

# Premium Cigar Industry Argues Case Against Deeming Rule

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(Washington, DC) Today, representatives from PCA, including President Greg Zimmerman, attended oral arguments in the United States District Court for the District of Columbia presented before Judge Amit P. Mehta in the case of Cigar Association of America et al. v. FDA. The case concerns the FDA's 2016 "Deeming Rule," which granted the FDA the authority to regulate "tobacco products," including premium cigars, under the Federal, Food, Drug, and Cosmetic Act. The question before the court is to decide whether the justifications and reasoning provided by the FDA for regulating premium cigars met the requirements of the Administrative Procedures Act.

The hearing began with arguments from the plaintiffs represented by Michael Edney of Steptoe & Johnson. Plaintiffs began by arguing that the sweeping regulatory scheme imposed because of the "Deeming Rule" is "arbitrary and capricious," because it did not sufficiently address the issue of patterns of use among premium cigar smokers. While the FDA discussed inhalation at length in the rule, it failed to address comments from industry groups about the significantly reduced health risks on the vast majority of premium cigar users, who smoke less than one cigar a day. In fact, a study cited by the FDA in the rule finds that there is no statistically significant increase in "all-cause mortality" for cigar smokers who smoke 1-2 cigars a day.

The FDA further failed to appropriately consider how the regulation would affect the behavior of premium cigar smokers, which is already infrequent. Plaintiffs also pointed to the definition of premium cigars provided by Judge Mehta in 2020, as a safeguard against concerns about adulteration, chemical manipulation, and youth access. Plaintiffs ultimately argued that the "Deeming Rule" should be vacated because the FDA failed to answer the questions it posed in the rule, did not address frequency of use, and relied on conflated data from studies with small sample sizes that were not specific to premium cigars.

"This is another example of the Premium Cigar Association's commitment to working with industry allies to challenge shoddy, cumbersome, and arbitrary regulations", says PCA Executive Director Scott Pearce. He continues "PCA is battling both legislation and regulations in the courts and in Congress to protect the business of specialty tobacco retailing in line with our stated mission".

**On Thursday May 26th at 3pm ET PCA will host a virtual government affairs update LIVE on Facebook and YouTube to discuss the oral arguments, pending flavor rule, self-regulation efforts, and more.**

