REPORT 5 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-18)
Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking (Resolution 403-A-17)
(Reference Committee D)

EXECUTIVE SUMMARY

Objective: This report examines the available evidence regarding harm reduction approaches to reducing tobacco-related mortality, with a focus on electronic cigarettes.

Methods: English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2014 to January 2018 using the search terms "tobacco" and "harm reduction," "nicotine," "electronic cigarette," "e-cigarette," "ENDS,", "noncombustible tobacco product," "smokeless tobacco," and " tobacco cessation." Additional articles were identified by manual review of the reference lists of pertinent publications. Recognizing the dynamic nature of the research being published on this topic, the Council deemed it appropriate to summarize the findings and conclusions of the recent National Academies of Sciences, Engineering, and Medicine (National Academies) report on the "Public Health Consequences of E-Cigarettes" related to harm reduction. Articles published subsequent to the National Academies report are cited, as appropriate.

Results: Despite reductions in combustible tobacco use, it still represents the leading cause of preventable death in the United States. A growing number of non-combustible tobacco products are thought to be less hazardous than combustibles, but limited evidence is available on their long-term health risks. E-cigarettes are among the most widely used non-combustible tobacco product. Available evidence suggests that those who completely substitute e-cigarettes for combustible tobacco cigarettes have reduced exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes. However, the efficacy of e-cigarettes in reducing health risks has not been adequately evaluated in well-designed epidemiological studies and RCTs. Benefits are not realized in dual users, who in fact may be exposed to additional adverse health effects.

Conclusion: Currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless. Significant concerns exist that novel, non-combustible products may pose a significant threat to tobacco cessation and prevention efforts. Smokers concerned about their health who see the claims for novel tobacco products may think that a safer cigarette genuinely exists, making them less inclined to try to quit smoking. Likewise, those who never used tobacco products may initiate tobacco use assuming that a safe tobacco product exists. E-cigarette use among youth and young adults is a public health concern. Available data suggest that youth who use e-cigarettes are more likely to smoke combustible cigarettes. AMA policy should recognize that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction. Evidence-based methods for tobacco cessation exist. More needs to be done to promote evidence-based cessation methods to those who are trying to quit smoking.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-A-18

Subject: Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking (Resolution 403-A-17)

Presented by: Robert A. Gilchick, MD, MPH, Chair

Referred to: Reference Committee D
(Shannon Kilgore, MD, Chair)

INTRODUCTION

Resolution 403-A-17, "Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking," introduced by the Resident and Fellow Section and referred by the House of Delegates, asks:

> That our American Medical Association (AMA) advocate for tobacco harm reduction approaches to be added to existing tobacco treatment and control efforts (New HOD Policy);
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> That our AMA educate physicians and patients on the myriad health effects of different nicotine products and emphasize the critical role of smoke and combustion in causing disease (Directive to Take Action);
>
> That our AMA encourage physicians to adopt patient-specific, individualized approaches to smoking cessation, particularly for patients with disease secondary to smoking and for patients who have otherwise failed traditional methods for smoking cessation (New HOD Policy);
>
> That our AMA continue its focus on research to identify and expand options that may assist patients to transition away from smoking, including nicotine replacement therapies and noncombustible nicotine products (including e-cigarettes) (Directive to Take Action);
>
> That the AMA reaffirm its position on strong enforcement of US Food and Drug Administration and other agency regulations for the prevention of use of all electronic nicotine delivery systems and tobacco products by anyone under the legal minimum purchase age. This shall include marketing to children, direct use or purchasing by children and indirect diversion to children. Further, that our AMA reaffirm physician education of patients to limit these products for children in any and all capacity. (Reaffirm HOD Policy)

Action of the AMA House of Delegates 2018 Annual Meeting: CSAPH Report 5
Recommendations Adopted as Amended, and Remainder of Report Filed.

The Council on Science and Public Health (Council) has issued two previous reports on electronic cigarettes, in 2010 and 2014, which helped establish our AMA's existing policy around non-combustible tobacco products.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2014 to January 2018 using the search terms "tobacco" and "harm reduction," "nicotine," "electronic cigarette," "e-cigarette," "ENDS,", "noncombustible tobacco product," "smokeless tobacco," and " tobacco cessation." Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal and state agencies and applicable regulatory and advocacy organizations also were reviewed for relevant information.

