RESOLVED, that the Bureau of State Government Affairs recommend that the following policy be REAFFIRMED as AMENDED:

H435-A/14  REGULATION OF E-CIGARETTES AND NICOTINE VAPING
The American Osteopathic adopts the following policy and recommendations as provided within the attached white paper, 2014

REGULATION OF E-CIGARETTES AND NICOTINE VAPING

BACKGROUND
In response to the negative health effects of tobacco products and cigarettes in particular, a natural market for smoking cessation and reduction products has emerged over the last 30 years. Accordingly, the use of electronic cigarettes (e-cigarettes) has reached a rapidly expanding consumer base. E-cigarettes are often used or promoted to reduce consumption of tobacco products. Alternative tools to reach these goals are switching to low or light cigarettes or using nicotine-infused chewing gum, lozenges, lollipops, dermal patches or hypnosis.

The e-cigarette name is an umbrella term that includes any battery powered device that vaporizes liquid nicotine for delivery via inhalation. These devices are most commonly referred to as electronic cigarettes, e-cigarettes, e-cigs, vaping, vape pens, vape pipes, hookah pens, e-hookahs, but could potentially be referred to by other terms.

Since its 2007 introduction in the United States, the e-cigarette market has grown to include more than 250 brands. Sales are expected to reach $1.7 billion by the end of 2013, according to the Attorneys General Association. Over the next decade, it is possible that sales of e-cigarettes will outstrip conventional cigarettes.

The attraction to e-cigarettes crosses many segments of the population, appealing to the tobacco cigarette smoker trying to quit and the non-smoker who wants to try nicotine without the harmful additives. Tobacco cigarette smokers can also use e-cigarettes as a source of nicotine in venues where conventional cigarettes are banned, although some states and municipalities have also started to ban e-cigarettes in these spaces.

Smoking costs the United States an estimated $96 billion annually in direct medical expenses and an additional $97 billion in lost productivity. Overall, e-cigarettes may be less harmful for heavy or moderate smokers because they may reduce exposure to carcinogens and other toxic chemicals that cause serious disease and death. However, the effect of long term consumption of only nicotine is unknown, and e-cigarettes have already been shown to leave behind indoor air pollution that could be both hazardous to users themselves along with second hand users. Additionally, many users of e-cigarettes are using them in a supplemental fashion, while continuing to utilize traditional tobacco cigarettes.
ANALYSIS

The Food and Drug Administration (FDA) does not currently regulate e-cigarettes. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), provides the FDA authority to regulate the manufacture, marketing and distribution of tobacco products. However, e-cigarettes are not in the purview of FDA regulation of tobacco products. Unlike tobacco cigarettes, e-cigarettes enjoy the ability to advertise on television and radio. This allows e-cigarette companies to market their product in a more liberal fashion in response to market demands, including the use of celebrity endorsements.

The Composition of E-Cigarettes

The e-cigarette is a smokeless, battery-powered device that vaporizes liquid nicotine for delivery via inhalation. The e-cigarette contains nicotine derived from tobacco plant and several secondary chemical ingredients. It is primarily composed of a nicotine cartridge, atomizer, and a battery. The atomizer, which converts the nicotine liquid into a fine mist, consists of a metal wick and heating element. When screwed onto the cartridge, the nicotine liquid from the cartridge comes into contact with the atomizer unit and is carried to the metal coil heating element. A single cartridge can hold the nicotine equivalent of an entire pack of traditional cigarettes.

While the typical e-cigarette is sold in the shape of a cigarette, many products are sold in the shape of discreet objects such as pipes, pens and lipsticks. Often, they can be legally used where traditional tobacco products are banned.

Federal Efforts to Regulate

The FDA can regulate e-cigarettes only if the manufacturers make a therapeutic claim, such as e-cigarettes are to be used as a cessation device. The FDA jurisdictional authority covers various products including food, cosmetics, animal and human drugs, medical devices and radiological products. Currently, e-cigarettes do not fall within the jurisdiction of the FDA. The FDA has made efforts to regulate e-cigarettes. When the FDA made a determination that certain e-cigarettes were unapproved drug/device combination products, they seized e-cigarettes being imported by Sottera, Inc., resulting in a lawsuit between the company and the FDA. The court held that the FDA lacked authority under the drug/device provisions to regulate tobacco products customarily marketed without claims of therapeutic effect.

