

New Tobacco Products Do Not Protect Public Health

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In 2019, the Food and Drug Administration (FDA) gave a green light to heated tobacco products becoming widely available on the U.S. market, allowing the marketing of the IQOS (“I quit ordinary smoking”) electronic device by Philip Morris through the premarket tobacco product application pathway (1). A modified risk tobacco product application is still pending at the FDA, but the decision through the premarket tobacco product application route indicates that the FDA has found that the product is appropriate for the protection of public health.

Different countries are following very different approaches to respond to this new generation of products, ranging from nonregulation to an increasing number of countries with complete bans on manufacture, importation, and sale of some new products, especially e-cigarettes. These countries compare the issue to the Boeing 737 Max: Regulatory authorities around the world have rightly applied the precautionary principle, in the interests of public health and life, to halt the use of these planes until the causes of the crashes and the real dangers are clarified. Governments trusted the airline industry to police itself, but it fell short, and the airline industry generally has a better reputation than the tobacco industry with regard to safety and concern for the public.

The 40 or so countries that have enacted bans on e-cigarettes have done so because there are too many unanswered questions about the ingredients, effects, and impact on public health in low- and middle-income countries. What are the toxic effects of inhaling the many chemicals, in addition to nicotine, that are vaporized by these products? Do the new products help smokers quit or conversely

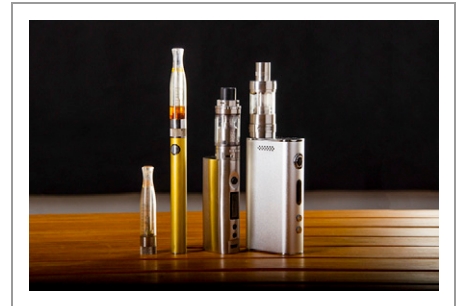
keep them smoking as dual users? Would some users use the new products as a long-term replacement for conventional cigarettes, which is not how true cessation products are designed to work? Do they encourage youth to enter the path to nicotine addiction and conventional smoking? Will these trendy products “renormalize” tobacco use? Is it right to consider e-cigarettes and heated tobacco products together in policy terms?

Harm reduction has a historical place in public health (2) as methadone maintenance does in heroin addiction. Harm reduction has also been interpreted as recommending alternative nicotine-containing products such as smokeless tobacco, e-cigarettes, or heated tobacco products instead of conventional cigarettes, thus replacing a very harmful product with a less but still harmful product. The concept is intuitive and attractive and therefore very tempting for smokers, health professionals, and politicians. Unfortunately, this is a one-sided view of a much more complex public health problem.

Motivated by the FDA approval of IQOS, we present arguments for why a harm reduction strategy should not be used as a population-based strategy in tobacco control. Tobacco harm reduction policy is based on incorrect assumptions and claims, which are outlined in the sections below.

“Smokers Cannot or Will Not Quit Smoking”

This premise is wrong. Millions of smokers worldwide have quit, and most have stopped



by willpower alone (3). The majority of smokers want to quit, and the main policy goal must be to motivate and support tobacco users to quit and achieve long-term abstinence (4, 5).

“Alternative Nicotine Delivery Products Are Highly Effective for Smoking Cessation”

There is lack of evidence to support the use of these new products as smoking cessation tools. Even the manufacturers of e-cigarette JUUL (Juul Labs, Inc.) admit their product is “not intended to be used as a cessation product, including for the cure or treatment of nicotine addiction” (6). In the United States, no e-cigarette or other noncombustible product has been approved by the FDA for smoking cessation; in fact, no applications have been made to the FDA for these products as being efficacious for cessation. On the contrary, in real-life settings, their use seems to undermine smoking cessation, possibly because the new products are promoted

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as “safe.” No independent studies have tested the effect of heated tobacco devices, such as IQOS, on long-term smoking cessation.

