

Study finds health risk in vaping fluid flavor chemicals, urges regulation

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In a study out today in *Tobacco Control*, a publication of the British Medical Association, a team led by Portland State University professor James F. Pankow found high levels of flavor chemicals in some e-cigarette fluids. Some of the flavor chemicals may pose health concerns for daily e-cigarette users, or "vapers."

All products analyzed were obtained in the U.S. market. In thirteen of 30 products tested, flavor chemicals were found to comprise more than 1% of the product weight. Six of the 24 major flavor chemicals identified are aldehydes, compounds recognized by toxicologists to be "primary irritants" of the mucosa of the respiratory tract. Example aldehyde flavor chemicals found are vanillin, used for a vanilla flavor, and benzaldehyde, used for a cherry flavor.

Some manufacturers of e-cigarette fluids advertise that flavor chemicals used in their products are "food grade" and/or are "generally recognized as safe" (GRAS) by the Flavor Extracts Manufacturers Association (FEMA). However, such distinctions actually apply only to ingestion not inhalation. Using a consumption rate of around 5 ml/day, a metric commonly reported on online vaping forums, vapers using some of the products tested would be exposed to twice the recommended occupational exposure limits for benzaldehyde and vanillin.

Pankow notes that FEMA states that it is false and misleading for suppliers of e-cigarette fluids to "represent or suggest that the flavor ingredients used in their products are safe because they have FEMA

GRAS status for use in food." The same FEMA GRAS designation requires food products to include relative proportions of ingredients. Manufacturers of e-cigarette fluids are not required to list any ingredients, let alone their relative composition or even the amount of nicotine, on product packaging.

"Many folks believe that daily use of e-cigarettes is less dangerous than smoking cigarettes. But no one really knows how safe chronic use of e-cigarettes is. It is also certainly true that there are more and less safe ways to 'vape' - and maybe even true that some ways of vaping are quite unsafe," explains Pankow. "The bottom line is that if I had to vape, I would definitely avoid high levels of flavor chemicals - particularly aldehyde flavor chemicals such as vanillin. The trouble is, there is no way for consumers to make informed decisions."

As of January 2014, a study conducted by researchers the University of California San Diego revealed that an astonishing 7,764 e-cigarette fluids with unique flavor names were available online under 466 different brands. These numbers continue to grow, perhaps quite rapidly, as the same report estimated an average of 242 additional unique flavors are being added to the e-cigarette marketplace every month. Of the 7,764 unique flavors, only a small fraction relate to the flavor of tobacco. The vast majority of e-cigarette fluids, also known as vaping fluids, evoke candy, fruit or other confectionary flavors such as chocolate, raspberry, cherry cheesecake, cotton candy, vanilla grape, apple, coffee, bubble gum and 'butter crumble.'

Public health officials have long linked the use of artificial flavorings in tobacco products to industry efforts to attract youth to tobacco. The 2009 Family Smoking Prevention and Tobacco Control Act banned the use of "characterizing flavors" in cigarettes. This law does not prohibit or regulate such flavorings in e-cigarette fluids.

At present there are no federal laws or regulations that limit the use of flavorings, dictate labeling requirements, nor prohibit minors from purchasing e-cigarette fluids or paraphernalia.

In April 2014, the U.S. Food and Drug Administration (FDA) proposed that it has federal regulatory authority over electronic cigarettes. Since that time the only specific regulation proposed by the agency under consideration is the prohibition of sales of e-cigarettes and associated vaping fluid sales to those under the age of 18.

U.S. Senator Jeff Merkley has pressed the FDA to enact rules to address the flavorings and marketing clearly designed to attract children, and to mandate child-proof packaging of liquid nicotine.

"I have repeatedly called on the FDA to regulate tobacco candy and e-cigarettes and this study from PSU researchers is just another example of why federal regulation is so important," said U.S. Senator Jeff Merkley. "Not only are flavors targeting children and inviting them to use e-cigarettes, but this study shows that flavor chemicals can be dangerous when inhaled. Without the federal regulation of e-cigarettes, we are putting our children at risk. The FDA has been asleep at the switch and needs to use the power Congress gave it to regulate these harmful products."

The FDA is expected to take final action on proposed regulation in June 2015.

More information: *TC Online First*, published on April 15, 2015.
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