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FDA to spend $270M on e-cig research

SHARON BEGLEY, *REUTERS*

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NEW YORK (Reuters) - One team of researchers assessing the risks of electronic cigarettes is counting the puffs taken by volunteer "vapers." Another will comb Facebook for posts on how people are tinkering with e-cigarettes to make the devices deliver extra nicotine. A third is building a virtual convenience store for 13-to-17-year-olds, measuring how e-cigarette displays and price promotions influence whether minors buy the increasingly popular devices.

The U.S. Food and Drug Administration is spending $270 million on these and 45 other research projects to determine the risks of e-cigarettes before millions more Americans become hooked on the devices.

"They want data and they want it yesterday," said Dr. Suchitra Krishnan-Sarin of Yale University, who is leading four projects.

"Yesterday," however, is years away.

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Final results may not be available before 2018, researchers leading the FDA-funded projects told Reuters. That timetable, which has not been reported before, underscores how the slow pace of science is contributing to a regulatory vacuum, allowing e-cigarette makers to sell their products virtually unchallenged.

To be sure, studies of e-cigarettes not funded by the FDA are also under way, and the agency can factor those results into any action it takes. But the FDA chose these 48 projects because they address questions central to future regulations.

The e-cigarette industry, which Wells Fargo Securities estimates will make $2 billion in global sales this year, says the FDA must wait for the results of the research before it issues any regulations, or manufacturers risk being driven out of business by unproven fears about their products.

"There shouldn't be regulations akin to those for cigarettes without evidence of similar health impact, especially since the preliminary evidence is positive for the industry" when it comes to comparing the contents of e-cigarette vapor to tobacco smoke, said attorney Bryan Haynes. His Richmond, Virginia-based firm Troutman Sanders represents e-cigarette manufacturers.

Backed by the world's biggest tobacco companies, the industry is aggressively expanding its marketing across the country. More than 14 million U.S. adults and nearly 2 million teens and tweens have used e-cigarettes, and the rate of use among high-

schoolers doubled from 2011 to 2012, the latest data available.

The FDA "will always make regulatory decisions based on the best available science," said an agency spokeswoman. "With regard to e-cigarettes, the agency does not believe it will take many years to create the regulatory framework" once the FDA has the basic authority to regulate the products, which could happen next year.

The missing science includes basic questions such as what compounds are in the vapor produced by e-cigarettes. It also includes complicated ones like whether flavors such as butterscotch and bubble gum entice children to vape, how e-cigarette displays in online stores affect teenagers' desire to buy vaping liquid and, perhaps most crucial, whether e-cigarettes will reduce the number of smokers or produce millions of new nicotine addicts.

The Yale team, for instance, will study whether menthol and flavors such as chocolate and cherry increase the appeal of e-cigarettes, especially to 16-to-18-year-old smokers or "dual users" who both smoke and vape. If that turns out to be the case, the FDA would have scientific support for regulating.

"We'll have the first results within two years" and complete ones in four to five, Krishnan-Sarin said.

REAL-TIME EXPERIMENT

As an uncontrolled experiment in public health, the use of electronic cigarettes is rivaled only by conventional tobacco smoking, a habit adopted by half of American men and one-third of women during its peak in the 1960s. The first Surgeon General's report on the health dangers of cigarettes was released in 1964, when more than 40 percent of American adults were already hooked. To date, more than 10 million Americans have died from illnesses tied to smoking tobacco.

Research on e-cigarettes has moved more quickly, partly because scientists can draw on regular tobacco research to establish the biological effects of vaping.

The cartridge-like devices were first introduced in the United States by start-up manufacturers in 2007. Now, the U.S. market is dominated by blu, a brand owned byLorillard Inc.

Other leading tobacco companies are making a big push for a share of the growing market: R.J. Reynolds Vapor Co., a subsidiary of Reynolds American, began selling its Vuse e-cigarette nationwide last month and Altria's NuMark subsidiary plans to do so with its MarkTen later this year.

The FDA got authority to regulate tobacco products, both traditional and novel, with the 2009 Tobacco Control Act. In April, the FDA proposed banning e-cigarette sales to minors, angering public health advocates who want more far-reaching prohibitions on online sales, advertising and flavors.

The FDA began funding e-cigarette research in 2012. An FDA-funded project at the University of Louisville in Kentucky illustrates why the pace of science is slow.

Scientists there will look at three or four brands of e-cigarettes and analyze their volatile organic compounds, flavorings and particulate matter to see how they affect lung and

other cells in lab mice, said lead researcher Dr. Sanjay Srivastata.

This spring, he began exposing the animals to e-cigarette vapor for up to six months, with full results expected in 2015. While those findings could help FDA quantify risks from vaping, results extending the conclusions to humans are as much as five years away.

THE 'PLEASURES OF NICOTINE'

Another crucial question researchers are trying to answer is whether e-cigarettes will be used mostly by nicotine newbies, including adolescents; by ex-smokers craving a nicotine hit without the carcinogens of tobacco; or by smokers trying to quit.

To get a handle on who is likely to use e-cigarettes, scientists at Georgia State University School of Public Health will conduct online surveys of 6,000 people to assess whether they perceive e-cigarettes as less harmful than the traditional kind, why those who have switched from the latter to e-cigarettes did so and what influences people's perceptions of the product's risk.

"This is the kind of research that is going to be informing the FDA's regulatory process," said Michael Eriksen, dean of the School of Public Health and leader of three FDA-funded projects on tobacco.

The FDA's proposed e-cigarette rules would give it the power to regulate the ingredients in the vaping liquid, but are silent on the plumes of vapor produced when the liquid is heated. According to research at Virginia Commonwealth University, that may be a dangerous oversight: a form of e-cigarettes called tank systems can get so hot the vapor can contain the carcinogen formaldehyde and other toxic compounds.

"We want to know what's in the emissions, not just the ingredients," said VCU toxicologist Robert Balster, who is helping to oversee four FDA-funded projects.

To find out, VCU engineers are constructing mechanical vaping devices to measure how temperature, voltage and other parameters affect the content of the plumes from e-cigarettes. They will next comb through Facebook and blog postings to see whether vapers like super-hot temperatures, for instance. Combining the results of the mechanical vaper and real-life habits should show what emissions people are exposed to.

"If it turns out that people are tinkering with the electronics to increase the voltage of e-cigarettes, and FDA regulations limit the maximum voltage, that's useful to know," since it may justify a requirement that the devices be tinker-proof, said Balster.

Full results are years away, he said, "but we're mindful of getting information to FDA in a timely manner. They're under a lot of pressure to get moving."

http://www.philly.com/philly/health/FDA_to_spend_270M_on_e-cig_research.html