Original Article

Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes?

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Abstract The issue of harm reduction has long been controversial in the public health practice of tobacco control. Health advocates have been reluctant to endorse a harm reduction approach out of fear that tobacco companies cannot be trusted to produce and market products that will reduce the risks associated with tobacco use. Recently, companies independent of the tobacco industry introduced electronic cigarettes, devices that deliver vaporized nicotine without combusting tobacco. We review the existing evidence on the safety and efficacy of electronic cigarettes. We then revisit the tobacco harm reduction debate, with a focus on these novel products. We conclude that electronic cigarettes show tremendous promise in the fight against tobacco-related morbidity and mortality. By dramatically expanding the potential for harm reduction strategies to achieve substantial health gains, they may fundamentally alter the tobacco harm reduction debate.
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Introduction

Harm reduction is a framework for public health policy that focuses on reducing the harmful consequences of recreational drug use without necessarily reducing or eliminating the use itself.[1] Whereas harm reduction policies have been widely adopted

for illicit drug use (for example, needle exchange programs[2]) and alcohol use (for example, designated driver programs[3]), they have not found wide support in tobacco control. Many within the tobacco control community have embraced nicotine replacement therapy (NRT) and other pharmaceutical products, but these products are designed as cessation strategies rather than recreational alternatives. Recently, however, a new product that does not fit neatly into any previous category has entered the nicotine market: the electronic cigarette. Electronic cigarettes do not contain tobacco, but they are recreational nicotine devices and the user closely mimics the act of smoking. Thus, they are neither tobacco products nor cessation devices. The novel potential of electronic cigarettes warrants revisiting the harm reduction debate as it applies to these products.

In this article, we first explain what electronic cigarettes are and why they are difficult to categorize. Second, we examine the available evidence concerning the safety and efficacy of electronic cigarettes. Then, we review the most common arguments made against harm reduction in the tobacco control literature, followed by an analysis of each of these arguments in light of the recent emergence of electronic cigarettes. Finally, we identify conclusions from this analysis and their implications for the public health practice of tobacco control.

What are Electronic Cigarettes and Why are They Novel?

Electronic cigarettes are hand-held devices that deliver nicotine to the user through the battery-powered vaporization of a nicotine/propylene-glycol solution. The act of 'smoking' an electronic cigarette is called 'vaping' and it mimics smoking; but, there is no combustion and the user inhales vapor, not smoke. Although the nicotine is derived from tobacco, electronic cigarettes contain no tobacco. Theoretically, we would expect *vaping* to be less harmful than smoking as it delivers nicotine without the thousands of known and unknown toxicants in tobacco smoke. Moreover, a product that mimics the act of smoking, in addition to delivering nicotine, can address both pharmacologic and behavioral components of cigarette addiction. Electronic cigarettes are not manufactured or distributed by the tobacco industry or by the

pharmaceutical industry. Hundreds of small distributors market them over the internet and in shopping mall kiosks. They have been on the market in the United States for more than 3 years and have become increasingly popular.

Review of Evidence Regarding the Safety of Electronic Cigarettes

As ~5300 of the estimated 10 000–100 000 chemicals in cigarette smoke have ever been identified,[4] we already have more comprehensive knowledge of the chemical constituents of electronic cigarettes than tobacco ones. We were able to identify 16 studies[5–17] that have characterized, quite extensively, the components contained in electronic cigarette liquid and vapor using gas chromatography mass spectrometry (GC-MS) (Table 1). These studies demonstrate that the primary components of electronic cigarette cartridges are propylene glycol (PG), glycerin, and nicotine. Of the other chemicals identified, the FDA has focused on potential health hazards associated with two: tobacco-specific nitrosamines (TSNAs) and diethylene glycol (DEG).[5]

TSNAs have been detected in two studies at trace levels.[5,6] The maximum level of total TSNAs reported was 8.2 ng/g.[6] This compares with a similar level of 8.0 ng in a nicotine patch, and it is orders of magnitude lower than TSNA levels in regular cigarettes.[18] Table 2 shows that electronic cigarettes contain only 0.07–0.2 per cent of the TSNAs present in cigarettes, a 500-fold to 1400-fold reduction in concentration. The presence of DEG in one of the 18 cartridges studied by the US Food and Drug Administration (FDA) is worrisome, yet none of the other 15 studies found any DEG. The use of a non-pharmaceutical grade of PG may explain this contamination.