“Smokers Will Replace Conventional Cigarettes with These New Products”

Studies show that the majority of e-cigarette users continue to smoke both conventional cigarettes and e-cigarettes (7–12), with a nonsignificant reduction in consumption of conventional cigarettes (13–15). There are limited data on heated tobacco products, but one independent study found that all current users continued to use cigarettes as well (16).

“Alternative Nicotine Delivery Products Are More or Less Harmless”

Conventional cigarettes have extraordinarily devastating health consequences; therefore, all other products in comparison will be “less harmful.” However, less harmful is not the same as harmless.

Independent studies have shown that harmful substances in emissions from these products are not reduced by the oft-claimed 95% (17–19). One study found that dual use was not associated with reduction in carcinogen or toxin levels (20), whereas another large study found that toxicant exposure was higher among dual users than among smokers of conventional cigarettes alone (12). These new products might even contain new harmful toxicants, such as those associated with flavorings.

Using only e-cigarettes instead of combustible cigarettes will probably reduce users’ overall exposure to toxicants (21), but reduction in exposure to toxicants does not necessarily lead to significant reduction in harm. Evidence supports a significant effect of very low-dose combustible tobacco smoke exposure (a few cigarettes per day or occasional use) in causing coronary heart disease (22); there is a nonlinear dose–response relationship, and the excess risk in smokers of only five

cigarettes per day is about 50% compared with nonsmokers (23). Reducing smoking-related health risks requires complete cessation.

There is little evidence on the health effects of heated tobacco devices, and most studies have been performed by the tobacco industry (24). Data show no improvement of lung function after switching from combustible to heated tobacco (24). The tobacco industry’s own data also fail to show a consistently lower risk of harm (24).

“These Products Do Not Encourage Youth Initiation”

These new products, especially with candy or fruit flavors, strongly appeal to youth (25), even youth at low risk of taking up smoking. Some countries have seen a significant spread of e-cigarette use among youth (26–28). The FDA commissioner stated that the United States is experiencing epidemic-level rises in youth e-cigarette use (29).

There is substantial evidence that youths’ use of these new nicotine-containing products increases their risk of future smoking (21, 30, 31, 32). Globally, the industry is using social media and young influencers to promote their products, seen by millions of mainly young people.

“The Tobacco Epidemic Cannot Be Curbed”

Countries with strong tobacco control (e.g., high price, plain packaging, comprehensive marketing bans, smoke-free public spaces and workplaces, intensive antismoking campaigns, free national cessation services) have experienced impressive declines in smoking prevalence (33).

The New Products Are the Industry’s Adaptation to Increased Regulation of Cigarettes and Declining Consumption and Acceptability of Smoking

These new products are primarily manufactured by the multinational tobacco industry, which has a strong economic

interest in expanding use of these products to as many smokers and nonsmokers as possible. Since the 1950s, the industry has manufactured “safer” tobacco products (filtered and light, mild, ultralight, and low-tar cigarettes). Publicly available internal tobacco industry documents show that the tobacco companies have attempted to deter smokers from quitting by developing products that appeared to be less harmful, less addictive, or more socially acceptable: “Quitters may be discouraged from quitting, or at least kept in the market longer.... The safe cigarette would have wide appeal, limited mainly by the social pressures to quit” (34). The industry had knowledge that such products had no health advantage and did not help smokers quit (35). The industry has not changed.

After the launch of their heated tobacco products, a major tobacco company last year announced plans to phase out manufacturing of cigarettes and move into smoke-free products (36). Yet, the tobacco industry continues to oppose tobacco control measures for ordinary cigarettes, such as tax increases and smoke-free areas, and persists with sophisticated advertising in low-income countries, such as Indonesia. Internal industry documents show that the tobacco companies have no intention, as some of them claim they do, to stop manufacturing conventional cigarettes (37). Evidently, tobacco companies are attempting to appear as responsible members of society and as part of the solution so that they may rehabilitate their reputation, more effectively influence decision makers, and sell more tobacco products.

