August 18, 2015

The Arizona Public Health Association (AzPHA) supports the adoption of the following APHA Policy Statement 20149 – Supporting Regulation of Electronic Cigarettes and its action step recommendations.

Policy Statement: 20149

Abstract:
Electronic smoking devices, or electronic nicotine delivery systems, include but are not limited to electronic cigarettes (e-cigarettes), vape sticks, hookah pens, and personalized vaping units. These battery-powered devices deliver an aerosol vapor, typically composed of nicotine, propylene glycol, and other chemicals. According to the World Health Organization, the safety of electronic cigarettes and their efficacy in smoking cessation programs have not been scientifically demonstrated, and what evidence exists is somewhat contradictory. Several studies have suggested that e-cigarettes may be effective as a smoking cessation tool. In the United States, use of e-cigarettes has increased among both minors and adult current and former smokers in recent years. In April 2014, the Food and Drug Administration proposed regulations that would extend its authority over e-cigarettes not marketed for therapeutic purposes. Currently, at least 38 states place restrictions on the sale of e-cigarettes to minors, more than 100 cities have moved to prohibit the use of e-cigarettes in public places, and several corporations have banned them in the workplace. Given the potential threat to lung health and the need for rigorous scientific research on the safety and effectiveness of e-cigarettes, the American Public Health Association supports efforts to regulate e-cigarettes as a tobacco product, urges applying advertising and promotion restrictions on e-cigarettes, encourages public places and workplaces to ban their use, and calls for evidence-based research on their therapeutic value as part of a smoking cessation program.

Problem Statement
The category of products known as electronic smoking devices or electronic nicotine delivery systems includes but is not limited to electronic cigarettes (e-cigarettes), vape sticks, hookah pens, and personalized vaping units. E-cigarettes heat chemical solutions to produce an inhalable aerosol vapor of nicotine and other chemicals including propylene glycol and glycerin.[1,2] Although the vapor does not appear to contain carcinogens, the health effects of vapor exposures among both users and nonusers are unclear. Unlike conventional tobacco cigarettes, e-cigarettes do not generate side-stream vapor (aerosol between puffs). However, e-cigarette users exhale secondhand vapors.[3]
There is evidence that both adults and young people in the United States are initiating e-cigarette use at increasing rates. Also, research suggests that use of e-cigarettes may lead minors to try other tobacco products, including conventional tobacco cigarettes.
Many e-cigarette manufacturers promote their products as a healthier alternative to and substitute for conventional tobacco cigarettes,[4] marketing them as a method to reduce or quit conventional tobacco smoking.[5] This harm reduction orientation considers the net costs and benefits relative to conventional tobacco smoking. Some scientists have also adopted this harm reduction approach, recognizing the burden of global tobacco-related morbidity and mortality. Thus, the public health value of e-cigarettes hinges on documenting their therapeutic benefit.

Currently in the United States, the Food and Drug Administration (FDA) can regulate only e-cigarettes that manufacturers market as therapeutic. In 2010, a federal court in *Sottera v. FDA*[6] ruled that the FDA needed to establish regulations for tobacco products such as e-cigarettes that are marketed without therapeutic claims, that is, tobacco products that are sold over the counter or in vending

machines. Subsequently, in April 2014, the FDA proposed a rule that would extend its tobacco authority to cover commercial sales of e-cigarettes as nontherapeutic tobacco products.[4] This FDA action focuses on e-cigarettes as a harm reduction strategy, acknowledging that if significant numbers of conventional tobacco cigarette smokers use e-cigarettes to quit and new e-cigarette users do not include children and adolescents who also begin using tobacco, the net impact at the population level could be positive. However, the FDA notes that the impact could be negative if the opposite is true: if current tobacco smokers continue to use both conventional tobacco and e-cigarettes or a significant number of people, especially young people, initiate tobacco use via e-cigarettes.[6] The FDA's proposal would not seek to restrict online sales of e-cigarettes, curb television advertising, or ban the widespread use of exotic flavors.[7]

