


A DEARTH OF DATA: E-CIGS & HEATED TOBACCO PRODUCTS

The Myth of Harm Reduction

 The tobacco industry has a long history of misleading the public to believe that some commercial¹ tobacco products are less harmful than others.² For this reason, federal law prohibits the marketing of any “modified risk tobacco product” (MRTP) without specific authorization from the U.S. Food & Drug Administration (FDA).

The Tobacco Control Act defines a “modified risk tobacco product” as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”³



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On July 7, 2020, the U.S. Food & Drug Administration (FDA) authorized the marketing of Philip Morris’ IQOS Tobacco Heating System as an MRTP, allowing it to be marketed as a product that reduces a user’s risk of exposure to harmful or potentially harmful chemicals compared to conventional cigarettes.⁴ Although the small stick of tobacco used with IQOS resembles a conventional cigarette, the IQOS system heats the stick using an electrical device that creates an inhalable aerosol.⁵

When it issued the IQOS marketing order, the FDA acknowledged that “the overall body of evidence was not sufficient to demonstrate that completely switching from combusted cigarette to the IQOS system reduces the risk of tobacco-related disease or harm.”⁶ In other words, even though Philip Morris had failed to show that the IQOS system would present a “modified risk” of harm to its users, the FDA authorized its marketing to claim that it could, in fact, do just that. This fact sheet looks at the tobacco industry’s history of using harm reduction in its marketing tactics, including its promotion of e-cigarette and heated tobacco products.

IQOS and Modified Risk Claims

Like JUUL and other e-cigarettes, IQOS uses harm reduction as a marketing strategy. Philip Morris, the maker of IQOS, claims that its product is less harmful to users than combustible cigarettes.^{7, 8, 9, 10, 11} Although no e-cigarettes have received similar MRTP marketing orders from the FDA, IQOS’ MRTP marketing authorization highlights the decade-long debate within the public health community about the potential risks and benefits of commercially available e-cigarettes.^{12, 13, 14, 15, 16, 17} Despite unequivocal evidence that e-cigarettes, especially flavored products, led to an epidemic of tobacco product use among youth and pose health risks to users, manufacturers of electronic nicotine products continue to market their products as tools to help adult cigarette users quit smoking.¹⁸ Misleading information about e-cigarettes and the role they play in helping adult smokers quit has been used to undermine sensible e-cigarette policies in the U.S. With no strong federal leadership, state and local governments have both an opportunity and an obligation to protect youth and consumers from harmful products that, contrary to industry claims, offer no proven benefits to adult cigarette smokers.

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History and Context of “Modified Risk” Products

The tobacco industry has no interest in protecting public health. To the contrary, tobacco manufacturers have vested interests in maximizing their profits. Tobacco companies make public-health oriented decisions only when they are required to so by law.

Although some e-cigarette companies have pitted themselves against “Big Tobacco” by claiming a role in hastening the “decline of cigarettes in America,”¹⁹ the tobacco industry has been interested in developing and marketing new, healthier-seeming products for more than half a century. As early as 1988, R.J. Reynolds Tobacco Company developed and introduced a heated tobacco product,²⁰ and Philip Morris’ current IQOS heated tobacco product is remarkably similar to an earlier product, Accord, introduced in 1998.²¹ More recently, Altria (the owner of Philip Morris) bought a 35 percent ownership stake in e-cigarette market leader, JUUL Labs.²² In reality, there really is little to no difference between the e-cigarette industry and the tobacco industry.

In fact, the tobacco industry has capitalized on the clean, modern design of new products and the lax regulation of social media outlets to attract a whole new generation of nicotine users.

E-cigarettes have become popular under the guise of providing a “safer” alternative and means to quit cigarette smoking.^{23,24} But as of January 2021, no e-cigarette or heated tobacco product has been approved as a smoking cessation medication by the FDA. Rather than offering scientifically proven smoking cessation support, e-cigarette companies have merely used the cessation aid tactic to position their products in the mass market.

