TOBACCO HARM REDUCTION 101

Everything you wanted to know, but were too afraid to ask

TAXPAYERS PROTECTION ALLIANCE

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David E. Williams, *President*
Tim Andrews, *TPA Senior Fellow*

1401 K Street, NW, Suite 502
Washington, D.C. 20005
(202) 930-1716
www.protectingtaxpayers.org

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AN INTRODUCTION TO TOBACCO HARM REDUCTION

Tobacco harm reduction and vaping – why should you care?

More than 34 million adults in the United States (U.S.) currently smoke cigarettes. Accounting for more than 480,000 deaths every year (or about 1 in 5), cigarette smoking is the leading cause of preventable disease and death in the U.S. In addition, more than 16 million Americans live with a smoking-related disease. For these reasons, it is a public health priority to reduce the number of smokers.

Eliminating smoking of combustible cigarettes will not only benefit sufferers of smoking-related illnesses and their families, but will also benefit taxpayers due to the reduced cost of care for these individuals. As such, smoking cessation should be a priority for anyone who cares about public health and reducing suffering and death.

In recent years, tobacco harm reduction (THR) through the use of reduced-risk products such as electronic cigarettes and "heat not burn" devices (collectively known as "Electronic Nicotine Delivery Systems" or ENDS), as well as snus, and oral nicotine products such as lozanges, has been proven to help smokers quit and help save lives. Unfortunately, considerable misinformation has spread, leaving most Americans unaware of the overwhelming scientific evidence regarding these products and their incredible benefit to society.

This Q&A is designed to help answer some of the most common questions about THR and its benefits.

What is harm reduction?

Harm reduction, sometimes known as harm minimization, is a proactive series of public health policies to reduce the negative effects associated with human behaviors such as recreational drug use and sexual activity. Harm reduction policies include measures like sex education programs, needle exchange programs, and opioid replacement therapies such as prescribing methadone to heroin addicts. Unlike abstinence-only approaches, harm reduction is based on a basic pragmatism recognizing that some individuals will always engage in risky or dangerous behaviors and that is smarter to seek to minimize the damage that these activities can cause rather than putting forth the futile effort to eliminate the behavior or activity.

Harm reduction in a myriad of activities has proven highly effective in saving millions of lives around the world.

How does harm reduction apply to smoking?

THR specifically refers to policies designed to help smokers transition to less harmful products. Traditionally, these THR methods have included nicotine replacement therapies like patches and gums, which deliver nicotine to the user without the harmful effects associated with combustible cigarettes. More recently, newer and more innovative nicotine delivery systems such as ENDS have been introduced, while other delivery systems such as snus and nicotine lozanges have seen users continue to use nicotine without the deadly chemicals caused by the process of combustion. These options pose a fraction of the risk presented by traditional tobacco products.

SOURCE: Cdc.gov, 2014 Surgeon General's Report: The Health Consequences of Smoking-50 Years of Progress.

SOURCE: Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults – United States, 2018. Morbidity and Mortality Weekly Report 2019; 68: 1013-1019 (accessed 14 Nov 2019).

Is nicotine harmful?

Nicotine is the key reason that people become addicted to smoking even though it is not the reason that people die from smoking. Nicotine is a mild stimulant similar to coffee, and while addictive, nicotine is not carcinogenic. It is a fundamental principle of tobacco tpolicy that people "smoke for the nicotine but die from the tar." Additionally, nicotine is not classified as a carcinogen by the International Agency for Research on Cancer and is relatively safe for human consumption in low concentrations.

Although potentially lethal at very high doses, the blood levels typically achieved by consuming nicotine via harm reduction products "does not result in clinically significant short- or long-term harms" which is why smokers have been using nicotine replacement therapies (NRT) for decades without incident. These products replace smoking with nicotine patches and gums, which provide users with controlled doses of nicotine. These patches and gums are widely sold as consumer goods, including to people under the age of 18. NRT products have been consistently approved for smokers as young as 12 years old for 30 years, with no noted adverse effects.

It is also worth noting that, regardless of its benign health impacts, millions of vapers go on to completely quit nicotine and thus eliminate their exposure to even nicotine itself.

SOURCE: World Health Organization International Agency for Research on Cancer. IARC monographs on the evaluation of carcinogenic risks to humans. Volume 83, tobacco smoke and involuntary smoking. Geneva: International Agency for Research on Cancer, 2004.

SOURCE: Greenland S, Satterfield M, Lanes S. A meta-analysis to assess the incidence of adverse effects associated with the transdermal nicotine patch. Drug Saf. 1998; 18:297–308.

SOURCE: Tobacco Advisory Group of the Royal College of Physicians. Nicotine without smoke – tobacco harm reduction. London: RCP, 2016.

SOURCE: Lee PN, Fariss MW. A systematic review of possible serious adverse health effects of nicotine replacement therapy. Archives of toxicology, 2016.

What are Electronic Nicotine Delivery Systems (ENDS)?

ENDS, usually known as vapes or electronic cigarettes (e-cigarettes), were invented in 2003 as a way to simulate the experience of smoking without the associated health effects of inhaling smoke. Since 2012, ENDS have become particularly popular as a method for smokers to quit their deadly habit. In particular, these products benefit users who have tried and failed at other methods of quitting.

Vaping products mimic the sensation of smoking and provide nicotine to addicted persons without the smoke from burning tobacco. Because ENDS mimic the sensation of smoking, they provide users a method of nicotine delivery similar to their habits. What is absent is the deadly cocktail of chemicals that make cigarettes dangerous to smokers themselves and those around them. As a result, public health bodies around the world have concluded that vaping is significantly safer than traditional products. Using ENDS products allows users to avoid the process of tobacco combustion entirely and thus the harmful health byproducts of smoking.

What types of vaping products are available?

Vaping products are broadly divided into two main categories. In one product category, nicotine is mixed with water and then heated and vaporized into steam. The aerosol is then inhaled. These liquid-based products are what most people consider e-cigarettes.

A newer technology, known as heat not burn, produces aerosol by the heating or steaming (instead of burning) of a tobacco-based mixture. Similar to other reduced-risk products, this process closely approximates a traditional smoking experience. However, as with e-cigarettes, the deadly chemicals present in traditional cigarettes are almost completely absent in these devices.

What is the difference between closed system and open system e-cigarettes?

