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E-cigarettes: How can they help smokers quit without addicting a new generation?

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Abstract

The dramatic increase in youth use of electronic nicotine delivery systems (ENDS; e.g., e-cigarettes) in the United States has focused regulatory efforts to address this concern while still encouraging smokers to switch completely to lower risk products or quit all tobacco product use. Increases in the minimum age for purchase of all tobacco products and changes in enforcement policy for ENDS have been recently enacted in an effort to address the youth vaping epidemic. Since all ENDS marketed after February 15, 2007 will be required to meet the "appropriate for the protection of public health" standard for marketing authorization of new products, ENDS manufacturers will have to demonstrate, in part, that their products help lessen the adverse impact on youth use. Some, such as disallowing flavors other than tobacco or menthol or limiting nicotine delivery, may help reduce youth use but could also inhibit smokers from quitting smoking. Other approaches, including reducing the high-tech appearance and discreteness of ENDS, discontinuing use of coupons and two-for-one type price incentives for ENDS, limiting retail sales of these products to adult-only facilities, and incorporating technological innovations such as biometrics or geofencing into ENDS, may help manufacturers demonstrate that marketing of their products would help reduce youth use of ENDS and lessen the epidemic, while still assuring adult smokers have access to products that encourage discontinuing combusted product use.

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1. Introduction

Because of the tremendous toll that tobacco use takes on the U.S. population (USHHS, 2014), the goal of both tobacco control and regulatory efforts is to reduce its harm, through reducing the toxicity of tobacco products and reducing the number of people using them. For the U.S. Food and Drug Administration (FDA) that approach is evidenced by the population health standard that encompasses three components: population risk and benefits, cessation, and initiation (FSPTCA, 2009). “Appropriate for the protection of public health” is the criterion upon which regulatory action by FDA hinges and is the basis for making decisions for new product marketing authorization or setting product standards. With approximately 480,000 Americans dying every year from tobacco product use, authorized marketing of a new product must reduce this harm to be appropriate for the protection of public health. In June of 2016, FDA promulgated the Deeming Rule, which brought under the authority of FDA, all products, not previously regulated, that meet the definition of a tobacco product. As part of that regulation, FDA used enforcement discretion so that newly deemed products that were on the market as of August 8, 2016 (unless they were grandfathered because they were on the market as of Feb 15, 2007) and have not been modified could remain on the market until August 8, 2022. This date has gone through several modifications, and is currently September 9, 2020. To remain on the market after that date, manufacturers must have submitted a Substantial Equivalence (SE) Report, an Exemption from Substantial Equivalence Application, or a Premarket Tobacco Product Application (PMTA) and have received FDA marketing authorization. Products for which marketing applications have been submitted and for which FDA has not determined the product does not meet the statutory requirements may remain on the market for one year until September 9, 2021. Any e-cigarette that a manufacturer wants to modify or introduce after August 8, 2016, must receive FDA marketing authorization before they make the change or introduce the product to market. Given the extensive number of products included under the Deeming Rule, FDA new product marketing decisions are likely to be the regulatory avenue that has the most influence over the next few years. Other regulatory activities, including restricting indoor use and setting price relative to other products through imposing taxes, are currently outside FDA’s authority (FSPTCA, 2009), but can be enacted by Congress, state and local authorities.

The last two components of the population health standard, increased cessation and decreased initiation, have been objectives pursued by tobacco control for the last 50 years. But, introduction of potentially reduced harm products (IOM, 2001) has expanded the well-accepted approach of focusing on reducing all tobacco use prevalence by introducing the alternative tactic of encouraging the use of a potentially reduced harm tobacco or nicotine product to decrease the prevalence of smoking cigarettes, the most lethal tobacco product (“harm reduction” approach). This different approach creates a natural tension that is more apparent in some proposed solutions than others.

