

## E-cigarettes ignite a debate over the safety of liquid nicotine

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In a nondescript strip of retail properties in Livingston — a few of which sport "For Lease" signs in their windows — is LOGIC Technology. At first glance, LOGIC looks much like the other businesses in the building — a small office tucked in the back, its co-founders, Eli Alelov and Howard Panes, often manning the phones themselves.

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But then you walk down a hallway and come upon a warehouse, stacked floor to ceiling with boxes and you learn that there's nothing small about LOGIC, one of three New Jersey-based companies that makes and distributes electronic cigarettes. Started about two and a half years ago, Alelov and Panes say their initial \$20,000 investment in

LOGIC has grown 600 percent into a multimillion dollar endeavor.

"It's hard to believe that we grew an eight-figure company out of a 600-square-foot office," says Panes, a former fitness trainer who lives in Short Hills.

The electronic cigarette is a battery-operated metal tube that turns a liquid solution of nicotine into a water-like vapor. It is virtually unregulated and still largely unstudied. Most are manufactured in China. Yet, despite a vigorous public health debate over its safety, smokers appear to be flocking to e-cigarettes as an alternative to traditional tobacco products.

Roughly 4 million Americans use e-cigarettes, representing an estimated \$1 billion in sales annually, according to Tom Kiklas, chief financial officer and co-founder of the Tobacco Vapor Electronic Cigarette Association. There are umpteen internet forums and websites devoted solely to news and reviews of the industry. And e-cigarettes, initially sold primarily online, have become increasingly available in convenience stores and other brick-and-mortar retailers.

"I'd say it's about 70 percent like a cigarette," says Gil Feldman, 25, of Paramus, a seven-year, half-a-pack-a-day smoker who turned to electronic cigarettes in December after his sister threatened to bar him from visiting his newborn niece.

"It mimics the oral fixation (a smoker needs) and you can visualize the smoke, which helps," he says.

For about \$20 to \$30, depending on the brand and design, an e-smoker can get a starter kit that contains two or three cartridges of liquid nicotine (the equivalent of two or three packs of tobacco cigarettes), a rechargeable battery and a USB power supply adapter.

"If you are a smoker and you're spending \$8 for a pack of cigarettes a day and you had the opportunity to buy (the equivalent of) three packs of cigarettes — along with a case, the battery and a charger — for \$20, sooner or later, it's worth taking a shot," says Kevin Dietz, director of sales for The Halo Company, an e-cigarette manufacturer in Pompton Plains. "You'll find that, wow, (an electronic cigarette) is pretty good. I can do this in my house. It's not stinking up the room. It's not lingering in the blinds. Why not? And without the thousands of other chemicals that are in cigarettes."

The U.S. Food and Drug Administration is scheduled this month to publish what's known as a proposed rule for public comment that could bring the e-cigarette under its regulatory control. In 2010, the agency lost a legal battle against a major e-cigarette company. The court ruling held that the FDA could only regulate the e-cigarette as a "tobacco product" as long as the device was not marketed as a therapeutic (i.e., smoking cessation) aid.

"The FDA intends to propose a regulation that would extend the agency's 'tobacco product' authorities — which currently apply only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco — to other categories that meet the statutory definition of 'tobacco product,'" Jennifer Haliski, public affairs officer for the FDA's Center for Tobacco Products, said in an e-mail. "Further research is needed to assess the potential public health benefits and risks of electronic cigarettes and other novel tobacco products."

Some e-cigarette manufacturers say they would welcome FDA oversight of a product they feel is a healthier alternative for smokers.

"We're doing a lot of things now that are not required of us because we want to provide a safer product for people and because when regulation does come, we want to be the first ones back on line, or the last ones standing when it happens," says Jeffrey Stamler, co-owner of Halo, which has 24,000 square feet of new office space and 31 employees, with plans to hire more.

Stamler says that while its e-cigarette hardware is made in China, the company has an exclusive arrangement with a U.S. laboratory to concoct and test its "e-liquid" nicotine mixture of propylene glycol, vegetable glycerin, and nicotine. A third-party testing lab, also in the United States, is further employed, he says, to spot-check certain batches for safety and nicotine content. Stamler also says that Halo uses flavoring ingredients previously approved by the FDA and the Flavor and Extract Manufacturers Association, and are used in other products.

Halo's co-founders say they use pharmaceutical-grade raw materials and that each Halo e-cig is tested for nicotine

content using cGMP standards (Current Good Manufacturing Practices), an FDA-enforced guideline. They prefer to keep the location of the lab secret because of the "proprietary equipment that was developed just for us."