E-cigarette awareness and use among adults in the U.S. increased rapidly over the past decade — alarmingly more so among youth. Between 2012 and 2019, the percentage of U.S. adults who reported regular e-cigarette use grew from 0.5 percent (992,000) to 4.5 percent (10.9 million).^{25,26}

Although awareness and use of heated tobacco products, such as IQOS, in the U.S. lags well behind that of e-cigarettes, recent evidence shows a similar potential for widespread adoption of these products as public awareness of them grows.²⁷ A nationally representative survey of U.S. adults between November 2019 and February 2020, found a low level of awareness (8.1 percent) and use (0.55 percent) of heated tobacco products.²⁸ Yet the percentage of people (18.2 percent) who tried the product and then became regular users was nearly identical to that observed for e-cigarettes (17.8 percent) in 2012, suggesting that more aggressive marketing could also lead to widespread adoption of heated tobacco products.²⁹

Health Impacts – How We Know What We Know

Public health and biomedical research tackles questions about human health risks and benefits caused by exposures to specific products, chemicals, or conditions through a collective, peer-vetted process. Demonstrating and verifying these risks or benefits often involves many studies, analyses, and reviews of the evidence by independent scientific bodies. This process can naturally take a few to many years. The process can also be artificially slowed down by industry duplicity and interference.

After the introduction of the mass-produced and aggressively marketed cigarette at the end of the 19th century, years passed before the rise in certain cancers in the early 20th century was suspected to be related to the increased prevalence of cigarette smoking in the U.S. The tobacco industry did its own research, which it withheld from the public, and came to understand that its products caused human disease and death, long before the scientific community was convinced.³⁰ In fact, it took decades of research to show that cigarette smoking causes specific diseases and death. This research resulted in publication of the first U.S. Surgeon General’s Report on Smoking and Health in 1964, which concluded that cigarette smoking causes lung cancer and laryngeal cancer and may cause other health problems.³¹ Today, the U.S. Surgeon General recognizes 35 diseases and conditions caused by active smoking and 10 by secondhand smoke.³²

E-cigarettes – Evidence for Public Health Harms & Benefits

Background

Some 110 years after the mass-marketed cigarette was introduced to consumers, digital-age versions of that original product emerged to attract new generations of customers with flavors, trendy designs, and marketing ploys.³³ Since 2011, e-cigarette use among U.S. youth has surged, overtaking cigarettes as the most commonly used tobacco product in 2014.³⁴ In 2020, nearly one in five (more than 3 million) high school students — and nearly 1 in 20 (550,000) middle school students — reported e-cigarette use during the past month.³⁵ Among these users, more than 80 percent reported using flavored e-cigarettes.³⁶ The high rate of youth use of these new products is a great public health concern, and recognized as an “epidemic” by the U.S. Surgeon General in 2018.³⁷

E-cigarettes were unleashed on the market — and targeted to children^{38,39} — before their potential harms or benefits were at all understood.⁴⁰ The scientific and public health communities have been trying to catch up, but well-designed research studies and legitimate debate take time. In fact, a seminal report by the U.S. National Academies of Science, Engineering and Medicine, *Public Health Consequences of E-Cigarettes* (“2018 National Academies Report”), published in 2018, is already significantly out of date. The report relied on evidence available through July 2017.⁴¹ Of the approximately 6,100 publications on e-cigarettes now listed in the U.S. National Library of Medicine, *more than 70 percent* were published *after* July 2017.⁴² Similarly, 70 percent of the mere 370 publications involving heated tobacco products were published after 2017.⁴³ Scientific understanding of the risks and benefits of these electronic nicotine products has deepened considerably in just the past few years.

Typical tobacco industry tactics have also delayed scientific consensus on appropriate public health actions to address e-cigarettes. For example, before an international Framework Convention on Tobacco Control meeting in 2014, a group of 53 people, including scientists, clinicians, and advocates, sent a letter to the World Health Organization (WHO) Director General accompanied by a slick public relations campaign that attracted global publicity. The letter sought to convince the WHO, without citing any scientific evidence, to dismiss concerns about e-cigarettes and adopt a tobacco harm reduction model centered on the

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“rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks.”⁴⁴ Within days, the British American Tobacco company issued a press release making many of the same arguments⁴⁵ and revealing obvious coordination, continuing a decades’ long pattern of corporate behavior designed to delay sound public health policy by interfering with authentic scientific debate and conclusions.⁴⁶

Co-opting the “Harm Reduction” Concept

Tobacco industry influence has also led to the co-opting of a legitimate public health concept of “harm-reduction” for the financial benefit of e-cigarette manufacturers. Harm reduction has been shown to be a viable public health strategy in some contexts; for example, needle-exchange programs have been shown to reduce harm among injection drug users. Yet, the analogy has been inappropriately applied to e-cigarettes and heated tobacco products. Unlike these products, clean syringes are not associated with substance use initiation and maintenance and do not have mass-market commercial interests behind them.^{47, 48} Remarkably, some e-cigarette advocates, to this day, continue to promote mass market e-cigarettes and write off the epidemic of youth e-cigarette use as an “unintended consequence” in pursuit of a higher value outcome, namely “reducing the immediate harms to smokers.”⁴⁹

