FDA suspends enforcement of stricter standards for e-cigarette, cigar industry

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By Juliet Eilperin, the Washington Post

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WASHINGTON — The Trump administration has suspended enforcement of a rule finalized last year that imposed strict oversight over electronic cigarettes and cigars for the first time.

The move, which the Justice Department revealed in court filings Monday night in both the District of Columbia and Alabama, comes as the vaping and tobacco industries are launching a concerted effort to roll back the Food and Drug Administration regulation through both legislation and litigation. A bipartisan group of lawmakers had tried over the weekend to insert language into a must-pass funding bill that would have exempted thousands of products from FDA scrutiny.

In the motions, Justice Department attorneys joined with industry groups challenging the rule to ask for an additional three-month delay in two different cases to give “new leadership personnel” at the Health and Human Services “additional time to more fully consider the Rule and issues raised in this case.”

According to FDA officials, the agency is postponing any deadline established under the rule - which extends the FDA’s regulatory authority to all tobacco products, including e-cigarettes, cigars, and hookah and pipe tobacco - set for May 10 or later.

As a result, as of next week, cigar manufacturers will not have to submit their plans for putting addictiveness warnings on their products. Information on what ingredients are contained in e-cigarettes and cigars will not have to be submitted starting Aug. 8, and interstate commerce of products including the label of “light,” “low” or “mild” will not be banned as of that date.

Aspects of the rule that went into effect last summer, including provisions that bar the sale of these products to anyone under 18 or the distribution of free samples, are still in effect.

Matthew Myers, president of the Campaign for Tobacco-Free Kids, said the legal and legislative jockeying shows how “the cigar and e-cigarette industry have waged a war to alter, gut and basically repeal” what public health advocates see as “critical.”

“From a pure public-health standpoint, there’s been no factual change from the overwhelming public record that prompted promulgation of the rule,” Myers said. “The administration’s decision yesterday means that the public will continue to lack the information what products are on the market, what effect they’re having and what’s in them.”

While the administration has not indicated what it will ultimately do about the 2016 rule, the decision to side with the industry in delaying the rule represents a sharp policy shift from the previous administration. Industry officials are optimistic that they will get a favorable hearing from the administration, especially considering that a large number of lawmakers are on their side.

“What we’ve got to do is rein it back in,” said Tobacco Vapor Electronic Cigarette Association president Ray Story, referring to the 2016 rule. When it came to the administration, he added, “I certainly think that they are going to curb regulation, just to curb regulation, because it’s bad for business.”

But he added, “I certainly don’t think they’re going to lift the veil and say, ‘Here you go, e-cigarettes, you can do whatever you want to do.’ “

Several senior Trump administration officials have ties to the tobacco and vaping industries. Chad Readler, the acting assistant attorney general for the civil division - whose name was on a March 1 brief asking the U.S. District Court for the Middle District of Alabama Northern Division for an extension in a case involving the rule - represented R.J. Reynolds at the law firm Jones Day before joining the Justice Department.

And newly confirmed FDA head Scott Gottlieb served on the board of the e-cigarette firm Kure until May 2016 and retained stock in the company even after he was nominated to his post. He pledged to sell his stock if he won Senate confirmation, which happened last week. He also said he would not weigh in on matters involving Kure for a year following his resignation from the board, which means this recusal period ends sometime this month.

The Justice Department said in a filing that Readler’s name appeared in filings “as a matter of course,” but he had not participated in the case.

An FDA spokesman referred any questions related to Gottlieb to the White House, which did not respond immediately.

Sen. Jeff Merkley of Oregon, the top Democrat on the appropriations panel overseeing the FDA, said Gottlieb’s one-year recusal “does not solve the conflict of interest at all.”

The Obama administration vigorously defended what is known as the “deeming” rule, which got its name because the Tobacco Control Act of 2009 gave the FDA jurisdiction over cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and “any other tobacco products that the [HHS] Secretary by regulation deems to be subject to this chapter.” It was finalized a year ago, and challenged by the Cigar Association of America and multiple e-cigarette companies.

Vaping proponents argue that their products can help wean smokers off combustible cigarettes, while critics argue that nicotine remains highly addictive and many e-cigarettes appeal to young people because of their combinations of candy and fruit flavors.

From 2011 to 2014, according to a brief the FDA filed in August, use of e-cigarettes among high school students rose from 1.5 to 13.4 percent.

“Vaping has evolved into an industry that’s targeted at our children,” Merkley said, adding that becoming addicted to nicotine “can have lifelong health impacts.”

Keith Nelson, the TVECA’s chief political officer, said that when it comes to the health impacts of electronic cigarettes, “most of it is somewhat premature, because this is a nascent industry.”

But he noted that two major e-cigarette companies - NJOY and Electronic Cigarettes International Group Ltd. - have gone bankrupt since the rule went into effect. And he added that the rule, which applies to any e-cigarettes introduced since Feb. 15, 2007, requires firms to conduct “not just health-based research but behavioral research and psychological research on the impact of your product and all the combinations of these products.

“The numbers start to add up,” Nelson said. “The industry needs some relief.”

While major tobacco companies such as R.J. Reynolds and Altria, which contributed $1 million and $500,000, respectively, to Trump’s inauguration, have not sued the federal government over the rule, they have pressed lawmakers to curtail it. Both firms have subsidiaries that manufacture electronic cigarettes.

“You can’t simply apply antiquated regulations on a category that did not exist when those regulations were passed,” said David Howard, a spokesman for Reynolds American Services Company, in a statement. “We do support,

however, a regulatory framework based on level of risk, one that enables responsible innovation of products that may present less risk compared to cigarettes."

The companies back language that Reps. Tom Cole, R-Okla., and Sanford Bishop Jr., D-Ga., sought to attach to this week's continuing resolution, which would have given the FDA oversight only over vaping products introduced as of Aug. 8, 2016. That provision was blocked by Senate Democrats.

A separate bill, which Rep. Duncan Hunter, R-Calif., introduced last week, would change the FDA classification so that e-cigarettes would no longer be classified as tobacco products.