"This is a highly competitive industry and we have many people trying to replicate our formulas," says Stamler. "We keep certain information close to the vest to maintain that competitive advantage."

"We are the only one I know of in the industry currently using Nicotine, USP (U.S. Pharmacopeia, a non-governmental, not-for-profit entity that sets officially recognized public health standards)," he adds.

Still, anti-smoking advocates say there are too many unknowns about an industry that currently polices itself.

"I have not seen any (electronic cigarette) manufacturer conduct clinical trials for short- and long-term efficacy or safety of their products, for the user and on the passersby exposed to the vapors," says Karen Blumenfeld, executive director of Global Advisors Smokefree Policy in Summit. "Even if chemicals are a certain grade, that does not imply that they are safe for use over the short- or long-term."

Certain e-cigarette companies, including Eonsmoke in Garfield, offer a variety of fruit-flavored vapors, despite concerns that flavors, such as cherry and mango, might entice young people and other first-time users to try the product.

"If kids really want to try cigarettes, being under 18 is not going to stop them. Fruit or no fruit (flavors), it really doesn't matter. If the FDA comes out and says they're going to ban flavored electronic cigarettes, then we're absolutely going to follow the regulatory framework. We're not going to be opposed to that," says Michael Tolmach, co-founder and chief executive officer of Eonsmoke. "We have a strawberry electronic cigarette which you technically need to be 18 in New Jersey to purchase. To say that attracts kids to smoke electronic cigarettes is a little naive."

Three years ago, New Jersey became the first state to ban the sale of e-cigarettes to people 18 years and younger and to prohibit their use in work and public places. Other states and municipalities have followed suit.

"The e-cigarettes have not been through rigorous FDA safety testing, are not pharmaceutical-grade nicotine and deliver random concentrations of nicotine that may not coincide with what is on the e-cigarette package (as tested by the FDA a few years ago)," Blumenfeld says. "There is no long-term conclusive evidence that e-cigarettes are safer than smoking. We know nothing about the benefits of e-cigarettes since there are no long-term studies on their health effects to the user, nor on the person exposed to the e-cigarette vapor."

"How do you do a long -term study without a long term?" Stamler says of an industry that is still relatively young. "We're very selective with the ingredients we use."

The electronic cigarettes have "no tar. No tobacco. No carbon monoxide. And no formaldehyde. Basically, no cancer,"

adds LOGIC's Alelov, a Livingston resident with a former pack-and-a-half-a-day habit. "There are more than 4,000 chemicals in traditional cigarettes. We don't have 4,000 chemicals. If the government is saying anything about electronic cigarettes, we ask them: 'Which is safer or healthier?' "

LOGIC sells its product worldwide and, along with its Livingston facility, has warehouses in New York and Florida. It has 18 employees and relies heavily on distributors to place its electronic cigarettes, which are available in two models (disposable and re-chargeable), two flavors (tobacco and menthol) and four nicotine levels: 2.4 percent, 1.8 percent, 1.4 percent and 0.01 percent (LOGIC Zero).

Alelov says LOGIC works with several facilities in China to manufacture and test its appliance and liquid nicotine mixture. He says he purchases liquid nicotine that already has been approved by SGS, a global testing and certification laboratory that, according to its website, ensures "that products and services comply with global standards and local regulations."

"If there was even one little thing wrong or not correct with LOGIC's product, you can just imagine how the FDA or the tobacco companies would go around us like wild animals," says Alelov, who moved to the United States from Israel in 2001. "So trust me, everything in our product has been tested so many times."

Alelov dismisses detractors who say, smokeless or not, the electronic cigarette still contains a highly addictive drug.

"It is true nicotine is addictive. This is why (the electronic cigarette) is not to be sold to minors under the age of 18. But Americans are addicted to nicotine. It is what it is," Alelov says. "Smoking is not a cool thing to begin with. But if you are smoking and you're already addicted to smoking, you might as well go for the new alternative — a tobaccofree alternative."

Eonsmoke's Tolmach says his company saw a 700 percent increase in sales from 2011 to 2012, and that his product is "manufactured to the highest of standards." Like Alelov, Tolmach prefers to not sugarcoat the issue.

"I personally tell everyone that the electronic cigarette is dangerous. They're not healthy for you. You need to use them responsibly," says Tolmach. "I'm sure, later in life, studies will show that they're less dangerous than actual combusting tobacco. But we're five or 10 years away from studies like that.

"We don't need to tell customers that it's safe for you or that it's a healthier alternative. We just know that we put it on the shelves, it's going to sell and we're going to market it very properly," he continues. "I put a Surgeon General's warning on my product to let everybody know that they need to use this responsibly and they can make their own damn decision."

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