



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH RESPONSE TO US
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
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To Whom It May Concern:

The California Department of Public Health (CDPH) appreciates the opportunity to comment upon the Food and Drug Administration (FDA) proposed rule published in the Federal Register on April 25, 2014. CDPH opposes the use of all tobacco products, including electronic cigarettes (e-cigarettes). 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. CDPH therefore believes that the federal government should regulate e-cigarettes in a manner consistent with combustible cigarettes.

Mainstream and secondhand e-cigarette aerosol contains at least ten chemicals (including nicotine) 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 cause many to become addicted.^{4,5} There is no scientific evidence that non-therapeutic e-cigarette devices help smokers successfully quit combustible cigarettes, and research has shown that the use of e-cigarettes actually inhibits people from successfully breaking a nicotine habit.⁶⁻¹⁰

Secondhand aerosol emissions from e-cigarettes also pose a major public health concern. Recent research has confirmed that e-cigarettes do not emit water vapor but rather dangerous chemicals in the aerosol form, which have been shown in testing to harm human cells and could be dangerous for both users and those exposed to the secondhand aerosol.^{2,3,11,12} Using a nicotine-containing e-cigarette for five minutes causes similar lung irritation, inflammation, and effect on blood vessels as smoking a combustible cigarette.¹³

The use of e-cigarettes may also lead to the use of combustible cigarettes—a particular concern if this contributes to more young people becoming addicted to nicotine. Research suggests that adolescents who may have never smoked cigarettes are becoming addicted to nicotine from the use of e-cigarettes.⁶ Candy and fruit flavoring added to nicotine containing liquids used for e-cigarettes and other similar products appeal to children and adolescents. The increasing use of these liquids – and their candy flavorings have resulted in a rising occurrence of calls to California poison control centers involving exposure to these liquids. In California, the number of calls to the poison control center involving e-cigarette exposures in children five and under increased 10-fold in just over a year, from seven calls in 2012 to 70 calls during the period of January 2013 - February 2014.¹⁴

CDPH, therefore, supports the FDA proposed rule to extend its authority to regulate additional tobacco products, including e-cigarettes, but believes that the proposed rule could be strengthened. CDPH is providing the following comments with the aim of strengthening the proposed rule and providing a comprehensive consumer and public health protection package against the dangers of e-cigarettes.

- 1. Prohibit the sale of e-cigarettes to anyone under the age of 18 nationally**
CDPH supports this proposed rule, but recommends that possession of e-cigarettes and any e-cigarette paraphernalia by anyone under the age of 18 nationally should also be prohibited. However, federal regulations must clearly include an exemption for minors participating in local, state, or federal enforcement or public health department scientific surveillance related to the illegal sale or possession of e-cigarettes by minors. Between 2011 to 2012 the use of e-cigarettes in the United States more than doubled among students in grades 6 through 12.¹⁵ Additionally, many e-cigarette devices look similar to ballpoint pens, making it harder for school officials and law enforcement to identify when someone is inappropriately using nicotine or other illegal substances. Stricter regulation would deter youth under the age of 18 from using e-cigarettes and decrease nicotine addiction and the subsequent harm to brain development associated with nicotine exposure.
- 2. Restrict vending machines to adult only facilities**
CDPH supports this proposed rule as it is consistent with the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) related to combustible cigarettes. Additionally, to be consistent with the treatment of cigarettes and other tobacco products under the Tobacco Control Act, self-service displays of e-cigarettes should also be restricted to adult-only facilities. This is critically important as the 2013 Healthy Stores for a Healthy

Community Survey of more than 7,300 retail stores found that 16.3 percent of stores in California displayed e-cigarettes on the counter, accessible to customers, including youth.¹⁶

3. Prohibit free samples

CDPH supports this proposed rule as it treats e-cigarettes consistent with combustible cigarettes under the Tobacco Control Act.

4. Require a nicotine health warning statement on packaging and advertisements

CDPH believes that the proposed regulation for a single static warning should be replaced by large, graphic, and easy-to-understand warning labels on all e-cigarette advertising and products. CDPH also believes that the warnings should include promotion of the 1-800-QUIT-NOW number which provides access to free cessation services.