The dramatic increase in use of electronic nicotine delivery systems (ENDS; e.g., e-cigarettes) among adolescents in the United States since 2014 and particularly over the last three years (FDA, 2019a; Cullen et al., 2019) exemplifies the concern over the “harm reduction” approach. While there is concern over the higher and rising current use of ENDS

by young adults (7.6% in 2018) compared to older adults (e.g., 2.1% in adults 45–64 years) (Bao, et al. 2019), manufacturers must confront the issue of youth uptake when their products are considered for marketing, because it will be prominent in FDA's evaluation criteria. This concern was evident in the modified risk tobacco product (MRTP) requirements for post-marketing studies and reporting of actions taken to restrict youth access and limit youth exposure to the products' labeling, advertising, marketing, and/or promotion following authorization of modified risk claims for particular Swedish Match snus products (FDA, 2019b). FDA is also likely to demand, under the premarket tobacco product application (PMTA) pathway, that ENDS manufacturers demonstrate how their product, when introduced on the market through the new tobacco product application pathway, will serve to lessen the youth vaping epidemic. To achieve maximum benefit while minimizing harm, product innovation should lead to ENDS products that are sufficiently appealing and satisfying to encourage cessation of combusted cigarettes completely and either continuing using ENDS or quitting use of nicotine entirely by adult smokers while not promoting uptake among non-users, especially youth.

Studies of ENDS use among youth point to potential strategies to discourage youth use. For example, in a study of middle and high school students in Connecticut (Kong et al., 2015), curiosity and flavors were the most common reasons for experimenting with ENDS among those who did not smoke cigarettes. Among adolescent cigarette smokers, the perception that ENDS can be used anywhere was a common motivation for ENDS use. Other reasons to use ENDS were smoke tricks, availability, convenience (e.g., indoor use), and the ability to hide ENDS use from parents and teachers. Accordingly, manufacturers might exploit specific product design and marketing strategies to demonstrate that their product should be authorized for marketing because they discourage youth use. But, in order to meet the population health standard, these actions should also minimally discourage adult smokers who have not been able to quit from switching completely to a lower harm product. The core public health question is which approaches can be most effective at achieving both goals.

The purpose of this paper is to highlight issues surrounding potential options for reducing youth use of ENDS while considering the impact on the likelihood that adult smokers would switch completely to potentially reduced harm products (Kistler et al., 2019). The purpose is not to debate whether certain alternative products are safer than cigarettes or whether they are more effective than nicotine replacement therapy for smoking cessation. There are others who are investigating those questions, which are a critical part of any new product application. Rather, our goal is to discuss strategies that might minimize uptake of ENDS by non-users, especially youth, while maximizing the complete transition of smokers to ENDS (with eventual transition to no nicotine use) (Zeller and Hatsukami, 2009; Shiffman et al., 2015). Specifically, we highlight the following four categories of actions for reducing youth ENDS use in the context of the public health impact for adult smokers: (1) limit product appeal, (2) limit ease of acquiring the product, (3) limit options for using the product, (4) and limit the addictiveness of the product. The Table lists the approaches described here and advantages/opportunities and disadvantages/limitations for each of these approaches.

2.1 Limit product appeal

A key factor in adoption of any commercial product is appeal. A consumer must be attracted to a product enough to make an investment in time and/or money to use it. Appeal encourages non-users to experiment with products, and repeated use of nicotine progresses to dependence and long-term use.

