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To Whom It May Concern:

The California Department of Public Health (CDPH) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding the public docket published in the Federal Register on December 1, 2014, in response to the first public workshop to gather scientific information about electronic cigarettes (e-cigarettes). Research and data indicate e-cigarettes are harmful and pose a significant health concern to those who use them and those who are exposed to the aerosol emitted from them.

Mainstream and secondhand e-cigarette aerosol contains at least ten chemicals that are known to cause cancer, birth defects, and other reproductive harm.^[1-3] Studies have shown that exposing adolescents to nicotine may harm brain development and serve as a gateway to future cigarette use.^[4,5] Youth are one of the highest risk groups, with one national survey finding that more than 17 percent of 12th graders had used an e-cigarette in the past month; a higher percentage than traditional cigarette use.^[6] While youth may likely be the highest risk group for using e-cigarettes, all e-cigarette users are at risk of adverse health effects.

CDPH appreciates the opportunity to share comments and published research regarding the threat of e-cigarettes to public health. CDPH is providing the following comments with the aim of informing the FDA about e-cigarettes and their public health impact.

1. Flavorings may enhance the abuse liability of e-cigarettes.

The liquid solution (e-liquid) used in e-cigarettes generally contains nicotine, flavorings, additives, and propylene glycol, and is available in a wide variety of fruit and candy flavors such as strawberry and bubble gum. Enticing “kid-friendly” e-liquid flavors may enhance the abuse liability of e-cigarettes and result in accidental poisoning through ingestion or dermal contact and a higher propensity to experiment with e-cigarettes among children and youth.^[7] Since 2010, the number of e-cigarette related calls to poison control centers in California and across the United States rose significantly, particularly for children. In California, from 2012 to 2014, the number of calls to the poison control center involving e-cigarette exposures in children ages five and under increased sharply from 7 to 154, representing 63.4 percent of all calls related to e-cigarette exposures in 2014.^[8]

2. Unique abuse liability risks may exist for e-cigarette users in specific subpopulations.

Youth are the highest risk subpopulation with regard to e-cigarette use, possibly due to the “kid-friendly” e-liquid flavorings and misconceptions that e-cigarettes are a safe product and that the e-liquid does not contain nicotine. Youth that would likely never had been exposed to nicotine in tobacco products are now becoming addicted to nicotine due to experimentation with e-cigarettes.^[9] An analysis of the 2014 Monitoring the Future Survey conducted by the University of Michigan found that e-cigarette use in the last 30 days was double that of traditional cigarettes for 8th graders (8.7 percent vs. 4 percent) and for 10th graders (16.2 percent vs. 7.2 percent). Among 12th graders, 17.1 percent reported e-cigarette use in the last 30 days (vs. 13.6 percent traditional cigarette use).^[6] A preliminary study by Yale University found that youth are highly aware of e-cigarettes (middle school: 84.3 percent; high school: 92.0 percent) and that there is an upward trend of e-cigarette use among youth.^[10]

3. E-cigarettes have unique characteristics that may affect uptake and use by nonusers, former smokers, and youth.

Since the majority of e-cigarettes contain addictive levels of nicotine, e-cigarettes may cause nicotine addiction among youth, causing them to turn to traditional tobacco products in the future. In California, young adults (18-29 years old) are three times more likely to use e-cigarettes than those 30 years of age and older, and research suggests that youth who would have never smoked cigarettes are now becoming addicted to nicotine through e-cigarette use.^[9,11] Youth, particularly high school students, are using e-cigarettes because of the variety of appealing flavors, some of

which are bubble gum, cherry, and chocolate. A study conducted by Yale found that e-cigarettes attracted youth because of sweet flavors and the ability to recharge the device.^[10] An additional study from Yale also found that of surveyed youth, 54 percent tried e-cigarettes out of curiosity and 43 percent were drawn to appealing flavors of e-cigarettes.^[12]

4. E-cigarette use can cause short and long-term health effects in experienced users.

Short-term health effects of e-cigarettes in experienced users cause similar lung irritation, inflammation, effect on blood vessels, and indoor air pollution as smoking combustible cigarettes.^[13-15] Long-term health effects of concern include cancer, chronic asthma, and cardiovascular disease, all of which are similar health effects to smoking traditional cigarettes.^[2,16]

Like other tobacco products, e-cigarettes contain nicotine, a highly addictive neurotoxin that raises the pulse and blood pressure by affecting the cardiovascular and central nervous systems, which may increase the risk of a heart attack.^[17,18] Nicotine also contributes to low birth weights, preterm deliveries, and stillbirths in pregnant women. As a neurotoxin, nicotine is even more dangerous to children. Critical brain development takes place during adolescence, and nicotine has been shown to cause neurobehavioral damage and serve as a gateway drug to other tobacco containing products.^[4,21,22]

