

American Academy  
of Pediatrics



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June 18, 2014

Testimony of  
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On behalf of the  
**American Academy of Pediatrics**

Before the  
**Senate Committee on Commerce, Science and Transportation**

Hearing on  
**Aggressive E-Cigarette Marketing and Potential Consequences for Youth**

Good afternoon. My name is Dr. Susanne Tanski, a practicing pediatrician and associate professor of pediatrics at the Geisel School of Medicine at Dartmouth. I am here today representing the American Academy of Pediatrics, a professional membership organization of more than 62,000 pediatricians dedicated to advancing the health and well-being of all children. I am the chair of the AAP's Tobacco Consortium, which advises the AAP in its scientific, education and policy efforts to protect children and youth from tobacco. I conduct research on tobacco and adolescents, with a particular focus on the impact of media on youth tobacco use.

Chairman Rockefeller, Ranking Member Thune, it is my pleasure to be here today to discuss e-cigarettes, a critically important issue for the health of children. Pediatricians have numerous and growing concerns about the known and unknown health impacts of e-cigarettes. At present, it is unknown if the availability of these products leads to smoking initiation among non-smoking youth, and whether experimentation with these leads to nicotine addiction. Without such data, we worry that e-cigarettes could lead to a lifetime of nicotine addiction for an adolescent and could serve as a gateway to use of traditional cigarettes or other tobacco products. The individual and public health risks of e-cigarettes are also largely unknown, as the products at present are highly variable and differ substantially across brands and types. In spite of the lack of definitive data on the impact of e-cigarettes, we do know enough to assert that we must protect children now from risks posed by these products.

The topic of today's hearing, the aggressive marketing of e-cigarettes and its impact on youth, is of particular concern to pediatricians. For the first time in over 40 years, tobacco products are being advertised on television. The historical evidence is robust that marketing directly influences youth, and a recent study has identified substantial exposure of youth to televised e-cigarette ads.<sup>1</sup> One e-cigarette company has even placed ads during the Super Bowl, which we know is watched by a substantial number of children. The nation's pediatricians are concerned that use of electronic cigarettes among teenagers is rising dramatically as reported in very recent studies, and that this is linked to its unfettered advertising.

### **What are E-Cigarettes and Nicotine-Containing Vapor Devices?**

E-cigarettes are a category of products that deliver nicotine and flavoring on inhalation of a battery-powered device that warms and vaporizes a nicotine-containing solution. These products are marketed widely on the internet and on U.S. television as alternatives to cigarette use and come in a variety of tobacco, fruit, and food flavor. Of primary concern for pediatricians is the potential for these devices to introduce non-tobacco users to nicotine addiction or to perpetuate smoking among smokers who would otherwise have quit. Use among young people is growing: in just one year, the ever and current use of e-cigarettes

doubled among U.S. high school students, from 4.7% in 2011 to 10.0% in 2012 (for ever-use). While the rate of having tried e-cigarettes is still far lower than that of cigarettes, as of 2012, approximately 1.78 million U.S. students reported using an e-cigarette. While the overwhelming majority of e-cigarette triers had also smoked cigarettes, some 7.2% of high school ever-users of e-cigs had never tried a traditional cigarette.<sup>2</sup> A more recent internet-based study in 2013-2014 found markedly higher rates of ever-use and current-use: 14% of 13-17 year olds had ever used an e-cigarette, and 9% currently used them. Among ever-cigarette users aged 13-17, 32% were current e-cigarette users.<sup>3</sup> Unfortunately, these numbers still may not tell the full story. With the introduction of “e-hookahs” and “vape-pens” to the category, asking only about “e-cigarettes” may significantly underestimate the use of nicotine-containing vapor devices.

### **Nicotine: Health Effects, Addiction, Toxicity and Poisoning Potential**

Nicotine itself is not a benign substance. Nicotine is a psychoactive drug that is well known for its high level of toxicity, as well as the ease with which dependence occurs. At low doses it acts as a stimulant, leading to a feeling of pleasure and a reversal of unpleasant withdrawal symptoms. Very simply, at the level of the brain, nicotine works within the reward pathways. There are targets for nicotine (receptors) throughout the body, however, allowing nicotine to have broad physiological effects. With repeated exposure to nicotine, tolerance to some of the effects of nicotine develops, and leads to needing more nicotine. Insufficient nicotine in someone who is dependent leads to craving and withdrawal symptoms of irritability, anxiety, restlessness, and anhedonia. The basis of nicotine addiction is reinforcement of behavior that restores nicotine and makes the user feel good and avoid withdrawal.<sup>4</sup> Regular users develop habits associated with nicotine use that also become connected with the rewarding feelings of nicotine use, creating cues for use. This is how smokers become cued to want a cigarette after a meal, or with coffee, or in certain locations, for example. Cigarettes are carefully engineered to deliver nicotine quickly and efficiently to the brain to reinforce addiction. The cigarette is the delivery device, but the nicotine is the basis of the psychoactive effects.