Liquid-based e-cigarettes are divided into two additional categories: open system and closed system. The health benefits of both compared to traditional cigarettes are nearly identical in that neither produces smoke, a byproduct of combustion. However, the design of the e-cigarette is different. Open systems are filled manually by the user with e-liquid generally obtained from a specialty vape store either in person or online. Many users prefer this as a quit-smoking aid as it allows for greater customization of the experience for the smoker's particular needs. Closed systems use pre-filled tanks that are directly inserted into the device and then disposed of when finished. Closed system users cite the convenience of pre-filled tanks compared to open, manual systems.

Are there any other tobacco harm reduction products besides ENDS?

Yes. Other harm reduction products include smokeless tobacco products and oral nicotine products. Smokeless tobacco, sometimes known as moist loose tobacco or snus, can be found in a teabag-like pouch and allows users to ingest nicotine without smoking it. This usually involves placing the product between the gum and the cheek. Other oral nicotine products include lozenges and similar products and do not contain any actual tobacco. In addition, nicotine replacement therapies such as patches and gums are also considered harm reduction products and have been available for decades.

Do ENDS help smokers quit and how do they compare to other nicotine replacement therapies?

Multiple studies have shown that smokers who make the switch to vaping either substantially reduce their cigarette intake or quit completely, and that 69.4 percent of people who use e-cigarettes intended to use e-cigarettes as a complete replacement for regular cigarettes.

Two recent studies out of the United Kingdom (U.K.) found that ENDS products are at least twice as effective as conventional smoking cessation aids, including traditional NRT products and "behavioral support." ENDS relative effectiveness is likely significantly higher in the U.S. as the U.K. places nicotine caps on vaping products, making them less appealing to smokers.

There are four main reasons why ENDS products are more effective than other nicotine replacement therapies:

- The action of vaping is similar to that of smoking, and therefore assists with the habit-forming part of smoking.
- Nicotine is delivered faster through the lungs than through the mouth or the skin (hence why some pharmaceutical companies market nicotine inhalers).
- Vapes are more customizable with a variety of flavors, strengths and sensations, allowing users to adapt the product to best suit their need.
- Appealing flavors have been instrumental in many adults successfully making the switch.

As a result, a majority of smokers now use vaping as their preferred smoking cessation method.

SOURCE: Berg CJ, Barr DB, Stratton E, Escoffery C, Kegler M. Attitudes toward e-cigarettes, reasons for initiating e-cigarette use, and changes in smoking behavior after initiation: a pilot longitudinal study of regular cigarette smokers. Open Journal of Preventive Medicine. 2014; 4(10):789-800.

SOURCE: Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. Addiction. 2011; 106(11):2017-2028.

SOURCE: Polosa R, Caponnetto P, Morjaria JB, Papale G, Campagna D, Russo C. Effect of an electronic nicotine delivery device (e-cigarette) on smoking reduction and cessation: a prospective 6-month pilot study. BMC Public Health. 2011; 11(1):786.

SOURCE: Jackson SE, Kotz D, West R, Brown J. Moderators of real-world effectiveness of smoking cessation aids: a population study. Addiction (Abingdon, England). 2019; 114(9):1627–38.

SOURCE: Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Ross L. A randomized trial of e-cigarettes versus nicotine-replacement therapy. New England Journal of Medicine. 2019; 380(7), 629-637.

SOURCE: Brose et al. Mental Health and Smoking Cessation – a population survey in England. BMC Medicine. 2020; 18:161.

SOURCE: Benmarhnia T, Pierce J, Leas E, White M, Strong D, Noble M, Trinidad D. Can E-Cigarettes and Pharmaceutical Aids Increase Smoking Cessation and Reduce Cigarette Consumption? Findings From a Nationally Representative Cohort of American Smokers. American Journal of Epidemiology. 2018; 187.

SOURCE: CASAA e-cigarette survey results.

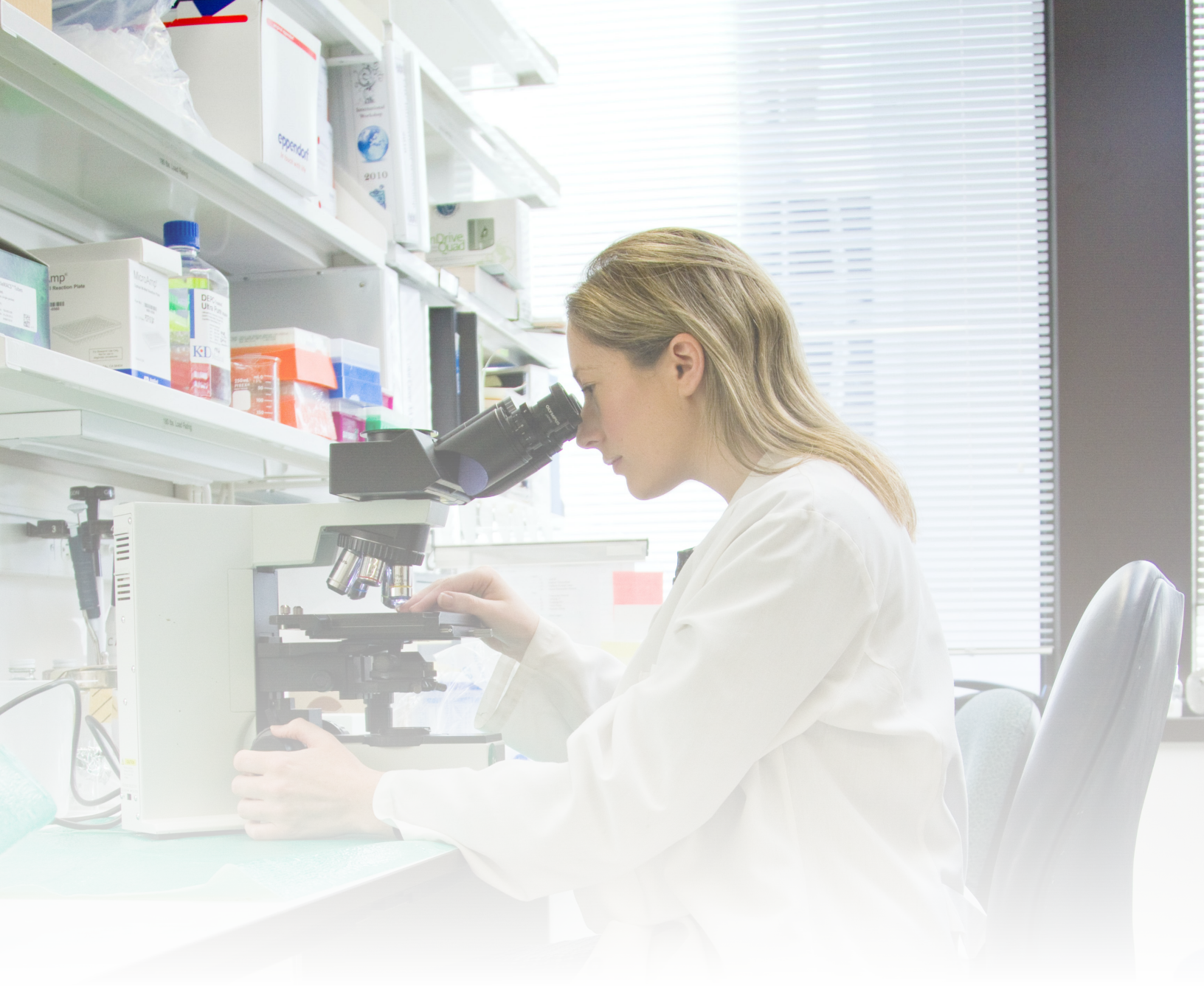
How many American lives could vaping save?