Currently, there is a lack of consistency in warning messages and the messages are confusing and easy to ignore. Additionally, there is no consistency on the use of warning labels on advertising, websites, displays, and products. Impactful warning statements on the harms of e-cigarettes, not just nicotine, are needed on all e-cigarette packaging and advertisements. CDPH conducted focus groups in June 2014 among e-cigarette users, smokers, and non e-cigarette/combustible cigarette users. From these focus groups it is evident that consumers and parents are unaware of the toxicity of e-cigarettes, the potential for nicotine poisoning, and of the health hazard they pose, especially to children and adolescents. The manufacturers of these products have a responsibility to uniformly communicate the health hazards associated with the use and exposure to these products in a manner that is meaningful and impactful.

5. Require all manufacturers to register their e-cigarette product with the FDA

CDPH supports this proposed rule as it lends itself to the establishment of quality control standards. E-cigarettes and related products have posed harmful threats to many adults and children when manufactured incorrectly. E-cigarette cartridges often leak and are not equipped with child-resistant caps, creating a potential source of poisoning through ingestion and skin or eye contact. Adults have also been harmed by exploding cartridges and lithium batteries that were not manufactured correctly. E-cigarette product registration with the FDA will hopefully decrease accidents and malfunctions that cause harm to people.

6. Require ingredients to be disclosed

This proposed rule would only provide ingredient information to the FDA and not to consumers. Ingredients of all tobacco products, including e-cigarettes, should be made easily available to all consumers and the general public on all e-cigarette product packages, advertisements and online (not just submitted to the FDA as currently proposed). Consumers should be fully informed of the chemicals and toxins in these products. As previously mentioned, at least ten chemicals found in the mainstream and secondhand e-cigarette aerosol are known to cause cancer, birth defects, and other reproductive harm. Consumer disclosure of the chemicals in e-cigarettes and the liquids within their cartridges (e-liquids) may encourage e-cigarette manufacturers to voluntarily reduce the toxicity of these products.

7. Allow the FDA to review any new or changed products before being sold

CDPH supports this proposed rule as it lends itself to establish quality control standards by avoiding the introduction of new toxins or harmful substances into the product.

8. Require manufacturers to show scientific evidence to support a claim that an e-cigarette product is less harmful and demonstrate the overall public health benefit

CDPH supports this proposed rule as it is consistent with the FDA's rules related to combustible cigarettes. However, the FDA needs to pay particular attention to any potential impact on youth, and should establish minimum public health standards for evidence that ensures that products do not contribute to further harms (e.g., nicotine poisonings, nicotine addiction) to children nor contribute to continued growth of e-cigarette use among youth.

In addition to the comments on the FDA's proposed rule, CDPH recommends the following actions:

- **Require Child Resistant Packaging**

Federal law, the Poison Prevention Packaging Act of 1970, requires the use of child-resistant packaging for prescription drugs, over-the-counter (OTC) drugs, household chemicals, and other hazardous materials that could pose dangers to children. It is noted, however, that the liquid cartridges of e-cigarettes containing highly toxic nicotine do not have similar child-resistant packaging. Nicotine poisoning to children, which has increased exponentially in the United States and in

California in recent years, cannot continue. Regulations should be added to require child-resistant packaging of e-cigarettes.

- **Ban Flavored E-Cigarettes**

CDPH believes that the FDA should treat e-cigarettes consistent with combustible cigarettes as it relates to characterizing flavorings. The Tobacco Control Act bans all cigarettes that have a characterizing flavor, including all fruit and candy flavors (other than menthol) because evidence shows that flavored cigarettes are “starter products” for youth.¹⁷ Additionally, the FDA’s proposed e-cigarette regulations acknowledge that flavored tobacco products, including e-cigarettes, can be especially attractive to youth. CDPH believes that a national approach, with FDA action to curb youth appeal of e-cigarettes by banning flavors, would lead to more consistent laws nationally and prevent health disparities.