Recognizing the dynamic nature of the research being published on this topic, the Council deemed it appropriate to summarize the findings and conclusions of the recent National Academies of Sciences, Engineering, and Medicine (National Academies) report on the "Public Health Consequences of E-Cigarettes" related to harm reduction. Articles published subsequent to the National Academies report are cited, as appropriate, in this report.

CURRENT AMA POLICY

It is the AMA's position that all tobacco products are harmful to health, and that there is no such thing as a safe cigarette. AMA policy urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA to have broad-based powers to regulate tobacco products. AMA policy also encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including the elimination of nicotine and elimination of additives that enhance addictiveness.

AMA policy encourages physicians to use evidence-based clinical practice guidelines on smoking cessation for the treatment of patients with nicotine dependence and urges physicians to promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers. Physicians should be prepared to counsel patients about the use of electronic nicotine delivery systems (ENDS), including electronic cigarettes (e-cigarettes), the potential for nicotine addiction, and the hazards of dual use of e-cigarettes with conventional cigarettes. Our AMA also encourages further clinical and epidemiological research on e-cigarettes as well as research and evaluation on promising smoking cessation protocols that promote abrupt cessation of smoking without reliance on pharmaceutical products.

HISTORY OF TOBACCO HARM REDUCTION

Tobacco products in any form are harmful and addictive and can cause disease and death.[1] Combustible cigarettes cause the majority of tobacco-related disease and are responsible for more than 480,000 deaths in the United States each year, and for millions more living with smoking-related diseases.[1,2] When used as intended, combustible cigarettes are addictive by design and are directly responsible for the deaths of at least half of all long-term users.[3]

Over the last decade, a new generation of tobacco products has entered the marketplace promising reduced exposure to toxicants in tobacco smoke and claiming to reduce the risk of cancer or other diseases.[4] This has resulted in a renewed discussion around harm reduction policies, which aim to reduce, but not eliminate tobacco-related health risks.[5]

Public health advocates have been hesitant to support harm reduction approaches for tobacco because of a lack of trust in tobacco companies and their ability or willingness to develop products that will actually reduce risks.[6] Several times in the last 50 years, the tobacco industry has developed a new cigarette, which it has promoted as safer. Large proportions of the smoking population switched to these products, mistakenly believing they were reducing their health risk, only to realize these were false promises.[7] Specifically, experience with products promoted by the tobacco industry as safer in the past, such as "light" cigarettes, resulted in increased toxicant exposures with smokers compensating for reduced nicotine by smoking with greater frequency and intensity.[6]

In 2001, the Institute of Medicine (IOM, now the National Academies) assessed the science base for tobacco harm reduction. The IOM committee concluded that for many diseases attributable to tobacco use, reducing the risk of disease by reducing exposure to tobacco toxicants is feasible.[8] However, such products have not been evaluated adequately to conclude they are in fact associated with reduced risks.[8] Furthermore, according to the IOM, "the regulation of all tobacco products is a necessary precondition for assuring a scientific basis for determining the effects of potentially reduced-exposure products and assuring the public has current, reliable information on the risks and benefits."[8] Finally, the public health impact of potential reduced-exposure products is unknown because their effect on public health will depend on their biological harm and individual and community behaviors around their use.[8]

In 2005, with funding from the American Legacy Foundation and the Robert Wood Johnson Foundation, the Strategic Dialogue on Tobacco Harm Reduction (Dialogue) was formed to address critically important aspects of the harm reduction debate including research priorities, overarching strategic considerations, policy recommendations, and communication methods.[4] Members of the Dialogue agreed on the concept of the continuum of risk, which is determined by the delivery of toxicants and nicotine.[4,9] Nicotine replacement therapy (NRT) (i.e., "gum," patch, and lozenge) is on the safer end, with combustible cigarettes on the more hazardous end, of the spectrum.[4] When users of combustible cigarettes switch to smokeless tobacco products, "maximal potential reduction in harm could only occur with products that result in the lowest exposure to toxicants, are subject to government regulation, and that avoid adverse consequences such as increased initiation of tobacco use or decreased cessation."[4]

THE CONTINUM OF RISK

There is a spectrum of tobacco and medicinal products that are designed to deliver nicotine to the user.[10] The toxicity associated with these products varies.[10]

FDA Approved Products for Treatment of Tobacco Use Disorder

FDA has approved several smoking cessation products designed to help users gradually withdraw from smoking by using specific amounts of nicotine that decrease over time. NRT products are safe and effective medications to help people stop smoking.[11] While NRT products contain nicotine in controlled amounts, they do not contain the other harmful chemicals found in tobacco products. NRT products are available over the counter and by prescription. Over-the-counter NRTs are approved for sale to people age 18 and older. They are available under various brand names (sometimes as generic products) and include transdermal nicotine patches, nicotine gum, and nicotine lozenges.[11] Prescription NRT is available under the brand name Nicotrol, and is available both as a nasal spray and an oral inhaler.[11] The FDA has approved two pharmacotherapy products for tobacco use disorder that do not contain nicotine. They are Chantix® (varenicline tartrate) and Zyban® (buproprion hydrochloride).[11] Both are available in tablet form and by prescription only.

