Lawsuit on FDA’s tobacco, nicotine regulation policy dismissed

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Tanya Albert Henry
Contributing News Writer

In 2009, Congress knew it needed to stop companies that manufactured tobacco and nicotine products from deceptively marketing new products such as “light cigarettes” and e-cigarettes as “healthier alternatives,” particularly to the nation’s youth.

In an effort to stop those tactics, lawmakers passed the Family Smoking Prevention and Tobacco Control Act (TCA) and charged the Food and Drug Administration (FDA) with putting new tobacco products through premarket reviews, including labeling and marketing plans. The TCA prohibited manufacturers from selling new tobacco products unless company executives could prove that each product was “substantially equivalent” to those commercially available in 2007, or that allowing its sale would be “appropriate for the protection of public health.”

But, as the U.S. District Court for the District of Maryland found, FDA officials didn’t follow through with what Congress mandated it to do under the TCA and youth tobacco and nicotine use has soared. The court told manufactures they must file premarket applications by May 2020, saying it was not lawful or reasonable for the FDA to abdicate its statutory obligations by delaying review until 2021 for combustible products and 2022 for noncombustible products.

With the health of the nation’s youth at stake, the Litigation Center of the American Medical Association and State Medical Societies urged a federal appeals court to uphold the lower-court decision in the case, American Academy of Pediatrics (AAP), et al. v. United States Food and Drug Administration, et al. The AMA Litigation Center joined with the Public Health Law Center and other medical associations in filing an amicus brief supporting the AAP and other plaintiffs in the case.

“Despite the claims of the profit-driven industries behind them, these products are not safe. Like cigarettes, e-cigarette use leads to nicotine addiction, which interferes with brain development and cigar smoking causes cancer, heart disease, lung disease, stroke and death. The FDA violated Congress’s mandate to hold the line at the pre-TCA baseline with devastating impacts for public health.”
health,” the brief told the court.

But the 4th U.S. Circuit Court of Appeals dismissed the lawsuit, ruling that it is moot because there was new guidance issued in 2020 that supersedes the 2017 guidance that this complaint was based upon. The judges said it “leaves no possible meaningful relief that this court could grant” and that any ruling “as to the procedural or substantive reasonableness of the [2017 guidance] would amount to nothing more than an advisory opinion.”

Learn more about why the AMA has declared vaping and e-cigarettes a public health epidemic and what should be done about it.

Since Congress passed the TCA, JUUL—an e-cigarette that looks like a USB flash drive and is popular with young people—came on to the market. The latest trend? A Puff Bar. The precharged, prefilled, disposable e-cigarette comes in flavors geared toward youth such as banana ice, sour apple and “O.M.G.”—which is short for orange, mango and guava. Teachers report routinely finding Puff Bars in school trash cans.

Read why the move to ban some vaping flavors is only the first step in the fight.

**Youth usage rates soar**

E-cigarette use among youth has reached “epidemic” proportions, the AMA Litigation Center brief informed the court. In addition to e-cigarettes, new little cigars and cigarillos and flavored cigars designed and marketed to attract youth have flooded the market. Since 2008, the number of unique cigar flavors on the market more than doubled 250, up from 108.

The brief highlighted e-cigarette use statistics showing that among the nation’s high-school students, the proportion who reported e-cigarette use in the past 30 days more than doubled between 2017 and 2019, rising to 27.5% from 11.7%.

Find out more about the cases in which the AMA Litigation Center is providing assistance and learn about the Litigation Center’s case-selection criteria.