Electronic Nicotine Delivery Systems (ENDS) in the 2014 Surgeon General's Report:
The Health Consequences of Smoking—Fifty Years of Progress
A Fact Sheet

Purpose: In January 2014, the Surgeon General released the 32nd report on tobacco use and health titled *The Health Consequences of Smoking—Fifty Years of Progress*. Broadly, the report explores the potential for public health benefits and harms associated with electronic nicotine delivery systems (ENDS), including e-cigarettes, e-hookahs, hookah pens, vape pens, e-cigars, and others. This fact sheet synthesizes key themes discussed in the SGR on the topic of ENDS, including excerpts from the report that contain supporting statements for each theme.

Theme	Source	Supporting Statement(s)
Tobacco control measures must employ a public health standard.	Ch. 16, p. 873	"A public health standard is critical because strategies that reduce potential harm from toxicant exposure to individual users of tobacco products could adversely affect other individuals and public health by increasing the number of new users and by reducing the number of quitters."
ENDS have a range of potential impacts on individual and population health. Significant questions remain regarding their safety and impact on patterns of tobacco use.	Ch. 15, p. 859	"This shift in patterns of tobacco use could have a number of potential impacts, ranging from the positive effect of accelerating the rate at which smokers quit smoking cigarettes completely to a negative effect of slowing down the decrease in the use of all tobacco products, especially cigarettes. Availability of these products may reduce or increase harm to the population."
	Ch. 16 p. 873	"Although these new products are entering the marketplace rapidly, and will soon be marketed by all three major tobacco manufacturers in the United States , significant questions remain about (1) how to assess the potential toxicity and health effects of the more than 250 electronic cigarette brands; (2) the magnitude of the potential reduced risk from electronic versus continuing use of conventional cigarettes for individual smokers; (3) the need to weigh the potential individual benefits and risks versus population benefits and risks; (4) how the advertising and marketing of these new products should be regulated; and (5) even assuming that electronic cigarettes could be sufficiently safe to users and offer net public health benefits, there are significant questions about the manner in which they should be regulated (Benowitz 2013)."
	Ch. 14, p. 780	"Studies and assessments by FDA and independent scientists have demonstrated enormous variability in design, operation, and contents and emissions of carcinogens, other toxicants, and nicotine from ENDS."
The impact of ENDS on population health is more likely	Executive Summary, p.	"The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will

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to be beneficial only if cigarettes and other combusted tobacco products are rapidly eliminated. In the current context cigarettes are still widely marketed and used.	4, Major Conclusion #9	dramatically reduce this burden."
	Ch. 16, p. 871	"It has been stated that 'The cigarette is also a defective product, meaning not just dangerous but *unreasonably* dangerous, killing half its long-term users. And addictive by design' (Proctor 2013, p. i27)."
	Ch. 15, p. 859	"The impact of the noncombustible aerosolized forms of nicotine delivery on population health is much more likely to be beneficial in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced especially among youth and young adults. For example, other end game strategies which could involve greater restrictions on sales, particularly at the local level, could significantly alter the strategic environment for tobacco control."
	Ch. 15, p. 858 Conclusion 2	"Evidence-based tobacco control interventions that are effective continue to be underutilized."
	Ch. 16, p. 874	"The promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced."
	Ch. 16, p. 873	"Even those who concur that the use of noncombustible tobacco products may not constitute a large direct risk to individual health propose that a strategy based on their use would increase total tobacco-related harm to health. Proponents of this position argue that the availability of noncombustible products can have adverse consequences, especially under current conditions with the widespread marketing and use of cigarettes."
ENDS are being aggressively promoted and use is increasing rapidly among youth and adults. Among youth and adults, patterns of use of e-cigarettes concurrently with cigarettes (i.e. "dual use") are being observed.	Ch. 15, p. 859	"A variety of unregulated noncombustible products with potential modified risk or reduced harm are being developed and aggressively marketed."
	Ch. 14, p. 780	"…all three major cigarette manufacturers plan to have electronic cigarettes on the market (Sizemore 2013)."
	Ch. 13, p. 742	"During 2011–2012, data from the National Youth Tobacco Survey (NYTS) suggested a doubling of electronic cigarette use among U.S. middle and high school students. Among all students in grades 6–12, ever use of electronic cigarettes increased from 3.3% to 6.8% (Tables 13.17–13.18); current electronic cigarette use increased from 1.1% to 2.1%, and current use of both electronic-cigarettes and conventional cigarettes increased from 0.8% to 1.6%. […]In 2012, among current electronic cigarette users, 76.3% reported current conventional cigarette

