Uneducating Americans on Vaping

False ideas about comparative risk result in deadly ignorance.

◆ BY JACOB JAMES RICH AND JONATHAN H. ADLER

igarette smoking continues to be a leading cause of avoidable death in the United States. Nearly half a million Americans die each year from smoking-related diseases according to the Centers for Disease Control and Prevention. Understandably, this makes reducing smoking and discouraging youth smoking significant public health priorities.

Fortunately, there are less dangerous ways for smokers to satisfy their nicotine habits than smoking cigarettes. Electronic cigarettes and other vaping products (so-called "electronic nicotine delivery devices" or ENDS) appear to be a substantially safer substitute for combustible cigarettes. Such products can even help some smokers quit altogether. Yet too few people know this, and the ignorance appears to be getting worse.

Since the Food and Drug Administration began regulating ENDS as "tobacco products," public understanding of the relative risks of various tobacco products has declined. The FDA and many other expert authorities accept that there is a "continuum of risk" and that vaping is less dangerous than smoking. Yet, a majority of Americans do not understand this to be true. Smokers in particular do not realize there are less dangerous alternatives to combustible cigarettes—alternatives that could save their lives.

What explains widespread and worsening understanding of the relative risks of vaping? And what can be done about it? Improved messaging and public statements from public health authorities could help, but we are unconvinced such efforts would be enough. The ability of government messaging to inform consumers is inherently limited, particularly when public trust in institutions

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is flagging. As we explain below, educating Americans about the relative risks of tobacco products may require rethinking the way we classify and regulate such products and in particular allowing those with an economic interest in educating Americans about the relative risks of nicotine products to do so.

A LESS UNHEALTHY NICOTINE PRODUCT

ENDS have been available in the United States for over 15 years. What distinguishes these products from traditional cigarettes is that they do not involve combustion. Instead, such products heat a liquid solution, often containing nicotine and some sort of flavoring, to generate a vapor not unlike the vapor generated by the smoke machines used in some theatrical productions and dance clubs. Users inhale the vapor much like a cigarette user would inhale smoke—hence the name "vaping."

Because vaping devices do not involve combustion, they appear to be substantially less dangerous to the user (and others) than traditional combustible cigarettes. The user is not exposed to the myriad contaminants and other combustion byproducts found in cigarette smoke. Thus, as the FDA has acknowledged, consuming nicotine via vaping is "of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."

> Existing research on ENDS consistently demonstrates that they pose fewer risks to users and others than combustible alternatives. As a 2018 National Academies of Sciences report concluded, "There is conclusive evidence that completely substituting e-cigarettes for combustible cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes," and "there is moderate evidence that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes."

> Substantial research further shows that vaping products like e-cigarettes at least have significantly safer short-term outcomes. For example, a 2017 study by Lion Shahab et al. published in the Annals of Internal Medicine concluded that former smokers who completely switched to ENDS had significantly lower levels of carcinogens in their salivary and urinary samples compared to current smokers. Research published the next year by Maciej Goniewicz et al. in JAMA Network Open supported these results, finding that within a year of cessation the levels of carcinogens found in the blood samples of former smokers who completely switched to e-cigarettes closely reflected those of people who were never tobacco users. Such findings (and others) have motivated historically anti-tobacco institutions like Public Health England to make the bold claim that e-cigarettes are 95 percent safer than conventional cigarettes.



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Although ENDS' long-term health consequences are largely unknown, there is a fairly broad consensus that vaping devices are significantly safer to consume than conventional cigarettes and that convincing smokers to switch to ENDS would save lives. A 2018 study by David T. Levy et al. in *Tobacco Control* estimated that if every American smoker switched to e-cigarettes over a 10-year period, approximately 6.6 million premature deaths from tobacco would be avoided.