Other than TSNAs and DEG, few, if any, chemicals at levels detected in electronic cigarettes raise serious health concerns. Although the existing research does not warrant a conclusion that electronic cigarettes are safe in absolute terms and further clinical studies are needed to comprehensively assess the safety of electronic cigarettes, a preponderance of the available evidence shows them to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products.

Table 1: Laboratory studies of the components in and safety of electronic cigarettes[5–17]

Study	*Brand tested*	*Main findings*
Evaluation of e-cigarettes (FDA laboratory report)[5]	NJOY, Smoking Everywhere	'Very low levels' of tobacco-specific nitrosamines (TSNAs) were detected in 5 of 10 cartridges tested. Diethylene glycol (DEG) was detected about 0.1% in 1 of 18 cartridges tested.
Safety Report on the Ruyan e-Cigarette Cartridge and Inhaled Aerosol[6]	Ruyan	Trace levels of TSNAs were detected in the cartridge liquid. The average level of TSNAs was 3.9 ng/cartridge, with a maximum level of 8.2 ng/cartridge. Polyaromatic hydrocarbon carcinogens found in cigarette smoke were not detectable in cartridge liquid. No heavy metals detected. Exhaled carbon monoxide levels did not increase in smokers after use of the e-cigarette. The study concluded that e-cigarettes are very safe relative to cigarettes and safe in absolute terms on all measurements applied.
Ruyan E-cigarette Bench-top Tests[7]	Ruyan	None of the 50 priority-listed cigarette smoke toxicants were detected. Toxic emissions score for e-cigarette was 0, compared to 100–134 for regular cigarettes.
Characterization of Liquid 'Smoke Juice' for Electronic Cigarettes[8]	Liberty Stix	No compounds detected via gas chromatography mass spectrometry (GC-MS) of electronic cigarette cartridges or vapors other than propylene glycol (99.1% in vapor), glycerin (0.46%), and nicotine (0.44%).
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Regular Smoking Liquid[9]	Gamucci	GC-MS detected propylene glycol (77.5%), glycerin (14.0%), nicotine (8.5%), and cyclotene hydrate (0.08%) in e-cigarette liquid. Levels of cyclotene hydrate were not believed to be of concern.
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Light Smoking Liquid[9]	Gamucci	GC-MS detected propylene glycol (80.4%), glycerin (14.4%), and nicotine (5.3%) in e-cigarette liquid. No other compounds detected.

Table 1 *continued*

Study	*Brand tested*	*Main findings*
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Ultra Light Smoking Liquid[9]	Gamucci	GC-MS detected propylene glycol (85.5%), glycerin (11.2%), and nicotine (3.3%) in e-cigarette liquid. No other compounds detected.
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Zero, Smoking Liquid[9]	Gamucci	GC-MS detected propylene glycol (84.3%), glycerin (7.6%), 1,3-bis(3-phenoxyphenoxy)Benzene (7.0%), 3-Isopropoxy-1,1,1,7,7,7-hexamethyl-3,5,5-tris(trimethylsiloxy)tetrasiloxane (0.77%), and α,3,4-tris[(trimethylsilyl)oxy]Benzeneacetic acid (0.39%) in e-cigarette liquid. No other compounds were detected. 1,3-bis(3-phenoxyphenoxy) Benzene is non-hazardous. The other two chemicals have an unknown safety profile, but are present at nominally low levels.
NJOY e-Cigarette Health Risk Assessment[10]	NJOY	The vapor constituents detected were propylene glycol, glycerin, nicotine, acetaldehyde, 1-methoxy-2-propanol, 1-hydroxy-2-propanone, acetic acid, 1-menthone, 2,3-butanediol, menthol, carvone, maple lactone, benzyl alcohol, 2-methyl-2-pentanoic acid, ethyl maltol, ethyl cinnamate, myosamine, benzoic acid, 2,3-bipyridine, cotinine, hexadecanoic acid, and 1'1-oxybis-2-propanol. No TSNAs, polyaromatic hydrocarbons, or other tobacco smoke toxicants were detected. On the basis of the amounts of these components present and an examination of the risk profile of these compounds, the report concludes that the only significant side effect expected would be minor throat irritation resulting from the acetaldehyde.
Characterization of Regal Cartridges for Electronic Cigarettes[11]	inLife	No DEG was detected in the cartridge liquid or vapors.