In summary, there may be a role for harm reduction in tobacco control for a minority of high-risk smokers. However, it is not a population-based strategy. Unfortunately, the FDA ruling on IQOS, and also allowing e-cigarettes freely on the market, might have global repercussions by implying the contrary. ■

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References

- Food and Drug Administration (FDA). FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway [news release]. 30 April 2019 [accessed 2019 Apr 30]. Available from: <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.
- Harm Reduction Coalition. Principles of harm reduction. New York, NY: Harm Reduction Coalition. [Accessed 2019 Sep 12]. Available from: <https://harmreduction.org/about-us/>.
- Edwards SA, Bondy SJ, Callaghan RC, Mann RE. Prevalence of unassisted quit attempts in population-based studies: a systematic review of the literature. *Addict Behav* 2014;39:512–519.
- Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York: Guilford Press; 1991.
- 2008 PHS Guideline Update Panel, Liaisons, and Staff. Treating tobacco use and dependence: 2008 update U.S. Public Health Service Clinical Practice Guideline executive summary. *Respir Care* 2008;53:1217–1222.
- Lopez L, Underwood-Davis J. Vaping company's ads under fire. 9 May 2019 [accessed 2019 Sep 12]. Available from: https://www.nbclosangeles.com/investigations/Vaping-Company_s-Ads-Under-Fire_Los-Angeles-509682142.html.
- Hedman L, Backman H, Stridsman C, Bosson JA, Lundbäck M, Lindberg A, et al. Association of electronic cigarette use with smoking habits, demographic factors, and respiratory symptoms. *JAMA Netw Open* 2018;1:e180789.
- Action on Smoking and Health (ASH). Use of e-cigarettes (vapourisers) among adults in Great Britain. [Accessed 2019 Sep 12]. Available from: <http://ash.org.uk/media-and-news/press-releases-media-and-news/large-national-survey-finds-2-9-million-people-now-vape-in-britain-for-the-first-time-over-half-no-longer-smoke/>.
- Christensen T, Welsh E, Faseru B. Profile of e-cigarette use and its relationship with cigarette quit attempts and abstinence in Kansas adults. *Prev Med* 2014;69:90–94.
- Jeon C, Jung KJ, Kimm H, Lee S, Barrington-Trimis JL, McConnell R, et al. E-cigarettes, conventional cigarettes, and dual use in Korean adolescents and university students: prevalence and risk factors. *Drug Alcohol Depend* 2016;168:99–103.
- Sung HY, Wang Y, Yao T, Lightwood J, Max W. Polytobacco use and nicotine dependence symptoms among US adults, 2012–2014. *Nicotine Tob Res* 2018;20(Suppl 1):S88–S98.
- Goniewicz ML, Smith DM, Edwards KC, Blount BC, Caldwell KL, Feng J, et al. Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes. *JAMA Netw Open* 2018;1:e185937.
- Manzoli L, Flacco ME, Fiore M, La Vecchia C, Marzuillo C, Gualano MR, et al. Electronic cigarettes efficacy and safety at 12 months: cohort study. *PLoS One* 2015;10:e0129443.
- Etter JF. A longitudinal study of cotinine in long-term daily users of e-cigarettes. *Drug Alcohol Depend* 2016;160:218–221.
- Huh J, Leventhal AM. Intraindividual covariation between e-cigarette and combustible cigarette use in Korean American emerging adults. *Psychol Addict Behav* 2016;30:246–251.
- Kim J, Yu H, Lee S, Paek YJ. Awareness, experience and prevalence of heated tobacco product, IQOS, among young Korean adults. *Tob Control* 2018;27(Suppl 1):s74–s77.
- Auer R, Concha-Lozano N, Jacot-Sadowski I, Cornuz J, Berthet A. Heat-not-burn tobacco cigarettes: smoke by any other name. *JAMA Intern Med* 2017;177:1050–1052.
- Bekki K, Inaba Y, Uchiyama S, Kunugita N. Comparison of chemicals in mainstream smoke in heat-not-burn tobacco and combustion cigarettes. *J UOEH* 2017;39:201–207.
