In Public Health Win, Federal Court Sets 10-Month Deadline for E-Cigarette Makers to Apply to FDA to Keep Products on the Market

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 an important victory for public health and especially for the nation's kids facing an epidemic of e-cigarette use, a federal judge today set a 10-month deadline of May 12, 2020, for e-cigarette manufacturers to apply to the FDA and submit their products for public health review if they want to keep them on the market. Products that do not submit applications by the deadline are subject to FDA enforcement to remove them from the market, and those that do submit applications can stay on the market for up to one year while the FDA considers the applications. It is critical that FDA use this legally required review process to remove from the market products that appeal to kids and have fueled the youth e-cigarette epidemic.

While our organizations had urged an even shorter application deadline of 120 days from the judge's order, the new deadline is a dramatic improvement of more than two years from the current deadline of August 2022 set by the FDA. It is also an improvement that the judge set a one-year deadline for the FDA to consider product applications, compared to current FDA policy of allowing products to stay on the market indefinitely during review.

Today's order was issued by U.S. District Judge Paul W. Grimm in a case brought by our public health and medical organizations, along with five practicing pediatricians. On May 15, Judge Grimm ruled that the FDA acted illegally when it allowed e-cigarettes to remain on the market until August 2022 before applying for FDA authorization and by permitting products to remain on the market indefinitely during review.

As Judge Grimm stated in his May ruling, the FDA's delay in reviewing e-cigarettes allowed manufacturers to introduce and market products that appeal to kids and set the stage for the youth e-cigarette epidemic. Manufacturers have introduced sweet-flavored, high-nicotine products like Juul without any review of their appeal to kids or public health impact. The result was a 78% increase in e-cigarette use among high school students in 2018, to 20.8% of students.

Judge Grimm today again emphasized that e-cigarette manufacturers have long been on notice that they are legally required to file applications and must receive FDA authorization in order to keep their products on the market, but have failed to do so. As Judge Grimm wrote, "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so." He added, "the record offers little assurance that, in the absence of a deadline for filing, the industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." E-cigarette manufacturers have no one to blame but themselves if they are not ready to submit the required applications.

Judge Grimm's order also imposes the May 2020 deadline on cigar manufacturers, instead of the 2021 deadline previously set by FDA.

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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