According to the most comprehensive peer-reviewed research on the effects of switching coordinated by the George Washington University Medical Center, if a majority of smokers in the U.S. quit smoking through the use of e-cigarettes over the next ten years, there would be 6.6 million fewer premature deaths with 86.7 million fewer life-years lost.

A further study was released in August 2020 which examined the proportion of U.S. smoking-produced mortality that e-cigarettes might eliminate and produced 360 possible scenarios. Of these 357 (99%) yielded positive estimates of life-years saved (LYS) due to vaping by 2100, from 143,000 to 65 million

SOURCE: Levy DT, Borland R, Lindblom EN, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control. 2018; 27:18-25.

SOURCE: David Mendez, PhD, Kenneth E Warner, PhD, A magic bullet? The potential impact of e-cigarettes on the toll of cigarette smoking, Nicotine & Tobacco Research.



THE SCIENCE OF VAPING

Are ENDS safer than smoking?

To be effective as a tobacco harm reduction strategy, vaping must be proven to be safer than smoking. With more than a decade of extensive research and thousands of academic papers, it has been conclusively proven that vaping is safer. The most comprehensive meta-analysis of all available studies was conducted by Public Health England (an agency of the British Government) and the Royal College of Physicians, the world's oldest medical body. According to the results, vaping is at least 95 percent safer than smoking. These figures have been consistently re-affirmed every year since the first analysis came out in 2015.

While some academics and policymakers may disagree with the exact 95 percent figure, there is no doubt that the lack of combustion in e-cigarettes makes them significantly safer than traditional cigarettes.

SOURCE: McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie HJ. E-cigarettes: an evidence update. A report commissioned by Public Health England. 2015.

SOURCE: Beaglehole R, Bates C, Youdan B, Bonita R. Nicotine without smoke: fighting the tobacco epidemic with harm reduction. The Lancet. 2019; 394(10200), 718-720.

SOURCE: Tobacco Advisory Group of the Royal College of Physicians. Nicotine without smoke – tobacco harm reduction. London: RCP. 2016.

How accurate is the estimate that vaping is 95 percent safer than smoking?

The estimate that vaping is 95 percent safer than smoking was first derived by Public Health England in 2015 and confirmed in a second review of the evidence in 2018. Independently of this, the identical estimate was arrived at by the Royal College of Physicians in 2016.

Public Health England is an executive agency of the Department of Health and Social Care in the United Kingdom. The Royal College of Physicians was founded in 1518, and is considered one of the world's most prestigious professional medical bodies. Both these organizations conducted rigorous metanalysis on hundreds of available studies to reach this conclusion.

These remain the two most thorough and comprehensive analysis of all available scientific data. It is noted that while other medical bodies have made statements confirming that e-cigarettes are far less harmful than combustible tobacco, they have generally not provided estimates, and these remain the "gold standard" in research.

It is also important to note that while the 95 percent figure is an estimate and not the exact number by which risk is reduced, there is no dispute whatsoever in the scientific community that vaping is considerably less harmful than smoking. So, whether the exact number is 90 percent or 99 percent, vaping works and saves lives.

SOURCE: E-cigarettes: an evidence update. Public Health England. 2015

SOURCE: E-cigarettes and heated tobacco products: evidence review Annual update of Public Health England's e-cigarette evidence review by leading independent tobacco experts, 2018

SOURCE: Nicotine without smoke: Tobacco harm reduction. Royal College of Physicians. 2016

What is the effect of vaping on the body?

While cigarette smoke is known to contain thousands of harmful chemicals, the vast majority of these chemicals are either completely absent in electronic cigarette aerosol or exist only at trace levels. Additionally, the emissions of toxicants were 82 to >99 percent lower on a per-puff basis for e-cigarettes compared to cigarettes.

There is "conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco" and "evidence supports the relative safety of e-cigarette emission aerosols for the respiratory tract compared to tobacco smoke."

Numerous studies have shown that switching to vaping drastically lowers the build-up of carcinogens and tar in the bodies of smokers. A 2016 study published in Nicotine and Tobacco Research found that after switching from tobacco to e-cigarettes, nicotine exposure remains unchanged, while "exposure to selected carcinogens and toxicants is substantially reduced." A long-term cross-sectional study also found that transitioning to ENDS from smoking drastically lowered the levels of tar, toxins, and carcinogenic chemicals found in the bodies of both former smokers and current dual users of both cigarettes and e-cigarettes.

The two most dangerous carcinogens in tobacco smoke, acrylonitrile and 1,2-butadiene, account for more than three-quarters of the cancer risk from smoking and are not found in vapor at all. Another class of carcinogens called tobacco-specific nitrosamines (TSNAs) is found in vapers at levels of only 2 percent of those found in smokers. It is of little surprise then that, of persons suffering from chronic obstructive pulmonary disease, 75.7 percent of persons switching from cigarettes to e-cigarettes had improved respiratory symptoms, compared to only 0.8 percent where symptoms continued to worsen. In the same way, respiratory exacerbations were halved in patients who quit or reduced substantially their tobacco consumption after switching to electronic cigarettes. Similar benefits were found in asthma patients.

