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Health Groups Sue FDA for Delayed E-Cig Regulation

— Delay poses a threat to children's health

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Multiple medical organizations have filed suit against the FDA, alleging that delays in the regulation of electronic cigarettes and cigars will unnecessarily expose children and teens to flavored, and other kid-friendly tobacco products, for years to come.

The lawsuit, filed in federal court Tuesday by the American Lung Association and others, challenges the FDA's 2017 decision to allow the products to stay on the market by delaying the deadline for applying for regulatory review.

The lawsuit contends that the years-long product review deadline delays (until 2022) for e-cigarettes, cigars, and other newly regulated tobacco products exceeds the FDA's authority under the 2009 law that extended the agency's regulatory authority to tobacco.

Other plaintiffs are the American Academy of Pediatrics and its Maryland chapter, the American Cancer Society Cancer Action Network, Campaign for Tobacco Free Kids, the Truth Initiative, and the American Heart Association, along with five individual pediatricians.

The legal action also asserts that the FDA delay is illegal because the public had no opportunity to comment on the change. E-cigarettes have grown into a $4-billion dollar industry in the U.S., even though there is little data on their long-term health effects, according to the *Associated Press*.

In a press release, the groups noted that while they "strongly support the FDA's new efforts to reduce nicotine levels in cigarettes to minimally or non-addictive levels," the decision to exempt e-cigarettes and cigars from review for years represents a threat to

teens and young adults as an example of this harm. The e-cigarette entered the market in 2015, and resembles USB flash drives, coming in flavors like creme brulee, mango, and fruit medley.

The manufacturer says each JUUL cartridge, which delivers about 200 puffs, contains as much nicotine as a pack of cigarettes.

The FDA extended its regulatory authority to e-cigarettes, cigars, and other previously unregulated tobacco products in August of 2016, stipulating that products already on the market must show that they pose no new health risks. Under the original staggered timeline for this regulatory review, manufacturers of e-cigarettes and other newly regulated products would have 2 years to apply for a new tobacco product application with the agency. The FDA would have an additional year to review the application.

In August 2017, the FDA delayed the deadline for filing until August of 2021 for cigars and other newly-regulated combustible products and until August of 2022 for e-cigarettes. FDA officials also set no deadline for completing its review of the products.

In delaying the filing deadline the FDA "offered no meaningful justification for ripping a hole in the statutory framework by more than half a decade, newly deemed products from premarket review -- review FDA previously described as 'central' to the regulatory scheme Congress enacted for tobacco products," the lawsuit states.