Another study found that exposure to e-cigarette emissions impairs pulmonary anti-bacterial and anti-viral defenses. E-cigarette use, even for brief periods, may have significant consequences on respiratory health. Further, the rising popularity of e-cigarettes among youth may lead to an emerging threat to public health with recurrent bacterial or viral infections due to impaired immune systems from e-cigarette use.^[23] Another study from the New England Journal of Medicine found that an e-cigarette user that smokes three milliliters of e-liquid per day on a "high voltage" setting (five volts) inhales nearly five times more formaldehyde than an individual smoking 20 cigarettes. This results in an exponentially higher cancer risk factor compared to cigarette smokers.^[24] Additionally, e-cigarettes have been found to contain at least ten chemicals on California's Proposition 65 list of chemicals known to cause cancer, which gives cause for concern.^[1,2]

5. Specific users may be at higher risk of adverse effects related to e-cigarette use.

Currently, youth are at a higher risk of adverse effects related to e-cigarette use, due to abuse liability risks and the susceptibility to developmental risks from nicotine during adolescence. Research has shown that 73 percent of youth ages 12-17 were exposed to e-cigarette advertising from the company Blu.^[25] Since youth are already susceptible to experimentation with e-cigarettes because of enticing flavors and curiosity, targeted advertising from e-cigarette companies may increase the risk of youth using and ultimately suffering from adverse effects.^[12] E-cigarettes typically contain varying levels of nicotine. The adverse health effects of nicotine on brain development in adolescents is well documented, with even a brief period of nicotine exposure in adolescence causing lasting neurobehavioral damage and may impact future tobacco use.^[4] Studies in the United States have shown that current e-cigarette users are more likely to smoke cigarettes. Therefore, if youth become regular users of e-cigarettes, there is the potential for traditional cigarette use and adverse health effects from nicotine exposure during adolescence.^[9,26] Additionally, dual users of e-cigarettes and traditional cigarettes confer similar risks to smoking combustible cigarettes.^[14] Dual use of e-cigarettes and traditional cigarettes confer a higher risk status compared to only e-cigarette users and non-smokers.^[27]

6. E-cigarette use can cause adverse events, as well as adverse health effects.

There have been some instances of user harm due to misuse and poor product performance, some of which include exploding cartridges and burning batteries that can seriously injure individuals.^[7] The Federal Aviation Administration has released a warning about e-cigarettes on airplanes, after reports of e-cigarette batteries causing fires in airplane cargo holds and subsequent evacuations.^[28] Additionally, use and exposure to e-cigarettes can cause adverse health effects, and there is increasing concern over the potential long term effects of e-cigarettes. Mainstream and secondhand e-cigarette aerosol contain at least ten chemicals such as formaldehyde, lead, nickel, and acetaldehyde, which are known to cause cancer, birth defects, or other reproductive harm.^[1-3] The majority of e-cigarettes also contain varying levels of nicotine (a highly addictive neurotoxin), which can harm adolescent brain development and predispose youth to future use of combustible cigarettes, as well as adversely affect maternal and fetal health during pregnancy.^[4,5] There are also multiple short term adverse health effects, including a weakened immune system, tissue inflammation, lung irritation, and elevated blood pressure, all of which are similar to smoking a combustible cigarette.^[13-15,23]

7. Consumers lack an adequate understanding of e-cigarette components and related risks. Effective communication of product information is necessary to mitigate risks from e-cigarettes.

CDPH conducted focus groups in June 2014 among e-cigarette users, smokers, and non e-cigarette/combustible cigarette users and found there is a lack of awareness of the toxicity and hazards of e-cigarettes. In order for consumers to understand e-cigarettes and mitigate risk, there needs to be public disclosure about the contents of, and possible health risks from, e-cigarette use. Currently, there is a lack of consistency in warning messages on e-cigarette packaging and advertisements. Additionally, there is no consistency on the use of warning labels on advertising, websites, displays and products. Impactful warning statements addressing the harms of e-cigarettes, not just nicotine, are needed on all e-cigarette packaging and in advertisements. Placing large and clear warning labels on combustible cigarettes have shown to be effective population based smoking cessation interventions and effective at increasing awareness about the risks associated with tobacco and nicotine.^[29,30]

CDPH is concerned about the public health threat posed by e-cigarette use. Youth are extremely susceptible to begin using e-cigarettes, which may lead to a myriad of adverse health effects. E-cigarette exposure has also been shown to cause adverse health effects to both users and non-users.

Youth are of particular concern, due to the detrimental effects of nicotine on brain development. Furthermore, multiple studies have shown that youth are extremely drawn towards e-cigarettes because of enticing flavors and curiosity. Dual users are also at a higher risk status than those who only smoke e-cigarettes. E-cigarettes also cause similar lung irritation, inflammation, and effect on blood vessels as traditional cigarettes. Finally, a lack of consumer product information and product safety regulation has led to adverse health outcomes such as injury from exploding e-cigarette batteries, fires on airplanes, and nicotine poisonings.

Thank you for this opportunity to comment. Do not hesitate to contact CDPH if you have any additional questions.

Sincerely,



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