A European study similarly concluded that, where cigarettes were assigned a 100 percent rating for "maximum relative harm" (MRH), e-cigarettes were only given a 4 percent rating of MRH.

Among e-cigarette users who had never smoked combustible tobacco, there is no evidence that current or former e-cigarette use is associated with any respiratory disease. This finding contradicts incorrect claims that the demonstrated relationship between e-cigarette use and respiratory disease is completely explained by e-cigarette users who are also current or former smokers of combustible tobacco.

SOURCE: National Academies of Sciences, Engineering, and Medicine. 2018. Public Health Consequences of E-Cigarettes. Washington, DC: The National Academies Press.

SOURCE: Chemical Research in Toxicology. 2016; 29, 10, 1662–1678. Publication date: 18 September 2016.

SOURCE: Polosa R, O'Leary R, Tashkin D, Emma R, Caruso M. The effect of e-cigarette aerosol emissions on respiratory health: a narrative review. Expert Review of Respiratory Medicine. 2019; 13(9):899-915.

SOURCE: Kenkel DS, Mathios AD, Wang H. E-Cigarettes and Respiratory Disease: A Replication, Extension, and Future Directions. NBER Working Paper No. 27507 July 2020 JEL No. I12.

SOURCE: Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. Annals of Internal Medicine. Epub ahead of print, 7 February 2017.

SOURCE: Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. 2014.

SOURCE: Polosa R, Morjaria JB, Prosperini U, et al. Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up. International Journal of Chronic Obstructive Pulmonary Disease. 22 Aug 2018; 13:2533–2542.

SOURCE: Goniewicz ML, et al. Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study, Nicotine and Tobacco Research. 2016.

SOURCE: Nutt DJ, et al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. European Addiction Research. 20 April 2014; 218–25.

SOURCE: Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. Annals of Internal Medicine. 2017.

SOURCE: Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products with those of tobacco smoke. Tobacco Control. 2017.

SOURCE: Xia B, Blount BC, Guillot T, et al. Tobacco-Specific Nitrosamines (NNAL, NNN, NAT, and NAB) Exposures in the US Population Assessment of Tobacco and Health (PATH) Study Wave 1 (2013-2014) [published online ahead of print, 27 July 2020]. Nicotine and Tobacco Research.

SOURCE: Polosa R, Caponnetto P, Sands MF. Caring for the smoking asthmatic patient. Journal of Allergy and Clinical Immunology. 2012; 130(5):1221–1224.

SOURCE: Margham J, McAdam K, Forster M, et al. Chemical composition of aerosol from an e-cigarette: a quantitative comparison with cigarette smoke. Chemical Research in Toxicology. 2016 Oct 17; 29(10):1662–1678.

SOURCE: Callahan-Lyon P. Electronic cigarettes: human health effects. Tobacco Control. 2014; 23(suppl 2):ii36–ii40.

SOURCE: Cotta KI, Stephen CD, Mohammad NU. A review on the safety of inhalation of propylene glycol in E-cigarettes. Global Journal of Pharmaceutical Science. 2017; 2(2):555584.

What do the world's major medical bodies have to say about vaping?

Almost every major public health organization has endorsed nicotine vaping as safer than smoking and an effective way to help smokers quit. This list includes Cancer Research U.K.; the British Medical Association; the British Lung Foundation; the New Zealand Minister of Health; the U.S. National Academies of Sciences, Engineering, and Medicine; the American Association of Public Health Physicians; the Royal Australian College of Physicians; the French National Academy of Pharmacy; and the German Federal Institute for Risk Assessment.

SOURCE: The statements of 27 respected scientific and public health organizations that have concluded that nicotine vaping is safer than smoking (and helps smokers quit).

Does vaping pose a risk to bystanders like passive smoking?

Vaping producesno smoke so there are no carcinogenic particles present in the air and inhaled by other people. Multiple studies have found that vaping products do not pose any material risk to passive smokers. Because of the non-existence of these risks, Public Health England recommends that smoke-free workplace laws and laws which prohibit indoor smoking do not apply to alternative nicotine delivery products.

SOURCE: Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. Addiction. 2015; 110:1061–7.

SOURCE: Burstyn I. Peering Through the Mist: Systematic Review of What the Chemistry of Contaminants in Electronic Cigarettes Tells Us About Health Risks. BMC Public Health. 2014.

SOURCE: Tobacco Advisory Group of the Royal College of Physicians. Nicotine without smoke – tobacco harm reduction. London: RCP, 2016.

SOURCE: Public Health England. Use of e-cigarettes in public places and work places. 2016.

What about chemicals or flavoring agents in e-cigarettes?

While electronic cigarettes do contain some flavoring agents, these chemicals occur at far lower concentrations than they do in tobacco smoke. Other chemicals, such as propylene glycol (a main component in the aerosol product) have been found to pose no threat when inhaled.

E-cigarette use (5g per day) represents a 79.0–96.8 percent reduction in formaldehyde, a 99.5–99.8 percent reduction in acetaldehyde, and a 96.0–99.5 percent reduction in acrolein exposure compared to smoking 20 tobacco cigarettes.

Does e-cigarette liquid contain formaldehyde?

A number of media reports have claimed that e-cigarettes contain high levels of formaldehyde. It is important to note that formaldehyde is normally present at low levels in both indoor and outdoor air and is commonly used in building materials and even household products.

However, high levels of formaldehyde are not present in electronic cigarettes. This claim was based on one—since discredited—study where researchers produced formaldehyde by deliberately overheating e-cigarettes to the point where the product was unusable. A standard nicotine vaper would not be inhaling high levels of formaldehyde.

SOURCE: Farsalinos K. E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users. Food and Chemical Toxicology. 2017.

Does vaping cause "popcorn lung?"

A common myth surrounding vaping is that it causes bronchiolitis, commonly called "popcorn lung" (after diacetyl, a buttery flavor, used in the manufacture of microwave popcorn was found to be associated with the illness).

In reality, not a single vaper has been found to have developed this condition, and multiple studies found no indications that e-liquids cause it. Even more importantly, diacetyl is contained in a combustible cigarette at 750 times the amount found in e-cigarette aerosol. Even at this relatively high level, there has not been a single case linking cigarette smoking to bronchiolitis.