Flavors

Several studies have determined that flavors are one of the primary reasons that youth experiment with ENDS, and flavor restrictions have been discussed as a possible action for reducing youth use of these products (Federal Register, 2018). A substantial segment (81.5%) of youth ENDS users in Wave 1 of the Population Assessment of Smoking and Health study (PATH) indicated that one of their reasons for using ENDS was because they came in attractive flavors (Ambrose et al., 2015). Adolescents preferred fruit and alcohol flavors compared to tobacco; used fruit, dessert, and alcohol-flavored ENDS products more frequently than tobacco flavor; and the total number of flavors was associated with more days of ENDS use for adolescents (Morean et al., 2018; Schneller et al., 2019). Data from PATH also indicated that among single flavor users, adolescents preferred fruit, candy and other flavors; young adults preferred fruit, candy and menthol/mint; and adults preferred tobacco or other flavors, fruit, and menthol/mint (Soneji et al., 2019). Recent data from Monitoring the Future indicated that youth preferred JUUL ENDS flavored as fruit, mango, or mint (Leventhal et al., 2019). In other studies, adults preferred a greater number of flavors than adolescents and were more likely to prefer flavors that were not sweet compared to adolescents (Morean, et al., 2018). ENDS initiation with tobacco flavor was highest among adults (47.5%) compared to young adults (21.0%) and youth (1.4%) (Harrell et al., 2016).

But, adults who use ENDS also are attracted to non-tobacco flavors. Similar to what has been found with youth, most (62.9%) current adult ENDS users used flavored products other than tobacco, and flavor is a common reason among adults for product initiation (Landry et al., 2019). Dedicated former-smoking ENDS users believed a choice of flavors was very important to their effort to quit or reduce smoking (Farsalinos et al., 2013a). Use of fruit and candy/dessert flavored ENDS at initiation was associated with higher odds of switching from cigarettes to ENDS as compared to rejecting ENDS for continued smoking (Jones et al., 2019). Analysis of current or former cigarette smokers and current or former ENDS users in Waves 1 and 2 of PATH showed that availability of flavors in ENDS and their reduced cigarette-like odor was associated with lower relapse to cigarette use. Thus, flavors may be important for encouraging adult smokers who are otherwise unable to quit to completely switch to ENDS. Restricting flavors may reduce the appeal of ENDS to youth, but it could also have a detrimental effect on attractiveness of ENDS to adult smokers and reduce the effectiveness of these products in helping adults who use them to switch completely instead of becoming dual users or rejecting ENDS entirely. Research to address the differential attraction of adolescents and adults to different flavors would inform manufacturers looking to use this as a means for limiting youth appeal while maintaining adult acceptance of the product.

High-tech appearance

Non-combusted inhaled tobacco products, including IQOS which was launched in Japan in 2015, and ENDS (WHO 2019), present a dramatic change to the appearance and characteristics of tobacco products. The introduction of electronic technology into the process for delivering nicotine aerosol to the user adds complexities to the nicotine delivery device and introduces new considerations in evaluating product design and how consumers interact with the product. Technophilia, “the enjoyment which stems from using technology” (Ronit 2011) has become a new concern when evaluating attractiveness of these devices for youth. McDonald and Ling (2015) studied young adult ENDS users and found that ENDS fit squarely into their technology culture. Further studies (Thrasher et al., 2016; Barrientos-Gutierrez et al., 2019; Zavala-Arciniega et al., 2019) have identified a link between technophilia of middle school students and awareness and trial of ENDS, whereas technophilia was not related to first use of other tobacco products (Barrientos-Gutierrez et al., 2019). Exploitation of the connection between technology and heated tobacco products is evident in the appearance of stores used to market these products (Churchill et al., 2020). Reducing the high-tech appearance and marketing of ENDS may reduce their appeal to adolescents who have become more and more focused on obtaining the latest electronic gadget. But considerations should also be made for what impact this could have on appeal to adult smokers.

2.2 Limit ease of acquiring the product

Price

It has been firmly established that raising the price of tobacco products reduces overall tobacco use (Chaloupka et al., 2011). Researchers also have found that tobacco use among young people is even more responsive to changes in taxes and prices than among adults (IARC, 2011; NCI, 2016; NCI, 2017). Several studies have evaluated this concept in relation to ENDS. Huang et al. (2014) found that ENDS sales were very responsive to changes in ENDS prices, and Pesko et al. (2018) found that higher disposable ENDS prices were associated with reduced number of vaping days among youth. These studies demonstrated that limiting rebates, discounts and coupons and imposing a tax on ENDS could reduce ENDS sales and ENDS use among youth. Some studies, however, due largely to the difficulties in accurately measuring ENDS costs, did not find a statistically significant influence of price on ENDS use (Cantrell et al., 2019; Cheng et al., 2016).

