REPORT 6 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-10)
Use of Electronic Cigarettes in Smoking Cessation Programs
Reference Committee D

EXECUTIVE SUMMARY

Objective. This report reviews current AMA Policy related to electronic cigarettes (e-cigarettes), the manufacture and characteristics of e-cigarettes, current regulations and the potential health impacts of e-cigarettes, and their potential role in smoking cessation.

Methods. Literature searches for review articles were conducted in the PubMed database and the Cochrane Database of Systematic Reviews using the search terms "electronic cigarettes," "e-cigarettes," "smokeless cigarettes," "tobacco-free cigarettes," "nicotine addiction," "nicotine inhaler," and "nicotine spray," in the article title and/or abstract. Web sites managed by federal agencies and applicable professional organizations also were reviewed for relevant information. Commercial Web sites of e-cigarette manufacturers and distributors and comments from concerned public health professionals and submissions regarding FDA regulatory powers over e-cigarettes also were consulted. Additional articles were identified by reviewing the reference lists of pertinent publications.

Results. E-cigarettes are non-flammable devices that deliver synthetic or tobacco-derived nicotine; they are similar in size, shape, and usage to their leaf tobacco counterparts. They are available worldwide through the Internet or increasingly in retail outlets. Little independent research has been conducted into their ingredients and health impacts, but they are commercially promoted by vendors and some health harm reduction advocates as a safe alternative to cigarettes, and in some instances, as smoking cessation aids or for cutting down smoking by those not wanting to quit or eliminate their nicotine dependence. However, manufacturers of e-cigarettes have not submitted the requisite applications for FDA approval of these products for smoking cessation. While e-cigarettes may produce or maintain nicotine dependence, the vapor released contains polyethylene glycol (PG), which looks like cigarette smoke (also used for theatrical smoke) and is also an FDA-approved food additive commonly found in deodorants, moisturizing lotions, toothpastes; pharmaceutical products, including some inhalers; and fat-free dairy products.

Because E-cigarettes have not been thoroughly tested, one cannot conclude that they do not produce any harmful products, even if they produce fewer dangerous substances than conventional cigarettes. In fact, analysis of two brands of e-cigarettes found detectable levels of known carcinogens and toxic chemicals (i.e., diethylene glycol, an ingredient used in antifreeze, small amounts of tobacco-specific nitrosamines, and certain other tobacco-specific impurities that may be harmful). To date, most research on e-cigarette ingredients, safety, health effects, and use by current smokers has been funded by manufacturers. Independent studies by the FDA and Demokritas, a publicly funded research institute based in Greece, raised questions about the actual ingredients found in commercial e-cigarettes, consistency of nicotine levels, and quality control in their manufacture. Whether the FDA will have regulatory control, and over which aspects, remains to be determined.

Conclusions. E-cigarettes might present an effective alternative to leaf tobacco use for some smokers, but clinical testing, larger population studies, and full analyses of their ingredients and manufacturing processes need to be conducted before their safety, viability, and impacts can be determined as either clinical tools or as widely available, effective alternatives to tobacco use. Whether e-cigarettes can safely help people quit smoking also is unknown, but with their fruit and candy flavors, they have a clear potential to entice new smokers.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 6-A-10

Subject: Use of Electronic Cigarettes in Smoking Cessation Programs

Presented by: C. Alvin Head, MD, Chair

Referred to: Reference Committee D
(Diana E. Ramos, MD, Chair)

INTRODUCTION

This report is being written in response to Resolution 420 (A-09), "Study of Appropriate Use of Electronic Cigarettes in Smoking Cessation Programs," (Policy D-490.975, AMA Data Base), introduced by the American Association of Public Health Physicians and adopted by the House of Delegates. Resolution 420 asks the Council to study the available evidence and develop recommendations on the appropriate use of electronic cigarettes (e-cigarettes) in smoking cessation programs. Accordingly, this report reviews current AMA Policy related to e-cigarettes, the manufacture and characteristics of e-cigarettes, current regulations and the potential health impacts of these products, and their potential role in smoking cessation.