SOURCE: Fujioka K, Shibamoto T. Determination of toxic carbonyl compounds in cigarette smoke. Environ Toxicol. 2006; 21:47–54.

SOURCE: Flavorings-related lung disease: diacetyl [Internet]. Washington, DC: Occupational Safety and Health Administration, U.S. Department of Labor.

SOURCE: Polosa R, Cibella F, Caponnetto P, et al. Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked. Scientific Reports. Vol. 7, 13825 (2017). https://doi.org/10.1038/s41598-017-14043-2.

What about recent severe lung injuries in the United States (EVALI)?

In late 2019, a number of, predominantly, young Americans were hospitalized, with some tragically perishing, due to a previously unknown respiratory illness. It was speculated that this illness was caused by vaping, and it was referred to as E-cigarette or Vaping Product Use-Associated Lung Injury (EVALI).

However, despite initial speculations, it has now been conclusively proven that all recent lung injuries were caused not by nicotine e-cigarettes, but rather that every case of illness and tragic death has been as a result of illicit, black-market tetrahydrocannabinol

(THC) vaping devices bought on the streets and laced with substances such as vitamin E acetate. No cases have been linked to legal nicotine e-cigarettes and restricting access to legal and regulated e-cigarettes will do nothing to address this problem. On the contrary, the effects will simply be to drive more people to purchase dangerous illegal bootleg vapes which will put even more lives in danger.

SOURCE: Center for Disease Control, Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products.

SOURCE: Butt YM, Smith ML, Tazelaar HD, Vaszar LT, Swanson KL, Cecchini MJ, Boland JM, Bois MC, Boyum JH, Froemming AT, et al. Pathology of Vaping–Associated Lung Injury. New England Journal of Medicine. 2019; 381:1780–1.

SOURCE: Blount B. C., Karwowski M. P., Shields P. G., Morel-Espinosa M., Valentin-Blasini L., Gardner M., et al. Vitamin E acetate in bronchoalveolar-lavage fluid associated with EVALI. N Engl J Med 2020; 382: 697– 705

Can't vitamin E acetate still be added to nicotine e-cigarettes?

It is impossible for vitamin E acetate to be added to nicotine-based e-cigarettes. While THC is oil-soluble and therefore can be mixed with oils such vitamin E, nicotine itself is only water soluble. Oils cannot be successfully mixed into any nicotine vaping liquid. While it is theoretically possible for some open-container vaping devices to be altered to accept illicit THC oils, evidence has shown that "governments should protect consumers by regulating rather than banning vaping products. Bans preclude regulation and encourage an illicit market in these products".

SOURCE: Hall W., Gartner C., Bonevski B. Lessons from the public health responses to the US outbreak of vaping-related lung injury. Addiction 2020.

SOURCE: A ban targeting only open-system e-cigarettes is unlikely to prevent a future EVALI-like outbreak among e-cigarette users.

Are heated tobacco products safer than cigarettes?

Despite containing tobacco, heated tobacco products (sometimes called heat not burn devices) do not burn the product or create smoke. Therefore, most carcinogens created by traditional cigarettes are not present, completely absent, or at hundreds of levels lower than traditional cigarettes. One of the more popular heat not burn products is IQOS, which has been on the market in Japan and Italy since 2014 and has gradually been rolled out to other countries. Dozens of scientific studies have shown that switching completely from conventional cigarettes to the IQOS device significantly reduces the body's exposure to 15 harmful or potentially harmful chemicals. Furthermore, IQOS emits "much lower amounts of carbonyl and PAH compounds than tobacco cigarettes."

SOURCE: Dusautoir R, Zarcone G, et al. Comparison of the chemical composition of aerosols from heated tobacco products, electronic cigarettes and tobacco cigarettes and their toxic impacts on the human bronchial epithelial BEAS-2B cells. Journal of Hazardous Materials Volume 401. 5 January 2021, 123417.

SOURCE: Food and Drug Administration, FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information. 2020.

What does the U.S. Food & Drug Administration say about heated tobacco?

In July 2020, the FDA authorized the marketing of the first "heat not burn" device on the U.S. market [known as IQOS] as a as "modified risk tobacco products." This means that the FDA, after a comprehensive multi-year investigation, has confirmed that it significantly reduces the production of deadly chemicals compared to combustible cigarettes.

As such, they can be marketed with the FDA approved information that heating, not burning, a product, "significantly reduces the production of harmful and potentially harmful chemicals" and that "scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

This is similar to a finding by the U.K. Government that similarly investigated all evidence relating to heat not burn products, and determined that "there would be a likely reduction in risk for smokers deciding to use heat-not-burn tobacco products compared with continuing to smoke cigarettes as the exposure to HPHCs is reduced" and that "a reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products."

SOURCE: Statement on the toxicological evaluation of novel heat-not-burn tobacco products, Committees On Toxicity, Carcinogenicity And Mutagenicity Of Chemicals In Food, Consumer Products And The Environment, Food Standards Agency, United Kingdom

SOURCE: FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information, U.S. Food & Drug Administration, July 7, 2020

What about snus or moist loose tobacco?

Snus or smokeless tobacco is a moist, powdered tobacco product that is placed under the consumer's lip and absorbed into the bloodstream without the need for smoking. It delivers nicotine and tobacco satisfaction, like cigarettes, but without the deadly smoke.

As a result, it has far lower levels of carcinogens than those released when smoking tobacco is consumed. With decades of data on use and effects, "literature reviews have estimated that users of snus have at least 90–95 percent less smoking-related mortality, with minimal reduction in life expectancy, if any at all. The health benefits of smokers who completely transition to snus use are similar to those reported for smoking cessation." Researchers have concluded that, "snus as an alternative to cigarettes has the potential to deliver enormous harm reduction benefits as demonstrated in Sweden, particularly in reducing the incidence of lung cancer and cardiovascular disease of which smoking is a known cause, where the product can be marketed and sold to adult smokers widely."

In the U.S., according to the National Health Interview Survey mortality linkage and the National Longitudinal Mortality Study, moist smokeless tobacco is far lower in health risks compared to conventional cigarettes, particularly for risk of lung cancer. The data demonstrates that smokers are more than 10 times as likely to die from lung cancer compared to smokeless tobacco users, three times as likely to die from any cancer compared to smokeless tobacco users, and twice as likely to die from any cause compared to smokeless tobacco users.

