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Academy, health groups sue FDA over e-cigarette regulation delays

by Melissa Jenco, News Content Editor

The Academy and six other groups have filed a lawsuit against federal health officials for delaying a review of e-cigarettes and cigars.

The groups say the Food and Drug Administration (FDA) is putting children at risk by allowing the products to stay on the market without adequate information about their impact.

"The FDA's decision to delay product reviews leaves young people more vulnerable to kid-friendly e-cigarettes and cigars that may lead to a lifetime of tobacco addiction," they said in a news release Tuesday.

In 2016, the U.S. [surgeon general concluded](#) e-cigarettes are addictive and harmful to developing brains and earlier this year the [National Academies of Science, Engineering and Medicine](#) found users are at increased risk for switching to traditional cigarettes.

"A lot of kids think they're smoking harmless water vapor when in fact they are putting nicotine into their bodies, inhaling it into their lungs which is changing the reward centers of their brain, upregulating nicotine receptors and causing them to become addicted to nicotine," said Jonathan P. Winickoff, M.D., M.P.H., FAAP, a member of the AAP Tobacco Consortium and professor of pediatrics at MassGeneral Hospital for Children and Harvard Medical School.

They also are inhaling toxic compounds that can cause cancer and other serious lung problems, according to Dr. Winickoff.

Despite the dangers, about 11% of high school students use e-cigarettes, according to the [2016 National Youth Tobacco Survey](#), and many are attracted to flavors like gummy bear, cotton candy and chocolate. The devices also have become easier to hide as some [resemble pens or computer memory sticks](#).

In 2016, the FDA expanded its authority to regulate tobacco products to include e-cigarettes and cigars. The agency said within two years manufacturers would have to provide information on their products' ingredients for review. A year later, it announced manufacturers would not have to provide such information about cigars and other combustible products until 2021 and e-cigarettes until 2022 and could continue to sell them in the meantime.

The Academy, AAP Maryland Chapter, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative and five pediatricians filed their lawsuit against the FDA, Department of Health and Human Services and the heads of both agencies claiming they are exceeding their authority by delaying the review and violating the law because there was no chance for public comment.

Delaying the review "makes it far more difficult and costly to evaluate the health risks" of the products and keeps medical and public health groups from fulfilling their mission of educating the public about those risks, according to the lawsuit filed in federal court in Maryland.

Dr. Winickoff is not a party to the lawsuit but stressed the importance of FDA review of these products.

"The FDA is enormously important in protecting the U.S. public against corporations whose only responsibility is to the shareholder," he said. "Without the FDA, we really wouldn't be able to put restrictions on the sale and marketing of these products, so my hope would be that through FDA action children will be protected from the harms."



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- [AAP policy "Electronic Nicotine Delivery Systems"](#)
- [Information for parents from HealthyChildren.org about e-cigarettes](#)
- [Pediatrics journal e-cigarette article collection](#)
- [Surgeon general's interactive website about e-cigarettes geared toward parents and others who work with youths](#)