Not only are ENDS less dangerous than combustible cigarettes, but there is growing evidence that they can help some smokers reduce their cigarette consumption if not quit altogether. Multiple studies have found that ENDS are more effective at assisting smokers to quit than are FDA-approved nicotine replacement therapies (NRTs) such as patches and gum. A literature review by Jamie Hartmann-Boycea et al. for the Cochrane Library concluded that e-cigarettes were approximately 70 percent more effective in helping smokers to quit than traditional nicotine-replacement products. Additional research suggests that the availability of ENDS even helps reduce smoking by adult smokers who had no intention to quit. As a recent review by David J.K. Balfour et al. in the *American Journal of Public Health* concluded, "Although not the final word, the totality of the evidence indicates that frequent vaping increases adult smoking cessation."

Among the public health considerations for e-cigarettes, the implications for pregnant mothers and their children might be the most visible. An abundance of literature shows that smoking during pregnancy leads to adverse outcomes such as low birth weights, complications that lead to miscarriages and premature births, and obesity during childhood. Some of these effects may be related to nicotine exposure in utero, but most of the research indicates that these adverse outcomes during pregnancy are much more related to mothers inhaling carbon monoxide from combustible tobacco products like conventional cigarettes. In particular, an American Journal of Obstetrics & Gynecology article by Brendan P. McDonnell et al. that reviewed the outcomes of 129 live births at Coombe Women and Infants University Hospital in Ireland among women who exclusively used e-cigarettes found that their babies' measurements were similar to nonsmokers and larger than cigarette smokers, with no cases of serious maternal morbidity. These results have been continuously replicated. A study by Suzanne Froggatt et al. in The Lancet's eClinicalMedicine reported:

Birth outcomes, namely birthweight, gestation and head circumference, did not differ for e-cigarette exposed infants compared with infants who were not prenatally exposed to nicotine. Cigarette exposed infants had a significantly lower birthweight ... and reduced head circumference ... in comparison to non-exposed infants.

Some adverse outcomes for infants, such as decreased motor maturity, have been correlated with e-cigarette use during pregnancy, but almost all studies on the topic conclude that e-cigarette use during pregnancy is substantially preferable to smoking. In

the United Kingdom, Public Health England has taken these findings to heart. If pregnant mothers are not able to quit smoking, doctors within the National Health Service are directed to encourage them to use e-cigarettes instead of conventional cigarettes until they give birth. This approach began in 2019 and has been followed by a 10 percent drop in the percentage of women who are known smokers at the time of birth. E-cigarettes were a common nicotine replacement tool among mothers during this period and were occasionally provided by maternity services free-of-charge. Because of the COVID-19 pandemic, it has been difficult to estimate the public health benefits of these interventions, but the UK's current tobacco control plan intends to reduce the prevalence of smoking during pregnancy from 9.1 percent to 6 percent with the help of e-cigarettes, which highlights their utility not just among mothers, but the general population.

REGULATING VAPING AS TOBACCO

In May 2016, the FDA used its authority under the Family Smoking Prevention and Tobacco Control Act to "deem" ENDS as "tobacco products" for the purposes of federal regulation. The FDA based this action on the fact that most nicotine in such products is "derived from" tobacco, and the decision survived legal challenge in the courts. In the FDA's view, regulating vaping products like other tobacco products would support public health, even though (as the FDA acknowledged in the *Federal Register* prior to adopting the rule) "several studies support the notion that the quantity of toxicants [in ENDS vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies."

A consequence of the FDA's decision is that electronic cigarettes are subject to the same federal regulatory regime as combustible cigarettes and other tobacco products. Accordingly, FDA regulations govern the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of vaping products. Further, the FDA's decision to "deem" vaping products to be tobacco products has required manufacturers to seek FDA approval before their products may be sold. Although the FDA and federal courts gave makers of existing products some time to submit applications before their products would be pulled from the market, this requirement is dramatically reducing the number of vaping products available to consumers. Since the pre-authorization requirement became effective, manufacturers have submitted over 6.5 million vaping product applications to the FDA. To date, the FDA has only approved about two dozen such products from only a handful of manufacturers. Multiple legal challenges to the FDA's denial of marketing orders are currently pending in court.

