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Leading Health Organizations Seek to Intervene in Defense of FDA Rule on E-Cigarettes, Cigars

Groups Express Concern Administration May Not Adequately Defend Essential Public Health Regulations Against Industry Challenges

WASHINGTON, D.C. – Six leading public health organizations today asked federal courts to allow them to intervene in two lawsuits brought by the electronic cigarette and cigar industries against the Food and Drug Administration’s 2016 rule establishing public health oversight of e-cigarettes, cigars and other previously unregulated tobacco products. The groups include:

- The American Academy of Pediatrics
- The American Cancer Society Cancer Action Network
- The American Heart Association
- The American Lung Association
- The Campaign for Tobacco-Free Kids
- Truth Initiative

The groups expressed concern that the Trump Administration may not adequately defend the rule (known as the “deeming rule”) or may seek to weaken or rescind it, putting the health of children and the public at risk.

Twice in recent months, the Department of Justice (DOJ) has delayed filing legal briefs defending the FDA rule in these two cases, *Cigar Association of America v. FDA* and *Cyclops Vapor 2, LLC v. FDA*. On May 1, the DOJ filed joint papers in court with the cigar and e-cigarette industry plaintiffs requesting that all deadlines in the cases be extended three months so that “new leadership personnel at the Department of Health and Human Services” can “more fully consider the Rule and the issues raised in this case and determine how to proceed.” In addition, the FDA announced it was extending, for three months, all compliance deadlines under the rule set for May 10, 2017, or later.

In contrast to the current Administration’s actions, the DOJ in August 2016 strongly defended the FDA rule as essential to protecting public health in another case brought by e-cigarette manufacturers,

Nicopure Labs, LLC v. FDA. On Friday, the [judge ruled in that case](#) and upheld the deeming rule as a proper exercise of the FDA's legal authority.

“Setting aside the deeming rule...would have a direct adverse effect on public health, particularly among youth. Public Health Intervenors are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products,” according to the health groups’ court filings. “Dismantling the regulatory structure adopted by the FDA in the Deeming Rule would increase the risk of those harms, particularly to young people.”

A 2009 law, the Family Smoking Prevention and Tobacco Control Act, gave the FDA immediate authority over cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco and authorized the agency to extend its jurisdiction to all other tobacco products. Issued in May 2016, the FDA's deeming rule established oversight of e-cigarettes, cigars and other previously unregulated tobacco products in order to protect public health and prevent youth use of these products.

The health groups expressed particular concern that e-cigarettes and cigars are sold in a wide assortment of sweet flavors that appeal to kids, with names like “Banana Split” and “Wild Rush” for cigars and “Unicorn Milk” and “I Love Donuts” for e-cigarette liquids. [An FDA study](#) found that 81 percent of kids who have ever used tobacco products started with a flavored product. In addition, 81.5 percent of current youth e-cigarette users and 73.8 percent of current youth cigar users say they used the products “because they come in flavors I like.” Studies have identified more than 7,700 e-cigarette flavors, with hundreds added each month, and at least 250 cigar flavors.

The recently released National Youth Tobacco Survey showed that youth use of e-cigarettes fell for the first time in 2016 after skyrocketing since 2011. However, 11.3 percent of high school students still use e-cigarettes, compared to 8 percent who use regular cigarettes. In addition, high school boys smoke cigars at a slightly higher rate than cigarettes. [A 2016 Surgeon General's report](#) concluded that youth use of nicotine in any form, including e-cigarettes, is unsafe, can cause addiction and can harm the developing adolescent brain.

In addition to their lawsuits against the deeming rule, tobacco interests have urged Congress to pass legislation to weaken the rule.

The public health groups are being represented on a pro bono basis by the law firm of WilmerHale, lawyers at Democracy Forward Foundation and the legal staff of the Campaign for Tobacco-Free Kids.

The filings were made in the U.S. District Court for the District of Columbia and the U.S. District Court for the Middle District of Alabama, where two of the challenges to the deeming rule are pending. The D.C. case is *Cigar Association of America v. FDA*. The Alabama case is *Cyclops Vapor 2, LLC v. FDA*.