Characterization of Regal Cartridges for Electronic Cigarettes – Phase II[12]	inLife	No TSNAs were detected in the e-cigarette liquid (limit of detection was 20 ppm).
Analysis of Components from "e-Juice XX High 36 mg/ml rated Nicotine Solution": ref S55434[13]	e-Juice	GC-MS detected propylene glycol (51.2%), 1,3-bis(3-phenoxy phenoxy)Benzene (20.2%), glycerin (15.0%), nicotine (10.0%), vanillin (1.2%), ethanol (0.5%), and 3-cyclohexene-1-menthol,. α.,.α.4-trimethyl (0.4%). No other compounds detected. 1,3-bis(3-phenoxyphenoxy)Benzene is non-hazardous. Vanillin and 3-cyclohexene-1-menthol,.α.,.α.4-trimethyl have unknown safety profiles.
Analysis of Chemical Components from High, Med & Low Nicotine Cartridges[14]	The Electronic Cigarette Company (UK)	The compounds detected by GC-MS were propylene glycol, water, nicotine, ethanol, nitrogen, and triacetin. Triacetin is not known to be hazardous. No other compounds were detected.
Chemical Composition of "Instead" Electronic Cigarette Smoke Juice and Vapor[15]	Instead	No DEG was detected in e-cigarette liquid or vapor for the two products tested.
Gas Chromatography Mass Spectrometry (GC-MS) Analysis Report[16]	Not specified	GC-MS detected propylene glycol, glycerin, nicotine, caffeine, tetra-ethylene glycol, pyridine, methyl pyrrolyl, pyridine, methyl pyrrolidinyl, butyl-amine, and hexadecanoic acid in the e-cigarette liquid.
Super Smoker Expert Report[17]	Super Smoker	GC-MS detected propylene glycol, glycerin, nicotine, ethanol, acetone ethyl acetate, acetals, isobutyraldehyde, essential oils, and 2-methyl butanal in the e-cigarette liquid. No other compounds were detected.

Table 2: Maximum tobacco-specific nitrosamine levels[a] in various cigarettes and nicotine-delivery products (ng/g, except for nicotine gum and patch that are ng/patch or ng/gum piece)[6]

Product	*NNN*	*NNK*	*NAT*	*NAB*	*Total*
Nicorette gum (4 mg)[18]	2.00	ND	ND	ND	2.00
NicoDerm CQ patch (4 mg)[18]	ND	8.00	ND	ND	8.00
Electronic cigarettes[6]	**3.87**	**1.46**	**2.16**	**0.69**	**8.18**
Swedish snus[18]	980	180	790	60	2010
Winston (full)[18]	2200	580	560	25	3365
Newport (full)[18]	1100	830	1900	55	3885
Marlboro (ultra-light)[18]	2900	750	1100	58	4808
Camel (full)[18]	2500	900	1700	91	5191
Marlboro (full)[18]	2900	960	2300	100	6260
Skoal (long cut straight)[18]	4500	470	4100	220	9290

[a]The concentrations here represent nanograms (ng) of toxin detected in 1 ruyan 16-mg multi-dose cartridge (which contains approximately 1 gm of e-liquid). They are compared to the amount of toxin contained in approximately one tobacco cigarette (approximately 1 gm of tobacco) or one unit of nicotine replacement product.
Abbreviations: NNN=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNK=N′-nitrosonornicotine; NAT=N′-nitrosoanatabine; NAB=N′-nitrosoanabasine.
ND=Not detected.

