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FDA, Pressed By Dems To Step Up E-Cig Oversight, Says It Lacks Resources

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House Energy & Commerce Committee ranking Democrat Rep. Frank Pallone (NJ) said FDA needs to act more quickly to clear the market of illegal e-cigarettes and vaping products, arguing it's hard to make the case to colleagues the agency should get more funding and authorities unless it can make progress on the problem. But a top FDA regulator suggested the agency's hands are tied unless it gets more resources first.

At a Tuesday (Sept. 10) committee hearing, many lawmakers said FDA needs to act more quickly to clear the market of illegal products and seize those that are being sold.

But Brian King, director of FDA's Center for Tobacco Products, said the center lacks the resources to conduct seizures from retail locations selling illegal products, noting that such actions would mean participating in thousands of district court cases. He said FDA needs time to conduct investigations of suppliers and that other agencies, including law enforcement, need to step up as well.

While Pallone agreed that FDA needs more resources and authorities, he said it's difficult to make that argument to colleagues if the agency can't show that it's making progress. "You just make it seem hopeless," he said.

King said he is optimistic about FDA's work on illegal products and the agency has made significant progress in youth smoking rates; FDA recently announced a survey shows the lowest rate of e-cigarette use among middle and high school students in a decade.

At the hearing, King said only 34 e-cigarette and vaping products have been approved out of the approximately 27 million submitted to FDA because only those few have met the bar for showing approval is in the interest of protecting public health.

Several lawmakers, including Rep. Morgan Griffth (R-VA), chair of the E&C subcommittee on oversight and investigations, criticized FDA for the small number of e-cigarette approvals. Griffith said FDA should not make it unnecessarily difficult for e-cigarettes to reach the market when they can be effective tools in helping people quit smoking cigarettes, which remain freely available.

But King said the standard for e-cigarettes should not be changed and that FDA has acted in accordance with the law and for protection of public health, including preventing youth non-smokers from starting with e-cigarettes. He said the burden is not on FDA to approve more products but on manufacturers to show their products can meet the standard Congress set specifically for e-cigarettes.

"The different pathways were set by Congress," he said.

King said the foundation set by Congress on tobacco regulation is strong and lawmakers just need to make changes accommodating the growth of e-cigarettes, like requiring manufacturers of electronic nicotine products to pay user fees. That's been proposed through the Tobacco User Fee Modernization Act, sponsored by Rep. Jennifer McClellan (D-VA).

FDA's regulation of e-cigarettes is also set to be scrutinized by the Supreme Court. The court will decide the case *Wages and White Lion Investments, LLC v. FDA* in its next term. The case revolves around whether FDA

must individually consider every product application for flavored e-cigarettes, rather than rejecting them *en masse* because of their impact on youth nicotine use.

One stakeholder weighing in on the case echoed Griffith's arguments in the hearing.

An *amicus* brief was submitted by Global Action to End Smoking, a controversial organization which advocates for e-cigarettes as a tool to help adults quit smoking combustible cigarettes and which the World Health Organization and others allege is a front for the tobacco industry. The organization was founded with funding from tobacco company Phillip Morris Industry, though the company says it has stopped accepting that money.

In its brief, Global Action to End Smoking says e-cigarettes are the best tool to allow adults to switch away from smoking combustible cigarettes. It says availability of flavored options can play a role in helping smokers quit, by making it more likely than they will make the decision to use e-cigarettes instead and more quickly they will stick to e-cigarettes instead of returning to combustible cigarettes. It also argues e-cigarettes are more effective alternatives that nicotine replacement options like patches and gums.

The group says FDA is contradicting Congress' intentions to make harm reduction products available through the Tobacco Control Act by effectively imposing a blanket ban on flavored e-cigarettes.

"In short: extensive experience, combined with mounting scientific evidence, shows that flavored e-cigarettes are exactly the sort of tool that Congress envisioned when it told FDA to identify and encourage the use of less-harmful alternatives," the organization wrote.

A coalition of medical associations and public health organizations also submitted an amicus brief in the pending Supreme Court case over FDA's regulation of e-cigarettes and vaping products, arguing that a judgment against the agency would significantly harm its efforts to keep nicotine products out of the hands of youth.

"Respondents' e-liquids and other flavored e-cigarette products have fueled persistently high rates of youth usage of highly addictive and harmful products. In denying marketing authorization for Respondents' products and thus requiring that they be removed from the market, FDA acted to protect public health," the brief says.

The groups include the American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Louisiana State Medical Society, Parents Against Vaping E-cigarettes, and Truth Initiative.

The organizations argue industry has deliberately used flavors and colorful designs to market their products to youth and that FDA's refusal to authorize such products is appropriate for the protection of public health, not arbitrary or capricious. Flavored products, they write, are more likely to lead to initial use as well as to more frequent repeated use.

FDA's denials of marketing orders, the groups say, were "based on (1) overwhelming evidence of harm to youth from flavored e-cigarette products, including Respondents' flavored e-liquids, and (2) a lack of demonstrated benefit from those flavored products to adults who smoke." Companies that submitted applications, they add, failed to establish through existing literature or their own studies that flavored products help adults quit smoking.

Numerous states also filed a brief in support of FDA's position. They argue that states have adopted numerous measures to restrict sales of flavored e-cigarettes, but that federal action is needed to stop the products from reaching youth through interstate commerce.

"*Amici* States cannot fully prevent flavored e-cigarettes from crossing state lines, especially because, while several states have enacted restrictions on flavored e-cigarettes, many others have not," the brief says. "The wide variety of restrictions and laws from one state to the next renders enforcement efforts difficult where such products flow easily through interstate commerce. And enforcement is further complicated by the ready availability of flavored e-cigarettes online."

The brief argues FDA must be able to exercise its authority to deny applications, rather than leaving the issue up to state and local jurisdictions.

The state signatories are Massachusetts, Arizona, California, Colorado, Connecticut, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island,

Vermont and Washington, as well as the District of Columbia.

Sixteen Democratic members of Congress submitted a brief saying FDA is correct in interpreting the Tobacco Control Act to allow *en masse* denials of tobacco products that appeal to youth.

“FDA correctly did the job Congress laid out for it when it reviewed--and denied--Respondents’ applications. The Fifth Circuit’s conclusions to the contrary rely on a misunderstanding of FDA’s role as an expert agency,” the lawmakers wrote.

Their brief argues FDA’s marketing denials follow Congress’ “clear instructions” in the Tobacco Control Act.

The members of Congress who submitted the brief include Pallone and Senate Majority Whip Dick Durbin (D-IL), as well as Democratic Sens. Jeff Merkley (OR), Ron Wyden (OR), Richard Blumenthal (CT), Tammy Baldwin (WI), Jack Reed (RI), Elizabeth Warren (MA), Jeanne Shaheen (NH) and Ed Markey (MA), and Democrat Reps. Raja Krishnamoorthi (IL), Diana DeGette (CO), Rosa DeLauro (CT), Kim Schrier (WA), Debbie Wasserman Schultz and Barbara Lee (CA). -- *Jessica Karins* (jkarins@iwpnews.com)

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