METHODS

Literature searches for review articles were conducted in the PubMed database and the Cochrane Database of Systematic Reviews using the search terms "electronic cigarettes," "e-cigarettes," "smokeless cigarettes," "tobacco-free cigarettes," "nicotine addiction," "nicotine inhaler," "nicotine spray," in the article title and/or abstract. Web sites managed by federal agencies and applicable professional organizations also were reviewed for relevant information. Commercial Web sites of e-cigarette manufacturers and distributors and comments from concerned public health professionals and submissions regarding the Federal Drug Administration's (FDA) regulatory powers over e-cigarettes also were examined. Additional articles were identified by reviewing the reference lists of pertinent publications.

CURRENT AMA POLICY RELATED TO E-CIGARETTES

Current AMA policy does not specifically address e-cigarettes; however, Policy H-495.985 (AMA Policy Database) addresses the use of snuff and chewing tobacco and contains language relevant to e-cigarettes. This policy "objects strongly to the introduction of "smokeless" cigarettes" and also "opposes the use of smokeless tobacco products by persons of all ages." Policy H-495.988 addresses the production and dissemination of all tobacco products and reaffirms the AMA position that all tobacco products are harmful to health; there is no such thing as a safe cigarette; tobacco is a raw form of the drug nicotine; and tobacco products are delivery devices for an addictive substance. This policy also supports the view that the FDA should continue to have broad powers and authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing, and urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco. Furthermore, the FDA and other appropriate agencies should conduct or fund

research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness. With regard to smoking cessation, Policy H-490.911 supports smoking cessation programs and seeks the passage of legislation that makes all workplaces smoke free. Policy H-490.917 outlines physician responsibilities for smoking cessation and advocates the use of surveillance approaches to measure changes in the use of alternative nicotine delivery systems. Finally, Policy D-490.977 urges physicians and health organizations to avoid providing patients and consumers with information or materials on tobacco that come from tobacco companies or other groups aligned with the tobacco industry.

USE OF ALTERNATIVES TO SMOKED TOBACCO IN SMOKING CESSATION

The key recommendations of the U.S. Department of Health and Human Services' Public Health Service clinical practice guidelines on treating tobacco use and dependence[1] recognize seven first-line medications (of which five contain nicotine) for use by patients attempting to quit smoking. Although counseling and medications are both effective in treating tobacco dependence, the combined use of counseling and medication is more effective than either alone. Nicotine-containing medications (usually referred to under the rubric of Nicotine Replacement Therapy or NRT are available in five delivery mechanisms including transdermal patch, chewing gum, nasal spray, lozenge, and inhaler formulations. The non-nicotine medications approved for smoking cessation are bupropion SR and varenicline.

ELECTRONIC CIGARETTES

Description

E-cigarettes and cigars (e-cigars) are non-flammable nicotine delivery devices that are roughly the same size and shape as their leaf tobacco counterparts but do not (apparently) use tobacco products. *Eclipse*®, produced and marketed by R.J Reynolds Tobacco Company, also is a nicotine delivery device that releases nicotine via heating rather than burning but, unlike e-cigarettes, the primary ingredients are tobacco and tobacco products. The nicotine in e-cigarettes is either synthetic (chemically developed) or is extracted from tobacco. E-cigarettes consist of three integrated parts contained in a stainless steel shell: the mouthpiece (or nicotine cartridge), the atomizer chamber (or vaporizer), and a smart chip lithium ion battery.[2]