As a result, the FDA has authorized manufacturers to market their product with the following statement: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

SOURCE: Lee PN, Hamling J. The relation between smokeless tobacco and cancer in Northern Europe and North America. A commentary on differences between the conclusions reached by two recent reviews. BMC Cancer. 2009; 9:256.

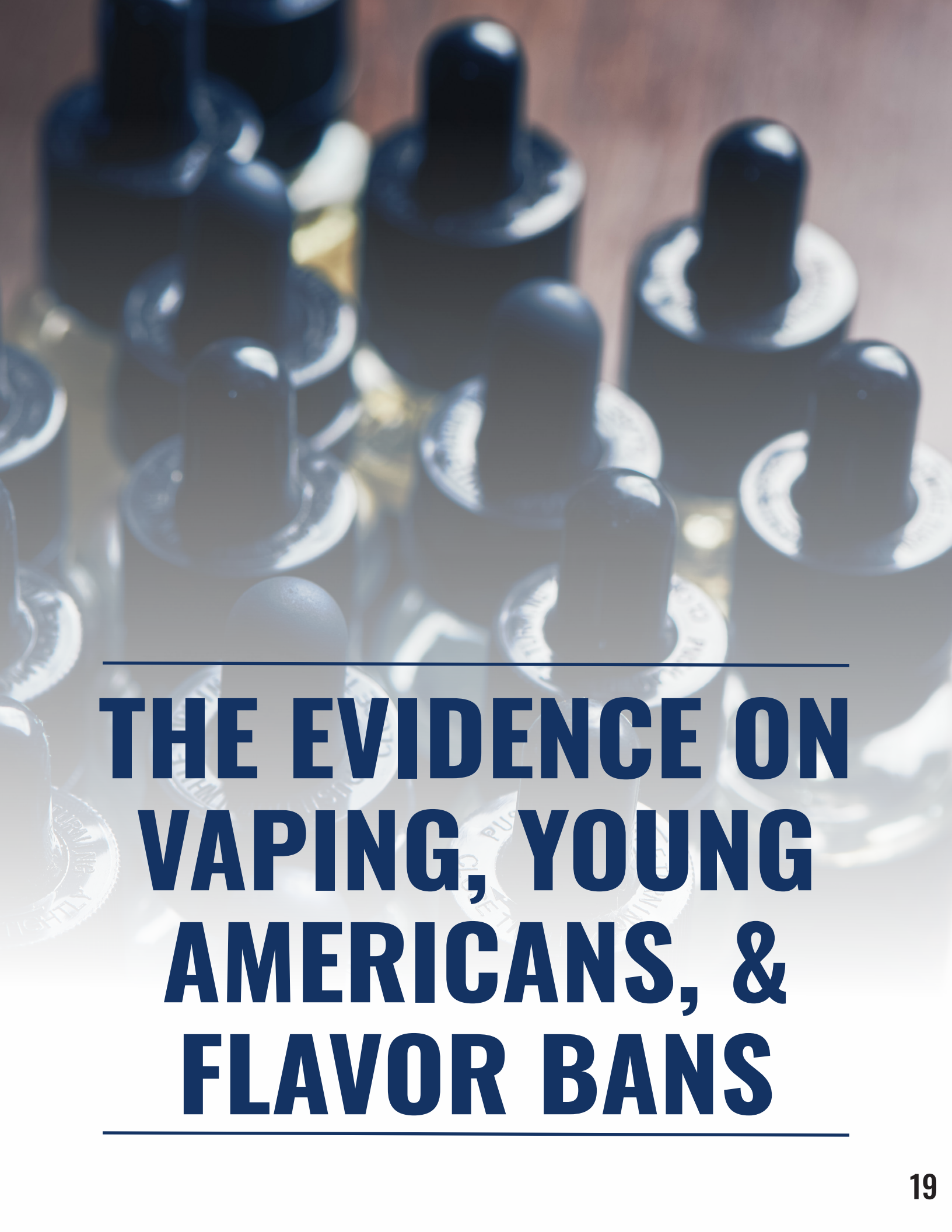
SOURCE: Ramström L, Borland R, Wikmans T. Patterns of smoking and snus use in sweden: implications for public health. International Journal of Environmental Research and Public Health. 2016; 13:E1110.

SOURCE: Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. The Lancet. 2007; 369:2010–4.

SOURCE: Levy DT, Mumford EA, Cummins KM, Gilpin EA, Giovino EA, Hyland A, Sweanor D, Warner KE. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: Estimates of a panel of experts. Cancer Epidemiology, Biomarkers and Prevention. 2004; 13:2035–42.

SOURCE: Broadstock M. Systematic review of the health effects of modified smokeless tobacco products. New Zealand Health Technology Assessment Report. Feb 2007.

SOURCE: FDA grants first-ever modified risk orders to eight smokeless tobacco products. 22 October 2019.



THE EVIDENCE ON VAPING, YOUNG AMERICANS, & FLAVOR BANS

Is there a youth vaping "epidemic?"

While some media reports have attempted to argue that there is an "epidemic" of youth vaping, these reports are not borne out by the evidence. These reports frequently conflate teenagers trying a puff of a vape at a party versus regularly using these products. Surveys routinely classify someone as a vaper if that person has tried even one puff in a 30-day period, resulting in artificially high response rates. A comprehensive analysis of the National Youth Tobacco Survey (NYTS) in the United States found that "data from the NYTS do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress."

One U.K. survey found that, while 40.5 percent of 15-year-olds reported ever having tried a vape, just 11.3 percent were current vapers (a definition that includes people who vape weekly as well as occasional vapers who vape less than once a week). Habitual vaping (i.e., those who vape weekly or more often) was estimated at just 3.9 percent. Another U.K. survey, which was more detailed and relied on a greater sample size than the aforementioned analysis, found that just 2.2 percent of 18-year-olds were habitual vapers; the figures were lower for younger participants.

In addition, academic analysis has found that data from the 2018 and 2019 NYTS survey "do not provide support for claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor for concerns that declines in youth tobacco addiction stand to be reversed after years of progress."

SOURCE: Sarah Jackson, Robert West, Jamie Brown. (2020). Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA?.

