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FDA: On the Verge of Regulating Cigars, Pipe Tobacco, & E-Cigarettes?

The wheels are turning and all signs point to the likelihood of the FDA asserting jurisdiction over additional tobacco products by regulation.

>BY TROUTMAN SANDERS TOBACCO TEAM

The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") significantly changed the regulatory landscape for tobacco products, giving the Food and Drug Administration immediate jurisdiction over certain tobacco products. Specifically, the Tobacco Control Act requires FDA to regulate cigarettes, roll-your-own tobacco and smokeless tobacco and permits FDA to regulate other tobacco products, such as cigars, pipe tobacco and electronic cigarettes. FDA must issue regulations to assert authority over the latter group.

All signs indicate that FDA regulation of these tobacco products will come later this year. In April 2011, FDA wrote a letter to industry stakeholders indicating that FDA intended to assert authority over all "tobacco products," which are defined under the Tobacco Control Act as any product "made or derived from tobacco that is intended for human consumption" but that is not a "drug," "device" or combination product under the Food, Drug and Cosmetic Act ("FD&C Act"). FDA's action came on the heels of the District of Columbia Circuit Court of Appeals' decision in Sottera, Inc. v. Food & Drug Administration, (D.C. Cir. 2010), in which the court concluded that FDA lacked authority to regulate electronic cigarettes under the FD&C Act, but that FDA had authority to regulate electronic cigarettes as "tobacco products" under the Tobacco Control Act. FDA's letter to stakeholders advised that FDA intended to propose a regulation that would extend the agency's "tobacco product" authority to other tobacco products. Those tobacco products presumably would include electronic cigarettes, pipe tobacco, cigars and dissolvable tobacco (which FDA has determined is not covered by its existing authority over smokeless tobacco).

Later that year, in July 2011, FDA advised interested parties that it anticipated issuing so-called "deeming" regulations, subjecting these additional tobacco products to its jurisdiction, by October 2011. FDA did not issue the regulations in October, and on October 14, 2011, Senators Richard Blumenthal (D-CT), Frank Lautenberg (D-NJ) and Sherrod Brown (D-OH) wrote to FDA Commissioner Dr. Margaret Hamburg to request FDA's action to regulate these tobacco products. The Senators urged FDA to "move swiftly" to issue the deeming regulations, and requested that FDA update its progress on the regulations and its timeline for releasing the regulations. The Senators also requested a meeting with Commissioner Hamburg to discuss the matter in more detail.

Based on FDA's prior commitment to issue the regulations in October, and the Senators' urgent request, industry observers expected that FDA would issue the regulations shortly. However, as of mid-March 2012, FDA still had not issued the deeming regulations.

In April 2012, FDA further reaffirmed its intent to issue deeming regulations, when it sent letters to electronic cigarette manufacturers requesting information regarding the safety of electronic cigarettes. The letters note that FDA has authority under the Tobacco Control Act to regulate electronic cigarettes, and that it intends to do so. The letters requested information from manufacturers regarding consumer complaints and "adverse event issues," reports of "consumer misuse," descriptions of product labeling and systems in place to review consumer complaints and adverse events.

In the meantime, there is legislation pending in Congress that would exempt so-called "traditional large and premium cigars" from FDA's reach. The bill, which has been introduced in both the Senate and House of Representatives," defines a "traditional and premium cigar" as a roll of tobacco wrapped in leaf tobacco, containing no filter, and weighing at least six pounds per 1,000 count. The bill would remove such cigars from FDA's potential authority under the Tobacco Control Act. Thus, under the legislation, "traditional" cigars would not be subject to FDA's authority, whereas smaller cigars that are

more similar to cigarettes would be potentially subject to FDA's authority. The bill, which was introduced in 2011, remains in committee and has not been scheduled for a hearing.

DEEMING REGULATIONS—A SQUARE PEG IN A ROUND HOLE?

When FDA issues the deeming regulations, the proposed regulations will be followed by a period of notice and comment, during which stakeholders will have an opportunity to shape how FDA will regulate these additional tobacco products. As FDA considers its deeming regulations, it will need to consider whether the existing regulatory landscape for cigarettes, roll-your-own tobacco, and smokeless tobacco can or should apply in the same ways to cigars, pipe tobacco and electronic cigarettes. In doing so, FDA will need to address several areas in which the current requirements may be ill-suited for these products. These issues are discussed below.