Modified Risk Tobacco Product (MRTP)

MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.[12] FDA can issue an order authorizing the marketing of a MRTP if the evidence demonstrates that the product will or is expected to benefit the health of the population.[12]

The FDA has not approved any MRTPs. Applications from R.J. Reynolds Tobacco Company for their Camel Snus smokeless tobacco product and Philip Morris Products for their IQOS system with Marlboro Heatsticks (a heat not burn tobacco device) are currently under scientific review.[12] In January 2018, the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) voted 8-0 with one abstention against Philip Morris' claim that the IQOS system can reduce the risks of tobacco-related diseases.[13] In considering whether switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes, the committee voted narrowly against the claim.[13] TPSAC's recommendations and votes are not binding on the FDA.

Non-Combustible Tobacco Products

A number of non-combustible tobacco products are promoted as less harmful than combustible cigarettes. However, limited data are available on the long-term health effects of these products. E-cigarettes are among the most popular of these products. In 2014, more than 460 brands of e-cigarettes, available in >7,700 unique flavors, were being sold on the internet.[14] E-cigarette liquids can expose users to toxicants, including solvents (propylene glycol and glycerol), flavorings, and other additives. Furthermore, heating and aerosolizing e-liquids can generate additional harmful substances.[5] The FDA currently regulates smokeless tobacco and some dissolvable tobacco products. The agency has finalized a rule extending its regulatory authority to all tobacco products, including e-cigarettes, cigars, hookah, and pipe tobacco, but recently extended the deadline for agency review.

Combustible Cigarettes

There are approximately 600 known ingredients in combustible cigarettes.[15] When burned, more than 7,000 additional chemicals are created, at least 69 of which are known to cause cancer, and many others are poisonous.[15] Smoking leads to disease and disability and harms nearly every organ of the body. For every person who dies because of smoking, at least 30 people live with a serious smoking-related illness.[16] Smoking causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease, including emphysema and chronic bronchitis.[16] Secondhand smoke exposure contributes to approximately 41,000 deaths among non-smoking adults and 400 infant deaths annually.[16] Secondhand smoke causes stroke, lung cancer, and coronary heart disease in adults.[16] Infants and children who are exposed to secondhand smoke are at increased risk for sudden infant death syndrome, acute respiratory infections, middle ear disease, more severe asthma, respiratory symptoms, and slowed lung growth.[16]

FDA PLAN FOR TOBACCO AND NICOTINE REGULATION

In 2017, the FDA announced plans to reduce the devastating toll of tobacco use. The plan involves two primary parts: (1) reducing the addictiveness of combustible cigarettes and (2) recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public

health.[2] The FDA also has acknowledged the need for medicinal nicotine and other therapeutic products to play a greater role in helping smokers to quit and remain nonsmokers.[2]

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA the authority to establish tobacco product standards that are appropriate for the protection of the public's health.[17] Standards may require the reduction or elimination of an additive, constituent, or other component of a tobacco product because it is or may be harmful.[18] In March 2018, the FDA issued two advance notices of proposed rulemaking, one to explore a product standard to lower nicotine in cigarettes to minimally or non-addictive levels and the other calling on stakeholders to share data, research, and information to inform the role that flavors play in initiation, use, and cessation of tobacco products.

Reducing cigarettes' addictiveness could potentially help addicted users quit more easily and help keep those who are experimenting from becoming regular smokers.[2] While the FDA's current plan does not include lowering nicotine levels in non-combustible tobacco products, conceptually the availability of potentially less harmful tobacco products could reduce risk while delivering levels of nicotine for adults who still want it.[2]

E-CIGARETTES AND HARM REDUCTION

In January 2018, the National Academies issued a report on the "Public Health Consequences of E-cigarettes." The report committee undertook a comprehensive review of the scientific literature regarding key constituents in e-cigarettes, human health effects, initiation and cessation of combustible tobacco cigarette use, and harm reduction.