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		smoking."
	Ch. 13 p. 750	"Although nationally representative surveillance data on [adult] awareness and use of electronic cigarettes remains limited, all available data show rapid increases in recent years. […] Data from the HealthStyles Survey show that […] ever use of electronic cigarettes nearly doubled among all adults during 2010–2011, from 3.3% to 6.2%. During the same period, the prevalence of ever electronic cigarette use among current cigarette smokers increased from 9.8% to 21.2%, while the prevalence among former cigarette smokers increased from 2.5% to 7.4%. Prevalence remained unchanged among never cigarette smokers (1.3%)."
Evidence from the 2012 Surgeon General's Report*, Preventing Tobacco Use Among Youth and Young Adults*, indicates that current tobacco industry practices raise concerns.	Ch. 16, pp. 873-4	"Even those who concur that the use of noncombustible tobacco products may not constitute a large direct risk to individual health propose that a strategy based on their use would increase total tobacco-related harm to health. Proponents of this position argue that the availability of noncombustible products can have adverse consequences, especially under current conditions with the widespread marketing and use of cigarettes. These consequences include (a) encouraging children to experiment with tobacco products (with the expectation that a percentage of those who become regular users of noncombustible products will graduate to smoking); (b) helping smokers maintain their addiction by using noncombustible products in environments where they cannot smoke; (c) acting as a non-risk-free substitute for cigarettes for smokers who otherwise would have quit; and (d) giving smokers an alternative means of satisfying their addiction that may lead to higher levels of recidivism to smoking. The evidence indicates that current industry practices raise concerns about all of these potential adverse consequences (USDHHS 2012). One study found that transnational tobacco companies promote less harmful tobacco products in order to maintain and extend the sales of cigarettes and to create alternative forms of tobacco use among young people who are no longer smoking (Peeters and Gilmore 2013).
	Ch. 14, p. 784	"Many changes in tobacco product form and marketing have been documented as efforts by the tobacco industry to contribute to tobacco use and addiction by fostering initiation among young people; making products easier and more acceptable to use; making and marketing products so as to address health concerns; and making and marketing products to perpetuate addiction through the use of alternate products, when smoking is not allowed or is socially unacceptable (Federal Register 1995, 1996; Kessler 2001; Philip Morris 449 F. Supp. 2d at 908; WHO 2001, 2007, 2012b; USDHHS 2012)."
	Ch. 15, p. 852	"The pace of social norm change could be slowed by […] the aggressive marketing and promotions for electronic cigarette brands (U.S. House of Representatives 2013)."