Typically, a disposable filter holds a cartridge containing synthetic nicotine dissolved in propylene glycol, water, and flavorings. In tests conducted by the FDA's Division of Pharmaceutical Analysis on two brands of e-cigarettes, additional ingredients were detected including diethylene glycol in one cartridge (a component of antifreeze and toxic to humans) and tobacco-specific nitrosamines (a known carcinogen) in half of the samples.[3] This is very concerning and adds to the premise that such items should be closely regulated. When the entire unit is assembled, the user creates an inhaling motion which activates the battery via pressure sensors. The battery powers the vaporizer, and the vaporizer heats the liquid housed in the mouthpiece. As such, the electronic cigarette is a delivery device for the addictive substance nicotine. The vapor released is polyethylene glycol (PG), which looks like cigarette smoke (also used for theatrical smoke) and is also an FDA-approved food additive. The volume released varies by brand, but when inhaled feels like cigarette smoke to users. Unlike tobacco smoke, the vapor quickly evaporates, leaves no remaining odor, but the secondhand smoke may still be irritating.

Compared with conventional cigarettes, which last for about fifteen puffs, e-cigarettes can sustain from 150 to 300 puffs, the equivalent of one-half to one pack of cigarettes. The cartridges vary in

nicotine strength, being characterized as "zero," low, medium, or high.[4,5] Disposable, non-refillable versions, equivalent to one or two packs of cigarettes, also are available.

Sales and Marketing

E-cigarettes were invented by an employee (Hon Lik) of a Chinese electronics company (Ruyan) headquartered in Beijing, which began marketing them in 2004. The Ruyan Group remains the leading manufacturer of e-cigarettes (sold as Ruyan® e-cigarettes), but additional manufacturers using similar devices have subsequently entered the market, offering their products worldwide via the Internet, in shopping malls, and via distributors. Ruyan claims it sold 300,000 devices in 2008, and two major U.S. e-cigarette importers claimed sales totaling 735,000 units.[6,7] U.S. sales of other products are not known, although an advertisement for the "Easy As Step 1,2,3" package of e-cigarettes says "millions of smokers have become smoke-free" using the package.[5] Prices for the devices (a charger, rechargeable battery, and five nicotine cartridges) range from about $80 to $150 with packages of replaceable cartridges, each good for several uses, costing $10 to $15 or the equivalent of 1 to 1.5 packs of cigarettes.[8]

HEALTH IMPACTS

In general, little independent research has been conducted into the ingredients of commercially available e-cigarettes or on their health impacts and potential risks. Marketing claims vary among manufacturers and vendors.

Claims and Chemical Exposures

Some public health advocates argue that as a form of harm reduction, e-cigarettes are far safer to use than conventional cigarettes for individuals who do not wish to eliminate their dependence on nicotine. In some cases, e-cigarettes are promoted either as nicotine delivery devices that do not produce the toxins and cancer-causing chemicals found in secondhand smoke or as devices that comply with the spirit of clean indoor air regulations. Some brands claim that e-cigarettes are useful for reducing smoking and are equivalent to nicotine spray and nicotine inhalation NRT formulations for smoking cessation.[6] Major U.S. distributors maintain they are not promoting e-cigarettes for smoking cessation but emphasize that these products are safer than cigarettes for those who are addicted to or want to use nicotine but no longer want to be exposed to the risks and dangers of smoking cigarettes.[8]

Given the limited research and pending further testing, it is generally agreed that e-cigarettes have far fewer ingredients, especially carcinogens and toxins, than conventional cigarettes (which have ~600 ingredients and contain or generate more than 40 recognized carcinogens). Although the vapor produced by e-cigarettes emulates tobacco smoke, it is odorless and does not contain tar or other tobacco by-products. It consists largely of propylene glycol which is commonly found in other consumer products, such as deodorants; moisturizing lotions; toothpastes; pharmaceutical products, including some inhalers; and fat-free dairy products. E-cigarette vendors argue that because the inhaled substance is a vapor and not derived from combustion, the vast majority of harmful products derived from smoking (and secondhand smoke) are not produced and therefore are not concerns with the use of this product. However, the lack of product testing does not permit the conclusion that they do not produce any harmful products, even if they produce fewer dangerous substances than conventional cigarettes.