SOURCE: West R, Brown J, Jarvis M. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios, 2019.

SOURCE: McNeill A, Brose LS, Calder R, Bauld L, Robson D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England, p. 40.

Does vaping lead to young people taking up the smoking of conventional cigarettes?

Vaping has almost exclusively been taken up by smokers attempting to quit or lower their intake. As a result of the introduction of vaping products, smoking rates in the US have plummeted in recent years. In 2018, 13.7 percent of US adults smoked, a sharp decline from 20.9 percent in 2005. Most of this decline has occurred since the introduction of e-cigarettes, as smokers now have more options than ever to kick their deadly habit. Particularly promising, only 5.8 percent of high school students smoke, down from more than 15 percent in 2011.

A systematic review of all available evidence has shown that there is no evidence that vaping serves to introduce young Americans to smoking. Only a miniscule 0.3 percent of adult vapers are people who have never smoked and almost all teens who use nicotine vapes had previously tried at least one cigarette. Similarly, fewer than 1 percent of U.S. adolescents who have tried an e-cigarette went on to became established cigarette smokers. And, adolescent initiation with e-cigarettes has been found to be associated with a reduced risk of subsequent cigarette smoking. This suggests that, "e-cigarettes were unlikely to have acted as a gateway towards cigarette smoking and may, in fact, have acted as a gateway away from smoking for vulnerable adolescents." In addition, other studies have found that any and all apparent relationships between e-cigarette use and current conventional smoking is "fully explained by shared risk factors."

In fact, the only and main study which ever showed vaping associated with an increase in smoking rates recently admitted this was caused by an error and retracted the finding.

SOURCE: McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie H. E-cigarettes: an evidence update. A report commissioned by Public Health England. PHE publications gateway number: 2015260 2015.

SOURCE: Britton J, Bogdanovica I, McNeill A, Bauld L. Commentary on WHO report on electronic nicotine delivery systems and electronic non-nicotine delivery systems. UK Centre for Tobacco and Alcohol Studies. 2016.

SOURCE: Centers for Disease Control and Prevention, Current Cigarette Smoking Among Adults in the United States. 2018.

SOURCE: Hallingberg B, Maynard OM, Bauld L, et al. Have e-cigarettes renormalised or displaced youth smoking? Results of a segmented regression analysis of repeated cross sectional survey data in England, Scotland and Wales. Tobacco Control. 2020; 29:207-216.

SOURCE: Jarvis M, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? Qeios, 2019.

SOURCE: Levy DT, Warner KE, Cummings KM, Hammond D, Kuo C, Fong GT, Thrasher JF, Goniewicz ML, Borland R. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. Tobacco Control. 2018; 20 p. 20.

SOURCE: Kim S, Selya AS. The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. Nicotine and Tobacco Research. 2020; 22(7):1123-1130.

SOURCE: Shahab L, Beard E, Brown J. Association of initial e-cigarette and other tobacco product use with subsequent cigarette smoking in adolescents: a cross-sectional, matched control study. Tobacco Control. Published Online First: 17 March 2020.

SOURCE: Zhu S. E-cigarette use and associated changes in population smoking cessation. BMJ. 2017.

SOURCE: ASH. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017.

SOURCE: Polosa R. A critique of the U.S. SG's conclusions regarding e-cig use among youth and young adults in US. Harm Reduction Journal. 2017.

SOURCE: Smoking Toolkit Study. Trends in e-cigarette use in England, July 2017.

SOURCE: O'Leary R, MacDonald M, Stockwell T, Reist D. Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, BC: Centre for Addictions Research of BC. 2017.

SOURCE: Prevalence of vaping and smoking among adolescents in Canada, England, and the United States: repeat national cross sectional surveys. BMJ. 20 June 2019.

Do flavors induce adolescents to start vaping?

A key argument behind banning the sale of flavored vapes is that these products are designed to hook teenagers. This, however, is not supported by the evidence. While the evidence shows that flavors encourage adult smokers to make the switch to vaping, these products have no effect on teen use.

A 2015 survey of nonsmoking teens aged 13-17 found interest levels in flavored e-cigarettes at 0.4 out of a possible score of 10. Additionally, fewer than a third of high school students self-report to care about flavors. Academic studies have found that teenage non-smokers' "willingness to try plain versus flavored varieties did not differ" and a mere 5 percent of vapers aged 14-23 reported it was the different flavors that attracted them to e-cigarettes.

SOURCE: Friedman AS, Xu S. Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. JAMA Network Open. 2020; 3(6):e203826.

SOURCE: Czoli CD, Goniewicz M, Islam T, Kotnowski K, Hammond D. Consumer preferences for electronic cigarettes: results from a discrete choice experiment. Tobacco Control. 2016; 25(e1):e30-e36.

SOURCE: Wood GG, Waselewski ME, Bryant AC, Sonneville KR, Chang T. Youth Perceptions of Juul in the United States. JAMA Pediatrics. 2020; 174(8):800–802.

What would be the effect of banning flavors?

Multiple studies have shown that banning all flavors in e-cigarettes (except tobacco flavor) would result in a decline in the use of e-cigarettes and an increase in the smoking of deadly combustible cigarettes. This deadly shift would occur because flavors "contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking." One such study found a simple ban on all flavors but tobacco in e-cigarettes would increase smoking by 8.3 percent.

In the U.K., Public Health England canvassed a number of vaper surveys and found that "banning flavored liquids would deter them [vapers] from using vaping products to help them quit or reduce their smoking. It could also push current vapers towards illicit products." Public Health England therefore concluded that, "a ban on flavored liquids could have adverse effects and unintended consequences for smokers using vaping products to quit." Concerningly, one nationwide British survey from 2019 found that if a vaping flavor ban were enacted, then 25 percent of vapers would still try to get flavors through the black market. Nearly 10 percent who use flavored liquids said they would stop vaping, and 20 percent said that they would either smoke more tobacco or return to smoking tobacco entirely.

In fact, adults who used flavored e-cigarette products have been found to be more than twice as likely to quit smoking combustible cigarettes than adults using non-flavored vaping products.

SOURCE: McNeill A, Brose LS, Calder R, Bauld L, Robson D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England, p. 13.

SOURCE: Buckell J, Marti J, Sindelar JL. Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment. Tobacco Control. 2019; 28: 168-175.

