, these newly covered products will be subject to the same regulatory requirements that currently only apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

• These requirements include registration, product listing, ingredient listing, warnings, restrictions on sales to minors and, most importantly, premarket review.
Deeming Regulation

• The Deeming Regulation proposes to deem unregulated products and components thereof to be “covered tobacco products” subject to same regulatory requirements – a “one-size-fits-all approach”.

• Given the wide variety of available tobacco products with different public health concerns, does this approach make sense?

• Many comments submitted to FDA arguing that the Agency should tailor regulatory requirements based on product types.
Deeming Regulation

• The lengthy preamble contains numerous questions, and makes clear that there are several novel considerations that must be weighed in determining whether and how to apply the Tobacco Control Act requirements to the newly regulated products.

• FDA asked whether it should consider different regulatory mechanisms, compliance policies for the SE pathway, and what other regulatory approaches it might consider.

• With respect to e-cigarettes, FDA requested information on effect on public health, how should be regulated based on the “continuum of risk”, and the impact on reducing cigarette usage and possible dual use.
Deeming Regulation: Scope

• Option 1 – all unregulated tobacco products, including components but not accessories, would become regulated, electronic cigarettes, dissolvable tobacco, pipe tobacco, hookah (water pipe) tobacco, nicotine gels, all cigars, and any future products that meet the tobacco product definition but are not yet on the market.

• Option 2 – same as above, except that “premium cigars” would be exempt from regulation.
Deeming Regulation: Scope

• Under both options, “components and parts” would be subject to Tobacco Control Act requirements, but not accessories. Components and parts of deemed tobacco products “are included as part of a finished tobacco product or intended for consumer use in the consumption of a tobacco product.”

• The term also includes those items sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product.

• Examples of products that would likely fall within this meaning of “components and parts” of e-cigarettes include the nicotine-containing e-liquid, as well as hardware parts that directly impact the inhaled aerosol, including the heating atomizer/cartomizer, tanks, and cartridges.
Deeming Regulation: Scope

- FDA considers “accessories” to be items “that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product.
- The term also includes items that may be used in the storage or personal possession of a proposed deemed product, such as hookah tongs, bags, cases, charcoal burners and holders, as well as cigar foil cutters, humidors, carriers, and lighters.
Deeming Regulation: Scope

• Option 2 proposes to exempt premium cigars from FDA regulation. What is reasoning for such an exemption?
• A premium cigar is defined as a cigar that is:
  – Wrapped in tobacco leaf
  – 100% leaf tobacco binder
  – Primarily long filler tobacco
  – Manually made
  – No filter or mouthpiece
  – Retail price of $10 per cigar or more
  – No characterizing flavor other than tobacco
  – Weighs more than 6 lbs. per 1000
Deeming Regulation: General Controls

• Deemed tobacco products would be subject to the same general control requirements as currently regulated products, including:
  – Registration under Section 905(b);
  – Product and Ingredient Listing under Section 904;
  – HPHC Reporting under Section 904(a)(3);
  and
  – Adulteration and Misbranding provisions.
Deeming Regulation: Warning Requirements

• All deemed products that contain nicotine must state: “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”

• Self-certification program for tobacco products that do not contain nicotine (e.g., nicotine-free cigarettes). This does not mean zero-nicotine e-liquids, which are not tobacco products.
Deeming Regulation: Warning Requirements

• Cigars captured would also have to rotate the following additional warnings:
  – Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even If You Do Not Inhale;
  – Cigar Smoking Can Cause Lung Cancer and Heart Disease;
  – Cigars Are Not a Safe Alternative to Cigarettes; and
  – Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers.

• Where cigars are sold individually and not packaged, the cigar warnings must be included on a sign located at the point-of-sale at each cash register in any retail establishment where the cigars are sold.
Deeming Regulation: Sales and Marketing Restrictions

- Ban on Youth Sales
- Ban on Vending Machine Sales
- Ban on Free Samples
- Ban on Unauthorized Modified Risk Claims
Deeming Regulation: Premarket Review Requirements

• “New” tobacco products must have FDA premarket authorization – any product that was not commercially marketed on the Grandfather Date (Feb. 15, 2007) or any grandfathered product that was modified in any way.

• What are the premarket pathways?
  – Premarket Tobacco Product Application (PMTA)
    • Section 910(b)
  – Substantial Equivalence (SE) Report
    • Section 905(j)
  – Minor Modification Exemption (MME) from SE
    • Section 905(j)(3)
Deeming Regulation: Compliance Policy for Deemed Products

• The Proposed Rule imposes the existing February 15, 2007 Grandfather Date to newly deemed products.

• Recognizing the difficulty that imposing the statutory Grandfather Date will have on manufacturers of deemed products (some like e-cigarettes were not on the market at that time) FDA has proposed a “compliance policy” that would delay enforcement of the premarket authorization requirements.
Deeming Regulation: Compliance Policy for Deemed Products

- Under this policy, any deemed product marketed after February 15, 2007 through two years *after* the effective date of the Deeming Regulation can remain on the market provided: (1) either a PMTA, SE Report or MME request for such product is submitted by the two year anniversary of the effective date of the regulation and (2) until such time as FDA denies the premarket submission.
Deeming Regulation: What’s not Included?

• What about use of **flavors** in deemed tobacco products?
• Electronic cigarettes are being used today with a variety of “e-liquid” flavors. These products, as well as other flavored tobacco products (e.g., hookah), are not subject to the Section 907 characterizing flavor ban.
• But does FDA even need to promulgate a new standard banning characterizing flavors in deemed products?
• If a flavored deemed product is not grandfathered, then the manufacturer would need to obtain FDA premarket authorization for that product by way of SE or PMTA.
  • Burden is on manufacturers to demonstrate that such flavored products are appropriate for protection of the public health.
Deeming Regulation: What’s not Included?

- Sales and advertising restrictions are not a focus of the deeming regulation.
- A particular “hot button” issue is the marketing and advertising of e-cigarettes, particularly toward youth.
- 29 State Attorneys General submitted a comment specifically asking FDA to, among other things, impose the same restrictions on youth advertising and marketing of e-cigarettes currently applicable to combustible tobacco cigarettes, and to ban all advertising of such products in electronic media.
Deeming Regulation: Potential Alternative Frameworks

- Impact of “one-size-fits-all” approach will greatly impact existing industries (i.e., cigars, e-cigs).

Ideas for alternative frameworks include:

- Nicotine-only products vs. tobacco leaf-containing products or combustion vs. vaporization.
- Continuum of Risk: The more harmful/riskier the product, the higher the regulatory burden should be.
- New “Grandfather Date”: February 15, 2007 vs. Effective Date of Rule?
- Evidence that e-cigarettes are “appropriate for the protection of the public health” already exists.
- Use of Product Standards.
Questions?

Thank you!

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