

Unproven claims run rampant in e-cigarette business

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Electronic cigarette makers and sellers are making all kinds of health claims, many of which likely won't stand up to scrutiny under recently announced FDA regulation, a new study has found.

Regulatory oversight of those claims, announced in May, brings all tobacco products, including liquids used in vaporizers and e-cigarettes, under the same government oversight. All products must now carry warnings they contain nicotine, which is addictive.

Sales of [e-cigarette](#) products are rising about 25 percent a year.

Now that electronic devices fall under the Family Smoking Prevention and Tobacco Control Act, manufacturers will have to submit applications to the FDA, which must review and authorize [health](#)-related claims.

But researchers from The Ohio State University say that prior to this new regulation, many unproven health claims have been circulating and that misinformation could have a lingering effect on consumers. And they emphasize the importance of the FDA now working consistently to prevent unapproved health claims.

"The FDA can and should take action to ensure that inaccurate and misleading claims are discontinued," they wrote in the study, which appears in the journal *Tobacco Regulatory Science*.

"The majority of smokers are interested in quitting and it is essential for the FDA to ensure that consumers are not misled into choosing products based on inaccurate health-related claims," said Elizabeth Klein, the study's lead author and associate professor of health behavior and health promotion at Ohio State.

The goal of the study was to assess the types of health claims that consumers might encounter if they went online to buy these products, Klein said.

The research team, which included experts in public health and law, conducted their work before the new regulation was enacted. They examined online claims by makers and sellers of e-cigarettes, vaporizers and similar products and analyzed those statements to see how they stacked up to current and pending regulation.

The study found that most manufacturer and retailer sites made at least one health-related claim, most often saying that they were less harmful than traditional cigarettes and didn't carry the same second-hand-smoke risks. Others claimed that e-cigarettes posed no health risks at all.

These messages shaped consumer perception of electronic cigarettes and similar devices and may have left the American public with false perceptions that will be difficult to reverse, Klein said.

"Once these messages are communicated to consumers, you can't un-ring that bell," she said. "We want to be sure that consumers are accurately and correctly informed about their health decisions, including decisions about e-cigarette use."

Now that the FDA rule is in place, prohibitions against unauthorized claims will be in effect as of early August. That means that manufacturers that want to market products as healthier or safer than

cigarettes must first apply to the FDA and provide evidence to back the claims.

Some experts have estimated electronic nicotine devices will overtake cigarette sales within a decade. Use among kids and teens already is more prevalent than cigarette use.

FDA oversight of "modified risk" claims emerged because of the tobacco industry's long history of finding ways to promote new products as safer. Think light and low-tar cigarettes.

Cigarette makers aren't allowed to indiscriminately boast that their products are better for you than others. Until the recent FDA action, electronic cigarette businesses could make all the claims they wanted about reduced risk. And they did.

Of the 110 websites studied, 71 percent of manufacturer sites and 47 percent of retailer sites made at least a single claim that fell into the "modified risk" category, where the sales pitch includes the idea that electronic devices are better for you than cigarettes or reduce your exposure to dangerous chemicals found in other tobacco products.

The researchers found the sites using six common terms consumers use for electronic nicotine devices on the search engines Google, Yahoo and Bing.

Among the claims they found: "The realistic experience of smoking without the serious health issues associated with tobacco cigarettes," "...you won't inhale any of the carcinogens or other harmful components found in smoking," and "Traditional cigarettes have over 4,000 harmful chemicals that are not found in SMOOTH Disposable Electronic Cigarettes."

The sites also commonly emphasized lower dangers from second-hand smoke.

And many said they would help people quit smoking cigarettes - an assertion that already falls under FDA's regulatory oversight but which so far has not prompted action by the federal agency.

"These are claims that they shouldn't be making, but they were relatively common," said Micah Berman, a study co-author and assistant professor of public health and law.

"The law is clear that companies cannot claim that their products help you to quit smoking, unless they provide scientific evidence to the FDA backing up that claim," he said.

On top of advertising the products as a good way to quit smoking, the sites also promoted them for other unproven health benefits - as sleep aids or to boost sex drive, for instance, said Natalie Hemmerich, an attorney and postdoctoral fellow with Ohio State's Center of Excellence in Regulatory Tobacco Science. Berman and Klein also are part of the center.

Some of the claims found in the study, including those promoting lesser health risks with electronic cigarettes, would likely survive the FDA's scrutiny, Hemmerich said. But not all would.

Claims without scientific support or those that manipulate the science to overstate a product's benefits could mislead consumers into buying electronic nicotine devices, she and her co-authors wrote.

"Some of these claims were clearly exaggerated, clearly false," Berman said.

Though previous research has looked at advertising of electronic devices, this is the first study to analyze those claims from a legal perspective, the researchers said.

Electronic cigarettes have led to a debate within the public health community. Some argue that they're a positive development that is better for people than lighting up; others are skeptical about their ability to help smokers quit and worry about the possibility that young people who start with electronic products could end up smoking cigarettes.

"No matter where you fall on the debate, everyone can agree that having a well-informed consumer, who is not misled by unsupported health claims, is beneficial for public health," Hemmerich said.

Berman and Klein said they're hopeful the team's research will be useful to the FDA as it exercises its oversight of marketing tactics of electronic cigarette makers and sellers for the benefit of public health.

The study is limited in its scope, because it focused solely on text-based claims and did not evaluate imagery that may imply health benefits. It also may have missed some sites because terminology used for electronic cigarettes and vape pens continues to change, Klein said.

Provided by The Ohio State University

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