UNEDUCATING AMERICANS

While the FDA accepts that there is a "continuum of risk" among tobacco products, and that non-combustible tobacco products are less dangerous than cigarettes, the public has not been getting that message.

Since the FDA deemed ENDS to be tobacco products subject to the same regulatory regime as cigarettes, the percentage of Americans who recognize that ENDS are less dangerous than combustible cigarettes has dropped substantially. In the United States, the public now believes that e-cigarettes are at least as dangerous as conventional cigarettes. According to researchers from the American Cancer Society, among adults surveyed in 2020, approximately 35.6 percent believed that e-cigarettes were "as harmful" as conventional cigarettes, while 28.3 percent believed that e-cigarettes were "more harmful" than conventional cigarettes, marking the first year that both beliefs together were held by a majority of Americans. In comparison to results from the same survey for previous years published by Jidong Huang et al. in JAMA Network Open, the proportion of

acknowledge the relative risk of ENDS compared to combustible smoking. This omission is understandable because the point of such campaigns is to discourage vaping, not present it as a desirable alternative to smoking, particularly for non-smoking youth. Yet the effect of such messaging, when there is a dearth of information or efforts to educate adults about relative risks, may be contributing to the lack of public understanding.

THE EVALI EPISODE

Many in the industry blame public misperceptions about the relative risks of vaping on a sudden outbreak of severe lung illnesses associated with vaping products. On August 21, 2019, the CDC identified 193 potential cases of severe lung illness asso-

> ciated with vaping products throughout the United States. It launched an investigation into the origins of the outbreak, originally attributing the hospitalizations to "vaping associated pulmonary illness." By September 6, the CDC had updated its guidance to the general public to "consider not using e-cigarettes" and later rephrased the cause as "e-cigarette, or vaping product, use associated lung injury" (EVALI).

Over the next six months, 2,807 cases of EVALI were identified, resulting in 68 deaths and many more permanent injuries. During the CDC's initial guidance in September, the National Opinion Research Center (NORC) conducted a poll reporting that approximately 46 percent of U.S. adults supported "outlawing e-cigarettes entirely," up from 39 percent the year before. Amid this public backlash, many policymakers and public health activists called for an indefinite ban on the sales of all ENDS.

Contrary to activist claims, the relationship between regulated ENDS like e-cigarettes and the EVALI outbreak was suspect from the first reports of vaping-related lung injuries. As became clear relatively quickly, the EVALI outbreak was largely (if not wholly) attributable to the use of black-market tetrahydrocannabinol (THC, the active ingredient in marijuana) fluid that some consumers used in vaping devices, not commercially marketed ENDS or e-cigarettes.

Nonetheless, the CDC originally attributed the initial reports of EVALI to "e-cigarettes" by name, describing that term as synonymous with "vaping" various types of substances in general. It did this despite its knowledge that many of those suffering from EVALI had (in the CDC's own words) "acknowledged recent use of tetrahydrocannabinol (THC)-containing products" before their injuries. Nonetheless, on September 6, the CDC gave a telebriefing recommending that residents stop using all e-cigarettes. Over the next six months, the CDC repeated this advice as it continued its EVALI investigation.

Despite the CDC's refusal to speak clearly on the subject, its own data showed that the EVALI cases were almost exclusive to

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Americans who believe e-cigarettes are "less harmful" to consume than conventional cigarettes peaked the first year the survey was conducted, at 50.7 percent in 2012, but it has declined over the past decade to only 11.4 percent of adults holding this belief in 2020.

What explains Americans' poor and declining understanding of the relative risks of vaping and other tobacco products? Sensational media reporting about the risks of vaping products and the threat of a youth vaping "epidemic" may well be part of the cause. According to a paper by Katherine East et al. in *Nicotine & Tobacco* Research, from 2017 to 2020 the proportion of articles discussing negative health risks from vaping increased from 18.0 percent to 64.6 percent in the United States. During the same period, the proportion of articles that clarified that vaping is less harmful than smoking decreased from 61.3 percent to 34.0 percent.