E-cigarettes were introduced in the United States in 2007. In a 2010–2011 national consumer-based survey of US adults 18 years or older, 6% of all adults and 21% of current conventional tobacco smokers reported that they had ever used e-cigarettes.[8] Initiation among young people has been rapid, with a statistically significant doubling of use in 2011–2012. This total includes the percentage of all students in grades 6–12 who had ever used e-cigarettes (6.8%), who currently used e-cigarettes (2.1%), and who currently used both e-cigarettes and conventional tobacco cigarettes (1.6%).[9] An analysis of the results of the 2011 and 2012 National Youth Tobacco Survey revealed that current e-cigarette use was associated with heavier smoking among conventional tobacco cigarette smokers (those who had smoked at least 100 cigarettes in their lifetime and had smoked in the preceding 30 days).[10] Another study analyzed data from the 2014 National Youth Tobacco Survey to determine the prevalence of use of 10 tobacco products including electronic cigarettes. The results showed that 45% of high school students and 1.1% of middle school students reported using e-cigarettes in the preceding 30 days. [43]

According to the World Health Organization (WHO), neither the safety of e-cigarettes nor their efficacy in smoking cessation programs has been scientifically demonstrated.[11] Studies focusing on the biochemical constituents, physiological and psychological effects, and health risks and benefits of e-cigarettes vary in terms of their methodological rigor, including sample sizes, recruitment techniques, and control for potential confounding variables.[12] In October 2014, the WHO Framework Convention on Tobacco Control acknowledged the need for regulation of e-cigarettes along the lines of policies concerning other tobacco products, including banning or restricting promotion, advertising, and sponsorship.[13]

Secondhand exposure: Although e-cigarettes do not generate side-stream aerosols between puffs, users do release aerosols upon exhalation.[3] Several laboratory smoking chamber studies have compared secondhand exposure to e-cigarette aerosols with secondhand exposure to conventional tobacco cigarette smoke. Results have shown that nicotine and probable carcinogens are released but at much lower levels than those associated with conventional tobacco cigarettes.[3,14,15] However, other studies have documented particle size distributions similar to those of conventional tobacco cigarettes, with some e-cigarettes delivering more particles than conventional cigarettes.[16,17] A comprehensive review of research on e-cigarettes concluded that e-cigarette aerosol is not merely "water vapor" as is often claimed in the marketing of these products.[5] Almost all human health research on e-cigarettes has focused on health risks and benefits among users. Full-scale epidemiological population studies of nonusers exposed to e-cigarette aerosols have not been reported.

Children and youth: Exposure to nicotine liquids is another health concern. Because the nicotine solution is sold in bottles and cartridges, accidental poisoning is a public health hazard for infants and young children. According to the American Association of Poison Control Centers, the number of poisoning cases linked to e-cigarette liquids tripled to 1,351 between 2011 and 2012,[18,19]and, similarly, the number of cases referred to hospitals in 2013 was triple that of 2012. Many of the cases were among infants and young children drawn to the liquids' bright colors and fragrant

flavorings.[20,21] A recent report reviewing 78 publications on e-cigarettes showed that youth are rapidly adopting e-cigarettes, which tend to contain candy flavors, and that young people who use e-cigarettes are heavier, not lighter, smokers of conventional tobacco cigarettes.[22]