TOBACCO CONTROL ACT'S PURPOSE

As FDA considers its regulations, it will be important to consider the Tobacco Control Act's purpose, as outlined in the law's preamble. The preamble addresses the health effects of tobacco use, and discusses court proceedings in which the major cigarette companies were found to have continued "to target and market to youth," to have "dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement," and to have "designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research." One could argue that Congress' rationale for enacting the Tobacco Control Act is inapplicable, or only partially applicable to other tobacco products. For example, Congress enacted the Tobacco Control Act in light of the undisputed health effects of cigarettes and the prior marketing conduct by the major cigarette companies. This rationale is arguably inapplicable to other types of tobacco products, such as electronic cigarettes, where the evidence of adverse health effects is scant and there has been no demonstrated pattern of marketing conduct.

> The FDA will need to consider whether the existing regulatory landscape for cigarettes, roll-your-own tobacco, and smokeless tobacco can or should apply in the same ways to cigars, pipe tobacco and electronic cigarettes.

NEW PRODUCT REQUIREMENTS

Under Section 905 of the Tobacco Control Act, if a company proposes to sell a new tobacco product (one that was not commercially marketed as of February 15, 2007, or a product that has been changed since February 15, 2007), the company must first show that the product is "substantially equivalent" to a pre-February 15, 2007 tobacco product or that any modifications to a pre-February 15, 2007 tobacco product are minor changes that do not present different public health issues. The product cannot be sold to consumers unless FDA has approved the product, although there was a limited exemption for products introduced prior to March 22, 2011.

The ostensible purpose of the "substantial equivalence" requirements is to make sure that any new tobacco products are not more harmful than existing tobacco products. The substantial equivalence requirements prompted the introduction of several new tobacco products after the Tobacco Control Act's passage

but before the March 22, 2011 deadline. Any products introduced after March 22, 2011 are subject to FDA approval before they can be sold to consumers. Manufacturers that introduced products before March 22, 2011 were required only to submit a substantial equivalence report, but FDA did not have to approve the products prior to their introduction.

The substantial equivalence requirements for "new tobacco products" present unique issues for other tobacco products that would be subject to FDA authority under the deeming regulations. For example, as applied to traditional cigarettes, any pre-February 15, 2007 cigarettes are grandfathered, and products that are substantially equivalent or have minor modifications to the pre-February 15, 2007 products may continue to be sold as long as the manufacturer submitted an appropriate and timely substantial equivalence report. As applied to other tobacco products, such as electronic cigarettes, few were sold before the grandfather date of February 15, 2007, and the products have changed since since they were first introduced. A showing of substantial equivalence may therefore be difficult.

A more significant problem is the fact that, under a literal application of the Tobacco Control Act's substantial equivalence requirements, no post-February 15, 2007 product (or any product that has changed since then) can be sold without FDA approval unless: (1) the product was sold before March 22, 2011, and (2) the manufacturer submitted a substantial equivalence report before March 22, 2011. This was impossible for manufacturers of cigars, pipe tobacco and electronic cigarettes, which were not subject to the Tobacco Control Act on March 22, 2011. If these requirements are strictly applied to these tobacco products, all post-February 15, 2007 products would have to be removed from the market, and could not be sold until FDA has approved the substantial equivalence filing. However, no such report could be filed or considered by FDA until FDA has promulgated final regulations governing these tobacco products. In order to avoid a severe disruption in the market for these products, FDA's deeming regulations will need to account for this issue.

NICOTINE CARTRIDGE VERSUS E-CIGARETTE ELECTRONICS

The Tobacco Control Act applies only to "tobacco products," and as discussed above, a "tobacco product" is defined as a product made or derived from tobacco and intended for human consumption, including any component, part or accessory of a tobacco product. This would clearly encompass the nicotine cartridges in electronic cigarettes to the extent they contain nicotine derived from tobacco. However, an open question is whether FDA will also assert jurisdiction over the electronic cigarette's electronic components, a task that the agency may be ill-suited to face.

REMOTE SALES

Section 906 of the Tobacco Control Act requires FDA to issue regulations governing the remote sale of tobacco products, such as through the Internet. FDA has not yet issued those regulations, apparently concluding that such regulations may be moot in light of the Prevent All Cigarette Trafficking ("PACT") Act's restrictions on the remote sale of cigarettes, smokeless tobacco and roll-your-own tobacco. However, the PACT Act is inapplicable to other tobacco products, such as cigars, pipe tobacco and electronic cigarettes. It is therefore possible that FDA will consider issuing regulations governing these products. An

argument can be made that the rationale for limiting remote sales of cigarettes, smokeless and roll-your-own does not apply to these products, although presumably there should at least be mechanisms for ensuring that the remote purchaser of these products is not a minor. FDA's consideration of this issue is critical for electronic cigarettes, which are sold primarily outside typical distribution channels, but also for cigars and pipe tobacco, where sales on the Internet appear to have increased since the PACT Act's passage.