Inhaled Nicotine-Containing Devices Used for Smoking Cessation

One inhaled nicotine-delivery device already in use for cessation is the Nicotrol® Inhaler (known as the Nicorette® inhaler outside of the U.S.). This device consists of a mouthpiece and a plastic cartridge delivering 4 mg of nicotine from a porous plug containing 10 mg nicotine. The cartridge is inserted into the mouthpiece prior to use and need not be inhaled deeply since the medication works in the mouth and throat, not in the lungs. Nicotine is released when air is inhaled through the device. The Nicotrol® Inhaler is approved as an effective aid to smoking cessation for the relief of nicotine withdrawal symptoms and as part of a comprehensive behavioral smoking cessation program. It is marketed as a safe alternative to smoking during the cessation process.[9] The recommended period of use may extend up to six months.

The Council was unable to identify any independently generated articles on e-cigarettes or inhaled nicotine delivery devices other than the extensive literature on the Nicotrol® Inhaler and a chemical analysis of one brand of e-cigarettes conducted by Demokritas, a publicly funded research institute based in Greece. Controlled studies on the use of e-cigarettes in smoking cessation or their effects on population use of tobacco products have not been published.

Apart from the FDA's analysis, the most comprehensive published study of e-cigarettes was conducted by Health New Zealand, Ltd. on Ruyan® e-cigarettes, although the study was funded by the manufacturer.[10] This study reviewed the existing literature on propylene glycol and its effects on humans and catalogued a variety of chemical studies conducted by different laboratories on the contents of e-cigarette cartridges, vapors, and mists, as well as an analysis of systemic carbon dioxide concentrations in users. Each puff contains one-third to one-half the nicotine in a tobacco cigarette; trace amounts of tobacco-specific nitrosamines and some other toxins are formed, but, in general, the product was considered a safer alternative to smoking conventional cigarettes. A preliminary report of a randomized crossover trial funded by Ruyan, comparing the Ruyan® e-cigarette containing 16 mg of nicotine with placebo capsules and the Nicorette® inhaler, found that the e-cigarette was as effective in reducing craving and other withdrawal effects as the inhaler, was well-tolerated, and had few adverse effects.[11] A report of a small study funded by the National Cancer Institute and conducted at Virginia Commonwealth University, however, concluded that e-cigarettes failed to deliver sufficient nicotine to eliminate craving or to significantly increase plasma nicotine concentrations with every puff.[12]

The FDA study of e-cigarettes used the Nicotrol® Inhaler as a control. Analysis of two brands of e-cigarettes confirmed their ability to deliver nicotine (in one case, twice as much as the control inhaler), and that the product contained detectable levels of known carcinogens and toxic chemicals (i.e., diethylene glycol, an ingredient used in antifreeze; small amounts of tobacco-specific nitrosamines; and certain other tobacco-specific impurities that may be harmful). The FDA also determined that: (1) some samples labeled as nicotine-free contained measurable amounts; (2) cartridges with the same labeled nicotine content emitted markedly different amounts of nicotine with each puff; and (3) products exhibited inconsistent or lack of quality control processes in product manufacturing.[2, 3] Most recently, Demokritas conducted a similar analysis of the Nobacco® e-cigarette with similar findings.[13]

FDA Advisories

As a result of its study and examination of other evidence, the FDA issued a consumer health warning regarding e-cigarettes expressing concern that:

- e-cigarettes can increase nicotine addiction among young people and their use may lead to experimenting with other tobacco products;
- these products may contain ingredients known to be toxic to humans;
- clinical studies about product safety and efficacy for their intended use have not been submitted; and
  - consumers have no way of knowing the doses they are inhaling, the types or concentrations of potentially harmful chemicals, or if e-cigarettes are safe for their intended use.[14]

Furthermore, some of these products are available in flavors such as strawberry, chocolate, and mint that may appeal to young people.