This ruling offers new challenges to FDA regulation because of the novel method of nicotine delivery, various mechanical and electrical parts, and nearly nonexistent safety data. Consumer use, marketing, promotional claims and technological characteristics of e-cigarettes have also raised decade-old questions of when the FDA can assert authority over products as drugs or medical devices.

State Efforts to Regulate

Attorneys General from 40 states have urged the FDA to regulate e-cigarettes. The pressure is mounting because of various reasons. For example, unlike traditional tobacco products, there are no federal age restrictions that would prevent children from obtaining e-cigarettes, nor are there any advertising restrictions.

Various jurisdictions, both states and municipalities, have enacted laws requiring licenses to sell e-cigarettes and banning sales to minors. A distinctive feature of the TCA is the broad latitude expressly preserved to state and local authority to regulate tobacco products. Thirty-nine states and 3,671 municipalities already have laws in-place restricting or prohibiting smoking in public places and workplaces. Currently, there are 100 local laws restricting e-cigarette use in 100%
smoke-free venues. However, there are only 3 state laws restricting e-cigarette use in 100% smoke-free venues and only 9 in other venues.

New Jersey became the first state to amend its public smoking laws to prohibit the use of e-cigarettes in all enclosed indoor places of public access as well as in working places; Minnesota enacted laws regulating the sale of e-cigarettes and impose criminal penalties for the sale of e-cigarettes to minors. New Hampshire also enacted a law that prohibits the sale of e-cigarettes and liquid nicotine to minors and distribution of free samples of such products in a public place. New Hampshire also prohibits the use of such products on the grounds of any public educational facility. Similarly, Utah enacted a regulation controlling the sale, gift and distribution of e-cigarettes by manufacturers, wholesalers, and retailers, and King County, Washington enacted an ordinance that bans the smoking of e-cigarettes in public places. Some state and local restrictions on the use of e-cigarettes are driven largely by the concern that they have similar damaging effects on bystanders as traditional cigarettes.

Arguments for E-Cigarettes

Smoking accounts for nearly 5.4 million cancer-related deaths worldwide each year. This includes 443,000 deaths in the United States. Proponents argue that e-cigarettes do not expose the user, or others close by, to harmful levels of cancer-causing agents and other dangerous chemicals normally associated with traditional tobacco products.

Various physician groups have defended the product, based on their opinion that e-cigarettes deliver nicotine without the tar and myriad of other chemicals found in regular cigarettes. At this point, no one knows whether the e-cigarette alternative to tobacco cigarettes carry any long-term detrimental health effects, however it is known that they contain less carcinogenic elements than traditional tobacco cigarettes. According to the American Lung Association there are approximately 600 ingredients in cigarettes. When burned, they create more than 4,000 chemicals. At least 50 of these chemicals are known to cause cancer, and many are poisonous. While e-cigarettes may have less component chemicals, a study found that the usage of e-cigarettes contributes to indoor air pollution. The results showed that e-cigarettes are not emission free, and that their pollutants could be a danger to both users as well as secondhand smokers.

The draw of the e-cigarette for smoking cessation is that it delivers nicotine to counter nicotine withdrawal symptoms. E-cigarettes evoke the psychological response to cigarette smoking because of its shape and the familiar behavior aspect of smoking. A 2011 survey of 104 e-cigarette users revealed that 66% started using them with the intention to quit smoking and almost all felt that the e-cigarette had helped them to succeed in quitting smoking. Another survey of 3,037 users of e-cigarettes revealed that 77% of them said that they used them to quit smoking or to avoid relapse. None said they used them to reduce consumption of tobacco with no intent to quit smoking. However, the overall effectiveness of e-cigarettes is still in question. In a randomized study, participants given e-cigarettes, nicotine patches and placebo e-cigarettes that lacked nicotine were able to quit smoking at roughly the same rates, with insufficient statistical power to conclude superiority of nicotine e-cigarettes.