Public Health Harm Evidence

Legitimately complicating efforts to characterize the personal and public health risks and benefits is the reality that an “e-cigarette” is not a singular, consistent product. There are various e-cigarette products available on the market. Yet the diverse “e-cigarette” product class has enough commonalities for widespread recognition among public health agencies, including the U.S. Centers for Disease Control and Prevention, that e-cigarette aerosols contain many harmful substances, including:

- Nicotine;
- Ultrafine particles that can be inhaled deep into the lungs;
- Flavoring such as diacetyl, a chemical linked to a serious lung disease;
- Volatile organic compounds;
- Cancer-causing chemicals; and
- Heavy metals such as nickel, tin, and lead.⁵⁰

E-cigarette use, including use of heated tobacco products, can lead to a range of public health harms.



The presence of these substances, along with other harmful characteristics of e-cigarettes, has led to a growing body of public health harm evidence showing that e-cigarette use, including use of heated tobacco products, can lead to a range of public health harms including nicotine poisoning, addiction, respiratory and cardiovascular disease, cancer, oral diseases, and reproductive effects, among other risks. While data specific to the heated tobacco product subset of e-cigarettes are more limited, available research shows that heated tobacco products present similar risks to those posed by the more prevalent forms of e-cigarettes and combustible tobacco products.

Poisoning, Burns, and Injuries. Acute hazards associated with e-cigarettes have been recognized for years. Nicotine poisoning of children and adults can be harmful or fatal and results from swallowing, breathing, or absorbing e-cigarette liquid through the skin or eyes. In addition, e-cigarettes can cause burns and injuries because of fires and explosions associated with defective batteries.⁵¹ Very little independent research is available about heated tobacco products and acute hazards. Some studies, however, have found that heated tobacco products may be associated with unique harms, compared to combustible cigarettes. Studies show

that they produce significantly higher levels of many potentially harmful chemical substances compared to cigarettes.⁵² One study, for example, indicated that IQOS users may be at risk for unique organ toxicity not associated with cigarettes.⁵³

Addiction. The nicotine intake from e-cigarettes and heated tobacco products is comparable to intake from combustible tobacco cigarettes and can cause addiction.^{54, 55, 56} Youth are especially vulnerable to developing nicotine addiction and can suffer related negative long-term impacts, including impaired memory and reduced attention span.⁵⁷

Youth Cigarette Smoking Initiation. Compelling recent evidence shows that e-cigarette use among youth acts as a gateway to future cigarette smoking.^{58, 59} A four-year nationally representative study published in 2021 found that U.S. youth who use electronic cigarettes are at a threefold higher risk of later daily cigarette smoking.⁶⁰ Very little independent research is available regarding heated tobacco products but suggests a similar pattern to e-cigarettes.⁶¹

Respiratory Diseases. While the 2018 National Academies Report found no available evidence to determine whether e-cigarette use causes respiratory disease such as asthma, chronic obstructive pulmonary disease (COPD), chronic bronchitis, and emphysema,⁶² more recent research shows that it does. Specifically, a 2020 meta-analysis of 24 studies, found strong evidence for e-cigarettes causing asthma and chronic obstructive pulmonary disease (COPD).⁶³ Furthermore, a four-year nationally representative study also found strong evidence for e-cigarette use leading to respiratory disease (asthma, COPD, chronic bronchitis, or emphysema).⁶⁴ In 2020, WHO recognized that e-cigarette use is independently associated with respiratory disease in humans.⁶⁵ Studies on heated tobacco products have shown that they contain similar levels of some harmful components of combustible cigarettes known to cause respiratory diseases.^{66, 67}

Cardiovascular Disease. According to the 2018 National Academies Report, “most studies suggested potential for cardiovascular harm from e-cigarette use.”⁶⁸ Research continues to support that finding — e-cigarette use increases the risk for cardiovascular disease.⁶⁹ In fact, enough evidence accumulated in the past few years that, in 2020, both the WHO and the European Union’s Scientific Committee on Health, Environmental, and Emerging Risks recognized a significant association between e-cigarette use and cardiovascular disease risk in humans.⁷⁰ ⁷¹ Although very little research is available on heated tobacco products, studies have shown that they impact cardiovascular disease biomarkers similarly to combustible cigarettes.^{72, 73}