Overdose of nicotine can cause nausea, vomiting, abdominal pain, headache, dizziness, and seizures. In very high doses nicotine can be lethal. Nicotine, in chemical form, is required to carry a material safety data sheet (MSDS) warning users to handle it with gloves, goggles, mask and protective clothing. The MSDS summarizes the acute potential health effects as follows:

*Skin: It can cause skin irritation and rash. It may cause dermatitis. It is well absorbed by dermal exposure route. May be fatal if absorbed through skin. Systemic effects similar to that of ingestion can occur from nicotine poisoning.*

*Eyes: It can cause eye irritation. Severe pain, lacrimation, conjunctival reaction, corneal infiltration, partial opacification of cornea.*

*Inhalation: It is well absorbed by inhalation exposure route. Inhalation can produce systemic effects similar to that of ingestion.*

*Ingestion: May be fatal if swallowed. It can cause gastrointestinal tract irritation/disturbances with nausea, vomiting, diarrhea, stomach pain, burning sensation of the mouth, throat, esophagus, and stomach, loss of appetite. Metabolic acidosis and hypokalemia can develop if there is severe diarrhea. It acts on the central nervous system and other parts of the nervous system such as the adrenal medulla, autonomic ganglia, and neuromuscular junctions with initial stimulation followed by depression. Early signs of toxicity from small doses include nausea, vomiting, headache, dizziness, tachycardia, hypertension, tachypnea, hyperpnea, sweating, and salivation. High exposure can cause dizziness, headache, tremors, anxiety, restlessness, seizures, hypotonia, decreased deep tendon reflexes progressing to paralysis, fasciculations, convulsions, weakness, incoordination, hallucinations, confusion, coma. Hypertension, tachycardia, and tachypnea followed by hypotension, bradycardia, and dyspnea, bradypnea can occur. Tachypnea is one of the principle signs nicotine poisoning. Respiratory failure may also occur. Other symptoms can include weak, rapid, and irregular pulse. Vasoconstriction, atrial fibrillation, and sinoatrial block, and ventricular fibrillation have also all been reported. Death is usually from respiratory depression secondary to CNS depression and peripheral blockade of respiratory muscles.<sup>5</sup>*

Given the tolerance that occurs for nicotine within regular users, a wide range of doses have been shown to lead to acute toxicity. The estimated lethal dose of nicotine is 1 to 13 mg per kilogram of body weight.<sup>6,7</sup> Toxic effects would be seen at much lower levels among the nicotine naïve, such as children, than among established users.

The potential for poisoning is a very real concern for pediatricians, and we fear it is only a matter of time before a child suffers a lethal poisoning from the refill solutions for e-cigarettes. Indeed, liquid nicotine sold to refill e-cigarettes, also called “e-liquid” or “e-juice” has caused a substantial recent spike in child poisoning, particularly among young children under the age of five. E-liquid is a likely candidate for ingestion by young children because it is colorful, candy flavored and scented, and there is no requirement for child-proof packaging. Given that nicotine is also dermally absorbed, e-liquid can be dangerous even if it only comes into contact with the skin. E-liquids are sold in highly concentrated form, some containing upwards of 36 mg of nicotine per milliliter of e-liquid. At this concentration, a small 15 mL dropper bottle of e-liquid would contain 540 mg of nicotine. Given the estimated lethal dose range of nicotine, even at the high end of this range this small bottle would contain enough nicotine to kill four 10 kg children (10 kg is an average weight for a one-year-old child). Even a single teaspoon of e-liquid at this concentration could kill a small child, and a smaller dose would make one quite ill. The CDC reported this year that in the month of February alone, poison control centers received 215 calls related to e-cigarette exposures, many of these in young children. As pediatricians, we are gravely concerned about these risks, and fervently support requiring child-safe packaging for all nicotine containing products.

We find it completely unacceptable that no federal laws or regulations currently require the sale of e-liquid in child-proof packaging. We believe that the Food and Drug Administration (FDA) has the authority to require poisoning prevention measures for tobacco products, and we are disappointed that the agency failed to propose any such measures in the proposed rule it published in April to deem e-cigarettes and other tobacco products subject to FDA regulatory authority. Further, the Consumer Product Safety Commission (CPSC), which generally has authority to require child-proof packaging of hazardous household products, is generally prohibited by law from regulating any type of tobacco. In effect, there are no regulatory safeguards in place to protect young children from e-liquid. If nothing changes, it will not be a matter of if but when we see the first child death caused by e-liquid. We call on Congress and the Administration to act quickly to ensure that this danger to children is eliminated.