- **Restrict Marketing and Advertising**

In recent years, both the money spent on marketing and advertising of e-cigarettes, and the number of ads has increased dramatically. We expect that advertising efforts will further increase as more e-cigarette brands come on to the market. We suggest the FDA expand the proposed rule to hold e-cigarettes to the same marketing restrictions that already exist for traditional products under the Tobacco Control Act. Such measures are needed to protect kids from the aggressive marketing of these addictive products. Additionally, marketers of e-liquid should be prohibited from using the term “juice” to describe and market nicotine infused-liquid. Such terminology implies to consumers that this is a safe product for consumption and poses no hazard to children and adolescents.

- **Establish Restrictions for Internet and Online Sales**

CDPH further recommends that additional restrictions be established for internet and online sales of e-cigarettes to ensure that e-cigarettes are not sold to minors. It is difficult to verify age when the buyer is not visually present in front of the seller when purchasing e-cigarettes. CDPH recommends that shipping and delivery agents be required to ensure that delivery is only to an individual that is 18 years or older. This would require verification of the identification (ID) and birthdate of the buyer through valid documents and photo IDs, during delivery of e-cigarettes.

- **Define a maximum allowable concentration of nicotine for e-cigarettes**

E-cigarettes have been found to contain nicotine at various concentrations. There is a danger that some may have concentrations above that of nicotine found in traditional cigarettes. Without regulation that restricts the concentrations and levels of nicotine, some e-cigarettes may have dangerously high levels of nicotine. To

address this issue, CDPH recommends that there be a maximum allowable limit on nicotine levels in e-cigarettes (levels above the maximum allowable limit would be considered a prescription drug).

- Define a maximum allowable volume for refillable e-liquid bottles containing nicotine
Since nicotine can be very harmful if ingested in large amounts or may cause harm through skin or eye contact, it is advisable to limit the volume and concentration of nicotine in e-liquid bottles or cartridges. Limiting volume as well as concentration would protect against nicotine poisoning in case of accidental overdose, spills, or due to damage to the e-liquid containers.
- Develop uniform guidelines on the proper disposal of unused e-liquid; consider developing guidelines for proper disposal of e-cigarette batteries
E-liquid contains nicotine and other chemicals that are highly toxic. In 2002, the United States Geological Survey sampled streams in 30 states. Of the 139 streams tested, 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Studies show exposure to even low levels of drugs has negative effects on fish and other aquatic species, and also may negatively affect human health.¹⁸

Additionally, many communities do not permit flushing of medications in order to protect water systems. It is important to keep toxic chemicals like those found in e-liquids out of water systems and landfills. The FDA should develop uniform guidelines for the proper disposal of unused e-liquid to prevent contamination of the environment and accidental poisonings. Such guidelines should require manufacturers to inform distributors and consumers on the proper disposal of unused e-liquid and should include take-back or mail back programs operated by manufacturers of e-liquid.

CDPH is also concerned that manufacturers of e-cigarette hardware are not required to include information on e-cigarette packaging that informs distributors and consumers about the proper disposal of lithium batteries in e-cigarette devices. In California, all batteries are considered hazardous waste when they are discarded, and are banned from disposal in household waste. (This includes both rechargeable and single use batteries.) Instead, batteries must be recycled, taken to a household hazardous waste disposal facility, a universal waste handler, or an authorized recycling facility to ensure that they do not end up in a regular landfill.¹⁹ Protecting the environment from the chemicals in batteries, including lithium batteries, is important to maintaining a healthy environment. When lithium batteries are disposed of in household waste, they end up in landfills where they enter the solid

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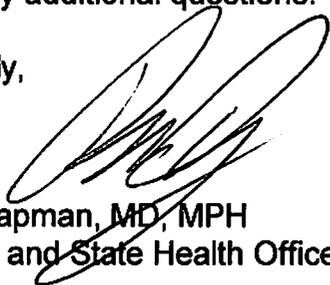
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waste stream and contaminate soil and water. Exposure to chemicals in these batteries can lead to respiratory problems and, in some cases, skin rashes. Additionally, when subjected to high temperatures, lithium batteries may explode.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Ron Chapman', is written over the typed name and title.

Ron Chapman, MD, MPH
Director and State Health Officer

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