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On July 15, 2014, the *New York Times* published the attached article, "E-Cigarette Makers Are in an Arms Race for Exotic Vapor Flavors," that documents the importance of flavored e-cigarettes, particularly in attracting youth to the use of nicotine.

The FDA should seriously consider this information, particularly the change in NJOY's assessment of the effects of flavors on youth between when it was not using flavors to when it decided to start using flavors to maintain its market share, and prohibit the use of flavors in e-cigarettes as part of the current rulemaking (and not delay action to a subsequent rule making).

The e-cigarette companies state that flavors are important for attracting not only youth but also adults to their products. The FDA needs to resist the urge to focus entirely on youth and consider these effects on adults, because the Family Smoking Prevention and Tobacco Control Act requires the FDA to apply a *population* public health standard to the entire population not just to youth.

Stanton A. Glantz, PhD Professor and Director



The New Hork Times http://nyti.ms/1ku9Hi4

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E-Cigarette Makers Are in an Arms Race for Exotic Vapor Flavors

By MATT RICHTEL JULY 15, 2014

Twista Lime, Kauai Kolada, Caribbean Chill, Mintrigue. Exotic cigarette flavors like those were banned in 2009 out of concern they might tempt young people.

But the flavors tobacco companies once sold look like plain vanilla compared with the flavor buffet now on offer — legally — by the fast-growing electronic cigarette industry.

News on Tuesday that Reynolds American had agreed to buy Lorillard, uniting two of the nation's biggest tobacco companies, highlighted how important e-cigarettes have become to the declining tobacco industry. Both Reynolds and Lorillard have pushed hard into e-cigarettes, which offer a new way of delivering a puff of nicotine.

For now, those companies' flavors are relatively modest, though they may feel pressure to expand into the explosion of competition for the consumer palate, with e-cigarette flavors such as banana cream pie and cotton candy.

Across the e-cigarette industry, more than 7,000 flavors are now available and, by one estimate, nearly 250 more are being introduced every month. The array of tastes goes far beyond anything cigarette companies ever tried.

Flavors have become central to the conversation because e-cigarette makers say that the rainbow of tastes differentiates them from deadly cigarettes.

But the claim that e-cigarette flavors won't attract children has prompted an outcry from some policy makers,

1 of 5 7/23/2014 6:54 AM who say consumers have been down this road before with tobacco. Federal health authorities have outlawed most cigarette flavorings except menthol, arguing that they lure the young into nicotine addiction. While the Food and Drug Administration has proposed regulations for e-cigarettes, it has not limited marketing or flavors, which the agency is studying.

At a Senate committee hearing in late June, lawmakers denounced manufacturers for marketing practices that they said appealed to children, including the embrace of flavors that are forbidden in ordinary cigarettes.

"I'm ashamed of you," Senator Jay Rockefeller, Democrat of West Virginia, told several executives. "You're what's wrong with this country."

Jason Healy, the president of Blu eCigs, told the Senate Committee on Commerce, Science and Transportation that the average age of people using cherry flavored e-cigarettes, for example, was 40. Such flavors "decrease the ability or possibility of adult users who use e-cigs switching back" to cigarettes, he said. Blu eCigs, a subsidiary of Lorillard, is being sold to the British company Imperial as part of the deal announced on Tuesday. Lorillard and Reynolds said they would focus their e-cigarette efforts on Reynolds' product Vuse, which in June was introduced in 15,000 stores nationwide.

For now, Vuse has only two flavors, original cigarette flavor and menthol, but the market is changing quickly as evidenced by the experience of other leading e-cigarette companies. Most notable is the experience of NJOY, which has turned to flavors to help stanch plummeting market share.

Ten months ago, NJOY's chief executive, Craig Weiss, said in an interview that other manufacturers used flavorings "to attract children." NJOY, he said then, was avoiding candy- and fruit-like flavorings, in part because "they drive regulators crazy."

NJOY's investors include Sean Parker, the Napster co-founder and former president of Facebook, and Bruno Mars, the pop star.