### **Health Risks of Recreational Nicotine: Leading to Dependence and Possible Transitions to Combusted Tobacco**

The adolescent brain appears uniquely susceptible to nicotine addiction, with symptoms of dependence appearing within days to weeks of intermittent tobacco use and well before daily smoking.<sup>8</sup> Nearly all adult smokers initiated smoking before the age of 20, and younger age of tobacco initiation predicts greater levels of dependence and difficulty quitting.<sup>9</sup> Animal studies have demonstrated that nicotine exposure during the adolescent period has long-standing effects in the brain including cell damage that leads to both immediate and persistent behavior changes.<sup>10</sup> These effects are not found with nicotine exposure to the adult, supporting the idea that the adolescent is uniquely susceptible to nicotine addiction. The weight of evidence suggests that nicotine exposure modifies the developing adolescent brain and has long-term impacts into adulthood.<sup>11</sup>

There is not a specific threshold of nicotine exposure that predicts addiction, but the source of the nicotine does seem to make a difference. It has been shown that nicotine replacement therapies have low potential for dependence due to how they are absorbed.<sup>12</sup> At present, it is not known how amounts and rates of nicotine delivery from e-cigarettes and nicotine-containing vapor devices affects nicotine addiction, nor is it known how many individuals beginning use with e-cigarettes persist with e-cigarettes alone or also initiate combusted tobacco use. Given that these products have only recently begun to be examined, there have not to date been any trajectory studies done with youth or young adult populations. The FDA and the National Institute on Drug Abuse (NIDA) are collaborating on the Population Assessment of Tobacco and Health (PATH) study that will assess these trajectories. However they are still recruiting the baseline sample and have no longitudinal data. The present cross-sectional data of adolescents and young adults from other studies suggests that dual use—using both e-cigarettes and combusted products like cigarettes—is the most common status among e-cigarette users. There is concern that e-

cigarettes may impede individuals from quitting smoking, by allowing them to maintain their nicotine addiction in places where combusted tobacco has been prohibited. If these individuals would otherwise have quit combusted tobacco completely, the maintenance of use supported by e-cigarettes is of concern.

### **Other Public Health Consequences of E-Cigarettes**

Anecdotal reports and limited data suggest that e-cigarettes may help smokers quit or reduce smoking. At this time, further research is necessary to determine if—and most importantly, under what conditions—e-cigarettes could play a beneficial role in reducing tobacco-related disease. E-cigarette companies are alluding to numerous potential health benefits from e-cigarettes in their marketing campaigns without appropriate data to support these implications. By comparison, FDA-approved nicotine replacement therapies such as nicotine gum have been carefully evaluated for their safety and efficacy in assisting in tobacco cessation in the context of specific, evidence-based instructions for use. In the case of e-cigarettes, there are no instructions on how to use the products to achieve smoking cessation. Additionally, data show that current e-cigarette users include distant-former smokers—smokers who quit more than 5 years ago—suggesting that e-cigarettes could be leading to the re-addiction of former smokers.<sup>13</sup> Given the vast differences in the engineering of e-cigarettes, the doses and chemosensory variations of the e-juice, and the complete lack of quality standards at present, it is extraordinarily difficult to quantify the public health consequences.

Beyond nicotine, e-cigarette vapor is made up of a humectant such as propylene glycol or vegetable glycerin, and flavoring. The humectants can cause lung irritation in the short term, but there is no research into the long-term impact of vaporizing and inhaling these agents into the lungs. The flavorings themselves are also cause for concern on multiple levels. There is limited data regarding the safety of vaporizing the chemical characterizing flavors, and there may be risks of flavorings to the user directly. There is also the known appeal of flavored tobacco products to youth. We know from the traditional cigarette example that flavors increase smoking initiation among youth, which led to the ban of all characterizing flavors (other than menthol) in cigarettes. The appeal of flavors for children is well understood by e-cigarette manufacturers. A parent education website sponsored by one e-cigarette company notes that “kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry.”<sup>14</sup> Despite understanding that these products appeal to children, that same company markets e-cigarettes in cherry, vanilla, piña colada and other candy flavors. Furthermore, some e-liquids come in flavors like “cotton candy” and “gummy bear” which seem clearly designed to entice new youth users.

The emissions from e-cigarettes have been publicized as “harmless water vapor,” but accumulating evidence demonstrates that the vapor inhaled into the user’s lungs does contain numerous known toxins and carcinogens such as formaldehyde and tobacco-specific nitrosamines, albeit at levels markedly lower than those found in traditional cigarettes.<sup>15</sup> The levels of particulates that are emitted from e-cigarettes are not very different from combusted cigarettes, however.<sup>16</sup> These particulates could have respiratory irritation potential for those nearby. In fact, preliminary animal model data shows damage to growing lungs resulting from second-hand exposure to e-cigarette vapor. The negative health impact of e-cigarettes on children and non-smokers deserves more research. However, until and unless we know that these emissions do not cause harms, particularly to developing lungs, there is an imperative to limit exposure of children and other non-smokers. We must extend all clean air laws to include the emissions from e-cigarettes.

