FDA'S "DEEMING RULE": WHAT DOES IT DO?

OVERVIEW

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) gave the Food and Drug Administration immediate authority to regulate cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. It also gave FDA authority to extend its jurisdiction over "other tobacco products" by issuing a regulation "deeming" those products subject to the statute.

On May 5, 2016, FDA issued its "deeming rule" extending the agency's regulatory oversight to electronic cigarettes, cigars, hookah and other previously unregulated tobacco products. The deeming rule establishes a foundation for further science-based regulation of these products and begins to bring under control the current "Wild, Wild West" of the unregulated electronic cigarette market. However, further regulations are needed to minimize the risks the deemed products continue to pose to public health.

SCOPE OF THE RULE: NO EXEMPTION FOR "PREMIUM" CIGARS

Although FDA had requested public comment on whether it should exempt from regulation what it termed "premium cigars," **the final deeming rule covers all cigars**. FDA recognized that all cigars are harmful and potentially addictive and that no public health justification exists for completely exempting any class of cigars from regulatory oversight. For those manufacturers who qualify as "small businesses" and many will, FDA provides additional time and technical assistance to minimize their burden and to enable them to comply

BASIC REGISTRATION AND REPORTING REQUIREMENTS

The deeming rule automatically extends to electronic cigarettes, cigars and other newly-regulated products basic registration and reporting requirements, and other basic authorities, contained in the Tobacco Control Act. By giving FDA the information it will need to make science-based regulatory decisions, **these provisions will lay the groundwork for FDA regulation of electronic cigarettes and other deemed products, going forward**. They include:

- Registration of manufacturers with the FDA, identification of manufacturing facilities and reporting of products.
- Reporting of ingredients, including all harmful and potentially harmful constituents by brand, as well as documents in the companies' possession concerning the health and other effects of the products.
- FDA authority to request additional documents related to research and marketing of the deemed products.
- FDA authority to bring enforcement actions for adulterated and misbranded products.
- FDA authority to establish good manufacturing practices.

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SALES AND MARKETING RESTRICTIONS TO CURB YOUTH ACCESS AND USE

The dramatic increase in youth usage of electronic cigarettes and related products is a serious public health concern underscoring the urgency of FDA regulation, as current e-cigarette use by high school students increased 10-fold from 2011-2015 and e-cigarettes became the most commonly used tobacco product among young people. Electronic cigarette advertising and marketing has mimicked many of the marketing strategies long used by cigarette companies to make their products appealing to kids. Also, high school boys now smoke cigars at about the same rate as cigarettes.

The deeming rule contains various provisions to protect against youth access and use of the deemed products:

- **Prohibits sale of electronic cigarettes, cigars and other newly-regulated products to persons under 18** and requires retailers to verify age for over-the-counter sales. While 46 states already prohibit the sale of these products to minors, in many of those states enforcement mechanisms and penalties are weak

- **Applies to the newly-regulated products some of the marketing restrictions applicable to cigarettes and smokeless tobacco** to curb youth usage, including:
    - Prohibiting free samples
    - Restricting vending machine sales to adult-only facilities

However, the deeming rule omits other protections necessary to reduce the appeal and access of these products to young people. For example,

- **The rule fails to prohibit self-service displays** of electronic cigarettes, cigars and other newly-regulated products in retail stores, which means that kids can still get easy access to electronic cigarettes and cheap cigars in brightly-colored displays near the candy aisle. Self-service displays are currently prohibited for cigarettes.

- **The rule permits brand sponsorship of athletic or musical events**, which may have large youth attendance. This is a longtime marketing tactic by the tobacco industry that is no longer permitted for cigarette and smokeless tobacco brands, but continues to be permitted for electronic cigarettes and cigars under the deeming rule.

- **The rule permits the distribution of non-tobacco merchandise carrying the logos of electronic cigarette or cigar brands**, thus continuing to allow brand logos to appear on t-shirts, hats, sporting goods and other popular products. This also is a traditional marketing tactic of the tobacco industry which is not permitted for cigarettes and smokeless products.

- **The rule imposes no requirement of minimum pack size** to prevent the sale of inexpensive single cigars or other products appealing to price-sensitive kids.

Of particular importance, although the deeming rule's prohibition of sales to minors applies to all retailers, including internet retailers, **the rule does not explicitly impose any age verification requirements on internet sellers**. Since research has shown that age-verification on electronic cigarette websites is woefully inadequate and that minors have easy on-line access to electronic cigarettes and other tobacco products, this is an omission that will have real public health consequences.

REGULATION OF FLAVORS IN ELECTRONIC CIGARETTES AND CIGARS

Many cigars are marketed with a variety of kid-friendly flavors, often described in youthful jargon, like "Banana Split," and sold in shiny, colorful packages that reinforce the appeal of fruit and candy flavors to young people. FDA's PATH study has found that over 71% of current cigar smokers age 12-17 use flavored cigars; over 73% of young cigar smokers say they smoke cigars because they "come in flavors I like."