Cancer. Recent studies have shown that e-cigarettes present elevated cancer risk. For example, researchers recently found that e-cigarette aerosol contains carcinogens that damage DNA,⁷⁴ deregulate genes associated with cancer,⁷⁵ and cause cancer in mice⁷⁶ — in ways both similar and different from conventional cigarette smoke. Furthermore, a 2020 meta-analysis found strong

evidence for elevated cancer risk from exposure to metals in e-cigarette liquids and aerosols.⁷⁷ A 2021 review found such strong basic science and molecular evidence for e-cigarette aerosol to cause lung cancer that, given the long lag time between exposure and later cancer, researchers made an urgent call for tighter regulation of the products.⁷⁸ Although very little independent research is available on heated tobacco products, studies have shown that they contain similar levels of some carcinogenic components found in combustible cigarettes⁷⁹ and many other potentially toxic substances at higher levels than in cigarette smoke.⁸⁰

Oral Diseases. Recent studies provide growing evidence that periodontal disease risk is significantly greater among e-cigarette users compared to non-smokers and possibly comparable to that of cigarette smokers. E-cigarette users have a far greater risk of developing gum disease, bone loss around teeth, and any periodontal disease compared to never-users.⁸¹ Population-based data from South Korea found e-cigarette users to be as likely as cigarette smokers to have periodontal disease, and both more than twice as likely as non-users.⁸²

Developmental and Reproductive Effects. The danger to pregnant women and fetuses from products containing nicotine is well established.⁸³ Recently published data from the U.S. Pregnancy Assessment Monitoring System found e-cigarette use during pregnancy was an independent risk factor for neonatal complications and was not a safer alternative to cigarette smoking during pregnancy.⁸⁴

Dual Use. The 2018 National Academies' Report found no available evidence to determine whether e-cigarette use among conventional cigarette smokers (i.e., dual use) changes death and disease outcomes compared with those who only smoke conventional cigarettes.⁸⁵ The high prevalence of dual use in the population (e.g., nearly 40 percent of U.S. adult e-cigarette users also smoke conventional cigarettes⁸⁶) makes understanding any dual use risks essential for public health. In fact, recent evidence shows that dual users may increase their risk for heart disease,^{87, 88, 89, 90} lung disease,^{91, 92} and cancer⁹³ compared to smoking alone. Although very little independent research is available, studies suggest that, like e-cigarettes, heated tobacco products contribute to dual- or poly-tobacco product use.^{94, 95}

Public Health Benefit Evidence

On the other side of the scale, evidence supporting the potential public health benefits of e-cigarettes or heated tobacco products is scant at best.

Smoking Cessation/Harm Reduction. Proponents of e-cigarettes have claimed for years, based on belief and scant scientific evidence, that the products could offer a public health benefit by providing current cigarette smokers a viable "off-ramp" to quit smoking and thereby reduce smoking-caused disease and death among them.⁹⁶ But the 2018 National Academies Report

found that there wasn't enough evidence linking e-cigarette use with smoking cessation.⁹⁷ Since that report, many peer-reviewed population and clinical studies have been published and scientific understanding of the potential role of e-cigarettes in smoking cessation has evolved.

In the 2018 National Academies Report, the scientific panel's analysis integrated evidence from both clinical trials and population-based observational studies into their conclusions about e-cigarettes and smoking cessation. A more recent review of e-cigarettes and smoking cessation used multiple meta-analyses to separately examine the association of e-cigarette use and smoking cessation in general population and in therapeutic settings: the review examined e-cigarettes as a consumer product and as a prescription therapy to quit smoking.⁹⁸ According to that review, studies strongly indicated that e-cigarette use, in a consumer product context, is *not* associated with quitting among smokers — even among smokers motivated to quit. A parallel meta-analysis of nine randomized clinical trials found that provision of free e-cigarettes as a therapeutic intervention was associated with more quitting than conventional therapy, suggesting they may have a role as a prescription therapy for individuals also receiving clinical cessation support.⁹⁹ To date, however, no company has applied for approval of an e-cigarette for use as a cessation device, much less received authorization for the e-cigarette to be prescribed and sold as such purposes.