The e-cigarettes have yet another cause for concern: the re-normalization of smoking. Smoking has become an unpopular behavior among young people, with smokers having to go outside and in many cases off campuses to smoke. As such, smoking is not as often seen as it was 20 years ago. The increase of people smoking e-cigarettes in places where smoking is not currently allowed creates confusion, particularly among children, who often cannot tell the difference between smoking and e-cigarette use. Anecdotally, when I’ve shown children pictures of people using e-cigarettes, they nearly always report that the person in the picture is smoking. We know that children do what they see, and they overestimate the prevalence of behaviors that they see in media, hence it is important that we not allow e-cigarette use to re-normalize the image of a smoker.

## **Marketing to Youth**

With tobacco companies now selling e-cigarettes, there is a significant amount of marketing and attention in the media to e-cigarettes. Beyond this are the marketing efforts of independent companies. While there is broad public consensus that e-cigarettes should not be sold or marketed to youth, there is substantial evidence that marketing reaches the adolescent demographic and is influencing them. Age limits on purchase will be ineffective without advertising restrictions.

The most recent Surgeon General’s report clearly stated: “The evidence is sufficient to conclude that advertising and promotional activities by the tobacco companies *cause* the onset and continuation of smoking among adolescents and young adults.”<sup>17</sup> (emphasis added) In spite of this, there remain no controls on the marketing of e-cigarettes, and there is significant penetration of e-cigarette marketing to youth audiences. Data released earlier this month show that youth exposure to e-cigarette marketing on television increased 256% between 2011 and 2013. The audience of the e-cigarette companies now includes 24 million youth.<sup>18</sup> A study from Legacy released last month found that 17.7 million or 73% of

12-17 year olds were exposed to one e-cigarette company's print and TV ads between June and November 2013, as just one example.<sup>19</sup> TV and radio ads for cigarettes were banned in 1971 to limit exposure to impressionable children. Our children in 2014 are no less impressionable. We believe tobacco advertisements have no place on television.

E-cigarettes are being advertised with many of the same tools that were used by big tobacco companies prior to the Master Settlement Agreement (MSA): celebrity endorsements, glamorous models, event sponsorships, and the previously mentioned flavors. While event sponsorships are expressly prohibited in the Tobacco Control Act for cigarettes and smokeless tobacco, e-cigarettes have no such restrictions. A recent investigation released by Chairman Rockefeller and other members of Congress identified that e-cigarette companies "sponsored dozens of athletic, musical, social and cultural events that appeal to youth."<sup>20</sup> In addition, e-cigarettes are being promoted with a variety of messages that are appealing to youth: freedom, rebellion, and independence. There are also implicit messages that e-cigarettes are a healthier alternative to smoking, again, a theme that is attractive to youth.

Because of the myriad ways tobacco advertising can negatively impact children, the AAP endorsed the *Protecting Children from Electronic Cigarette Advertising Act of 2014*, which would prohibit e-cigarette marketing practices that appeal to children, and give the Federal Trade Commission (FTC) the authority to enforce violations.

### **E-Cigarette Regulation to Protect Children and the Public Health**

America's pediatricians believe that strong regulation of e-cigarettes is absolutely essential to protecting children from the risks posed by these products. Some e-cigarette proponents argue that the products should not be regulated. We disagree. We do not believe it is inconsistent to both strongly regulate e-cigarettes for protection of children and allow e-cigarettes to play a role in reducing smoking if research is able to demonstrate that appropriately regulated e-cigarettes could benefit the public health as a whole. Until such evidence is available, however, there is an urgent need to control the exposure of children and youth to these products, and to immediately exert all appropriate regulatory authority over them.

In fact, the Tobacco Control Act gives the FDA the authority to regulate tobacco products based on a protection of the public health standard. In determining what policies would benefit the public health, the FDA is required to assess the impact of policy choices on both users and non-users of tobacco products. We support this regulatory approach. It would be a tragedy if we fail to regulate e-cigarettes in a way that protects children and only later find out that a lax regulatory approach caused more harm than good. We cannot and should

not repeat the mistakes that were made in the public health response to traditional cigarettes.

As such, the Academy supports strong FDA authority to regulate all tobacco products, including e-cigarettes. We applaud the agency for issuing a proposal in April to expand its jurisdiction to include all types of tobacco products. We are currently in the process of submitting comments to FDA on its proposal.

The message of America's pediatricians on e-cigarettes is simple: we have a duty to first protect children. Thank you for the opportunity to provide this testimony. We look forward to working with this committee to address the risks e-cigarettes pose to children.

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