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Flavored e-cigarette company challenges FDA marketing denial

By Nate Raymond

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A claim this epically loaded shouldn't be dropped in the lede to what is supposed to be a brief note of an appellate hearing. The case has nothing to do with "youth vaping" but with regulatory overreach. And if Reuters is intent on shoehorning the subject into its coverage, it should note that by the government's own data youth vaping is sharply down in recent years.

A federal appeals court on Monday weighed whether the U.S. Food and Drug Administration wrongly barred a flavored e-cigarette manufacturer from marketing its products, in a case that could curtail the regulator's efforts to ~~combat youth vaping~~ take away the most effective smoking cessation device from adults.

Not just "some promise," the head of FDA's Center for Tobacco Products cautioned that denying adults who want to quit smoking access to vaping products would be a "public health outcome that should be avoided if at all possible."[1]

Which anti-smoking groups and on the basis of what evidence? To give space to third parties' accusation that thousands of small businesses are illegally "targeting children" with age-restricted products is bad journalism. To do so in the absence of any substantiation is outrageous.

The FDA had viewed e-cigarettes as having some promise to help adult smokers transition from conventional cigarettes, but faced pressure to restrict the sale of flavored e-cigarettes, which anti-smoking groups said targeted children.

It didn't just "differ". Long-term studies were not required in earlier guidance.

The requirement for long-term studies differed from earlier FDA guidance and was a "surprise switcheroo," a 5th Circuit panel concluded in October when it allowed Triton to keep selling e-cigarettes until another panel could hear its appeal.

Notice how Reuters frames this quote from the judge who finds Triton's case compelling. First, she's "conservative," which implies that she's biased - unlike the other judges on the panel, whom everyone knows are completely objective. Then the reporter hints at the idea that the judge might be skeptical of COVID vaccines to make her look like a kook, when she was in fact referring to the FDA's poor messaging and mismanagement of the vaccine approval process.

At Monday's oral arguments, Eric Heyer, Triton's lawyer at Thompson Hine, said the FDA's requirement was "arbitrary and capricious, a position conservative U.S. Circuit Judge Edith Jones appeared to agree with.

"It seems to me that's the height of arbitrariness and capriciousness, to say we are the FDA, trust us, which I might say some of us are becoming skeptical about in light of recent vaccine experiences," she said, alluding to COVID-19 vaccines.

Yes, not only are flavors like this appealing to adults who vape to quit smoking, they're essential. One study found that 1 in 3 young adult vapers would switch back to cigarettes if flavors were banned. Another survey found that over a quarter of adults would turn to black markets to continue using flavored vaping products if they could no longer access them equally.[2,3,4]

U.S. Circuit Judge Gregg Costa asked whether Triton's products, such as one called Jimmy the Juiceman Strawberry Astronaut, were really targeted to adults.

"That's supposed to be appealing to a 40-year-old?" he asked.

Except the FDA originally told companies applying for approval that they didn't need to submit long-term clinical studies. Companies like Triton spent millions of dollars to submit studies that satisfied the FDA's initial guidance only for the agency to change the standards AFTER their applications were submitted. Let's not forget that the FDA did not publish its final guidance until October 5, 2021 - after it had already issued denial orders for thousands of product applications.

And U.S. Circuit Judge Catharina Haynes questioned why companies like Triton did not have enough time to develop such support for their products' health benefits for adults given the years they have had to prepare for FDA regulation.

The FDA in 2016 deemed e-cigarettes to be tobacco products like traditional cigarettes subject to agency review under the Tobacco Control Act. Manufacturers were ultimately given until 2020 to seek approval to market them.

Missing is any discussion of the guidance—or lack thereof—given to manufacturers seeking such approvals from the FDA. Readers also deserve to know that this is an onerous, and very expensive process, and that many vape flavor manufacturers are small businesses without the legal firepower or bureaucratic know-how to navigate the "switcheroo" dropped on them by FDA.

Hmmm, do you think it could be because the FDA kept changing the requirements for the types of studies it wanted?

"All of these years have passed with little in the way of detailed studies," Haynes said.

1. https://www.clivebates.com/documents/MarylandZellerDeclarationJune2019.pdf
2. https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6
3. https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntab154/6332852
4. https://www.sciencedirect.com/science/article/pii/S0306460321003373?via%3Dihub