Review of Evidence about the Effectiveness of Electronic Cigarettes in Smoking Cessation

No studies have measured directly the effectiveness of electronic cigarettes in helping smokers cease smoking. Two published studies have examined the effectiveness of the product by measuring their effect on cravings and other short-term indicators. We summarize them briefly in Table 3.[19,20] Bullen *et al*[19] demonstrated that electronic cigarettes deliver nicotine effectively, more rapidly than a nicotine inhaler. In this study, electronic cigarette use significantly reduced craving, a similar effect to what was observed with a nicotine inhaler. Nicotine delivery and reduction in cigarette craving was much less than with a regular cigarette. Eissenberg[20] found that 10 puffs on one brand of electronic cigarettes delivered a small amount of nicotine, again far less than a tobacco cigarette, whereas another brand delivered little to none. The first brand was able to significantly reduce cigarette craving.

Taken together, this evidence suggests that electronic cigarettes are capable of reducing cigarette craving, but that the effect is not due exclusively to nicotine. Bullen *et al* observe that 'the reduction in

Table 3: Studies of the effectiveness of electronic cigarettes in reducing cigarette craving and other nicotine withdrawal symptoms[19,20]

Study	*Brand tested*	*Summary of findings*
Effect of an E-Cigarette on Cravings and Withdrawal, Acceptability and Nicotine Deliver: Randomized Cross-Over Trial[19]	Ruyan	The 16 mg electronic cigarette delivered nicotine more rapidly than a nicotine inhaler, but less rapidly than cigarettes. Electronic cigarette use significantly reduced craving, but less than cigarettes. The reduction of craving was similar to that observed with the nicotine inhaler. The electronic cigarettes produced fewer minor side effects than the nicotine inhaler.
Electronic Nicotine Delivery Devices: Ineffective Nicotine Delivery and Craving Suppression after Acute Administration[20]	NJOY and Crown Seven	After 10 puffs on an electronic cigarette, one of the two brands tested significantly reduced the craving for a cigarette. Nicotine delivery was found to be minimal.

desire to smoke in the first 10 min[utes] of [electronic cigarette] use appears to be independent of nicotine absorption' (p. 100).[19] The sizable craving reduction achieved by the 'placebo' – a nicotine-free electronic cigarette – demonstrates the ability of physical stimuli to suppress cravings independently.[19] Many studies have established the ability of *denicotinized* cigarettes to provide craving relief.[21,22] Barrett[21] found that denicotinized cigarettes reduce cravings more than a *nicotinized* inhaler, supporting Buchhalter *et al*'s[22] conclusion that although some withdrawal symptoms can be treated effectively with NRT, others, such as intense cravings, respond better to smoking-related stimuli.

Although more research is needed before we will know how effective electronic cigarettes are at achieving smoking abstinence, there is now sufficient evidence to conclude that these products are at least capable of suppressing the urge to smoke. There is also reason to believe that they offer an advantage over traditional nicotine delivery devices '[t]o the extent that non-nicotine, smoking-related stimuli alone can suppress tobacco abstinence symptoms indefinitely' (p. 556).[22]

The Most Common Arguments against Harm Reduction

Our review of the existing literature identified five primary arguments against harm reduction as a tobacco control strategy. These arguments explain why, in the past, harm reduction has not been accepted as a tobacco control strategy.

Promotion of safer alternatives will inhibit smoking cessation/ prevention efforts

The core fear is that smokers who might otherwise have quit smoking altogether will instead become addicted to another harmful product. In addition, a product that reduces harm to the individual may attract new, nonsmoking users, and thus undermine efforts to prevent tobacco use.[23]

Skepticism about the role of combusted products in harm reduction

The argument here, based on numerous related concerns, is that the combustion of tobacco produces inherently dangerous exposures and thus the search for a 'safer' cigarette is futile. It is impossible to assess the risks of a new product using machine measured delivery of smoke constituents, because there is no good way to simulate actual smoking behavior.[23] We cannot, moreover, easily infer human risk from chemical measurements because no reliable toxicity indices exist.[24] A widespread school of thought in tobacco control holds that the very nature of tobacco combustion precludes safer cigarettes, and therefore attempts to develop them should be abandoned.[25]

Alternatives promoted as safer may prove more dangerous, or they may be equally dangerous, leading to false or unsupported claims and to the misleading of the public