E-CIGARETTES AND SMOKING CESSATION

Due to the lack of rigorous chemical and animal studies, as well as clinical trials on commercially available e-cigarettes, neither their value as therapeutic aids for smoking cessation nor their "safety" as cigarette replacements is established and remains speculative. Although one manufacturer advertises that "Millions of smokers have become smoke-free" with the use of its product,[5] evidence is lacking that these products are effective clinical cessation instruments. Manufacturers of e-cigarettes have not submitted the requisite applications for FDA approval of these products for smoking cessation.

Nicotrol® has been studied for its effectiveness as a NRT and is approved for clinical use. Fagerstrom and colleagues conducted several studies evaluating the effects of this inhaler on smokers and found that it decreased the number of cigarettes smoked by 86% and reduced exhaled carbon monoxide by 47%, with no decrease in effect over time.[15] Even where cigarette smoking continued, nicotine concentrations did not rise, and adverse reactions were not apparent in Nicorette® users.[16]

The use of inhalers as nicotine delivery devices has a number of advantages over cigarettes, apart from containing considerably fewer toxins. Because absorption occurs primarily via the mucosa of the oral cavity, arterial nicotine concentrations rise more slowly and to lower peak levels than with cigarettes. Therefore, the impact to the lungs is minimal, and the arterial nicotine concentration spike that occurs with cigarette smoking is avoided, thus decreasing the likelihood for abuse.[17] Although the absorption of nicotine via an inhaler requires more puffing, as with all NRT formulations, the extent of nicotine absorption is sufficient to prevent smoking relapse by reducing withdrawal symptoms and the craving associated with abrupt smoking cessation. Despite their cigarette-like appearance and their association with usage behaviors that smokers typically associate with the sensory and ritual elements of smoking, little treatment dependence or abuse has been reported with inhalers.[18] In clinical trials, inhalers appear similar to cigarette smoking in levels of satisfaction and reductions in urges to smoke.[19] These features can make inhalers attractive to those who are not ready to quit but are interested in changing their smoking behaviors. Inhaler users also minimize other harms including significant decreases in exhaled carbon monoxide, reduced risk markers for cardiovascular disease, and only minor use-related adverse events, such as throat irritation and cough. Therefore, it is established that the nicotine inhaler can help smokers who are unable or unwilling to quit to reduce daily cigarette consumption, which may provide some (relative) health benefits and further promote quitting.[20]

Nicotine Replacement Therapy

A systematic review of clinical research on nicotine inhalers and other forms of NRT concluded that all forms of NRT are associated with more frequent and successful quit attempts.[21] The available evidence indicates no overall differences in the effectiveness of different NRT formulations, although heavy smokers may need higher doses of NRT. Furthermore, NRT works without additional counseling and does not need to be prescribed by a physician. The use of NRT does not appear to increase the risk for heart attacks; however, it is possible that the results observed in clinical trials and in smoking cessation programs may differ at the population level.

Another systematic review evaluated the ability of NRT to assist in reducing harms from continued tobacco use.[22] Although use of nicotine gum and/or inhalers significantly reduced daily cigarette use by 50% compared with placebo, only a small percentage in either the treatment or control groups successfully sustained a reduction of 50% or more in cigarette use. In addition, reductions in the markers of exposure to tobacco smoke (levels of carbon monoxide and cotinine) did not decline accordingly. The authors concluded the evidence is insufficient to support the use of NRT interventions designed to help smokers reduce, but not quit, tobacco use and that the degree of health benefit is uncertain.

