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Testimony from:
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In OPPOSITION to R384-415, "ELECTRONIC CIGARETTE SUBSTANCE STANDARDS."
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About Us

The R Street Institute is a nonprofit, nonpartisan public policy research organization based out of Washington, D.C. We strive to promote free markets and effective government policies in many areas, including harm reduction.

My academic background is in epidemiology, the study of how diseases and health outcomes are distributed throughout the population and how to apply this information to public health problems. Over the past several decades, public health has made great strides in decreasing smoking initiation and promoting smoking cessation. However, no cessation or prevention program is 100 percent successful—many people are left behind. To that end, I believe that harm reduction approaches can positively affect the health and welfare of people who use addictive substances, including nicotine.

The R Street Institute's ultimate goal is to bring harm reduction approaches into equal standing as a third pillar of tobacco control alongside demand reduction (increased cessation and prevention measures) and supply reduction (shifting to economies that do not rely on tobacco production). From a public health perspective, it is important to incentivize people to use less harmful products. Allowing their availability alongside combustible cigarettes will encourage people to choose alternatives.

E-cigarettes are a harm reduction and smoking cessation tool

The Royal College of Physicians; the National Academies of Science, Engineering and Medicine; and the U.S. Food and Drug Administration (FDA) have recognized nicotine products exist on a continuum of risk, with e-cigarettes at the lower end near traditional nicotine replacement therapies and combustible cigarettes at the highest end of the risk spectrum.[1] Importantly, in its comprehensive report, Public Health England stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes.[2] These products are recognized as presenting a reduced risk because they do not employ the traditional cigarette combustion process that releases around 7,000 chemicals—some of which are highly carcinogenic. In fact, former FDA Commissioner Scott Gottlieb made reduced-risk products like e-cigarettes central to the FDA's roadmap:

> While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels that kills people. This fact represents both the biggest challenge to curtailing cigarette addiction – and also holds the seeds of an opportunity that's a central construct for our actions. E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products.[3]

Indeed, e-cigarettes have quickly become the number one quit tool in many parts of the world, allowing an untold number of smokers to quit cigarettes. Public health modeling suggests that e-cigarettes are contributing to more rapid declines in smoking rates than were seen in previous years.[4] In the United States and United Kingdom, e-cigarettes have outpaced traditional quit methods (varenicline, nicotine replacement therapies and counseling) and demonstrate a higher degree of success.[5] Furthermore, in a randomized trial, smokers who used e-cigarettes as a cessation device achieved sustained abstinence at roughly twice the rate of smokers who used nicotine replacement therapy.[6]

Nicotine Concentration

One important consideration for the ability of nicotine to be a viable substitute for combustible cigarettes is that the nicotine concentration in an e-cigarette must mimic that of combustible cigarettes.

We oppose R384-415 because it proposes a maximum nicotine concentration of 36 milligrams (mg)/milliliters (ml) or 3 percent for sealed alternative nicotine delivery systems, as this is likely to discourage some smokers from transitioning from combustible cigarettes.[7] A 2014 article assessing nicotine absorption from e-cigarettes asserts that "nicotine delivery to the bloodstream is important in determining the addictiveness of ECs, but also their efficacy as smoking substitutes."[8] It also indicates that e-liquids with a nicotine concentration of approximately 50 mg/ml are necessary to deliver nicotine in a similar profile to combustible cigarettes.

The ability to achieve a similar nicotine delivery profile to that of combustible cigarettes is likely one reason that e-cigarettes are more effective cessation devices than pharmaceutical nicotine replacement therapy treatments.[9] During daily smoking, typical peak blood nicotine concentrations range from 19 to 50 nanograms (ng)/ml, while typical concentrations immediately prior to smoking another cigarette range from 10 to 37 ng/ml; depending on how the cigarette is smoked, each cigarette increases blood nicotine concentrations by 5–30 ng/ml.[10] By contrast, unrestricted use of nicotine replacement therapy products generally achieves only one to two thirds of the blood nicotine concentrations achieved from combustible cigarettes.[11] For an individual with high nicotine dependence, the ability to duplicate the nicotine delivery profile of combustible cigarettes with e-cigarettes more accurately may be what makes their quit attempt succeed when previous attempts failed.

Studies found that 20 percent of e-cigarette users initiated use with e-liquids that contained nicotine concentrations greater than 20 mg/ml and nearly a quarter used nicotine concentrations greater than 20 mg/ml at the time they stopped using combustible cigarettes.[12] They also found that only 19 percent of e-cigarette users were able to switch completely from combustible cigarettes while using e-liquids with nicotine concentrations between 6 and 10 mg/ml. These results suggest that increasing the availability of e-liquids with nicotine concentrations greater than 20 mg/ml may assist smokers who have not quit with the products currently available.

It cannot be emphasized enough that for those who are unable to quit without assistance, chances for a successful, long-term transition away from combustible cigarettes will increase if alternative products are able to deliver nicotine in a similar fashion to that of combustible products.

Furthermore, studies have shown that people who use e-cigarettes adjust their consumption patterns based on the nicotine concentration of available e-cigarettes. Researchers found that experienced vapers instructed to use study e-cigarettes as frequently as they desired consumed a significantly greater volume of e-liquid when given e-cigarettes with lower nicotine concentration than they did when given e-cigarettes with higher nicotine concentration.[13] The greater consumption of e-liquid was due to participants taking more frequent and longer puffs.[14] The study also found that lower nicotine

concentrations resulted in stronger urges to vape and withdrawal symptoms, suggesting that lower nicotine concentrations are less effective at satiating cravings.[15]

In addition, this study found that compensatory puffing of e-cigarettes with lower nicotine concentration resulted in greater exposure to formaldehyde, a known human carcinogen.[16] This finding is likely due to participants using more e-liquid and engaging in compensatory puffing. Other studies confirm this finding and expand it to other carbonyl compounds.[17] These findings indicate that lower nicotine concentrations increased exposure to carbonyl compounds compared to use of higher nicotine concentrations. Since higher nicotine concentrations decrease exposure to carbonyl compounds, which are known to have negative health effects, instituting nicotine concentration limits risks exposing people who use e-cigarettes to greater levels of harm.

When considering regulations aimed at reducing the burden of smoking, we strongly urge policymakers to consider the utility of harm reduction and reduced-risk products alongside prevention measures. It is imperative that access to e-cigarettes and vapor products remain at a level that encourages, rather than discourages, people to choose these less harmful products. Doing so will reduce the incidence and cost of tobacco-related disease.

Respectfully submitted,

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