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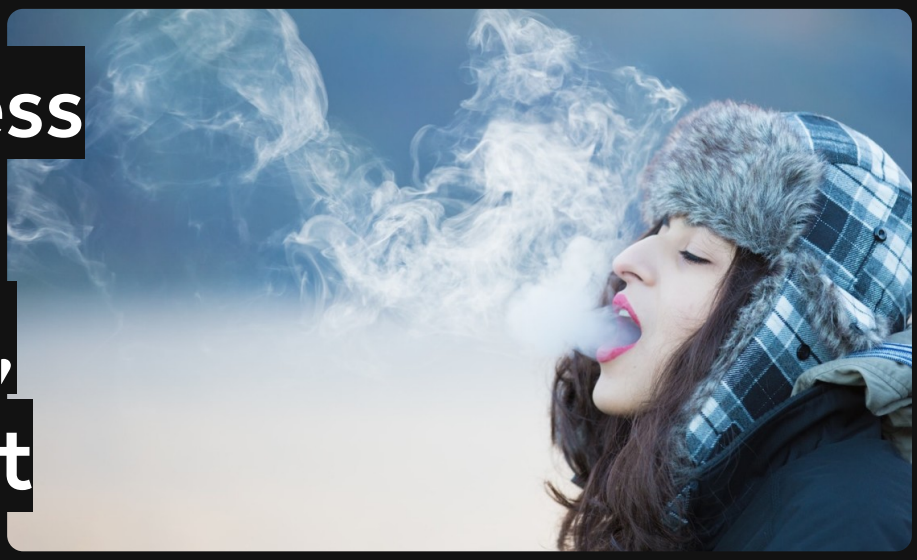
FDA to Assess Tobacco Regulations, Enforcement



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The increasing number of novel tobacco products has prompted the agency to review its processes, procedures and leadership structure

By Jennifer Taylor

Work is poised to get underway on a somewhat rare internal review by the U.S. Food and Drug Administration (FDA) that could impact how the agency processes new tobacco products and enforces the sale of them by retailers.

Susan Winckler

Last month, FDA commissioner Robert M. Califf announced in a statement that "greater challenges lie ahead" as the agency navigates complex policy issues and determines enforcement activities for an increasing number of novel tobacco products that could have "significant consequences" for public health. The FDA has commissioned the Washington D.C.-based Reagan-Udall Foundation, an independent partner organization for the agency, to conduct the evaluation, which will also review FDA's Human Foods Program, including the Office of Food Response and Policy (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), as well as relevant parts of the Office of Regulatory Affairs (ORA).

The scope of the work examining the FDA's Center for Tobacco Products (CTP) will focus on how the agency currently operates and how it could do so in a changing environment, Susan Winckler, CEO of the Reagan-Udall Foundation, told TreatmentMagazine.com. Specific details on exactly what the foundation will be examining were not forthcoming at the time, but Winckler noted that the FDA is in the middle of "an onslaught" of work, and the Reagan-Udall Foundation will be evaluating how the agency can better navigate all that is coming to the CTP and be more strategic in its regulatory responsibility.

The evaluation is expected to take 60 business days once it is initiated. Upon completion, Winckler said, a report with recommendations will be submitted. "We'll all be working to look at [the CTP] and put that into the information synthesis, as well as [have] an opportunity to meet with as many stakeholders as we can," Winckler says.

A Need for Change

The recent legal back and forth between the FDA and e-cigarette manufacturer Juul coupled with the agency's response to the national baby formula shortage—both drawing public ire—prompted the agency's top official to consider if changes in operations and leadership were warranted.

"In light of certain events that have transpired in recent months, the commissioner has determined that these areas deserve a closer evaluation of certain processes, procedures and resourcing, as well as a look at the current leadership structure," an FDA spokesperson told TreatmentMagazine.com.

> **Recently, according to the FDA, a growing number of companies ... began using synthetic nicotine to make their products in an attempt to evade regulation.**

In June, the FDA banned the sale of all tobacco products manufactured by Juul Labs Inc., when it issued a marketing denial order (MDO) requiring the e-cigarette manufacturer to stop selling and distributing all of its products on the U.S. market. The FDA said Juul didn't submit sufficient data on toxicology. Within 24 hours, Juul sued the FDA, and a federal court ruled on June 24 that Juul's products can stay on the market for now. On July 5, the FDA itself stayed its ban while it reviewed the MDO.

Recently, according to the FDA, a growing number of companies—including manufacturers of some of the e-cigarette brands most popular with kids—began using synthetic nicotine to make their products in an attempt to evade regulation. An important new federal law went into effect in April clarifying the FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine, and the agency continues to implement the law.

Tobacco control advocates and the FDA noted in September 2020 the unprecedented task of reviewing applications for more than 6.7 million "deemed" new tobacco products. Most applications were premarket tobacco product applications (PMTAs) for electronic nicotine delivery systems (ENDS) products, like e-cigarettes, which had never previously been through the FDA review process, an FDA spokesperson said.

The FDA maintains that despite these challenges, it has taken actions on approximately 99% of these products, including the authorization of marketing (marketing granted orders or MGOs) for 23 e-cigarette products and issuing MDOs for more than 1 million flavored ENDS products.

Top photo: Saad Chaudhry

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