Research on the likelihood that smokers, independent of health care settings, would use NRT for cessation has demonstrated that the form of nicotine delivery impacts use. One study found that use was highest for the patch, lower for gum, and very low for the spray and the inhaler; user embarrassment may play a role in lower use of the inhaler.[23] A recent study of non-combustible, reduced-exposure tobacco products intended to reduce the harm associated with smoking, showed that the products decreased the exposure to many of the toxicants found in cigarettes but failed to suppress tobacco abstinence symptoms as effectively as combustible products.[24] Although the only non-tobacco derived nicotine delivery device used in this study was a nicotine lozenge, the results suggest that the viability of inhalers as a mass marketed, over-the-counter instrument for either harm reduction or cessation may depend on their ability to deliver nicotine levels equivalent to cigarettes, rather than merely being sufficient to reduce withdrawal symptoms and craving (as is the case with inhalers). This, of course, would also affect their widespread use for cessation purposes.

On a population-wide basis, a strong possibility exists that e-cigarettes would not be used by large numbers of smokers for either cessation or for harm reduction purposes, although concentrated marketing efforts might influence their use by smokers. At this time, and despite over-the-counter availability of some forms of NRT, less than one in five smokers use NRT in their efforts to quit.[25] A variety of explanations has been advanced for this behavior: (1) inadequate dosage strengths and formulations of available NRTs; (2) smokers' perceptions that they are costly; (3) purchase age restrictions; (4) concerns of smokers about the safety and efficacy of NRTs due in part to provider misinformation or lack of knowledge; and (5) failure of providers to actively recommend or mention NRT use for smoking cessation. Smoker's preferences for cigarettes as their means to obtain nicotine also plays a role despite the fewer hazards of inhalers.[26] A recent survey of California smokers found that 76% expressed no interest in replacing smoking with a tobacco substitute, although smokers with past or current quit attempts were more receptive.[27] On the other hand, estimates of the net public health gains from replacing cigarettes with nicotine inhalers support the view that this approach could be a feasible tobacco control strategy; the possible adverse health effects and the risks must be studied and the goals of such a strategy would need to be clearly defined.[28]

Implications for the Marketing of e-Cigarettes

Certainly, a strong possibility exists that the size of the nicotine dependent population could grow – especially if promotions for e-cigarettes approach the magnitude used for other consumer products. Promoting their use in places where smoking is not allowed implies that users need not have any intention of quitting and that the use of e-cigarettes may, in fact, be added on to smoking cigarettes. This pattern of use could either lower or raise a smoker's systemic nicotine concentration and further reinforce nicotine dependence. In addition, claims that e-cigarettes are safer than tobacco products might also imply that they are desirable for those seeking the effects of nicotine, even if they are not currently smokers.

Depending on marketing strategies, and in the absence of regulation, e-cigarettes might be marketed to youths. Certainly, much of the promotional literature implies that few risks exist for nicotine dependence or for other hazards attributable to nicotine exposure, including coronary artery disease, acute ischemic events, hypertension, stroke, and use by minors or women who are pregnant.

Given the absence of a regulatory framework for their manufacture and sale, commercial brands of e-cigarettes probably vary widely in their actual nicotine content and delivery and in the presence of other ingredients. These variables will affect the extent to which the use of e-cigarettes satisfies smokers' cravings or staves off withdrawal. If, for example, e-cigarettes were used as supplements to smoking in order to stave off withdrawal when individuals are in places where tobacco use is not allowed, their impacts might be very different. At this time it is not established what the public health/population-level impacts of wide distribution of pure nicotine delivery devices would be, nor do we know if they will work at a population level as effective smoking cessation aids.

CURRENT REGULATIONS

In 2008, the World Health Organization (WHO) noted that:

> "Contrary to what some marketers of the electronic cigarette imply in their advertisements, the WHO does not consider it to be a legitimate therapy for smokers trying to quit. WHO knows of no evidentiary basis for the marketers' claim that the electronic cigarette helps people quit smoking. Indeed, as far as WHO is aware, no rigorous peer-reviewed studies have been conducted showing the electronic cigarette is a safe effective nicotine replacement therapy."[29]

The WHO statement did not discount the possibility that e-cigarettes could be useful as a smoking cessation aid but reaffirmed that clinical studies and toxicity analyses need to be done within a proper regulatory framework. Canada, however, fully banned the devices in March 2009 (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php).