In addition to issuing the final deeming rule, **FDA has indicated its intention to propose that the current prohibition of characterizing flavors in cigarettes imposed in the Tobacco Control Act be extended to cigars. Because the current ban on characterizing flavors in cigarettes does not include menthol, menthol as a characterizing flavor in cigars would still be permitted.** Thus, cigar manufacturers could continue to sell mentholated products, just as cigarette companies are able to do, even though FDA's own scientific review concluded that menthol cigarettes pose health risks greater than that of non-menthol cigarettes.

While FDA indicated its intention to propose a prohibition of characterizing flavors in cigars, **the final deeming rule proposes no action to limit flavors in e-cigarette products**, despite a proliferation of fruit and candy flavors in e-cigarette products and despite the popularity of flavored products with young people. FDA's own PATH data shows that over 85% of current users of e-cigarettes aged 12-17 use flavored products and that 81% of those users report that they use e-cigarettes because they like the flavors. Although the final rule does not propose a new product standard limiting flavors in e-cigarettes, FDA can consider the public health implications of flavored products as part of its premarket review of specific products currently on the market.

REGULATION OF CLAIMS OF REDUCED RISK

The deeming rule will subject electronic cigarettes, cigars and other deemed products to the provisions of the Tobacco Control Act governing claims by manufacturers that their products are less hazardous than other tobacco products. Under the rule, **manufacturers of electronic cigarettes, for example, will be prohibited from making such claims of reduced risk unless they can support them** with scientific evidence and demonstrate that making such claims will benefit public health as a whole, not just individual users.

REGULATION OF NEW PRODUCTS

The deeming rule applies to electronic cigarettes, cigars and other deemed products the premarket review requirements already applied to cigarettes and smokeless tobacco, with some adjustments related to products already on the market. Because the tobacco industry has a long history of introducing new products that are more addictive, more appealing and more toxic, premarket review of new products is a key component of FDA regulation.

The newly-regulated products are subject to the premarket review requirements of the Tobacco Control Act in the following ways:

- **Electronic cigarettes and other deemed products introduced to the market after February 15, 2007 must undergo review by FDA to determine if they are "appropriate for the protection of public health."** However, under the Tobacco Control Act, new products need not meet this public health standard if they are "substantially equivalent" to a product already on the market as of February 15, 2007.

- Products that entered the market on or before February 15, 2007 are "grandfathered" and need not undergo review.

- **The deeming rule gives manufacturers of the newly-deemed products a "compliance period" of twenty-four months** to submit a new product application (showing the product meets

the public health standard) and eighteen months to submit a substantial equivalence application (showing the product is substantially identical to a product on the market as of the 2007 grandfather date).

  - Therefore, products can stay on the market during the compliance period and, if an application is filed, can remain on the market during the FDA review process. In order to provide an incentive for manufacturers to file complete and well documented applications, and to provide greater certainty to the process, FDA has set a 12 month time limit for completion and review of the applications. Any product that has not had a fully completed application filed, and an order issued by FDA approving the application by the end of that time period, may no longer be marketed. However, FDA retains the discretion to extend that period for applications where the company has submitted all of the required information and the review process is near completion.

- Thus, the deeming rule subjects currently marketed electronic cigarettes and other deemed products to FDA review to ensure that they are not adversely affecting public health. At the same time, it gives manufacturers ample opportunity to submit evidence supporting their products while keeping those products on the market.

- **Although industry argued for a change in the "grandfather date," FDA correctly concluded that it had no authority to change the date,** which is prescribed by the statute. Changing that date to the date of the final deeming rule, as requested by some in the industry, would have completely exempted electronic cigarettes and cigars now on the market from a science-based product review by FDA to determine if they are damaging public health.

AUTHORITY TO SET PRODUCT STANDARDS

The deeming rule subjects electronic cigarettes, cigars and other newly-deemed tobacco products to FDA's broad authority to set product standards through additional rulemaking. This authority could be used, for example, to require the reduction of harmful substances in electronic cigarettes.

HEALTH WARNING LABELS

The deeming rule mandates a health warning about the addictiveness of nicotine for all nicotine-containing products, including electronic cigarettes and cigars: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." This is the first federally-mandated health warning for electronic cigarettes.

In addition, **the deeming rule requires five additional rotating health warnings for cigars**, similar to the warnings already required under a 2000 FTC consent order involving the seven largest cigar manufacturers, thus extending those warnings to other cigar manufacturers. The required warnings address (1) the risk of cancer of the mouth and throat; (2) the risk of lung cancer and heart disease; (3) the risk of lung cancer and heart disease from secondhand smoke, (4) the risk of harm to pregnant women, and (5) that cigars are not a safe alternative to cigarettes.