In contrast, a 2015 study reported that many flavored vaping fluids contain diacetyl, a compound that may cause a type of lung disease known as "popcorn lung" if inhaled, and called for "urgent action" to address the health threat. This study prompted dozens of media reports on the dangers of vaping. What the study and subsequent news reports did not mention, however, is that the levels of diacetyl in combustible cigarettes is many times higher than was found in the flavored vaping fluids, and yet combustible cigarettes have not been linked to "popcorn lung" (though they clearly cause other forms of lung disease). Yet to this day some people think vaping poses a meaningful risk of "popcorn lung."

Government and nongovernmental organization advertising campaigns aimed at discouraging youth vaping also fail to

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states that had not yet regulated commercial marijuana markets, increasing the likelihood that marijuana consumers in those states would rely on illicit sources for THC vaporizers. An analysis one of us co-authored on *Reason.com* in December 2019 showed that states with either medical or recreational marijuana liberalization experienced approximately 6.7 fewer lung injuries per million residents, which accounted for almost all the EVALI cases. A 2020 *JAMA Network Open* article by Coady Wing et al. reported similar findings. By February 2020, the CDC had stopped collecting lung injury data from the states, claiming that it had identified the primary cause of EVALI as illicitly sourced THC products. The CDC eventually narrowed its recommendation, urging that people not consume THC vaporizers from illicit sources, thus effectively conceding that regulated ENDS had nothing to do with EVALI.

Despite the CDC's later concession, the EVALI episode accelerated the public's misguided skepticism of whether ENDS are safer than conventional cigarettes, and little has been done to correct the record. In 2016, respondents rejected the proposition that "vaping is healthier than traditional cigarettes" by a margin of 47 percent to 32 percent in Reuters–Ipsos polling. After the EVALI outbreak in 2019, the same proposition was rejected 63 percent to 23 percent. A similar shift was observed on the question of whether "vaping is a good way to help people quit smoking." Respondents rejected that proposition 43 percent to 37 percent in 2016 and 58 percent to 29 percent in 2019.

Yet it would be a mistake to blame public ignorance about the relative risks of ENDS on the EVALI episode alone. While the outbreak does appear to have increased public concern about the risks of vaping products, the miseducation of the public began well before. The downward trend in public understanding of the relative risk of vaping products appears to have begun around the time the FDA first began considering subjecting ENDS to the same regulations as tobacco products.

According to the aforementioned Huang et al. study of changing perceptions of harm from ENDS versus combustible cigarette use, "From 2012 to 2017, the proportion of US adults who perceived e-cigarettes as less harmful than cigarettes decreased significantly" and that "during the same time period, the perception of e-cigarettes to be equally or more harmful than cigarettes increased significantly." Interestingly enough, the study found the greatest change between 2012 and 2015. And it was in April 2014 that the FDA formally proposed regulating e-cigarettes as tobacco products.

THE CAUSES OF MISEDUCATION

The widespread and worsening risk perceptions about the relative risk of tobacco products has significant public health implications, particularly for the approximately 30 million Americans who continue to smoke. While youth smoking rates have declined dramatically in recent years, faulty risk perceptions could threaten this progress, as perceptions about the relative risks of tobacco products influence decisions about whether to use such products,

which products to use, and in the case of smokers, whether to attempt to switch to non-combustible products.

Quitting smoking is notoriously difficult. Smokers who do quit successfully are often motivated by the health benefits of quitting. While most ENDS users understand that vaping is less dangerous than smoking, a large proportion of smokers do not. Surveys find that smokers would be more likely to use vaping products and are more likely to try and use such products to reduce or quit smoking if they believe the products are less dangerous.