Consequences of E-Cigarettes

Charting in unknown territory always poses the risk for consequences. Advocates contend that e-cigarettes are less risky and harness the possibility to reduce smoking or even be a complete smoking cessation. A major concern is that it appeals to youth by being flavorful, trendy and a convenient accessory. The flavorings being used, such as candy and other sweet flavorings are
particularly appealing to younger populations. For this reason, these flavorings are banned in traditional cigarettes.

Further, e-cigarette usage among children is increasing. During 2011-2012, the percentage of middle school students who have tried e-cigarettes jumped from 1.4% to 2.7%. Among high school students, the jump was from 4.7% to 10%, and 80.5% of high school students who use e-cigarettes also smoke conventional cigarettes. These numbers could also be largely underestimating the percentage of children using e-cigarettes, as many call the devices by other names. Manufacturers and sellers of e-cigarettes have begun using other product names such as “hookah pens,” “e-hookahs,” or “vape pens.” Even though these products differ only in name and appearance from e-cigarettes, many school age children that used these devices failed to identify them as such.

Aside from the carcinogenic and toxic effects of tobacco, smokers become addicted to the nicotine. Nicotine addiction is characterized as a form of drug dependence recognized in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Nicotine addiction is a combination of positive reinforcements, including enhancement of mood and avoidance of withdrawal symptoms. E-cigarette cartridges contain up to 20 times the nicotine of a single cigarette, and the process of “vaping” lacks the normal cues associated with cigarette completion, such as the butt of the cigarette ending a dose.

Conditioning has a secondary role in nicotine addiction. Smokers associate particular cues with the high of smoking, often causing relapse when those seeking to quit smoking are confronted with those cues. E-cigarettes allow quitting smokers to respond to those cues. This poses a risk of overconsumption. The lack of finality to an e-cigarette is determined only by the battery or nicotine cartridge. Distinguishable from tobacco cigarettes, smokers who have turned to the e-cigarette no longer have the butt of the cigarette as a cue to stop smoking.

E-cigarettes are manufactured from metal and ion components that introduce concerns about faulty products and malfunctions. In the United States there has been at least 2 reports of e-cigarettes exploding in users’ faces and hands causing severe injuries including blown out teeth, extensive burns and tissue damage to lips and tongues, burns to the hands and hearing and vision loss.

CONCLUSION
The AOA supports FDA and state regulation of the ingredients of all electronic cigarette cartridges, requiring ingredient labels and warnings, and eliminating the usage of flavors that are banned in traditional cigarettes.

The AOA supports the FDA and state regulation prohibiting sales and advertisements of electronic cigarettes to persons under the age of 18. Advertisements for electronic cigarettes should be subject to the same rules and regulations that are enforced on traditional cigarettes.

The AOA further encourages federal, state and local government action to banning the use of electronic cigarette devices in spaces where traditional cigarettes are currently barred from use.

The AOA promotes tobacco and nicotine cessation treatment, and the usage of any such treatment that has been proven safe and effective by the FDA.

The AOA supports research by the FDA and other organizations into the health and safety impact of e-cigarettes and liquid nicotine.

THE AOA SUPPORTS PHYSICIANS CONSIDERING THE RISKS OF RECOMMENDING E-CIGARETTES TO PATIENTS, AS WELL AS REQUESTING
THAT THEIR PATIENTS SUBMIT VOLUNTARY REPORTS TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES SAFETY REPORTING PORTAL (WWW.SAFETYREPORTING.HHS.GOV) IF THEY SUSTAIN ADVERSE REACTIONS TO E-CIGARETTES.

The AOA supports physicians considering the risks of recommending e-cigarettes to patients, as well as requesting that their patients submit voluntary reports to the U.S. department of health and human services safety reporting portal (www.safetyreporting.hhs.gov) if they sustain adverse reactions to e-cigarettes.

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Explanatory Statement:
The conclusions in the white paper are still relevant, with one additional edit. The analysis in the body of the white paper is outdated and therefore should be deleted.

ACTION TAKEN ______________________________

DATE ______________________________