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FDA commissioner calls meetings with e-cig makers 'constructive'

By Richard Craver Winston-Salem Journal Oct 31, 2018

Reynolds American Inc. confirmed Wednesday it supports the Food and Drug Administration's expected recommendation that Congress raise the national minimal age for buying all tobacco products to 21.

The company said its pledge will be included in a submission next week to FDA Commissioner Dr. Scott Gottlieb.

The agency has given the five largest electronic cigarette manufacturers 60 days to provide a plan on how they would curb youth use of e-cigs.

Those manufacturers — Juul Labs Inc., R.J. Reynolds Vapor Co, Fontem Ventures, NuMark LLC and Japan Tobacco International USA Inc. — represent about 97 percent of the U.S. e-cig market share. Juul leads at 74.5 percent, followed by Reynolds at 9.6 percent, according to the latest Nielsen data.

"Youth access to vapor products is a concerning issue, and we share (the commissioner's) commitment that youth should not use e-cigarettes or any tobacco product," Reynolds spokesman Michael Shannon said.

The Reynolds decision was disclosed the same day that Gottlieb said he had “constructive meetings” with the manufacturers as the FDA prepares “to forcefully address youth use” of the products.

Gottlieb indicated in a statement Wednesday that disclosing the next “in an escalating series of steps” would come as soon by mid-November.

Reynolds said it “identified several specific actions that our companies would take, and additional regulatory proposals we believe that FDA should consider implementing across the industry.”

Those include:

- Supporting legislation to raise the age of purchase to 21 for all tobacco products;

Reynolds said its support of a minimum age of 21 also extends to any potential state action.

- Imposing penalties to contracted retailers who sell to youth; and
- Implementing additional safeguards on online purchases to address youth purchase and straw purchases.

Shannon defined straw purchases as “any person who purchases on behalf of an underaged person.”

Altria Group Inc. threw its support Friday behind minimum age of 21. Juul Labs Inc., maker of top-selling e-cig Juul, pitched its support in April and began in August requiring age-21 verification for online sales.

Six states — California, Hawaii, Maine, Massachusetts, New Jersey and Oregon — have passed laws mandating age 21. There are at least 350 municipalities that have done the same, including Boston, Chicago, Cleveland, Minneapolis, New York City, San Antonio and Kansas City, Mo.

A bipartisan bill was introduced by Rep. Donny Lambeth, R-Forsyth, in the N.C. General Assembly in March 2017 to raise the smoking and vaping age to 21. House Bill 435 was sent immediately to the Committee on Rules, Calendar and Operations and has not been acted upon since.

More restrictions

Among the restrictive elements the FDA is considering include: how different types of e-cig products are used by kids; the popularity of various products, such as cartridge-based e-cigs popularized by Juul; the popularity of non-tobacco flavors; and the strength of various distribution methods in ensuring robust age verification.

Gottlieb has said for months that youth use of e-cigs has reached “epidemic levels.” Gottlieb told CNBC on Oct. 21 that in the past year, there has been a 77 percent increase in high school students’ use of e-cigs based on a small sample size nationally.

“For the e-cigarette industry, my message was simple: step up,” Gottlieb said Wednesday.

“Even as the FDA builds a framework to mandate additional restrictions and actions to address these trends, we welcome voluntary steps by companies to address these concerns.”

Gottlieb said the manufacturers “presented thoughtful proposals.”

According to Gottlieb, among the suggestions made by the manufacturers include: the FDA restrict distribution of certain flavored products to channels with enhanced age verification processes; the FDA require certain products that are more appealing to kids to come off the market until these products receive premarket authorization from the agency.

Wells Fargo Securities analyst Bonnie Herzog said Wednesday she was “particularly struck by the commissioner’s collaborative tone toward the top tobacco manufacturers.”

“We continue to believe changes will include some combination of bans/restrictions on sales of certain e-cig flavors, excluding tobacco and menthol flavors, which we believe are too important to adult smoker conversion and fraught with potential unintended consequences,” Herzog said.

Juul draws scrutiny

Juul entered the mainstream retail marketplace in January 2015. Juul is sold in the form of a pen or a USB flash drive that's easy to use — and hide — because the vapor typically does not have a smell and quickly dissipates.

That product model and non-tobacco flavorings have drawn scrutiny from the FDA and public health groups because they say it appeals to teenagers.

On Friday, NuMark parent Altria Group Inc. said it was removing the pod versions of its e-cig from the retail marketplace, namely MarkTen Elite and Apex by MarkTen products.

“In order to firmly confront and reverse these trends — and fulfill the central premise of our public health mandate — we may need to take actions that might narrow the off-ramp from smoking for adults in order to close the on-ramp to nicotine addiction to kids,” Gottlieb said.

“Some (manufacturers) stated explicitly that preventing youth use must be a priority, and that any potential benefits of e-cigarettes for adult smokers cannot justify significant increases in youth use and addiction.”

Shannon said that Reynolds “agrees with the FDA that vapor products can play an important role for adult smokers looking for potentially less harmful alternatives to cigarettes.”

“We understand the increase in youth vapor use is challenging the careful balance that FDA is pursuing both to provide adult smokers with alternatives and prevent youth use.”

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Letter: JUUL backs Tobacco 21



(Steven Senne | AP file photo) In this April 11, 2018, photo, a high school student uses a vaping device near a school campus in Cambridge, Mass. Though education surveys show vaping use is down among Idaho high school students, health officials are concerned about vaping's rising popularity among teens nationwide. According to the National Institute of Drug Abuse, vaporized nicotine saw a dramatic uptick from 2017 to 2018 nationwide.

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Our mission is to improve the lives of the world's 1 billion adult smokers by eliminating cigarettes, because smoking is still the leading cause of preventable death.

In Utah, 1,300 adults die from smoking-related illnesses annually, which is why we believe it is critical adult smokers have access to a true alternative to combustible cigarettes.

The fact it has taken off with youth is appalling to us. Many of us at JUUL Labs are parents and know that strong action is required.

We implemented an aggressive action plan in November, overhauling our business with renewed focus on limiting youth access, appeal and use of JUUL products.

We strongly support raising the purchasing age for tobacco products, including vapor products, to 21 in Utah. Backing Tobacco 21 legislation is vital, as we believe it will take the industry and lawmakers working together to solve this urgent problem.

Ashley Gould is the chief administrative officer for JUUL Labs, based in San Francisco, Calif.

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