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Claims that ENDS will lead cigarette smokers to completely quit smoking rest on several unproven assumptions.	Ch. 14, p. 780	"The marketing claims for [electronic nicotine delivery systems] ENDS also vary widely and have included claims of safety, use for smoking cessation, and statements that they are exempt from clean air policies that restrict smoking (WHO 2009c; Cobb et al. 2010; Henningfield and Zaatari 2010; American Legacy Foundation 2012; Cheah et al. 2012)."
	Ch. 16, p. 873	"Currently, there are varying scenarios being discussed. In one scenario, noncombustible tobacco products would be substituted for cigarette smoking among a subset of smokers (people who otherwise would not quit smoking and thus are at high risk for smoking-caused diseases). Proponents claim that such a switch would significantly reduce the burden of death and disease attributable to smoking if smokers completely substituted combustible products with noncombustible products. The perspective rests on the assumption that (a) noncombustible tobacco products, used alone, are far less dangerous to individual users than continued smoking, a conclusion that appears correct based on current understanding (Levy et al. 2004; USDHHS 2010b); (b) with proper marketing, differential taxation, and other carefully calibrated policies, noncombustible products would be adopted as a complete substitute for smoking by significant numbers of current smokers, a thus far unproven assumption; (c) smokers who switched to noncombustible products otherwise would continue to smoke (as opposed to quitting), another area with significant uncertainty; and (d) the net impact on health of all the various outcomes, intended and unintended, would contribute meaningfully to tobacco harm reduction, a proposition that has been explored only once in the literature (Mejia et al. 2010)."
Several FDA-approved prescription and non-prescription cessation products are available, including nicotine replacement therapies (NRT), and are safe when used as directed. **Because of the harmful effects of nicotine, evidence is already sufficient to caution youth and pregnant women about ENDS. Evidence is needed on the health effects of long-term exposure to nicotine.**	Ch. 5, p. 112	"NRT medicines, which are designed to minimize addiction risk, carry a low risk of establishing addiction, and are generally substantially easier to discontinue than tobacco products (Henningfield et al. 2011; WHO 2012)."
	Ch. 5, p. 126, Conclusion 5	"The evidence is suggestive that nicotine exposure during adolescence, a critical window for brain development, may have lasting adverse consequences for brain development."
	Ch. 5, p. 126	"The evidence is already sufficient to provide appropriately cautious messages to pregnant women and women of reproductive age as well as adolescents about the use of nicotine-containing products such as smokeless tobacco and electronic cigarettes, and newer forms of nicotine-containing tobacco products, as alternatives to smoking. All tobacco products contain toxicants, so all tobacco product use poses some health risks. Because of the potential for fetal and adolescent nicotine exposure to have long-term detrimental effects on brain development, measures should be taken to ensure that nicotine is not perceived by the public as a cognitive-enhancing substance. It also does not have an established role in the management of people with a severe mental illness."

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	Ch. 14, p. 780	"Given the level of evidence linking tobacco product use to ill health, all products containing tobacco and nicotine should be assumed to be both harmful and addictive, although the risk from the use of tobacco products depends not only on the type of product but also on how they are used (i.e., the actual doses of toxins that are taken in, and whether the product is used in addition to other products, promotes initiation of tobacco use, or delays smoking cessation) (WHO 2006, 2007)."
	Ch. 5, p. 126	"The number of people exposed to nicotine long-term may grow under a number of potential future scenarios; for example, expanding use of multiple products or the replacement of conventional combustible cigarettes with other nicotine delivery systems […], or increased appeal and uptake of nicotine product use because of their apparent relative safety in comparison to cigarettes. In considering such scenarios, information will be needed on the risks of long-term exposure to nicotine, including the consequences for reproductive health and adolescent cognitive development, compared with cigarette smoking, and no tobacco products use at all."
Full implementation of FDA's authority for tobacco product regulation is key to reducing ENDS' potential for harm to the population.	Ch. 15, p. 859	"Availability of these products may reduce or increase harm to the population. New regulatory actions described as end game strategies may offer tremendous opportunities to address these challenges and transform approaches to ending the tobacco epidemic. In addition to a product standard reducing the nicotine content to make cigarettes less addictive, FDA has the authority to establish strict standards for levels of toxicants in tobacco products, as well as standards to make some or all tobacco products less appealing."
	Ch. 15, p. 852	"The pace of social norm change could be slowed by […] the aggressive marketing and promotions for electronic cigarette brands (U.S. House of Representatives 2013)."
ENDS—in combination with rigorous surveillance and aggressive strategies to end combustible cigarette use—could help complement "end game" strategies by allowing nicotine substitution.	Ch. 15, p. 855	"End game strategies might be aided by future approaches and devices for nicotine delivery that better substitute for the cigarette. […]Warner (2013) suggests that the introduction and marketing of new products like these could complement an end game strategy. However, the potential risks of continuing the use of addictive levels of nicotine on the population would need careful consideration (see Chapter 5, "Nicotine") if users completely switch from traditional (or conventional) combusted cigarettes to noncombusted products which continue to deliver high levels of nicotine. Also, as noted in Chapter 13, given the rapid increase in electronic cigarette use among both adults and adolescents, rigorous surveillance of these products is particularly important, including their impact on the initiation and cessation of conventional tobacco use and concurrent use with other conventional tobacco products. "