FDA pulled into federal court on delay in regulating e-cigarettes

OCT 5, 2018

Tanya Albert Henry
Contributing News Writer

Every day the Food and Drug Administration (FDA) delays regulating e-cigarettes, flavored cigars and other tobacco products aimed at attracting new nicotine users—particularly teens and children—the public's health is at risk, a dozen organizations, including the AMA, have told a federal court.

"It is illegal, unreasonable and devastating for the public health for the FDA to postpone its oversight obligations any further," the AMA and others said in an amicus brief supporting a lawsuit that the American Academy of Pediatrics (AAP) and others filed in the U.S. District Court for the District of Maryland challenging the FDA's decision to delay regulating these products.

In 2016, the FDA used its "deeming authority" to regulate e-cigarettes, pipe tobacco and cigars. It's a power the FDA received under the Family Smoking Prevention and Tobacco Control Act of 2009, in which Congress directed the agency to regulate certain tobacco products and gave it authority to require that such products go through premarket review and approval before they could be marketed to the public. The FDA went through the notice-and-comment rulemaking process to promulgate the rule.

But when the administration changed in 2017, the FDA issued a "guidance" that essentially exempts manufacturers of newly deemed products from premarket review until 2022—which, in practice, could mean indefinitely.

"It is neither lawful nor reasonable for the FDA to abdicate its statutory obligations for so many years," the AMA and others told the court in its amicus brief, supporting the AAP's case, *AAP v. FDA.* "The public health consequences alone explain why."

FDA reconsidering policy

FDA Commissioner Scott Gottlieb, MD, has announced steps to address the youth e-cigarette use epidemic, including saying the FDA would “revisit” the premarket review policy that the AAP’s lawsuit challenges.

AMA President Barbara L. McAneny, MD, said the FDA is taking “a step in the right direction,” but that it could do “much more to address this epidemic.” And in a statement, the AAP called on the FDA to back up its statement “with meaningful regulatory action to protect children from e-cigarettes and other tobacco products,” and urged the FDA to use its authority to immediately regulate all e-cigarettes.

The AMA brief outlines why regulation is so important.

E-cigs, flavored cigars hurt teens

The AMA and others in the brief tell the court that flavored e-cigarettes and cigar products are being used to addict a new generation of children and teens to nicotine, a habit that leads to cancer, heart disease, lung disease, stroke and death. The brief notes research showing that e-cigarettes lead to cigarette use and do not support smoking cessation.

E-cigarette use has surged among middle and high school students, even those with no history of smoking, and has become the tobacco product that young people most commonly use. Data from the 2015 Youth Risk Behavior Survey found that among sixth to 12- graders, 11.3 percent reported using an e-cigarette in the past 30 days, up from 1.1 percent in 2011. About 45 percent of high school students reported trying e-cigarettes, according to the survey cited in the brief.

The e-cigarette industry uses flavors and marketing techniques to attract youth, similar to historical techniques the tobacco industry used to target youth, the brief notes. For example, there are fruity and dessert-like flavors such as Unicorn Milk (strawberries and cream), Wild Watermelon, Summer Peach and FruitApalooza. The products often come in brightly colored packaging that resembles candy wrappers and advertisements use celebrity endorsements to depict e-cigarette’s as “glamorous, rebellious, sexy and masculine.”

The brief notes similar concerns for flavored and minicigars, or cigarillos, flooding the market with names like Maui Pineapple and Cherry Dynamite, along with candy-style packaging. Flavored cigar sales skyrocketed 50 percent since 2008 and now make up half of the entire cigar market.

The AMA and others caution the court that “if this agency delay continues, a full generation of adolescents will be at risk of a lifetime of addiction. They go on to say “that is the opposite of what Congress legislated with the Tobacco Control Act.”