In addressing harm reduction, the National Academies noted the absence of randomized controlled trials and longitudinal observational studies on the effects of switching from combustible tobacco cigarettes to e-cigarettes to reduce harm.[5] Therefore, they relied on evidence regarding the exposure to toxicants present in e-cigarette aerosols compared with those in cigarette smoke, nicotine and toxicant exposures in e-cigarette users as an intermediate outcome, and comparisons of health effects on any health outcome from e-cigarette use compared with combustible tobacco cigarette smoking.[5]

Based on a limited number of laboratory studies comparing emissions of harmful and potentially harmful chemicals from e-cigarette devices with those from combustible tobacco cigarettes, aerosol emitted from e-cigarettes is substantially less complex than tobacco smoke.[5] Several potentially toxic substances have been identified in e-cigarette aerosol, but at significantly lower levels than in combustible tobacco smoke.[5] The National Academies found that "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."[5]

While the health effects of using e-cigarettes are not well understood, current evidence points to e-cigarettes being less harmful than combustible tobacco cigarettes.[5] All but one of the studies reviewed by the National Academies showed significant short-term improvements in health outcomes in smokers who switched from combustible tobacco cigarettes to e-cigarettes.[5] Thus, they concluded that "there is substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems."[5]

Dual use of tobacco cigarettes and e-cigarettes is highly prevalent among adults and youth but little evidence exists about dual users' patterns of use. On dual use, the National Academies concluded that, "there is no available evidence whether or not long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes" and "there is insufficient evidence that e-cigarette use changes short-term adverse health outcomes in several organ systems in smokers who continue to smoke combustible tobacco cigarettes (dual users)."[5]

No long-term studies exist comparing the health effects resulting from passive exposure to secondhand aerosol from e-cigarettes with effects in non-smokers passively exposed to tobacco smoke.[5] A limited number of studies compared secondhand exposure to e-cigarette emissions to combustible tobacco cigarette smoke.[5] While e-cigarette use in indoor environments exposes non-users to nicotine and particulates, it is at lower levels compared to tobacco smoke from combustible cigarettes.[5] The National Academies concluded that, "there is moderate evidence that secondhand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes."[5]

CURRENT USE PATTERNS

In 2013 and 2014, more than a quarter (27.6 percent) of adults were current users of at least one type of tobacco product.[19] A total of 8.9 percent of youths had used a tobacco product in the previous 30 days and 1.6 percent of youths were daily users. Approximately 40 percent of tobacco users used multiple tobacco products, with cigarettes plus e-cigarettes as the most common combination.[19] Although consumption of combustible tobacco products has decreased, the consumption of non-cigarette combustible tobacco and smokeless tobacco has increased.[20]

In 2014, 12.6 percent of adults had ever tried an e-cigarette (at least one time) and 3.7 percent of adults currently used e-cigarettes.[16] In 2016, 20.2 percent of surveyed high school students and 7.2 percent of middle school students reported current tobacco product use.[21] E-cigarettes are the most commonly used tobacco product among high (11.3 percent) and middle (4.3 percent) school students.[21] In 2018, health officials raised concerns about Juul, a brand of e-cigarette that looks like a flash drive.[22] The devices are difficult to distinguish from a real flash drive and their vapor dissipates quickly making them easy to hide. Each Juul cartridge lasts about 200 puffs and has as much nicotine as an entire pack of cigarettes. "Juuling" has become widespread enough that school districts in several states have voiced concerns and, in some cases, have amended school policy to address the issue.[23]

Use of e-cigarettes, hookah, non-cigarette combustible tobacco, or smokeless tobacco by youth is associated with cigarette smoking one year later.[24] Furthermore, the risk of progressing to conventional cigarette smoking is increased with use of multiple forms of non-cigarette tobacco, suggesting that novel tobacco products have the potential to undermine public health gains in combatting the smoking epidemic.[24] Among adolescent cigarette experimenters, using e-cigarettes has been positively and independently associated with progression to current established smoking, suggesting that e-cigarettes may encourage cigarette smoking in this population.[25] E-cigarette use among youth and young adults is a public health concern, and coordinated efforts are needed to protect young people from a lifetime of nicotine addiction.[26]