There are remaining questions about the impact of ENDS prices on ENDS use and what would be the impact of differential pricing (i.e., cigarettes more expensive than ENDS) on youth and adult ENDS use. If higher ENDS price substantially discourages ENDS use more in adolescents than in adults, this strategy might accomplish the goals of population health. But this falls outside FDA’s authority and would require actions by Congress, state, or local governments. By eliminating coupons, two-for-one deals, and keeping prices from falling below a minimum threshold that discourages youth purchases, manufacturers could help reduce youth use. But, increases in price are likely to discourage adult use, especially among low-income smokers, and may encourage dual use of ENDS with combusted cigarettes. These concerns could be alleviated by imposing higher taxes on combusted products, thus

making unit price, which can be measured by either the equivalent unit (Cheng et al., 2020; Liber et al., 2017) or based on nicotine content (Chaloupka et al, 2020) of combusted products, more expensive than that of ENDS. If the objective is minimizing youth uptake while encouraging complete switching by smokers, increases in both the price of ENDS and combusted products with a greater increase in the price of combusted products, may help achieve both goals.

Increase minimum age/ Limit sales to adult-only in-person facilities

On Dec. 20, 2019, President Trump signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to 21 years (U.S. House, 2019). Because 86.9% of cigarette smokers start smoking before the age of 18 (USHHS, 2014), this action could reduce adolescent and, eventually, adult use. Previously, 18-year-old students who were still in high school were able to legally purchase tobacco products, providing a natural pathway for underage students to obtain products (Meyers et al., 2017; Merianos et al., 2019). Raising the legal purchasing age to 21 may lessen access to tobacco products for students under age 18 (NASEM, 2018). Legislation that raised the smoking age to 21 decreased 30-day smoking from 13% to 7% versus 15% to 12% in comparison communities (Kessel-Schneider et al., 2016). Restricting sales to facilities that only allow access to customers over the age of 21 may also prevent youth use (Henriksen et al., 2008; Gwon et al., 2017; Robertson et al., 2014). In a similar manner, reducing the density of retail outlets that sell ENDS, especially around schools could help reduce youth access to these products. However, some adult-only retail sectors (tobacco-only retailers, smoke and vape shops) violated the law at a higher rate than commercial non-adult-only facilities (supermarkets, pharmacies, and convenience stores) (Zhang et al., 2018).

Reducing retail sales to adolescents by increasing the minimum age of purchase or limiting to adult-only facilities may not be the complete answer. Numerous studies have shown that most ENDS obtained by under-18 users are not purchased in retail stores, but are obtained from social sources including friends and family, bummed, taken, or purchased over the internet (Liu et al., 2019; Meyers et al., 2017; Tanski et al., 2019). In one study (Meyers et al., 2017), 54.5% of under-18 ENDS users had last obtained the devices from sources that should have had age-checking or were adult-only facilities (smoke shops and liquor stores). In addition, asking others to purchase products, stealing products, and complicit clerks who sell to under-age youth undermine minimum age requirements or restrictions of sales to adult-only facilities (DiFranza et al., 2001). Issues have arisen with using minimum age or adult-only facilities to minimize youth use of ENDS (Merianos et al., 2019, Hammal et al., 2016).

If minimum age and/or adult-only facilities are intended to prevent adolescent acquisition of tobacco products, effective means for age verification for internet sales and active and effective retail sales enforcement is critical (Farber et al., 2016; Lee et al., 2018). However, restricting to adult-only facilities is likely to also reduce product availability for adult smokers because of lower number and accessibility of sources of the product sources.