- Simonavicius E, McNeill A, Shahab L, Brose LS. Heat-not-burn tobacco products: a systematic literature review. *Tob Control* 2019;28:582–594.
- Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU. Nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users: a cross-sectional study. *Ann Intern Med* 2017;166:390–400.
- Stratton K, Kwan LY, Eaton DL, editors; National Academies of Sciences, Engineering, and Medicine. Public health consequences of e-cigarettes. Washington, DC: National Academies Press; 2018.
- Schane RE, Ling PM, Glantz SA. Health effects of light and intermittent smoking: a review. *Circulation* 2010;121:1518–1522.
- Law MR, Wald NJ. Environmental tobacco smoke and ischemic heart disease. *Prog Cardiovasc Dis* 2003;46:31–38.
- Glantz SA. PMI's own in vivo clinical data on biomarkers of potential harm in Americans show that IQOS is not detectably different from conventional cigarettes. *Tob Control* 2018;27(Suppl 1):s9–s12.
- Campaign for Tobacco Free Kids; American Lung Association; American Heart/Stroke Association; American Cancer Society; American Academy of Pediatrics. The flavor trap: how tobacco companies are luring kids with candy-flavored e-cigarettes and cigars. 2017 March 17 [accessed 2019 Sep 12]. Available from: https://www.tobaccofreekids.org/microsites/flavortrap/full_report.pdf.
- Associated Press. US officials call teen vaping 'epidemic': FDA did not predict an 'epidemic of addiction' among youth. 2018 September 12. Available from: <https://www.cbc.ca/news/health/vaping-fda-1.4820204>.
- Goniewicz ML, Gawron M, Nadolska J, Balwicki L, Sobczak A. Rise in electronic cigarette use among adolescents in Poland. *J Adolesc Health* 2014;55:713–715.
- Melka AS, Chojenta CL, Holliday EG, Loxton DJ. Predictors of e-cigarette use among young Australian women. *Am J Prev Med* 2019;56:293–299.
- Food and Drug Administration (FDA). Statement from FDA Commissioner Scott Gottlieb, M.D., on new data demonstrating rising youth use of tobacco products and the agency's ongoing actions to confront the epidemic of youth e-cigarette use. 11 February 2019. Available from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631112.htm>.
- Soneji S, Barrington-Trimis JL, Wills TA, Leventhal AM, Unger JB, Gibson LA, et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis. *JAMA Pediatr* 2017;171:788–797.
- Soneji S, Sargent JD, Tanski SE, Primack BA. Associations between initial water pipe tobacco smoking and snus use and subsequent cigarette smoking: results from a longitudinal study of US adolescents and young adults. *JAMA Pediatr* 2015;169:129–136.
- Chien YN, Gao W, Sanna M, Chen PL, Chen YH, Glantz S, et al. Electronic cigarette use and smoking initiation in Taiwan: evidence from the first prospective study in Asia. *Int J Environ Res Public Health* 2019;16:E1145.
- Joossens J, Raw M. The Tobacco Control Scale 2016 in Europe. Brussels, Belgium: Association of European Cancer Leagues; 2017. Available from: https://www.cancer.be/sites/default/files/tobacco_control_scale.pdf.
- Creative Research Group. Project Viking Volume III: Product Issues - February–March, 1986. April 1987. Available from: <https://www.industrydocuments.ucsf.edu/docs/zzlg0045>.
- Cataldo JK, Malone RE. False promises: the tobacco industry, "low tar" cigarettes, and older smokers. *J Am Geriatr Soc* 2008;56:1716–1723.
- MacGuill D. Did the company that makes Marlboros announce they intend to stop producing cigarettes? Philip Morris International sells the iconic brand outside the United States, and has for years expressed a plan to end production of cigarettes altogether. Snopes Media Group Inc.; 11 January 2019. Available from: <https://www.snopes.com/fact-check/marlboro-cigarettes-production/>.
- Agence France-Press. Philip Morris looking towards cigarette phase-out. *Ind Week* 2016 Nov 30.