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In short, present research supports these conclusions:

- As consumer products, e-cigarettes are not associated with increased smoking cessation;¹⁰⁰
- E-cigarettes may be more effective than conventional cessation therapies for smokers motivated to quit *when accompanied by behavioral support and specific instructions on e-cigarette use* (and only after having gone through the appropriate regulatory processes for approval)^{101, 102}
- Most smokers who use e-cigarettes to quit smoking continue to use e-cigarettes, expending financial resources to maintain a nicotine addiction and continuing to be exposed and exposing others to harmful aerosols;¹⁰³
- Many smokers who use e-cigarettes to quit in a therapeutic setting keep smoking and become dual users.¹⁰⁴

The U.S. Preventive Services Task Force (PSTF), an independent panel of clinical experts that reviews the scientific evidence of preventive clinical services, recommended not using e-cigarettes to help smokers quit.¹⁰⁵ Instead, the panel recommended the use of other tobacco cessation interventions with proven effectiveness and established safety.¹⁰⁶ In addition to finding insufficient evidence to recommend the use of e-cigarettes for smoking cessation, the task force noted the high uptake of e-cigarettes among youth, the harms of dual use, and the lack of knowledge on how to help with e-cigarette cessation once users quit smoking conventional cigarettes.¹⁰⁷

Although far less independent research is available about heated tobacco products and cessation or harm reduction specifically, available evidence suggests that they are more likely to be used in conjunction with other tobacco products than they are as effective cessation or harm reduction tools.^{108, 109} And even if evidence suggested they might be useful to help smokers quit, no e-cigarette or heated tobacco product has received authorization from the FDA to be sold as a cessation aid.

Conclusion

Current evidence shows that e-cigarettes and heated tobacco products pose harms to users and the public. There is no evidence that any of these new products help with smoking cessation at a population level. Moreover, to date, no e-cigarettes or heated tobacco products have been approved by the FDA as smoking cessation products.

According to WHO, e-cigarettes, including products like IQOS, “are undoubtedly harmful, should be strictly regulated, and, most importantly, must be kept away from children.”¹¹⁰

E-cigarette and Heated Tobacco Product Market Uncertainty

Concerns about flavors, youth use, dual use, health harms to users and non-users (via secondhand aerosol exposure) persist for e-cigarettes and heated tobacco products as the FDA reviews applications for millions of new tobacco products. The FDA's tobacco product marketing approvals to date have been strongly criticized by legal¹¹¹ and public health experts.^{112, 113, 114} In fact, the marketing approval for IQOS so concerned the WHO that it issued a formal statement in July 2020 stating, "given that health may be affected by exposure to additional toxins when using [heated tobacco products], claims that [heated tobacco products] reduce exposure to harmful chemicals relative to conventional cigarettes may be misleading."¹¹⁵

The Takeaway

Without strong federal leadership, state, local, and Tribal governments have an important opportunity to protect youth and consumers from harmful tobacco products such as e-cigarettes and heated tobacco products that offer no proven health benefits.

For information about adopting state and local policies to regulate e-cigarettes and heated tobacco products, see the [Policy Playbook for E-Cigarettes \(2020\)](#) produced by the Public Health Law Center (PHLC) and the Vaping Prevention Resource. For examples of tribal and state policy actions on e-cigarettes and heated tobacco products, visit the Public Health Law Center's blog post [States and Tribes Stepping in to Protect Communities from the Dangers of E-cigarettes: Actions and Options](#). For information about adopting Tribal policies to regulate e-cigarettes and other products, see the National Native Network's [Commercial Tobacco Smoke-Free Tribal Policy Toolkit](#).

This publication was prepared by the American Lung Association in California and the Public Health Law Center, a nonprofit organization that provides information and legal technical assistance on issues related to public health. The Center does not provide legal representation or advice. The information in this document should not be considered legal advice. This case study was made possible by funds received from Grant Number 19-10229 with the California Department of Public Health, California Tobacco Control Program, and the American Lung Association in California.

Endnotes

- 1 The Public Health Law Center recognizes that traditional and commercial tobacco are different in the ways they are planted, grown, harvested, and used. Traditional tobacco is and has been used in sacred ways by Indigenous communities and tribes for centuries. Comparatively, commercial tobacco is manufactured with chemical additives for recreational use and profit, resulting in disease and death. For more information, visit: <http://www.keepitsacred.itcmi.org>. When the word "tobacco" is used throughout this document, a commercial context is implied and intended.
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