Biometrics

Adolescents have devised ways to obtain tobacco products, both cigarettes and ENDS, even when faced with legal restrictions against their purchase. Therefore, it is worthwhile to consider other ways to prevent unauthorized youth use of these products even after acquisition. There may be several innovative ways to do so; one of these may be building biometric identification into each ENDS device. Biometrics has been defined as "the automatic recognition of individuals based on their physiological and/or behavioral characteristics" and is used "to ensure that the rendered services are accessed only by a legitimate user and no one else" (Jain et al., 2004). There are many systems to which biometrics have already been applied and shown to be beneficial including firearms, building access, computers, cell phones, and Automated Teller Machines. When an ENDS device is originally purchased, the purchaser's biometric signature would be incorporated into the device's memory and only the purchaser would be able to operate it subsequent to purchase. Modification of the biometric signature would require age verification face-to-face. Stolen ENDS, ENDS loaned or given by friends, and ENDS purchased in bulk for resale would be non-operational for secondary users. Since these are the most common ways that adolescents obtain ENDS, these avenues would be effectively removed. This would not prevent the use of these products by adult legal purchasers of ENDS since most adult ENDS users purchase the products themselves. As there would be additional requirements when the device is purchased, this would complicate internet sales of these devices, and, at least initially, would raise the price of the products, have the unintended effect of limiting their accessibility to low-income adult smokers seeking potentially reduced harm products, and could encourage more use of consumer-made products both among youth and adults. Incorporation of biometrics may also allow the tobacco companies to obtain private information on users' activities and encourage targeted marketing beyond what is already occurring. It is important that proper limits on the use of the information obtained from this technology be in place and enforced. But, a company which incorporates this type of technology into their systems would have a rationale that authorizing the marketing of their products would help reverse the trend in increasing youth use.

2.3 Limiting options for using the product

Ban indoor use

Requiring smoke-free indoor air is one of the most widely accepted tobacco control policies. While this typically has been based on protection of nonsmokers from exposure to secondhand smoke (Klarqvist, 2017), it has had the secondary benefit of encouraging smoking cessation (Eriksen and Cerak, 2008; Azagba et al., 2019). There is clear evidence that smoke-free legislation can make smoking less socially acceptable and reduce smoking rates and that social acceptability is a common reason for ENDS use in general (Romijnders, et al. 2018), but there is less clarity regarding the overall public health impact of restricting the indoor use of ENDS. One study on children age 6–10 showed that, when observed at a distance, children may misperceive ENDS use as smoking (Faletau et al., 2013). Other studies demonstrated that ENDS use behavioral cues increased the desire to smoke a cigarette among young adult smokers (King et al., 2015; King et al., 2016). There is also concern for secondhand exposure to nonusers if ENDS use is allowed indoors. Elevated

levels in indoor air of several compounds of concern have been found in secondhand aerosol from ENDS use (Hess et al., 2016). But, results are limited and more research is needed to determine the health risk to secondhand ENDS aerosol exposure to nonusers.

Some studies have suggested that restricting indoor ENDS use discourages the use of these products and, therefore, leads to less use of them as a means for smoking cessation (Farrimond, 2016; Lee et al., 2019). These studies support the proposition that aerosol-free indoor use policies could discourage complete switching to ENDS by smokers trying to quit. On the other hand, other investigators found that only 12% of vapers who were in restricted locations found it difficult to refrain from vaping in places it was not allowed, suggesting that this limitation is not as impactful as might be inferred (Yingst et al., 2017). An analysis of current or former cigarette smokers and current or former ENDS users in Waves 1 and 2 of PATH, found that using ENDS because they can be used where smoking is not allowed was associated with reduced odds of quitting cigarettes (Soule et al., 2019), which may be because this allows ready access to nicotine even when indoor smoking is not allowed. Thus, evidence does support that confusion about enforcement of indoor air laws may occur if ENDS use is allowed indoors, but the science is not clear that allowing ENDS use indoors would encourage more complete switching.

