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Federal Judge Rules FDA Acted Illegally in Delaying Required Review of E-Cigarettes, Cigars

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

WASHINGTON, D.C. – In a major victory for America’s kids and public health, [a federal judge ruled](#) Wednesday that, in August 2017, the U.S. Food and Drug Administration (FDA) acted illegally by allowing e-cigarettes to remain on the market until 2022 before applying for FDA authorization and by permitting products to remain on the market indefinitely during review.

In March 2018, our public health and medical organizations, and several individual pediatricians, filed suit in federal court challenging this FDA decision. Our [lawsuit](#) argued the FDA’s decision was unlawful, put kids at risk and harmed public health. The FDA’s delay allowed e-cigarettes – including candy, fruit, mint and menthol-flavored products that clearly appeal to kids – to stay on the market for years without a review of their public health impact. The FDA also delayed the deadline for cigar manufacturers to file such applications until 2021.

On Wednesday, U.S. District Judge Paul W. Grimm of the U.S. District Court for the District of Maryland ruled in our favor, finding that the FDA had exceeded its legal authority and the FDA’s delay had played a role in the skyrocketing youth use of e-cigarettes. Judge Grimm ruled that the FDA’s delay gave “manufacturers responsible for the public harm a holiday from meeting the obligations of the law.”

“Instead of addressing public health concerns associated with tobacco use by minors and others, the August 2017 Guidance [which delayed the product review requirement] exacerbates the situation by stating, in essence, that manufacturers can continue to advertise and sell products that are addictive and that target a youth market ... at a time when minors’ use of tobacco products like e-cigarettes is at an epidemic level and rising,” Judge Grimm wrote.

“Arguably, the five-year compliance safe-harbor has allowed the manufacturers enough time to attract new, young users and get them addicted to nicotine before any of their products, labels, or flavors are pulled from the market, at which time the youth are likely to switch to one of the other thousands of tobacco products that are approved – results entirely contrary to the express purpose of the Tobacco Control Act,” Judge Grimm continued.

Judge Grimm has rightly recognized that the FDA's years-long delay in reviewing e-cigarettes and cigars is causing great harm to kids and public health and cannot be allowed to stand. Judge Grimm gave the plaintiffs 14 days to tell him what remedial action they want him to order and the FDA 14 days to respond. It is now the FDA's responsibility to take immediate action to protect our kids and require manufacturers to apply to the FDA if they want to keep their products on the market, including products like Juul that have fueled the youth e-cigarette epidemic.

Judge Grimm noted that manufacturers have had plenty of time to meet this requirement, writing that "manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making."

The lawsuit was filed on March 27, 2018, by the American Academy of Pediatrics and its Maryland chapter, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative and five individual pediatricians.

The health groups are being represented by the legal staff of the Campaign for Tobacco-Free Kids, lawyers at Democracy Forward Foundation and the law firm of Brown, Goldstein & Levy.

For background on the lawsuit and the FDA's delay of the product review requirement, see our [March 27, 2018, press release](#).

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