Cessation research: Although cessation research is limited, some of the most rigorous studies suggest that e-cigarettes are comparable to, but not more effective than, other means of quitting smoking of conventional tobacco cigarettes. Because smokers of conventional cigarettes become addicted to nicotine, nicotine replacement therapies (NRTs) such as gum, patches, nasal spray, inhalers, and tablets or lozenges can double a smoker's chances of quitting.[23]
The results of a randomized and controlled trial among adults that controlled for gender and level of nicotine dependence and biochemically verified continuous abstinence at 6 months showed that nicotine e-cigarettes were not superior to patches or placebo e-cigarettes.[24] All were modestly effective in helping smokers to quit. Somewhat different findings were reported in a less rigorous cross-sectional study that included approximately 5,000 adults who smoked and had made at least one attempt to quit with an e-cigarette only, NRT only, or no aid at all. This study, which controlled for confounding variables including nicotine dependence, revealed that e-cigarette users were more likely to self-report abstinence over a 12-month period than either of the other two groups.[12] A longitudinal Internet survey of people enrolled on websites dedicated to e-cigarettes and smoking cessation showed that almost all respondents who used e-cigarettes daily took the same number of puffs each day over the yearlong study. Among dual users of e-cigarettes and conventional tobacco cigarettes at baseline, 22% had stopped smoking after 1 month and 46% after 1 year. However, dual users who were still smoking conventional tobacco cigarettes did not reduce their cigarette consumption over the year.[25] These studies suggest that e-cigarettes are, at best, on a par with other NRT products sold commercially; additional research is needed to confirm that e-cigarettes can wean smokers from conventional tobacco cigarettes and reduce or eliminate their nicotine dependence.

Advertising and marketing: At present, e-cigarettes hold a competitive advantage over conventional tobacco cigarettes in terms of advertising and marketing. The Public Health Cigarette Smoking Act of 1970, the Tobacco Master Settlement Agreement of 1998, and the Family Smoking Prevention and Tobacco Act of 2009 prohibit the advertising and marketing of conventional tobacco cigarettes on television and in print media with high youth readership; they also prohibit cigarette manufacturers from sponsoring sporting events and music festivals. Historically, manufacturers of conventional tobacco cigarettes have used an advertising and marketing strategy of product differentiation (e.g., offering filter tips and menthol flavors) and market segmentation (e.g., targeting youth and women).[26,27] Many current e-cigarette advertising and marketing campaigns resemble those used over the years to promote conventional tobacco cigarettes, especially to teenagers.[28] For example, recent e-cigarette marketing campaigns have included celebrity endorsements in high-profile commercials and the airing of these commercials during live broadcasts such as the Golden Globe Awards, *The Late Show with David Letterman*, and *The View*.[29] This role modeling may induce minors to try e-cigarettes.
As of August 2014, at least 38 states prohibited sales of electronic cigarettes or vaping/alternative tobacco products to minors,[30] and more than 100 municipalities, including New York, Los Angeles, and Chicago, prohibited the use of e-cigarettes in 100% smoke-free indoor environments.[4] Minnesota[31] and North Carolina[32] have taxed the nicotine liquid used in e-cigarettes. In addition, price increases have been shown to reduce youth initiation and adult consumption rates.[33]

Opposing Evidence/Alternative Points of View

Other researchers, as well as the tobacco industry, have been less cautious in promoting e-cigarettes as a harm reduction strategy. They claim that e-cigarettes can be effective in the fight against tobacco-related morbidity and mortality and will expand the potential for harm reduction strategies and substantial health gains.[34] In addition, a 2010–2012 survey of 1,567 adult daily smokers conducted in Hawaii concluded that respondents who tried e-cigarettes to quit smoking were more serious about wanting to quit than other smokers. Smokers who used NRTs were more likely to have also used e-cigarettes as cessation aids.[35]

The efficacy of existing tobacco cessation therapies should be considered in evaluating the therapeutic role of e-cigarettes. A 2008 Cochrane Collaboration review[36] of 132 NRT trials showed that heavier smokers may need higher doses of nicotine than those provided by gum, patches, or tablets/lozenges. Smokers who use NRT to quit are likely to further increase their chance of success by using a combination of the nicotine patch and a faster acting form of nicotine. Similarly, those who want to quit may use e-cigarettes to receive higher doses of nicotine in a faster acting form. Current conventional tobacco smokers may also find e-cigarettes more desirable since they mimic smoking. However, as noted above, more recent cessation research suggests that e-cigarettes alone are not any more effective than other strategies.