FLAVORING

Under Section 907 of the Tobacco Control Act, cigarettes cannot have a "characterizing flavor" (other than tobacco or menthol), such as strawberry, cinnamon, grape, etc. In other words, although cigarettes can have licorice flavoring (as most do), the licorice flavoring cannot predominate, nor could the product be described as a "licorice" cigarette. Smokeless tobacco is not subject to the characterizing flavor prohibition. Since the characterizing flavor prohibition took effect, sales of flavored cigars, pipe tobacco, and other tobacco products appear to have flourished. Although it is unclear whether FDA would have authority to limit characterizing flavors of these products, FDA will likely consider these issues in drafting its deeming regulations.

ADVERTISING AND MARKETING RESTRICTIONS

The Tobacco Control Act required the FDA to re-promulgate advertising and marketing regulations that FDA had originally issued in 1996. (The Supreme Court vitiated those regulations after determining that FDA lacked congressional authority to regulate tobacco products.) Those regulations specifically apply only to cigarettes and smokeless tobacco. FDA presumably will consider whether to apply those requirements to other tobacco products.

Those requirements include: (1) Samples—free samples of cigarettes are prohibited, and free samples of smokeless tobacco are permitted in limited circumstances; (2) Sales to Minors—the regulations have restrictions on sales to minors, such as age verification requirements and limitations on self-service displays; (3) Minimum Package Size—cigarettes may be sold only in packages of at least 20; (4) Advertising—the regulations have a number of prohibitions regarding outdoor and color advertising, although a First Amendment challenge by a number of cigarette manufacturers resulted in an injunction against these prohibitions; and (5) Gift Restrictions—the regulations prohibit manufacturers for distributing non-tobacco items bearing a tobacco brand name, or giving free items (such as hats, t-shirts, etc.) in exchange for tobacco purchases.

Assuming FDA has the authority to apply these advertising and marketing restrictions to additional tobacco products (and it is not clear it does), FDA will need to consider how these restrictions will apply to other products. The case for prohibiting sales to minors seems clear, but will FDA limit self-service displays of cigars or e-cigarettes? Will FDA seek to ban sampling of e-cigarettes, which is arguably critical for a growing industry, or will it seek to limit sampling as it does with smokeless tobacco? Minimum package size requirements seem inappropriate for more expensive products like cigars and e-cigarettes.

HEALTH WARNINGS

The Tobacco Control Act mandates a number of new warning labels for cigarettes and smokeless tobacco, including

graphic pictures for cigarettes. There are no defined warning labels for other tobacco products, such as cigars, pipe tobacco, and e-cigarettes, although FDA presumably will consider mandating such labels through regulations.

USER FEES

FDA's enforcement of the Tobacco Control Act is funded by user fees paid by tobacco manufacturers and importers. Since FDA currently regulates only cigarettes, smokeless and roll-your-own, the user fees are currently paid by manufacturers and importers of those products. As FDA expands its jurisdiction to cover other tobacco products, manufacturers and importers of those products will be subject to their proportionate share of the user fees. The user fees are calculated based on federal excise tax payments.

This presents an issue for electronic cigarettes, upon which no federal excise taxes are levied. There is therefore no way under current law to subject electronic cigarettes to FDA user fees. Assuming FDA has the authority—and it is not clear it does—FDA may consider ways to require e-cigarette manufacturers to pay a share of FDA administration costs.

> As manufacturers of cigarettes, RYO, and smokeless tobacco can already attest, FDA authority has added significant regulatory burdens in an already heavily-regulated industry. Manufacturers of cigars, pipe tobacco and electronic cigarettes will soon see those same regulatory burdens.

CONCLUSION

Since the Tobacco Control Act's passage in 2009, and certainly since FDA first specifically signaled its intent to regulate other tobacco products in April 2011, the industry has apprehensively awaited these regulations. Such apprehension is justified. As manufacturers of cigarettes, roll-your-own tobacco and smokeless tobacco can already attest, FDA authority has added significant regulatory burdens in an already heavily-regulated industry. Manufacturers of cigars, pipe tobacco and electronic cigarettes will soon see those same regulatory burdens.

However, potentially even more disconcerting for the industry is the fact that current FDA requirements may be ill-suited for other tobacco products, and if applied literally, could result in a severe disruption in these companies' businesses. The industry will no doubt evaluate FDA's forthcoming regulations with a critical eye, and would be well-advised to participate actively in that process. S

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