Other tobacco-related policies can influence whether nicotine consumers satisfy their cravings with cigarettes or less dangerous alternatives. Although smoking has generally dropped among all age groups over the past two decades, observational studies show that increases in e-cigarette sales are followed by faster reductions in conventional cigarette sales. At the same time, restrictions on ENDS products or policies that make ENDS more expensive to consumers appear to increase smoking, particularly among youth.

According to a paper by Henry Saffer et al. in the *Journal of Risk and Uncertainty*, an e-cigarette tax in Minnesota that consequently reduced e-cigarette sales prevented approximately 32,400 smokers from quitting. The authors further estimate that a similar nation-wide tax would prevent 1.8 million smokers from quitting. City-level research by Abigail S. Friedman and published in *JAMA Pediatrics* in 2021 showed that a comprehensive tobacco flavor ban (including vapor products) led to more youth smoking in San Francisco. These sorts of studies show that cigarettes and e-cigarettes are substitutes, not compliments, and that increasing access to e-cigarettes would reduce consumption of conventional cigarettes.

CURING MISEDUCATION

If Americans, and smokers in particular, do not understand the relative risks of combustible and non-combustible products, how can this be addressed? The traditional answer is better public health campaigns: push government agencies to develop and promote more balanced and accurate public health messages while avoiding sensationalist media coverage like what occurred with popcorn lung and EVALI.

Better messaging from governmental authorities may help, but it can only do so much, particularly at a time of reduced trust in authorities. In the wake of the COVID-19 pandemic, public health authorities have taken a massive credibility hit. A 2021 poll by the Robert Wood Johnson Foundation and the Harvard T.H. Chan School of Public Health found that barely half of Americans put significant trust in the CDC and only 37 percent put much trust in the National Institutes of Health or the FDA. America today is a low-trust environment, and governmental health authorities are not well-trusted by large swaths of the American population. So, what is the alternative?

The public health challenge is how to educate Americans—and smokers in particular—about the relative risks of ENDS compared to combustible cigarettes. More precisely, the challenge is to discover how to convey that information most effec-

tively. Insofar as discovery is what is necessary, competitive marketplace dynamics are more promising than governmental edicts issued from on high. As Friedrich Hayek noted, competition is "first and foremost a discovery procedure." If we want to discover how to teach consumers that ENDS are less dangerous than cigarettes and can help smokers quit, we want to harness self-interest and enable those who stand to benefit from the discovery of such knowledge to compete with each other. As Hayek explained, "Competition as a discovery procedure must rely on the self-interest of the producers, that is it must allow them to use their knowledge for their purposes, because nobody else possesses the information on which they must base their decision." The problem, however, is that the existing regulatory

In the 1980s, the Kellogg Company launched a marketing campaign for its All-Bran cereal, emphasizing the National Cancer Institute's conclusion that high-fiber diets could reduce the risks of some cancers. This initiative led to an increase in health claims about high-fiber foods, an increase in food product fiber content, and an increase in consumer fiber consumption. Allowing firms to communicate the health benefits of their products both led to healthier products and healthier consumer choices. Why wouldn't we want there to be a similar dynamic for nicotine products? If Volvo can pitch its cars by highlighting their relative crashworthiness (which necessarily requires highlighting the risk of car crashes), why should an ENDS manufacturer not be allowed to explain why its product is less dangerous than the

alternatives?

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regime makes it difficult-and in some cases illegal-for producers to attempt to educate their own consumers about the potential benefits and relative risks of their products.

At present, ENDS manufacturers compete with each other, and against combustible tobacco products, across a range of product attributes such as price, convenience, taste, mouth feel, nicotine content, and aesthetics. By differentiating their products from others, they hope to gain market share. However, they are legally limited in their ability to compete on the product attributes of health and safety. ENDS manufacturers are not allowed to make claims about the relative risks of their products as compared to other ENDS products, or even of combustible cigarettes, without first getting FDA approval. Nor do FDA regulations allow ENDS manufacturers to tell consumers that vaping might help them reduce or quit smoking unless they wish to go through the process for drug and device approval.