Discreteness

Because of minimum age and indoor use restrictions for ENDS, stealth use has become an important behavior, and characteristics which facilitate stealth use are an important ENDS feature (Peters et al., 2013). Expeditious consumption and surreptitious concealment are primary reasons that 40% of teens use ENDS (Peters et al., 2013; Hammal et al., 2016; Wagoner et al., 2016). Among experienced adult ENDS users, two out of three had stealth vaped and 31% of vapers owned a separate device for stealth vaping, including at work (46.8%), bars/nightclubs (42.1%), restaurants (37.7%), movies (35.4%), and in airports/airplanes (11.8%) (Yingst et al., 2019).

Manufacturers have promoted products that look like common consumer items, with low visibility plumes or subtle odor (Ramamurthi et al., 2018). E-liquids with more propylene glycol (PG) and less vegetable glycerin (VG) produce aerosol clouds that are less conspicuous due to differences in particle mass number distribution (Vena et al., 2019; Baassiri et al., 2017). An ENDS/e-liquid combination that produces a bigger cloud would be more obvious to bystanders, parents and teachers. As discussed above, this may also trigger the desire to smoke in others (Vena et al., 2019). Accordingly, changes to reduce ENDS discreteness might include product characteristics that are unrelated to smoking (e.g., alternative smells, lights or sounds). Manufacturers seeking marketing authorization for products that promote discreteness by mimicking common consumer items such as USB devices will be hard-pressed to demonstrate how these will not encourage youth use.

Geofencing

One approach that has not been widely discussed to date is to use the advanced technology available in ENDS as a means to limit where they can be used. Geofences are virtual perimeters around specific geographical locations. Most people who own a cell phone have

already experienced geofencing since it is used by companies to send notifications to potential customers when they enter a boundary close to a place of business (Chamberlain 2016). Geofences are already in use to help prevent logging accidents, monitor staff, and track children and patients with Alzheimer's disease (Zimbelman et al., 2017; Connor and Herzig, 2016; Yuce et al., 2012). One geofencing approach is to identify when a device enters a restricted zone and prevent them from entering. In 2015, Senator Charles Schumer (Schumer, 2015) proposed requiring software on every aerial drone that would prohibit flying near airports and other sensitive areas based on the concept of geofencing. The inherent technological nature of ENDS could be leveraged to improve the likelihood these products would be appropriate to protect public health. Products with Bluetooth technology have already been introduced onto the market in the European Union (Staal et al. 2018). Devices could contain software to recognize geofences and be non-operational within these geofences. Installation of geofences around schools and other locations at which youth gather could reduce youth use with minimal effect on adult use.

2.4 Limit the addictiveness of the product

Limit nicotine delivery

Adjusting the level of nicotine delivered to the user may provide a way to prevent the development of dependence in new users. The physiological impact of nicotine varies with the amount of nicotine and the relative amount between the freebase or protonated form (Chen, 1976). As pH increases due to reduction of acidic species or increases in basic species, the amount of nicotine in the freebase form increases. With a constant total nicotine amount, increases in pH increase both physiological impact and harshness of the aerosol (Chen, 1976). The marketing of JUUL and the concurrent rise in adolescent vaping has raised substantial concerns about the influence of low pH, high nicotine ENDS products on youth use. Since JUUL gained popularity, there has been a rush of new products with high nicotine concentrations (Jackler and Ramamurthi, 2019). JUUL's patent indicates that use of nicotine in the salt form has resulted in more efficient transfer to the lungs, absorption in the plasma, and higher satisfaction (JUUL Labs, 2014). Because nicotine in a salt form (more acidic, lower pH) is less harsh and bitter, consumers are able to inhale a larger amount of nicotine without severe aversive response (Jackler and Ramamurthi, 2019). Among adolescent and young adult ENDS users, those who used pod-based ENDS like JUUL were more likely to be daily users and those daily users were more likely to be younger than other ENDS users (Boykan et al., 2019). Accordingly, a possible approach to addressing youth use of ENDS would be to set a maximum nicotine concentration and minimum pH value so that ENDS will be more aversive and less attractive and addictive to tobacco-naive adolescents. For example, in its Tobacco Product Directive (TPD), the European Union set the maximum nicotine level in e-liquids to 20 mg/mL (European Commission, 2014).