Experience with potentially reduced exposure products in the past has revealed that products promoted by the tobacco industry as potentially safer have ended up either not being safer or resulted in increased toxicant exposures.[23] In particular, a broad consensus within the public health community holds that 'light' cigarettes

misled consumers into thinking that they were being exposed to lower levels of toxic chemicals.[26] Smokers ended up compensating for the reduced nicotine in 'lights' by smoking with greater frequency and intensity, resulting in higher exposures than originally reported.[23]

NRT has not been effective, meaning that harm reduction equals harm maintenance

Pierce[27] argued that using NRT for tobacco harm reduction is, in fact, harm maintenance because NRT is so ineffective that it essentially ensures that Big Tobacco (the large tobacco industry companies) will not lose its customers. Smokers simply do not like products that merely deliver nicotine, and therefore 'we should not assume that smokers would be willing and able to substitute a nicotine maintenance product for their cigarette smoking' (p. S54).

Big Tobacco cannot be trusted to develop and market a safer tobacco alternative

The final argument is that the tobacco companies, based on their history of lies and deception, simply cannot be trusted to develop and market a safer tobacco alternative.[28] Fairchild and Colgrove[28] make a related point, that 'prioritizing the reduction of harm, however great or minimal, may necessitate some level of cooperation with the tobacco industry and will *certainly prove lucrative for it*' (our emphasis added, p. 201) Thus, tobacco harm reduction will necessarily benefit the tobacco industry regardless of what else might be achieved.

Analysis of Arguments in Light of the Emergence of Electronic Cigarettes

With the emergence of electronic cigarettes, the harm reduction debate in tobacco control has changed. We now address the five major arguments against harm reduction in light of the emergence of electronic cigarettes.

Promotion of safer alternatives will inhibit smoking cessation/ prevention efforts

In contrast to reduced risk cigarettes or smokeless tobacco products, electronic cigarettes are not tobacco products. Thus, switching to electronic cigarettes is not an alternative to smoking cessation, but rather a form of smoking cessation akin to long-term use of NRT. Moreover, because 'low absolute abstinence rates suggest that nicotine alone may not be sufficient to suppress … abstinence symptoms effectively' (p. 551),[22] higher abstinence rates are likely to obtain from a product that better addresses these symptoms. Crucially, electronic cigarettes could entice smokers who were not otherwise inclined, to attempt to quit. Although the use of electronic cigarettes by nonsmokers is a theoretical concern, there is no existing evidence that youths or nonsmokers are using the product. Regulations can address the sale and marketing of these products to minors.

Skepticism about the role of combusted products in harm reduction

Electronic cigarettes, such as NRT, are not tobacco products and no combustion takes place.

Alternatives promoted as safer may actually be equally or more dangerous

Thus far, none of the more than 10 000 chemicals present in tobacco smoke,[4] including over 40 known carcinogens, has been shown to be present in the cartridges or vapor of electronic cigarettes in anything greater than trace quantities. No one has reported adverse effects, although this product has been on the market for more than 3 years. Still, the FDA struck a more ominous tone in its July 2009 press release, warning of the presence of carcinogens at 'detectable' levels.[29] Yet it failed to mention that the levels of these carcinogens was similar to that in NRT products (Table 2). Whereas electronic cigarettes cannot be considered safe, as there is no threshold for carcinogenesis, they are undoubtedly safer than tobacco cigarettes.

NRT is unappealing and ineffective

Pharmaceutical products for dispensing nicotine are unappealing 'by design' (p. S123)[30] to avoid 'abuse-liability'.[30] Electronic cigarettes, on the other hand, were designed with the express purpose of replicating the act of smoking, without using tobacco.[31] An investment newsletter reports that demand thus far has been explosive.[32] Intense consumer interest in electronic cigarettes has already spawned a vibrant online community of 'vapers' who compare and contrast the performance of various brands and models according to their durability, battery life, thickness of vapor, and other criteria.[33] No non-tobacco nicotine product has heretofore elicited such dedication among its users, suggesting the rare promise of the electronic cigarette as a smoking cessation tool.