FDA restrictions on the ability of producers to differentiate their products through health and safety claims foreclose a potentially promising way to educate consumers about the potential health benefits of switching from smoking to vaping. Research on product marketing has shown the consumer benefits of allowing product manufacturers to make truthful and non-misleading health-related claims. Where competing producers can position their products as healthier or less dangerous than their competitors, they have an incentive to both educate consumers about the relative health benefits of their products as well as to develop products about which truthful positive health claims can be made.

It is certainly true that all nicotine products pose risks, but the risks are not equivalent. Allowing manufacturers to educate consumers about relative risks both makes safety a more salient product characteristic and helps increase consumer knowledge. Barring ENDS manufacturers from explaining the relative health benefits of their products makes as much sense as prohibiting car makers from advertising about auto safety.

Allowing ENDS manufacturers the ability to make their products more desirable than cigarettes on health grounds will give them a substantial incentive to figure out how to communicate that message to consumers, and smokers in particular. Unlike a product manufacturer with skin in the game, the U.S. surgeon general does not have to worry about losing market share if a public education campaign flops.

The problem is that both federal law and the FDA's regulatory restrictions stand in the way. Under the federal Tobacco Act, it is unlawful for the manufacturer of any tobacco product—a category that now includes ENDS-to "explicitly or implicitly" claim that its product presents a lower risk of tobacco-related disease or is otherwise less harmful than other commercially marketed tobacco products without first going through a special approval process for "modified risk tobacco products." This includes claims that a product contains less of a given substance or contaminant. As interpreted by the FDA, this means that factually true claims, such as "this product is a healthier alternative to smoking" or "this product is less risky for pregnant women" would require FDA approval, a lengthy and time-consuming process.

The FDA has also concluded that ENDS producers cannot make any claims about their products helping smokers quit without going through the drug and medical device approval process. In the FDA's view, this requirement applies to such anodyne claims as noting that some smokers find ENDS to be helpful in quitting. The FDA has itself acknowledged that "some individual smokers may potentially use ENDS to transition away

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from combustible tobacco products," but if an ENDS manufacturer were to put that in an advertisement or on a product label without FDA approval, it would be in hot water. Under the FDA's interpretation of its own authority, a manufacturer could be sanctioned for merely quoting the FDA's own statements in an advertisement or on a webpage, even if followed by a prominent disclaimer indicating that the FDA had not sanctioned or approved the manufacturer's claim. (The FDA acknowledges that such a prohibition may raise First Amendment concerns,

consequence, public health advocates are deprived of a potentially powerful tool in the campaign to reduce the health consequences of smoking. R

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Such discovery is not compatible with government-imposed prior restraints on what sorts of truthful claims manufacturers are allowed to make.

but this has not changed its legal position.) Any such efforts to encourage or facilitate smoking cessation are only allowed if first approved by the FDA—and subjecting simple, truthful marketing claims to FDA approval is not a way to get the message out. If there is going to be competitive discovery of ways to educate smokers about the relative risks of nicotine products, it must occur in a dynamic, competitive marketplace. Such discovery is not compatible with government-imposed prior restraints on what sorts of truthful claims manufacturers are allowed to make.

CONCLUSION

Public health experts are rightly concerned about the long-term consequences of ENDS use, but leading medical journals continue to highlight the urgent need to accurately communicate to the public that these products are substantially safer to consume than conventional cigarettes. Relying upon government public health authorities to convey timely, accurate, and accessible information to consumers about the relative risks of nicotine products has failed. Americans are less informed about the relative risks of ENDS as compared to combustible cigarettes than ever before, and this lack of understanding has public health consequences.

Were ENDS manufacturers allowed to make truthful and substantiated health claims about their products, they would be free to engage in market-driven competitive discovery of how to inform smokers of the potential health benefits of switching to their products. These incentives would also motivate the manufacturers to make their information more salient and digestible to potential customers. The existing regulatory framework and the FDA's interpretation of its own regulatory authority make such market-driven consumer education unlawful, however. As a

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