However, smokers looking to ENDS as a means of smoking cessation are more likely to switch completely when ENDS delivers an amount of nicotine that they are accustomed to receiving from their cigarettes (Farsalinos et al., 2013b; Lopez et al., 2016). ENDS users of lower nicotine concentration e-liquids consume more liquid and take longer puffs than those in higher nicotine conditions (Dawkins et al., 2016, Lopez et al., 2016). In an experimental

study on nicotine delivery, heart rate, puff topography and subjective effects, ENDS use suppressed withdrawal symptoms but depended on the nicotine concentration (Hiler et al. 2017a). The TPD was intended to limit the addictiveness of ENDS to be no higher than that of commercial cigarettes. But, like cigarettes, users can change the way they smoke in order to inhale more or less nicotine (Jarvis et al. 2001). ENDS also have other characteristics, such as wattage and coil configuration, that enable users to change the nicotine delivery. So, simply setting a maximum allowed nicotine level is unlikely to accomplish the desired outcome.

Ideally, there is a combination of total nicotine concentration, pH, and product design that would deliver enough nicotine to smokers in a way that encouraged complete switching, but not enough nicotine in a form that made it easy for tobacco-naïve adolescents to experiment and become addicted ENDS users (Etter, 2015). Shihadeh and Eissenberg (2015) have proposed the concept of “nicotine flux”, nicotine emitted per puff second by ENDS, as a means of evaluating product design and its nicotine delivery efficiency and regulating these products. But, it remains to be seen if a combination can be found that encourages adult users to switch completely without attracting youth to a lifetime of nicotine addiction. If this is the approach, users’ ability to modify the product’s nicotine concentration, coil voltage, and other characteristics must be nullified by effective product design, which might mean restriction to closed systems only. Future actions to reduce the addictiveness of ENDS may be critical to achieving the overall goal of transition to no tobacco use.

3. Discussion

Because of the length of time required for notice and comment rulemaking, the most likely decisions FDA will make in the near future related to ENDS will be in response to pre-market tobacco applications, determining which products will be allowed on the market when enforcement discretion is removed. For ENDS to be authorized for marketing, manufacturers will need to demonstrate that their products are likely to lessen youth initiation of ENDS use while still encouraging adult smokers to stop smoking combustible cigarettes and switch completely to demonstrated lower-risk products. This provides ENDS manufacturers with a roadmap for innovation, one not aimed at increasing sales, but at improving public health. Manufacturers may need to think creatively, because many of the approaches suggested to date will not be effective for achieving both objectives.

While research has been carried out to understand the effectiveness of several (e.g., flavor and price restrictions) of these proposed actions, for others (e.g., biometrics, geofencing) the data are limited or non-existent. Because these data would be used to support new product marketing applications, the burden to provide evidence rests on the applicants. Tobacco companies have a long history of researching the impact of product characteristics and marketing strategies on product use through focus groups, quantitative surveys and choice experiments, which could be used to provide data supporting their approach.

There are actions that manufacturers can take that could tilt the scale to more likely achieve the goal of minimizing youth use while encouraging adult smokers to switch completely. Manufacturers could reduce the high-tech appearance of their products in order to address

the adolescent attraction to new technology; stop issuing coupons and two-for-one type price incentives to keep their prices in a range that would reduce the ease of youth purchase; limit the retail sales of their products to adult-only in-person facilities and insist on active age verification and enforcement to prevent youth purchase; incorporate technological innovations such as biometrics or geofencing into their products to help reduce youth use of products they have not legally purchased and in places where youth predominantly use these products; and ensure their products are less discrete to make it easier for teachers and parents to identify ENDS use. All of these steps could minimize youth use without a substantial barrier to helping adult smokers switch completely to a less harmful product, and a combination of approaches is likely necessary.