SMOKING CESSATION

The United States Preventive Services Task Force (USPSTF) recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, provide behavioral interventions and

offer FDA-approved pharmacotherapy for cessation to adults who use tobacco.[27] In 2015, 68 percent of adults smokers wanted to quit smoking, 57 percent had been advised by a health professional to quit, and 31 percent had used cessation counseling and/or medications when trying to quit.[28] Fewer than one-third of persons used evidenced-based cessation methods when trying to quit smoking.[28] To enhance cessation rates, health care providers should consistently identify smokers, advise them to quit, and promote the use of evidenced-based cessation treatments.[28]

The USPSTF also examined the evidence on the use of e-cigarettes or ENDS and concluded that the current evidence is insufficient to recommend ENDS for tobacco cessation in adults, including pregnant women.[27] Furthermore, a large prospective study of recently hospitalized smokers (n=1357) who planned to quit found a negative association between the use of e-cigarettes after discharge and subsequent tobacco abstinence.[29] Not only does the intermittent and concurrent use of e-cigarettes with other cessation aids not aid quitting, it may hamper it.[29] The USPSTF recommends that clinicians direct patients who smoke tobacco to cessation interventions with established effectiveness and safety.[27]

CONCLUSION

Despite reductions in combustible tobacco use, it still represents the leading cause of preventable death in the United States. A growing number of non-combustible tobacco products are thought to be less hazardous than combustibles, but limited evidence is available on their long-term health risks. The FDA has the authority to designate products as MRTP, but to date, no products have met the criteria and been approved through this pathway.

E-cigarettes are among the most widely used non-combustible tobacco products. Available evidence suggests that those who completely substitute e-cigarettes for combustible tobacco cigarettes have reduced exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes, resulting in reduced short-term adverse health outcomes in several organ systems. However, long-term studies on the health effects of e-cigarettes are lacking. Furthermore, the efficacy of e-cigarettes in reducing health risks has not been adequately evaluated in well-designed epidemiological studies and RCTs. Benefits are not realized in dual users, who in fact may be exposed to additional adverse health effects.

Significant concerns exist that novel, non-combustible products may pose a significant threat to tobacco cessation and prevention efforts. Smokers concerned about their health who see the claims for novel tobacco products may think that a safer cigarette genuinely exists, making them less inclined to try to quit smoking. Furthermore, ex-smokers may start smoking again, thinking they can now safely consume tobacco products. Likewise, those who never used tobacco products may initiate tobacco use assuming that a safe tobacco product exists. E-cigarette use among youth and young adults is a public health concern. Available data suggest that youth who use e-cigarettes are more likely to smoke combustible cigarettes.

Evidence-based methods for tobacco cessation exist. The FDA has approved several smoking cessation products designed to help users gradually withdraw from smoking by using specific amounts of nicotine that decrease over time. The USPSTF has reviewed the evidence and recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, provide behavioral interventions, and offer FDA approved pharmacotherapy for cessation to adults who use tobacco. More needs to be done to promote evidence-based cessation methods to those who are trying to quit smoking.

RECOMMENDATIONS

The Council recommends that the following statements be adopted in lieu of Resolution 403-A-17, and the remainder of the report be filed.

1. That Policy H-495.988, "FDA Regulation of Tobacco Products," be amended by addition and deletion to read as follows:

H-495.988 FDA Regulation of Tobacco Products

1. Our AMA: (A) ~~reaffirms its position~~ acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and ~~is associated with~~ increases youth risk of ~~the~~ using ~~of~~ combustible tobacco cigarettes ~~in youth~~; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D~~B~~) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E~~C~~) reaffirms its position that the Food and Drug Administration (FDA) does ~~have~~, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F~~D~~) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G~~E~~) urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA have broad-based powers to regulate tobacco products; (H~~F~~) encourages the FDA and other appropriate agencies to 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; and (I~~G~~) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products… (Amend Current HOD Policy)

2. That Policy H-495.972, "Electronic Cigarettes, Vaping, and Health: 2014 Update," be amended by addition and deletion to read as follows, with a change in title:

Electronic Cigarettes, Vaping, and Health~~: 2014 Update~~

1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly. 2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes~~.~~ ;~~3. Our AMA~~ (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes~~.~~; and (c) recognizes that the use of products containing

nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction. (Amend Current HOD Policy)

3. That Policy H-495.973, "FDA to Extend Regulatory Jurisdiction Over All Non- Pharmaceutical Nicotine and Tobacco Products," be amended by addition and deletion to read as follows:

H-495.973 FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of ~~18~~21; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth. (Amend Current HOD Policy)

4. That Policy, H-490.917, "Physician Responsibilities for Tobacco Cessation" be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: less than $500

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