SOURCE: Farsalinos KE, et al. Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey. International Journal of Environmental Research and Public Health. 10 December 2013; 7272–82.

SOURCE: Friedman AS, Xu S. Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. JAMA Network Open. 2020; 3(6):e203826.

What about vulnerable populations?

Smoking disproportionately affects those most in need, such as the indigent, racial minorities, LGBTQ persons, and those suffering from mental illness and substance use disorders.

In particular, smoking is the leading cause of the poor health of persons suffering from mental illness, who are more likely to smoke and smoke more heavily than other smokers. Vaping is critical to assist these vulnerable populations in quitting their deadly habit. E-cigarettes have been found to be particularly successful for persons suffering from mental health problems; far more so than any other form of quitting aid, including pharmaceutical products such as varenicline and bupropion, or other nicotine replacement therapies.

SOURCE: Tobacco use among U.S. racial/ethnic minority groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, Hispanics. A Report of the Surgeon General. Executive summary. MMWR Recomm Rep. 1998; 47(RR-18).

SOURCE: Levinson AH, Hood N, Mahajan R, Russ R. Smoking cessation treatment preferences, intentions, and behaviors among a large sample of Colorado gay, lesbian, bisexual, and transgendered smokers. Nicotine and Tobacco Research. Aug 2012; 14(8):910-918.

SOURCE: Brose LS, Brown J, McNeill A. Mental health and smoking cessation—a population survey in England. BMC Medicine. 2020; 18, 161.

SOURCE: Royal Australian and New Zealand College of Psychiatrists, Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia. March 2018.

HOW SHOULD REDUCED RISK PRODUCTS BE TAXED & REGULATED?

How should vaping be regulated?

E-cigarette sales should be regulated and safety standards must be ensured by enforcing strict product guidelines on battery development, ingredients, and other associated technologies, in the same manner as other consumer goods. All ingredients contained in their vapor products and, in particular, the ingredients contained in any e-liquid In additions should similarly be listed by manufacturers. In addition, regulations should ensure underage persons are unable to access these products, and these must be enforced to ensure high levels of compliance. However, regulations prohibiting advertising ought to be treated with a great degree of caution so as not to prevent smokers receiving accurate information about the health benefits of making the switch to these life-saving reduced-risk products.

What is the impact of taxes on vaping and smoking rates?

To tax safer products at a higher rate than deadlier ones goes against every principle of sound public or health policy. In addition, these regressive taxation policies ensure that the poorest members of society are the hardest hit. As previously stated, poorer individuals are disproportionately likely to be addicted to tobacco products and stand to lose the most through the penalization of reduced-risk alternatives.

As the price of a product increases, it is likely that its use decreases. The same occurs with taxes on vaping, which have been proven to increase smoking rates as people shift back to deadly combustible cigarettes. According to a study released in December 2020 and posted by the National Bureau of Economic Research, taxing e-cigarettes at the same rate as cigarettes would boost traditional cigarette smoking by about 8 percent, and deter some 2.75 million smokers from quitting.

Another study funded by the National Institutes of Health determined that a 10 percent increase in e-cigarette prices results in traditional cigarette sales increasing by 11 percent. Extrapolating from here, a national e-cigarette tax of $1.65 per milliliter of vaping liquid would increase the proportion of adults who smoke cigarettes daily by approximately 1 percent, translating to 2.5 million more adult daily smokers. Overall, the sale of cigarette packets would increase by a staggering 291,820,000 nationally.

Similar results were found in Europe, where an analysis of e-cigarette prices in six countries found that a 10% increase in price reduces e-cigarette sales by 11.5% in the longer term.

SOURCE: Saffer H, Dench D, Grossman M, et al. E-cigarettes and adult smoking: Evidence from Minnesota. Journal of Risk and Uncertainty. 2020.

SOURCE: Pesko MF, Courtemanche CJ, Maclean JC. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. Journal of Risk and Uncertainty. 2020.

SOURCE: Stoklosa M, Drope J, Chaloupka FJ. Prices and E-Cigarette Demand: Evidence From the European Union. Nicotine Tob Res. 2016 Oct;18(10):1973-1980

Do taxes on vaping reduce youth vaping rates?

While evidence is still preliminary, given the relative recent imposition of vaping taxes, states such as Pennsylvania, which imposed a 40 percent vaping tax, have reported no impact on youth vaping rates. In fact, youth vaping increased in the following year. This is highly suggestive that these taxes prevent smokers from switching to vaping but do not prevent youth use—the exact opposite of the intended policy outcome.

SOURCE: 2019 Pennsylvania Youth Survey Empowering Communities to Develop Strategic Prevention Programming.

SOURCE: Stroud, L.

What about revenue lost from tobacco taxes as people make the switch?

It is grossly unethical to argue that persons should continue to smoke – and die – just so that governments can continue to receive revenue from tobacco excise. Such an argument should be dismissed out-of-hand and not be taken seriously.

However, it is worth noting that persons making the switch to vaping will, in fact, save the government money through reduced health care expenditures. Estimates suggest that Medicaid savings will be $2.8 billion annually if just one percent of enrollees switch from smoking to vaping. Similarly, tobacco use costs the military $1.6 billion annually, and savings from this could be utilized to offset the cost of tobacco tax revenues falling.

SOURCE: Belzer, RB. Expected savings to Medicaid from substituting electronic for tobacco cigarettes. R Street Institute. 2017.

SOURCE: Pentagon aims to curb tobacco use by military: memo. Reuters, 26 April 2016.

Why is it important that reduced risk products devices can be ordered online and delivered via mail?

Given the clear public health benefits for persons transitioning from traditional cigarettes to reduced-risk products, it is imperative that they be as widely available and easy to access as possible. Unfortunately, many Americans live significant distances from distributors. This is particularly acute in areas outside of major cities, an issue even more pressing due to higher incidence of smoking in remote areas. For many individuals wishing to quit smoking by way of reduced-risk products, purchasing online and obtaining them via mail is the only method available. By prohibiting online sales, these people will have no choice other than return to easily obtainable deadly combustible cigarettes, or to purchase e-cigarettes and other alternatives through dangerous black market suppliers. Therefore, while strict enforcement measures to ensure, for example, age verification, are necessary, prohibition on online sales will doubtless lead to an increase in easily avoidable deaths from tobacco-related illnesses.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