There are other approaches which we have not discussed in this review, including marketing restrictions, effective science-based communications and careful review and authorization of modified risk claims. We are sure that others may conceive other ideas not evident to us. But, manufacturers will need to address both youth use and complete adult switching as they propose to FDA products that they claim are appropriate for the protection of public health.

Accompanying the current discourse on e-cigarettes and the risk to adolescent health they engender, we must also not lose sight of the products that need to be most sorely addressed, combusted tobacco products. Dr. Scott Gottlieb (ex-Commissioner of FDA) and Mitch Zeller (Director of the FDA Center for Tobacco Products) proposed a bold vision for addressing the tobacco product harm issue when they discussed a multi-faceted approach that included reducing nicotine levels in combusted products, removing all flavors from combusted products, including menthol from cigarettes; and promoting public health innovation of ENDS (Gottlieb and Zeller, 2017). A combination of innovative strategies that involve product characteristics, marketing, and regulatory actions for both ENDS and combustible tobacco products are critically needed in order to address the youth vaping epidemic while also promoting adult smoking cessation. We fully expect that FDA will continue to hold workshops, give public presentations, and issue guidance intended to encourage discussion and actions needed to address the issue of youth vaping.

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Highlights:

- ENDS manufacturers must address youth vaping in new product applications
- Some approaches might discourage smokers from quitting combusted product use
- Innovative approaches (e.g., biometrics, geofencing) may accomplish both objectives

Table.

Factors in the Viability of Approaches to Reducing Youth Use of Electronic Nicotine Delivery Systems

Approach	Advantages/Opportunities	Disadvantages/Limitations
Limiting flavored ENDS	• Flavors are a key reason for youth ENDS use • Youth prefer sweet flavors more than adults	• Adults are also attracted to flavors • May inhibit adult smokers from switching from smoking to exclusive ENDS use
Reducing the high-tech appearance of ENDS	• High-tech appearance of ENDS fits squarely into youth and young adult technology culture	• May also limit appeal among adult smokers who might benefit from potentially reduced-risk products
Raising taxes or discontinuing use of coupons and price incentives for ENDS	• Youth are more responsive to price than adults	• Could reduce ENDS use among adult smokers, particularly those with low income • Could discourage a complete switch from smoking to ENDS if price of combusted products is not also increased
Limiting minimum age of sales or purchase of ENDS to adult-only facilities	• Could reduce retail sales as an avenue for youth acquisition	• Some adult-only facilities have a higher violation rate than non-adult-only facilities • Most ENDS obtained by youth are from social sources • Limiting to adult-only facilities would reduce access locations for adult smokers
Incorporating biometrics into ENDS	• Would largely eliminate social sources as means of obtaining ENDS by youth	• Would complicate internet and retail sales for adults • Could increase the cost of ENDS, and reduce its uptake among adult smokers, particularly those with low income • May encourage more consumer-made devices • Could also allow tobacco companies to obtain private information about user behaviors
Ban indoor use of ENDS	• Would reduce misperceptions about indoor bans on smoking • Would reduce secondhand aerosol exposure	• Discreteness of ENDS may make it difficult to enforce
Reducing discreteness	• Discreteness is more critical for youth use	• Would reduce adult stealth vaping, which could deter ENDS use among adult smokers
Incorporating geofencing	• Could be targeted to schools or other locations where youth gather	• May be used to track users for marketing purposes
Limiting nicotine delivery	• Could minimize likelihood of youth appeal or addiction	• May inhibit adult smokers from switching from smoking to exclusive ENDS use • Multiple characteristics must be addressed (e.g., pH and product design features)

Approach	Advantages/Opportunities	Disadvantages/Limitations
		• Would only allow authorization of closed systems

ENDS – Electronic nicotine delivery systems, e.g., e-cigarettes.