The health effects of the aerosol vapors have also been questioned. A study conducted for an e-cigarette advocacy group examined e-cigarette users' exposure to propylene glycol and glycerin. The study calculated occupational threshold limit values (TLVs) to evaluate the potential risks to e-cigarette users and reported no evidence that use of e-cigarettes produces inhalable contaminants that exceed TLV limits among users.[37] However, a comprehensive appraisal of peer-reviewed published research concluded that it was inappropriate to apply TLV limits to exposures among coworkers and people with medical conditions.[5] Moreover, according to this review, industry claims that e-cigarettes help smokers quit are not supported by the evidence

Former Surgeon General Richard Carmona, who is now on the board of e-cigarette maker NJOY, supports e-cigarettes provided that NJOY requests FDA regulation, conducts its own research, and publishes that research in peer-reviewed journals, even if the findings hurt the bottom line. He also stipulates that NJOY not use his name or refer to the surgeon general in its advertising campaigns and that the company not market to minors.[38] Carmona notes some evidence that gums, patches, and sprays are effective as smoking cessation tools but are not effective enough. He adds that although early evidence suggests that e-cigarettes can enhance tobacco cessation, more research is needed.

In May 2014, 53 nicotine science and public policy specialists[39] wrote the director of WHO arguing that regulation should exploit the considerable health opportunity to reduce harm from combustible tobacco products. They argued that (1) outcome measures, rather than focusing on nicotine use per se, should focus primarily on reducing smoking to decrease the prevalence of disease and premature death; (2) it is counterproductive to ban the advertising of e-cigarettes and other low-risk alternatives to smoking; (3) it is inappropriate to apply legislation designed to protect bystanders or workers from tobacco cigarette smoke to e-cigarette aerosol vapors; and (4) the tax regime for nicotine products should reflect risk and be organized to create incentives for users to switch from smoking to low-risk harm reduction products. The American Heart Association (AHA) has called for including e-cigarettes under state and federal laws on smoke-free air; marketing, advertising, and sales to minors; quality control over manufacturing; and standards for contaminants.[40] Although noting that current evidence does not support the use of e-cigarettes as a primary cessation aid, AHA would support patients' wish to use e-cigarettes to help them quit if they did not succeed with initial cessation treatments, provided that they are warned that e-cigarettes may contain low levels of toxic chemicals and have not been proven as cessation devices and that they are advised to consider setting a quit date for using e-cigarettes as a cessation method.

However, some within the public health community have argued that supporting a harm reduction approach that encourages smokers who could not quit to switch to a less harmful, “safer” cigarette has not worked in the past.[41,42] This suggests that e-cigarettes may not be the panacea of smoking cessation.

Action Steps

Therefore, APHA urges:

1. The Food and Drug Administration to establish regulations that hold e-cigarettes to at least the same marketing and advertising rules as conventional tobacco cigarettes. This would include media advertising and appropriate warning labels, prohibiting flavors, banning sports and entertainment sponsorships, and placing e-cigarette products behind counters in stores.

2. The Consumer Product Safety Commission to add nicotine to its list of substances covered by regulations and to require special packaging, such as childproof packaging and warning labels, on nicotine solution cartridges to prevent childhood poisoning.

3. States and municipalities to enact and enforce laws restricting sales of e-cigarettes to minors, prohibiting the distribution of all free samples of and coupons for e-cigarettes, and prohibiting the use of e-cigarettes in all enclosed areas of public access and places of employment. These standards should be incorporated into existing clean indoor air laws.

4. States and municipalities to impose a tax on the nicotine liquid used in e-cigarettes.

5. Congress to amend the Prevent All Cigarette Trafficking Act to include e-cigarette products, which would prohibit Internet venders from distributing them through the US Postal Service.

6. Employers to prohibit the use of e-cigarettes on their premises.

7. Federal agencies and voluntary health organizations to fund research on the short- and long-term health effects of e-cigarettes on users and nonusers and the efficacy of e-cigarettes as a harm reduction/smoking cessation strategy.

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