FDA Prevails in Court in Round One Over Cigars

A federal district court rejects most industry claims, but does direct FDA to reconsider the issue of retailers who blend pipe tobaccos. And so the cigar industry's war against deeming regulations rages on.

>BY BRYAN M. HAYNES

The United States Food and Drug Administration recently obtained summary judgment on several cigar industry claims challenging the FDA's Deeming Regulations. The case was filed by industry plaintiffs Cigar Association of America, the International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America on July 15, 2016, shortly after the FDA issued the final regulations.

The federal district court's May 15, 2018 order denied the industry-challengers' motion for preliminary injunction regarding the regulations' health warning requirements and granted the FDA's motion for summary judgment with respect the industry's claims regarding the FDA's health warnings, user fees, and regulation of pipes. The Court did find that the FDA unlawfully designated as "manufacturers" retailers who blend pipe tobacco, and directed the agency to reconsider the issue.

THE INDUSTRY'S CHALLENGE TO DEEMING REGUTIONS

The plaintiffs' Complaint challenges several aspects of the Deeming Regulations:

- The plaintiffs argue that the FDA's premarket review process (as applied to premium cigars) is arbitrary and capricious in that in that it favors previously-regulated products like cigarettes. The cigar industry must "look back" nine years for predicate products for substantial equivalence comparisons, whereas the cigarette industry only had to "look back" two and a half years. Moreover, cigarettes were permitted by law to remain on the market while the FDA completed its review, whereas cigars were not given the same consideration.

- The plaintiffs assert that the FDA's imposition of user fees on cigars is arbitrary in that e-cigarette suppliers are exempted from such payments.

- The plaintiffs claim that the Deeming Regulations did not employ a proper cost-benefit analysis in that it failed to quantify the regulations' enormous costs.

- The plaintiffs argue that the FDA arbitrarily declined to exempt from regulation a defined category of premium cigars, and in so doing, failed to consider the regulations' devastating impact on the industry.

- The plaintiffs argue that the warning label requirements violate the First Amendment to the U.S. Constitution by impermissibly infringing cigar companies' free speech.

- The plaintiffs assert that the FDA arbitrarily regulated retailers who blend pipe tobacco as "manufacturers"

- The plaintiffs contend that the FDA improperly regulated pipes (which contain no tobacco) as "tobacco products."

In early 2017, the newly-installed FDA administration signaled a willingness to reconsider several aspects of the prior administration's policy on newly-deemed products. The litigants then agreed to multiple extensions of the case in order to allow the FDA to more fully reconsider the relevant issues. That reconsideration culminated in the FDA's July 28, 2017 announcement of a "new comprehensive plan" for regulating tobacco products. Under the plan, the FDA delayed certain key deadlines, shifting the deadline for cigar companies' pre-

market review submissions from February 2018 to August 2021.

The FDA also announced a plan to reconsider its approach to regulating premium cigars. The FDA stated that it would issue an Advanced Notice of Proposed Rulemaking ("ANPRM") seeking public comment on "the patterns of use and resulting public health impacts from premium cigars." The FDA indicated that it was interested in scientific information "that might support" exempting premium cigars from the Deeming Regulations, or regulating them differently. The FDA issued the ANPRM in March and, as of this writing, comments are due in July 2018.

As a result of the FDA's announcement, the industry-challengers agreed to defer resolution of certain claims in the litigation. The plaintiffs agreed to defer consideration of the premarket review process, the FDA's decision to regulate premium cigars, and the agency's cost-benefit analysis. However, because warning label requirements are slated to take effect on August 10, 2018, the plaintiffs sought preliminary injunctive relief. The plaintiffs also sought summary judgment on other aspects of the Deeming Regulations that were not affected by the FDA's July 2017 announcement.

> For the foreseeable future, retailers who blend pipe tobacco will not be regulated as "manufacturers," and the FDA likely will have to conduct another rulemaking if it wishes to regulate them as such.

THE COURT'S DECISION

Although the Court rejected most of the plaintiffs' claims, the Court did criticize the FDA's "grossly unfair exercise of agency authority." The court noted that "the cigar industry has expended millions of dollars in designing and creating" new packaging with the required warning labels. At the same time, the FDA has indicated that it could reconsider its approach to regulating premium cigars, including exempting premium cigars altogether or eliminating or changing the required warnings. The Court therefore asked, "Why is the agency insisting that the premium cigar industry expend millions of dollars to conform to regulatory mandates that might be rescinded only months after their effective date?" Stating that this "smacks of basic unfairness" the Court suggested that the FDA should voluntarily stay the warning requirement for premium cigars.

Although the Court was clearly displeased with the FDA's approach, the Court concluded that "[i]ts hands are tied by both the law and the posture of the case." The Court noted that agencies are free to change their minds about regulations. The Court also pointed out that the plaintiffs did not challenge the FDA's refusal to stay the warning requirement during the pendency of the ANPRM. Noting that the FDA delayed other aspects of the Deeming Regulations in similar circumstances (most notably, the premarket review requirements), the Court suggested that a future challenge to the differential treatment might be successful.

The Court also rejected the FDA's approach to regulating retailers who blend pipe tobacco on par with traditional manufacturers and directed the agency to reconsider the issue. The Court found that the FDA incorrectly analyzed the relevant statutory provisions, but noted that the FDA could plausibly assert that the act of blending pipe tobacco constitutes the "manufacture, preparation, compounding, or processing of a tobacco product." Since the agency did not make that argument during the rulemaking process, the Court required the agency to reconsider the issue if it wishes to regulate retailers who blend pipe tobacco. What this means is that, for the foreseeable future, these retailers will not be regulated as "manufacturers," and the FDA likely will have to conduct another rulemaking if it wishes to regulate them as such.

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NEXT STEPS

Although the Court rejected several of the plaintiffs' claims, their core challenges remain. These challenges strike at the heart of the Deeming Regulations' requirements for premium cigars. For example, the Court still must consider the plaintiffs' claims that the FDA failed to exempt a defined category of premium cigars from regulation. The Court also must consider the plaintiffs' challenges to the substantial equivalence / premarket review process, which is perhaps the most onerous of all FDA requirements. Finally, the Court must consider the implications of the FDA's flawed cost-benefit analysis. If all or any of these claims are successful, the regulations' requirements for premium cigars would be substantially gutted or even eliminated. As Yogi Berra once said, "It ain't over until it's over!" S

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