But NJOY's share of the convenience store market has gone into free fall, dropping more than half in the last year to less than 10 percent, according to Wells Fargo Securities. Consumer surveys suggest that most people who use e-cigarettes — including those who have smoked — tend to prefer flavors other than tobacco. In the next few

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weeks, NJOY plans to expand into flavors like "Butter Crumble" and "Black and Blue Berry." Mr. Weiss said in an interview that the company had little choice after focus groups showed that flavors were "critical."

"Flavor is essential to vapers' satisfaction," Mr. Weiss said. He added that research funded by his company showed that flavors "provide no additional appeal to youth."

The e-cigarette market is rapidly shifting, and flavors are central to that. Viking Vapor, one of hundreds of websites selling e-cigarettes, offers 13 pages of alphabetized flavors, from Apple to Watermelon Menthol. But the market for disposable e-cigarettes, commonly found in convenience stores and sold by the likes of NJOY, Vuse and Blu eCigs, appears to be slowing — consumers seemed to be switching to more powerful devices, analysts said. According to Wells Fargo, consumer sales of e-cigarettes at convenience stores fell 17 percent in the month that ended June 7, after falling 10 percent the month earlier — the first time since e-cigarettes came onto the market that consumers spent less at convenience stores. Wells Fargo hypothesized that sales were gravitating to the Internet and "vape" stores, where figures are harder to measure.

Some in public health circles see the debate over flavorings as a sideshow. The central question, they say, is whether e-cigarettes are effective tools to get people to stop smoking tobacco. Others say the issue of flavors crystallizes the debate about the risks and benefits of these products, which many consider far safer than conventional cigarettes. At the same time, there is widespread concern that use of e-cigarettes will renormalize the act of smoking and invite in a new generation of participants, particularly through the lure of flavors.

"It defies logic to think that such flavors would not make e-cigarette use more appealing and even normal for children," said James Pankow, a chemistry professor at Portland State University in Oregon, who has studied cancer risk from cigarettes.

Mr. Weiss of NJOY, hoping to address personal concerns about flavors, funded a study this year to see if the company's new flavors would appeal to young nonsmokers. The study, an online survey conducted by Saul Shiffman, a pharmaceutical industry consultant and psychology professor at the University of Pittsburgh, found that young people were not particularly attracted to the flavors. Flavors did make e-cigarettes more attractive to adult smokers, Professor Shiffman concluded.

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Senator Richard J. Durbin, an Illinois Democrat who has called for e-cigarettes to be regulated like conventional cigarettes, said that those results came as no surprise given that NJOY paid for the research.

"Let me be as dismissive as possible: When they start talking about their own research, I say 'been there, done that,' "Mr. Durbin said in an interview. "We listened to those tobacco companies for decades while their so-called experts tried to divert our attention from the obvious."

Mr. Weiss said NJOY did not influence the findings. "I get the appearance of a — 'quote-un-quote' — industry funded study," he said. "But we didn't have time to get it funded by a third party."

In reality, the study took only a few weeks, Mr. Shiffman said, allowing for the possibility that other studies could be done quickly by independent sources. Asked about that prospect, Mr. Weiss said: "What's the magic number of studies? Two studies? Four studies?"

About a year ago, NJOY, based in Scottsdale, Ariz., named to its board Dr. Richard H. Carmona, the former surgeon general who had been an ardent foe of tobacco companies. Before joining the NJOY board, Dr. Carmona said he asked the company about the use of flavors and was told it "was not on the table at that time."

Dr. Carmona, who also works at a nonprofit health organization, the Canyon Ranch Institute, said that NJOY's research was a good start but that it was critical that independent researchers validate the findings. Like Mr. Weiss, Dr. Carmona said he was willing to take the chance and go forward, given that e-cigarettes have the potential to get people to stop smoking conventional cigarettes.

"Research like that could take months or years," Dr. Carmona said. "So we go with a theory, we go with a hypothesis. It's no different than any other market."

Correction: July 18, 2014

An article on Wednesday about the growing number and popularity of flavored electronic cigarettes rendered incorrectly the name of a website that sells e-cigarettes. It is Viking Vapor, not Viking Vapors.

A version of this article appears in print on July 16, 2014, on page B1 of the New York edition with the headline: E-Cigarettes' Fruit Cocktails.

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http://www.nytimes.com/2014/07/16/business/e-cigarette-makers-are-in-an-arms-race-for-exoti...

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