In early 2009, the FDA issued an import alert prohibiting e-cigarettes from entering the country on the basis that they were unapproved drug-device combinations. Although the FDA has the authority to regulate tobacco products, two distributors of electronic cigarettes sought an injunction against the import ban claiming that their products were cigarette replacements and thus not governed by the FDA.[30] In January 2010, the U.S. District Court for the District of Columbia granted such an injunction, which the FDA appealed. In March 2010, the U.S. Court of Appeals agreed to permit the FDA's continued import ban while it considers the FDA appeal from the lower court ruling. The court went out of its way in its brief ruling to suggest that the FDA was correct in declaring the product illegal, noting that "appellants (FDA) have satisfied the stringent standards required for a stay pending appeal." Oral arguments are to be heard this fall.

Oregon and California Attorneys General have filed lawsuits against Smoking Everywhere, Inc. for marketing to children and false health claims. Smoking Everywhere, Inc. also has argued in these cases that e-cigarettes are tobacco products under the Family Smoking Prevention and Tobacco Control Act and, as such, the Oregon and California AG's do not have the authority to bring those lawsuits.

Final decisions about the regulation of e-cigarettes may take some time and are likely to be adjudicated by the courts.

CONCLUSION

E-cigarettes are not comparable to FDA-approved nicotine-delivery devices that have been shown to help people quit smoking. At this time, their dosage, manufacture, and ingredients are not consistent nor are the products clearly labeled, thus making their use by smokers wanting to quit an uninformed proposition. More importantly, the manufacturers of e-cigarettes have not submitted the requisite applications for FDA approval of these products for smoking cessation. Only one small clinical trial, funded by an e-cigarette manufacturer has been published on their efficacy as a smoking substitute (but not as a cessation aid).

The FDA has rejected claims by e-cigarette makers and distributors that their devices are safer than real cigarettes and mitigate the harm of smoking. While some distributors have implied that their products help people quit smoking tobacco products, the agency views them as unapproved synthetic nicotine delivery devices with unknown safety and efficacy. Whether e-cigarettes can safely help people quit smoking also is unknown, but with their fruit and candy flavors, they have a clear potential to entice new smokers, especially teens. In addition, because of the unregulated dosing of nicotine, they clearly can be addictive.

It is evident from what little information we have that the concentration levels of the nicotine and other compounds are variable, and that there are toxins and carcinogens present. Thus, controlled trials and test market studies are needed to determine if they are safe and effective as a smoking cessation device as is being reported in the media and on the manufacturers' Web sites.[31] As most clean indoor air ordinances are written, it is likely that e-cigarettes can and will be used in smoke-free environments. Whether this would weaken the health benefits of such antismoking regulations is not known. Additionally, it is not established that e-cigarettes will serve as an effective means for harm reduction and as an additional tool for tobacco control. In fact, it is not inconceivable that the number of nicotine dependent individuals could increase. Thus far, much of the discussion about the use of e-cigarettes has been based on advocacy for their use, and/or assumptions of population-wide benefits which have yet to be demonstrated. Similar to concerns regarding the manufacture and sale of tobacco products, the actual content, performance as a nicotine delivery device, safety, and purity of e-cigarettes is largely unknown.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report be filed:

Our American Medical Association urges that:

1. E-cigarettes be classified as (nicotine) drug delivery devices and should be subject to FDA regulation with appropriate standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use, including age of the user. (New HOD Policy)

2. State legislatures prohibit the sales of e-cigarettes and all other nicotine devices that are not FDA-approved. (New HOD Policy)

3. As currently marketed, e-cigarettes be included in smokefree laws but separately defined from tobacco products. (New HOD Policy)

4. Policy D-490.975, "Study of Appropriate Use of Electronic Cigarettes in Smoking Cessation Programs," be rescinded. (Rescind HOD Policy)

Fiscal Note: Less than $500

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