Big Tobacco cannot be trusted

Electronic cigarettes are not tobacco products and not produced by tobacco companies. They were invented in Beijing by a Chinese pharmacist Hon Lik, whose employer, Golden Dragon Holdings, 'was so inspired that it changed its name to Ruyan (meaning "like smoke") and started selling abroad'.[31] Rather than being helpful to cigarette makers, electronic cigarettes compete directly against them.[32] Thus David Sweanor, adjunct law professor specializing in tobacco control issues at the University of Ottawa, says they are 'exactly what the tobacco companies have been afraid of all these years'.[31]

Conclusion

Tobacco cigarettes are the leading cause of disease in the United States, which is why the 'primary goal of tobacco control is to reduce mortality and morbidity associated with tobacco use' (p. 326).[23] Electronic cigarettes are designed to mitigate tobacco-related disease by reducing cigarette consumption and smoking rates. The evidence reviewed in this article suggests that electronic cigarettes are a much safer alternative to tobacco cigarettes. They are likely to improve upon the efficacy of traditional pharmacotherapy for smoking cessation.

In light of this evidence, it is unfortunate that in the United States, the American Cancer Society, American Lung Association, American

Heart Association, Campaign for Tobacco-Free Kids, Action on Smoking and Health, American Legacy Foundation, American Academy of Pediatrics, and the Association for the Treatment of Tobacco Use and Dependence have all issued statements supporting FDA efforts to take them off the US market.[34] In the United States, the courts will ultimately determine whether the FDA has the legal authority to do this, but we question the ethical and health policy merits of this approach.

Do products with established user bases warrant a different regulatory approach than entirely new products? This would seem to follow from consistent application of the principal of nonmaleficence – 'do no harm.' Products yet to enter the market have only *potential* beneficiaries, people who can only speculate about what the precise therapeutic effects of the product will be for them. In contrast, products already on the market have users who may already be deriving benefits. By definition, enacting a ban will harm current users, unless the evidence suggests that the harms outweigh the benefits *for those already using the product*. The burden of proof is on the regulatory agency to demonstrate that the product is unreasonably dangerous for its intended use.

How does this principle apply to electronic cigarettes? For the many vapers who report using them in place of cigarettes,[33] the benefits of the product are readily observable, already established. Simply demonstrating that electronic cigarettes are 'not safe' may not be sufficient grounds to ban them. Unless the evidence suggests that vaping does not yield the anticipated *reduction* in harm to the user, enacting an electronic cigarette prohibition will do harm to hundreds of thousands of vapers already using electronic cigarettes in place of tobacco ones – a clear violation of nonmaleficence.

The essential rationale for the FDA's pre-market approval process – to keep dangerous products out of the marketplace – may not easily extend to new nicotine products because a range of extraordinarily deadly nicotine products is already grandfathered into the market. This has led to an awkward nicotine regulatory structure where dirty tobacco products face few barriers to market entry whereas cleaner products are subject to oft onerous hurdles. The FDA contends that they can and should regulate electronic cigarettes as 'drug-device combinations' that are required to meet stringent Federal Food Drug and Cosmetic Act (FDCA) safety standards. The FDA reasons that

electronic cigarettes do not qualify for the usual exemption from FDCA standards afforded to most other recreational nicotine products because 'much less is known about the safety of E-Cigarettes' and 'it may be possible for E-Cigarettes … to satisfy the FDCA's safety, effectiveness, and labeling requirements and obtain FDA approval' (p. 26).[35] Ironically, the only nicotine products exempted from FDCA safety requirements are those that are too obviously harmful to have any chance of meeting these requirements. Litigation presently before the US Court of Appeals for the District of Columbia may ultimately determine whether the FDA can legally regulate electronic cigarettes as drug-device combinations.[36] Regardless of the court's decision, we believe a better regulatory approach would not actively discourage producers of harm reduction products.

Fairchild and Colgrove[28] conclude that 'the later history of tobacco industry deception and manipulation was an important factor contributing to the erosion of public health support for harm reduction' (p. 201). With entrenched skepticism toward harm reduction now manifested as deep cynicism about electronic cigarettes – a distinct product that actually *does* reduce risk and threatens cigarette makers – the tobacco industry is ironically benefiting from its own past duplicity. The push to ban electronic cigarettes may repeat the mistakes of the past in the name of avoiding them. Regulatory policy for electronic cigarettes and other novel nicotine products must be guided by an accurate understanding of how they compare to tobacco cigarettes and NRT in terms of reducing toxic exposures and helping individual smokers quit.

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